COMMERCIAL PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: April 1, 2024 Notification Posted: February 16, 2024

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

• Program Summary: Rivfloza (nedosiran)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
TBD	Rivfloza 128 mg single-dose prefilled syringe	nedosiran		1	Syringe	30	DAYS			
TBD	Rivfloza 160 mg single-dose prefilled syringe	nedosiran		1	Syringe	30	DAYS			
TBD	Rivfloza 80 mg single-dose vial	nedosiran		2	Vials	30	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by ONE of the following: A. Genetic testing of the *AGXT* gene indicates a pathogenic mutation **OR** B. Liver biopsy demonstrates absent or significantly reduced alanine:glyoxylate aminotransferase (AGT) activity **AND** 2. The requested agent will be used to lower urinary oxalate levels **AND** 3. The patient has an estimated GFR (eGFR) greater than or equal to 30 mL/min/1.73^2 **AND** 4. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 5. ONE of the following: A. The patient has tried and had an inadequate response to potassium citrate or sodium citrate **OR** B. The patient has an intolerance or hypersensitivity to potassium citrate or sodium citrate therapy **OR** C. The patient has an FDA labeled contraindication to BOTH potassium citrate AND sodium citrate **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that BOTH potassium citrate AND sodium citrate cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 6. ONE of the following: A. The patient has tried and had an inadequate response to pyridoxine (vitamin B6) for at least 3

Module	Clinical Criteria for Approval
	months **AND** ONE of the following: 1. The patient is unresponsive to pyridoxine (vitamin B6) (unresponsive defined as less than or equal to 30% decrease in urine oxalate after 3 months of treatment with maximally tolerated pyridoxine) **OR** 2. The patient is responsive to pyridoxine (vitamin B6) (responsive defined as greater than 30% decrease in urine oxalate after 3 months of treatment with maximally tolerated pyridoxine) **AND** will continue treatment with pyridoxine (vitamin B6) in combination with the requested agent **OR** B. The patient has an intolerance or hypersensitivity to pyridoxine (vitamin B6) therapy **OR** C. The patient has an FDA labeled contraindication to pyridoxine (vitamin B6) **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that pyridoxine (vitamin B6) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 7. The patient has not received a kidney or liver transplant **AND** 8. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 9. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent (e.g., decrease in urinary oxalate levels) **AND** 3. The patient has an estimated GFR (eGFR) greater than or equal to 30 mL/min/1.73^2 **AND** 4. ONE of the following: A. The patient's medication history includes pyridoxine (vitamin B6) **AND** ONE of the following: 1. The patient will continue treatment with pyridoxine (vitamin B6) in combination with the requested agent **OR** 2. The patient was unresponsive to pyridoxine (vitamin B6) (unresponsive defined as less than or equal to 30% decrease in urine oxalate after 3 months of treatment with maximally tolerated pyridoxine) **OR** B. The patient has an intolerance or hypersensitivity to pyridoxine (vitamin B6) therapy **OR** C. The patient has an FDA labeled contraindication to pyridoxine (vitamin B6) **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause

Module	Clinical Criteria for Approval
	harm **OR** E. The prescriber has provided documentation that pyridoxine (vitamin B6) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 5. The patient has not received a kidney or liver transplant **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of Approval:** 6 months (Initial); 12 months (Renewal)

● Program Summary: Xdemvy

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☑ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
86106050002020	Xdemvy	lotilaner ophth soln	0.25 %	1	Bottle	50	DAYS			

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Step Therapy	<table><tr><th>TARGET AGENT(S)</th><th>PREREQUISITE AGENT(S)</th></tr><tr><td>Xdemvy</td><td>ivermectin oral tablet</td></tr></table> **Target Agent(s)** will be approved when ONE of the following is met: 1. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**

Module	Clinical Criteria for Approval
	C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. The patient has a medication history of use in the past 90 days with ONE prerequisite agent **OR** 3. BOTH of the following: A. The prescriber has stated that the patient has tried a prerequisite agent **AND** B. The prerequisite agent was discontinued due to lack of effectiveness or an adverse event **OR** 4. The patient has an intolerance or hypersensitivity to ONE prerequisite agent **OR** 5. The patient has an FDA labeled contraindication to ALL prerequisite agents **OR** 6. The prescriber has provided documentation that the prerequisites cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval:** 2 months NOTE: if Quantity Limit applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. BOTH of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **Length of Approval:** 2 months

• Program Summary: Zilbrysq (zilucoplan)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
TBD	Zilbrysq 16.6 mg/0.416 mL	zilucoplan		28	Syringes	28	DAYS			
TBD	Zilbrysq 23 mg/0.574 mL	zilucoplan		28	Syringes	28	DAYS			
TBD	Zilbrysq 32.4 mg/0.81 mL	zilucoplan		28	Syringes	28	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of generalized Myasthenia Gravis (gMG) AND ALL of the following:

Module	Clinical Criteria for Approval
	1. The patient has a positive serological test for anti-AChR antibodies (lab test must be submitted) **AND** 2. The patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification class of II-IVb **AND** 3. The patient has a MG-Activities of Daily Living total score of greater than or equal to 6 **AND** 4. ONE of the following: A. The prescriber has assessed the patient's current medications and discontinued any medications known to exacerbate myasthenia gravis (e.g., beta blockers, procainamide, quinidine, magnesium, anti-programmed death receptor-1 monoclonal antibodies, hydroxychloroquine, aminoglycosides) **OR** B. The prescriber has provided clinical rationale indicating that discontinuation of the offending agent is not clinically appropriate **AND** 5. ONE of the following: A. The patient has tried and had an inadequate response to at least ONE conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **OR** B. The patient has an intolerance or hypersensitivity to ONE conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **OR** C. The patient has an FDA labeled contraindication to ALL conventional agents used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that conventional agents used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** F. The patient required chronic intravenous immunoglobulin (IVIG) **OR** G. The patient required chronic plasmapheresis/plasma exchange **OR** B. The patient has another FDA approved indication for the requested agent **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient will NOT be using the requested agent in combination with any of the following for the requested indication:

Module	Clinical Criteria for Approval
	A. Rystiggo (rozanolixizumab-noli) B. Soliris (eculizumab) C. Ultomiris (ravulizumab-cwvz) D. Vyvgart (efgartigimod) E. Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The prescriber has provided information that the patient has had clinical benefit with the requested agent (e.g., improved MG-Activities of Daily Living total score, improved quantitative myasthenia gravis total score) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient will NOT be using the requested agent in combination with any of the following for the requested indication: A. Rystiggo (rozanolixizumab-noli) B. Soliris (eculizumab) C. Ultomiris (ravulizumab-cwvz) D. Vyvgart (efgartigimod) E. Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the

Module	Clinical Criteria for Approval
	requested indication **Length of Approval:** Initial 3 months, Renewal 12 months

POLICIES REVISED

• Program Summary: Anti-Obesity Agents

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☑ Coverage / Formulary Exception

TARGET AGENT(S)

Adipex-P® (phentermine)[a]
Benzphetamine[a]
Contrave® (naltrexone/bupropion)
Diethylpropion[a]
Lomaira™ (phentermine)
Phendimetrazine[a]
Phentermine[a]
Qsymia® (phentermine/topiramate)
Saxenda® (liraglutide)
Wegovy™ (semaglutide)
Xenical® (orlistat)
Zepbound™ (tirzepatide)
a – Generic equivalent available

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
Adipex-P (phentermine)[a]			
37.5 mg capsule	61200070100120	M, N, O, or Y	1 capsule
37.5 mg tablet	61200070100310	M, N, O, or Y	1 tablet
Benzphetamine[a]			
25 mg tablet	61200010100305	M, N, O, or Y	3 tablets
50 mg tablet	61200010100310	M, N, O, or Y	3 tablets
Contrave (naltrexone/bupropion)			
8 mg / 90 mg tablet	61259902507420	M, N, O, or Y	4 tablets
Diethylpropion[a]			
25 mg tablet	61200020100305	M, N, O, or Y	3 tablets
75 mg extended-release tablet	61200020107510	M, N, O, or Y	1 tablet
Lomaira (phentermine)			
8 mg tablet	61200070100305	M, N, O, or Y	3 tablets
Phendimetrazine[a]			
35 mg tablet	61200050100305	M, N, O, or Y	6 tablets
105 mg extended-release capsule	61200050107010	M, N, O, or Y	1 capsule
Phentermine[a]			
15 mg capsule	61200070100110	M, N, O, or Y	1 capsule
30 mg capsule	61200070100115	M, N, O, or Y	1 capsule
Qsymia (phentermine/topiramate)			
3.75mg/23mg capsule	61209902307020	M, N, O, or Y	1 capsule
7.5mg/46mg capsule	61209902307030	M, N, O, or Y	1 capsule
11.25mg/69mg capsule	61209902307040	M, N, O, or Y	1 capsule
15mg/92mg capsule	61209902307050	M, N, O, or Y	1 capsule

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
Saxenda (liraglutide)			
6 mg/mL, 3 mL/pen	6125205000D220	M, N, O, or Y	0.5 mL
Wegovy (semaglutide)			
0.25 mg/0.5 mL pen*	6125207000D520	M, N, O, or Y	8 pens (4 mL)/180 days
0.5 mg/0.5 mL pen*	6125207000D525	M, N, O, or Y	8 pens (4 mL)/180 days
1 mg/0.5 mL pen*	6125207000D530	M, N, O, or Y	8 pens (4 mL)/180 days
1.7 mg/0.75 mL pen~	6125207000D535	M, N, O, or Y	4 pens (3 mL)/28 days
2.4 mg/0.75 mL pen	6125207000D540	M, N, O, or Y	4 pens (3 mL)/28 days
Xenical (orlistat)			
120 mg capsule	61253560000120	M, N, O, or Y	3 capsules
Zepbound (tirzepatide)			
2.5 mg/0.5 mL pen*	6125258000D520	M, N, O, or Y	4 pens (2 mL)/180 days
5 mg/0.5 mL pen	6125258000D525	M, N, O, or Y	4 pens (2 mL)/28 days
7.5 mg/0.5 mL pen	6125258000D530	M, N, O, or Y	4 pens (2 mL)/28 days
10 mg/0.5 mL pen	6125258000D535	M, N, O, or Y	4 pens (2 mL)/28 days
12.5 mg/0.5 mL pen	6125258000D540	M, N, O, or Y	4 pens (2 mL)/28 days
15 mg/0.5 mL pen	6125258000D545	M, N, O, or Y	4 pens (2 mL)/28 days

a – Generic equivalent available

* - These strengths are not approvable for maintenance dosing

~ - The 1.7mg formulation is allowed as maintenance for pediatric patients

FORMULARY EXCEPTION CRITERIA FOR APPROVAL

Initial Evaluation

(Patient new to therapy, new to Prime, or attempting a repeat weight loss course of therapy)

Target Agents will be approved when ALL the following are met:

1. The requested agent is not excluded under the patient's current benefit plan
   AND
2. ONE of the following:
   A. The patient is 17 years of age or over and ALL of the following:
      i. ONE of the following:
         a. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 30 kg/m^2 OR a BMI greater than or equal to 25 kg/m^2 if the patient is of South Asian, Southeast Asian, or East Asian descent
            OR
         b. The patient has a BMI greater than or equal to 27 kg/ m^2 with at least one weight-related comorbidity/risk factor/complication (e.g., diabetes, dyslipidemia, coronary artery disease)
            AND
      ii. The patient has been on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications for a minimum of 6 months prior to initiating therapy with the requested agent

AND

iii. The patient did not achieve a weight loss of 1 pound or more per week while on the weight loss regimen prior to initiating therapy with the requested agent

AND

iv. The patient is currently on and will continue a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications

OR

B. The patient is 12 to 16 years of age and ALL of the following:

i. ONE of the following:

a. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 95th percentile for age and gender

OR

b. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 30 kg/m^2

OR

c. The patient has a BMI greater than or equal to 85th percentile for age and gender AND at least one severe weight-related comorbidity/risk factor/complication

AND

ii. The patient has been on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications for a minimum of 6 months prior to initiating therapy with the requested agent

AND

iii. The patient did not achieve a weight loss of 1 pound or more per week while on the weight loss regimen prior to initiating therapy with the requested agent

AND

iv. The patient is currently on and will continue a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications

AND

3. If the patient has an FDA approved indication ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent
   OR
   B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication

AND

4. The patient does NOT have any FDA labeled contraindications to the requested agent

AND

5. The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication

AND

6. ONE of the following:
   A. The patient has no evidence of a targeted weight loss agent in the past 12 months of claims history
   OR
   B. The patient has evidence of a targeted weight loss agent for a previous course of therapy in the past 12 months of claims history AND the prescriber has provided information supporting the anticipated success of repeating therapy

AND

7. ONE of the following:
   A. The requested agent is benzphetamine, diethylpropion, phendimetrazine, phentermine, or Zepbound
   OR
   B. The requested agent is Qsymia and ONE of the following:
      i. The requested dose is 3.75mg/23mg
      OR
      ii. The patient is currently being treated with Qsymia, the requested dose is greater than 3.75 mg/23 mg AND ONE of the following:
         a. The patient has demonstrated and maintained a weight loss of greater than or equal to 5% from baseline (prior to the initiation of requested agent)

OR

b. The patient received less than 14 weeks of therapy

OR

c. The patient's dose is being titrated upward

OR

d. The patient has received less than 12 weeks (3 months) of therapy on the 15mg/92mg strength

OR

iii. The prescriber has provided information in support of therapy for the requested dose for this patient

OR

C. The requested agent is Contrave and ONE of the following:

i. The patient is newly starting therapy

OR

ii. The patient is currently being treated and has received less than 16 weeks (4 months) of therapy

OR

iii. The patient has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of requested agent)

OR

D. The requested agent is Xenical and ONE of the following:

i. The patient is 12 to 16 years of age and ONE of the following:

a. The patient is newly starting therapy

OR

b. The patient is currently being treated and has received less than 12 weeks (3 months) of therapy

OR

c. The patient has achieved and maintained a weight loss of greater than 4% from baseline (prior to initiation of requested agent)

OR

ii. The patient is 17 years of age or over and ONE of the following:

a. The patient is newly starting therapy

OR

b. The patient is currently being treated and has received less than 12 weeks (3 months) of therapy

OR

c. The patient has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of requested agent)

OR

E. The requested agent is Saxenda and ALL of the following:

i. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent

AND

ii. ONE of the following:

a. The patient is 18 years of age or over and ONE of the following:

1. The patient is newly starting therapy

OR

2. The patient is currently being treated and has received less than 16 weeks (4 months) of therapy

OR

3. The patient has achieved and maintained a weight loss of greater than or equal to 4% from baseline (prior to initiation of requested agent)

OR

b. The patient is pediatric (12 to less than 18 years of age) and BOTH of the following:

1. The requested agent is NOT being used to treat type 2 diabetes

AND

2. ONE of the following:

A. The patient is newly starting therapy
OR
B. The patient is currently being treated and has received less than 20 weeks (5 months) of therapy
OR
C. The patient has achieved and maintained a reduction in BMI of greater than or equal to 1% from baseline (prior to initiation of requested agent)

OR

F. The requested agent is Wegovy and ALL of the following:
   i. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent
   AND
   ii. The patient does NOT have a history of pancreatitis
   AND
   iii. ONE of the following:
      a. The patient is newly starting therapy
      OR
      b. The patient is currently being treated and has received less than 52 weeks (1 year) of therapy
      OR
      c. ONE of the following:
         1. The patient is an adult AND has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of the requested agent)
         OR
         2. The patient is pediatric (12 to less than 18 years of age) AND has achieved and maintained a reduction in BMI of at least 5% from baseline (prior to initiation of the requested agent)

AND

8. ONE of the following:
   A. The patient has tried and failed at least three (or as many as available, if fewer than three) formulary alternatives
   OR
   B. The prescriber has indicated that available formulary alternatives are contraindicated, likely to be less effective, or likely to cause an adverse reaction or other harm

AND

9. ONE of the following:
   A. The requested quantity (dose) does NOT exceed the program quantity limit
   OR
   B. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
      AND
      ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
      AND
      iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit
   OR
   C. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
      AND
      ii. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
      AND
      iii. The prescriber has provided information in support of therapy with a higher dose for the requested indication

Length of Approval: For Saxenda pediatric patients (age 12 to less than 18): 5 months
For Saxenda (adults) and Contrave: 4 months
For Wegovy, Zepbound: 12 months
For all other agents: 3 months

Renewal Evaluation
(Patient continuing a current weight loss course of therapy)

Target Agent(s) will be approved when ALL of the following are met:

1. Requested agent is not excluded under the patient's current benefit plan
   AND
2. The patient has been previously approved for the requested agent through the plan's Prior Authorization process
   AND
3. The patient is currently on and will continue to be on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications
   AND
4. The patient does NOT have any FDA labeled contraindications to the requested agent
   AND
5. For Saxenda only, BOTH of the following:
   A. The requested agent is NOT being used to treat type 2 diabetes in pediatric patients (12 to less than 18 years of age)
      AND
   B. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent

   AND
6. For Wegovy only, ALL of the following:
   A. The requested dose is 2.4 mg
      AND
   B. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent
      AND
   C. The patient does NOT have a history of pancreatitis

   AND
7. The patient meets ONE of the following:
   A. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of requested agent)
      OR
   B. For Saxenda only, ONE of the following:
      i. If the patient is 18 years of age or over, the patient has achieved and maintained a weight loss greater than or equal to 4% from baseline (prior to initiation of requested agent)
         OR
      ii. If the patient is pediatric (12 to less than 18 years of age), the patient has achieved and maintained a reduction in BMI of greater than or equal to 1% from baseline (prior to initiation of requested agent)

      OR
   C. For Qsymia only, the patient has achieved and maintained a weight loss less than 5% from baseline (prior to initiation of requested agent) and BOTH of the following:
      i. The patient's dose is being titrated upward (for the 3.75 mg/23 mg, 7.5 mg/46 mg or 11.25 mg/69 mg strengths only)
         AND
      ii. The patient has received less than 12 weeks of therapy on the 15mg/92mg strength

      OR
   D. For Xenical only, ONE of the following:
      i. The patient 12 to 16 years of age AND has achieved and maintained a weight loss greater than 4% from baseline (prior to initiation of requested agent)
         OR

ii. The patient is 17 years of age or over AND has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of requested agent)

OR

E. For Wegovy only, ONE of the following:
   i. The patient is an adult AND has received less than 52 weeks of therapy on the 2.4 mg dose
   OR
   ii. The patient is pediatric (12 to less than 18 years of age) AND ONE of the following:
      a. The patient has received less than 52 weeks of therapy on the maximum-tolerated dose (2.4 mg or 1.7 mg)
      OR
      b. The patient has achieved and maintained a reduction in BMI of at least 5% from baseline (prior to initiation of requested agent)

AND

8. If the patient is 12 to less than 18 years of age, the current BMI is greater than 85th percentile for age and gender

AND

9. The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication

AND

10. ONE of the following:
    A. The patient has tried and failed at least three (or as many as available, if fewer than three) formulary alternatives
    OR
    B. The prescriber has indicated that available formulary alternatives are contraindicated, likely to be less effective, or likely to cause an adverse reaction or other harm

AND

11. ONE of the following:
    A. The requested quantity (dose) does NOT exceed the program quantity limit
    OR
    B. ALL of the following:
       i. The requested quantity (dose) is greater than the program quantity limit
       AND
       ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
       AND
       iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit
    OR
    C. ALL of the following:
       i. The requested quantity (dose) is greater than the program quantity limit
       AND
       ii. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
       AND
       iii. The prescriber has provided information in support of therapy with a higher dose for the requested indication

Length of Approval: Qsymia: greater than or equal to 5% weight loss from baseline (adults); greater than or equal to 5% reduction in BMI from baseline (pediatrics): 12 months
Qsymia: less than 5% weight loss from baseline (adults) less than 5% reduction in BMI from baseline (pediatrics): 3 months
All other agents: 12 months

• Program Summary: Arikayce

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
07000010121830	Arikayce	Amikacin Sulfate Liposome Inhal Susp 590 MG/8.4ML (Base Eq)	590 MG/8.4ML	28	Vials	28	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of *Mycobacterium avium* complex (MAC) lung disease as confirmed by BOTH of the following: A. Information has been provided that indicates the patient has at least ONE of the following clinical findings: pulmonary or systemic symptoms; nodular or cavitary opacities on chest radiograph; a high-resolution computed tomography scan that shows multifocal bronchiectasis with multiple small nodules **AND** B. Information has been provided that indicates the patient has at least ONE of the following microbiological findings: positive culture results from at least two separate expectorated sputum samples; positive culture result from at least one bronchial wash or lavage; transbronchial or other lung biopsy with mycobacterial histopathologic features (granulomatous inflammation or acid-fast bacilli [AFB]) AND positive culture for nontuberculous mycobacteria (NTM); biopsy showing mycobacterial histopathologic features (granulomatous inflammation or AFB) AND one or more sputum or bronchial washings that are culture positive for NTM **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient has positive sputum cultures despite at least 6 consecutive months of treatment with guideline-based combination antibiotic therapy for MAC lung disease (e.g., standard combination may include a macrolide [clarithromycin, azithromycin], a rifamycin [rifampin, rifabutin], and ethambutol) **AND** 4. The patient will continue treatment with guideline-based combination antibiotic therapy for MAC lung disease with the requested agent (e.g., combination may include a macrolide [clarithromycin, azithromycin], a rifamycin [rifampin, rifabutin], and ethambutol) **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., infectious disease, immunologist, pulmonologist, thoracic specialist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. ONE of the following: A. The patient is NOT currently being treated with another inhaled antibiotic (e.g., aztreonam for inhalation, tobramycin for inhalation) **OR** B. The patient is currently being treated with another inhaled antibiotic AND ONE of the following: 1. The patient will discontinue the other inhaled antibiotic prior to starting the requested agent **OR** 2. The prescriber has provided information in support of another inhaled antibiotic used concurrently with the requested agent **AND**

Module	Clinical Criteria for Approval
	7. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient will continue treatment with guideline-based combination antibiotic therapy for *Mycobacterium avium* complex (MAC) lung disease with the requested agent (e.g., combination may include a macrolide [clarithromycin, azithromycin], a rifamycin [rifampin, rifabutin], and ethambutol) **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., infectious disease, immunologist, pulmonologist, thoracic specialist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. ONE of the following: A. The patient is NOT currently being treated with another inhaled antibiotic (e.g., aztreonam for inhalation, tobramycin for inhalation) **OR** B. The patient is currently being treated with another inhaled antibiotic AND ONE of the following: 1. The patient will discontinue the other inhaled antibiotic prior to starting the requested agent **OR** 2. The prescriber has provided information in support of another inhaled antibiotic used concurrently with the requested agent **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of Approval:** 12 months

• Program Summary: Attention Deficit [Hyperactivity] Disorder (ADHD/ADD) Agents

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

OBJECTIVE QUANTITY LIMIT

The Quantity Limit (QL) program will apply to all ages.

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
6110001000G110		Amphetamine Extended Release Susp 1.25 MG/ML	1.25MG/ML	450	mLs	30	DAYS			
614000201002		methylphenidate hcl cap er	10 MG; 20 MG; 30 MG; 40 MG; 50 MG; 60 MG	30	Capsules	30	DAYS			
61400020107048		Methylphenidate HCl Cap ER 24HR 60 MG (LA)	60 MG	30	Capsules	30	DAYS			
61400020100530		Methylphenidate HCl Chew Tab 10 MG	10 MG	180	Tablets	30	DAYS			
61400020100510		Methylphenidate HCl Chew Tab 2.5 MG	2.5 MG	90	Tablets	30	DAYS			
61400020100520		Methylphenidate HCl Chew Tab 5 MG	5 MG	90	Tablets	30	DAYS			
61400020100403		Methylphenidate HCl Tab ER 10 MG	10 MG	90	Tablets	30	DAYS			
61400020100405		Methylphenidate HCl Tab ER 20 MG	20 MG	90	Tablets	30	DAYS			
61400020107518		Methylphenidate HCl Tab ER 24HR 18 MG	18 MG	30	Tablets	30	DAYS			
61400020107527		Methylphenidate HCl Tab ER 24HR 27 MG	27 MG	30	Tablets	30	DAYS			
61400020107536		Methylphenidate HCl Tab ER 24HR 36 MG	36 MG	60	Tablets	30	DAYS			
61400020107554		Methylphenidate HCl Tab ER 24HR 54 MG	54 MG	30	Tablets	30	DAYS			
61109902100310	Adderall	Amphetamine-Dextroamphetamine Tab 10 MG	10 MG	60	Tablets	30	DAYS			
61109902100312	Adderall	Amphetamine-Dextroamphetamine Tab 12.5 MG	12.5 MG	60	Tablets	30	DAYS			
61109902100315	Adderall	Amphetamine-Dextroamphetamine Tab 15 MG	15 MG	60	Tablets	30	DAYS			
61109902100320	Adderall	Amphetamine-Dextroamphetamine	20 MG	90	Tablets	30	DAYS			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		Tab 20 MG								
61109902100330	Adderall	Amphetamine-Dextroamphetamine Tab 30 MG	30 MG	60	Tablets	30	DAYS			
61109902100305	Adderall	Amphetamine-Dextroamphetamine Tab 5 MG	5 MG	60	Tablets	30	DAYS			
61109902100307	Adderall	Amphetamine-Dextroamphetamine Tab 7.5 MG	7.5 MG	60	Tablets	30	DAYS			
61109902107010	Adderall xr	Amphetamine-Dextroamphetamine Cap ER 24HR 10 MG	10 MG	60	Capsules	30	DAYS			
61109902107015	Adderall xr	Amphetamine-Dextroamphetamine Cap ER 24HR 15 MG	15 MG	30	Capsules	30	DAYS			
61109902107020	Adderall xr	Amphetamine-Dextroamphetamine Cap ER 24HR 20 MG	20 MG	30	Capsules	30	DAYS			
61109902107025	Adderall xr	Amphetamine-Dextroamphetamine Cap ER 24HR 25 MG	25 MG	30	Capsules	30	DAYS			
61109902107030	Adderall xr	Amphetamine-Dextroamphetamine Cap ER 24HR 30 MG	30 MG	30	Capsules	30	DAYS			
61109902107005	Adderall xr	Amphetamine-Dextroamphetamine Cap ER 24HR 5 MG	5 MG	30	Capsules	30	DAYS			
61400020107068	Adhansia xr	Methylphenidate HCl Cap ER 24HR 25 MG	25 MG	30	Capsules	30	DAYS			
61400020107073	Adhansia xr	Methylphenidate HCl Cap ER 24HR 35 MG	35 MG	30	Capsules	30	DAYS			
61400020107078	Adhansia xr	Methylphenidate HCl Cap ER 24HR 45 MG	45 MG	30	Capsules	30	DAYS			
61400020107083	Adhansia xr	Methylphenidate HCl Cap ER 24HR 55 MG	55 MG	30	Capsules	30	DAYS			
61400020107088	Adhansia xr	Methylphenidate HCl Cap ER 24HR 70 MG	70 MG	30	Capsules	30	DAYS			
61400020107091	Adhansia xr	Methylphenidate HCl Cap ER 24HR 85 MG	85 MG	30	Capsules	30	DAYS			
6110001000H440	Adzenys xr-odt	Amphetamine Tab Extended Release Disintegrating 12.5 MG	12.5 MG	30	Tablets	30	DAYS			
6110001000H450	Adzenys xr-odt	Amphetamine Tab Extended Release Disintegrating 15.7 MG	15.7 MG	30	Tablets	30	DAYS			
6110001000H460	Adzenys xr-odt	Amphetamine Tab Extended Release	18.8 MG	30	Tablets	30	DAYS			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		Disintegrating 18.8 MG								
6110001000H410	Adzenys xr-odt	Amphetamine Tab Extended Release Disintegrating 3.1 MG	3.1 MG	60	Tablets	30	DAYS			
6110001000H420	Adzenys xr-odt	Amphetamine Tab Extended Release Disintegrating 6.3 MG	6.3 MG	60	Tablets	30	DAYS			
6110001000H430	Adzenys xr-odt	Amphetamine Tab Extended Release Disintegrating 9.4 MG	9.4 MG	30	Tablets	30	DAYS			
61400020107055	Aptensio xr	Methylphenidate HCl Cap ER 24HR 10 MG (XR)	10 MG	30	Capsules	30	DAYS			
61400020107060	Aptensio xr	Methylphenidate HCl Cap ER 24HR 15 MG (XR)	15 MG	30	Capsules	30	DAYS			
61400020107065	Aptensio xr	Methylphenidate HCl Cap ER 24HR 20 MG (XR)	20 MG	30	Capsules	30	DAYS			
61400020107070	Aptensio xr	Methylphenidate HCl Cap ER 24HR 30 MG (XR)	30 MG	30	Capsules	30	DAYS			
61400020107075	Aptensio xr	Methylphenidate HCl Cap ER 24HR 40 MG (XR)	40 MG	30	Capsules	30	DAYS			
61400020107080	Aptensio xr	Methylphenidate HCl Cap ER 24HR 50 MG (XR)	50 MG	30	Capsules	30	DAYS			
61400020107085	Aptensio xr	Methylphenidate HCl Cap ER 24HR 60 MG (XR)	60 MG	30	Capsules	30	DAYS			
61409802800120	Azstarys	Serdexmethylphenidate-Dexmethylphenidate Cap	26.1-5.2 MG	30	Capsules	30	DAYS			
61409802800130	Azstarys	Serdexmethylphenidate-Dexmethylphenidate Cap	39.2-7.8 MG	30	Capsules	30	DAYS			
61409802800140	Azstarys	Serdexmethylphenidate-Dexmethylphenidate Cap	52.3-10.4 MG	30	Capsules	30	DAYS			
61400020100460	Concerta; Relexxii	Methylphenidate HCl Tab ER Osmotic Release (OSM) 18 MG	18 MG	30	Tablets	30	DAYS			
61400020100465	Concerta; Relexxii	Methylphenidate HCl Tab ER Osmotic Release (OSM) 27 MG	27 MG	30	Tablets	30	DAYS			
61400020100470	Concerta; Relexxii	Methylphenidate HCl Tab ER Osmotic Release (OSM) 36 MG	36 MG	60	Tablets	30	DAYS			
61400020100480	Concerta; Relexxii	Methylphenidate HCl Tab ER Osmotic Release (OSM) 54 MG	54 MG	30	Tablets	30	DAYS			
6140002000H420	Cotempla xr-odt	Methylphenidate Tab Extended Release Disintegrating 17.3 MG	17.3 MG	60	Tablets	30	DAYS			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
6140002000H430	Cotempla xr-odt	Methylphenidate Tab Extended Release Disintegrating 25.9 MG	25.9 MG	60	Tablets	30	DAYS			
6140002000H410	Cotempla xr-odt	Methylphenidate Tab Extended Release Disintegrating 8.6 MG	8.6 MG	30	Tablets	30	DAYS			
614000200059	Daytrana	methylphenidate td patch	10 MG/9HR; 15 MG/9HR; 20 MG/9HR; 30 MG/9HR	30	Patches	30	DAYS			
61100030100305	Desoxyn	Methamphetamine HCl Tab 5 MG	5 MG	150	Tablets	30	DAYS			
61100020107010	Dexedrine	Dextroamphetamine Sulfate Cap ER 24HR 10 MG	10 MG	120	Capsules	30	DAYS			
61100020107015	Dexedrine	Dextroamphetamine Sulfate Cap ER 24HR 15 MG	15 MG	120	Capsules	30	DAYS			
61100020107005	Dexedrine	Dextroamphetamine Sulfate Cap ER 24HR 5 MG	5 MG	90	Capsules	30	DAYS			
6110001000H210	Dyanavel xr	Amphetamine Chew Tab Extended Release	5 MG	30	Tablets	30	DAYS			
6110001000H220	Dyanavel xr	Amphetamine Chew Tab Extended Release	10 MG	30	Tablets	30	DAYS			
6110001000H230	Dyanavel xr	Amphetamine Chew Tab Extended Release	15 MG	30	Tablets	30	DAYS			
6110001000H240	Dyanavel xr	Amphetamine Chew Tab Extended Release	20 MG	30	Tablets	30	DAYS			
6110001000G120	Dyanavel xr	Amphetamine Extended Release Susp 2.5 MG/ML	2.5 MG/ML	240	mLs	30	DAYS			
61100010100320	Evekeo	Amphetamine Sulfate Tab 10 MG	10 MG	180	Tablets	30	DAYS			
61100010100310	Evekeo	Amphetamine Sulfate Tab 5 MG	5 MG	90	Tablets	30	DAYS			
611000101072	Evekeo odt	amphetamine sulfate orally disintegrating tab	10 MG; 15 MG; 20 MG; 5 MG	60	Tablets	30	DAYS			
614000161003	Focalin	dexmethylphenidate hcl tab	10 MG; 2.5 MG; 5 MG	60	Tablets	30	DAYS			
614000161070	Focalin xr	dexmethylphenidate hcl cap er	10 MG; 15 MG;	30	Capsules	30	DAYS			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
			20 MG; 25 MG; 30 MG; 35 MG; 40 MG; 5 MG							
613530301075	Intuniv	guanfacine hcl tab er	1 MG; 2 MG; 3 MG; 4 MG	30	Tablets	30	DAYS			
61400020107094	Jornay pm	Methylphenidate HCl Cap Delayed ER 24HR 100 MG (PM)	100 MG	30	Capsules	30	DAYS			
61400020107067	Jornay pm	Methylphenidate HCl Cap Delayed ER 24HR 20 MG (PM)	20 MG	30	Capsules	30	DAYS			
61400020107077	Jornay pm	Methylphenidate HCl Cap Delayed ER 24HR 40 MG (PM)	40 MG	30	Capsules	30	DAYS			
61400020107087	Jornay pm	Methylphenidate HCl Cap Delayed ER 24HR 60 MG (PM)	60 MG	30	Capsules	30	DAYS			
61400020107090	Jornay pm	Methylphenidate HCl Cap Delayed ER 24HR 80 MG (PM)	80 MG	30	Capsules	30	DAYS			
61353020107420	Kapvay	Clonidine HCl Tab ER 12HR 0.1 MG	0.1; 0.1 MG	120	Tablets	30	DAYS			
61400020102030	Methylin	Methylphenidate HCl Soln 10 MG/5ML	10 MG/5ML	900	mLs	30	DAYS			
61400020102020	Methylin	Methylphenidate HCl Soln 5 MG/5ML	5 MG/5ML	450	mLs	30	DAYS			
61109902107060	Mydayis	Amphetamine-Dextroamphetamine 3-Bead Cap ER 24HR 12.5 MG	12.5 MG	30	Capsules	30	DAYS			
61109902107065	Mydayis	Amphetamine-Dextroamphetamine 3-Bead Cap ER 24HR 25 MG	25 MG	30	Capsules	30	DAYS			
61109902107070	Mydayis	Amphetamine-Dextroamphetamine 3-Bead Cap ER 24HR 37.5 MG	37.5 MG	30	Capsules	30	DAYS			
61109902107075	Mydayis	Amphetamine-Dextroamphetamine 3-Bead Cap ER 24HR 50 MG	50 MG	30	Capsules	30	DAYS			
61100020102020	Procentra	Dextroamphetamine Sulfate Oral Solution 5 MG/5ML	5 MG/5ML	1800	mLs	30	DAYS			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
61354080207020	Qelbree	Viloxazine HCl Cap ER	100 MG	30	Capsules	30	DAYS			
61354080207030	Qelbree	Viloxazine HCl Cap ER	150 MG	60	Capsules	30	DAYS			
61354080207040	Qelbree	Viloxazine HCl Cap ER	200 MG	90	Capsules	30	DAYS			
6140002010H220	Quillichew er	Methylphenidate HCl Chew Tab Extended Release 20 MG	20 MG	30	Tablets	30	DAYS			
6140002010H230	Quillichew er	Methylphenidate HCl Chew Tab Extended Release 30 MG	30 MG	60	Tablets	30	DAYS			
6140002010H240	Quillichew er	Methylphenidate HCl Chew Tab Extended Release 40 MG	40 MG	30	Tablets	30	DAYS			
6140002010G220	Quillivant xr	Methylphenidate HCl For ER Susp 25 MG/5ML (5 MG/ML)	25 MG/5ML	360	mLs	30	DAYS			
61400020100475	Relexxii	Methylphenidate HCl Tab ER Osmotic Release (OSM)	45 MG	30	Tablets	30	DAYS			
61400020100485	Relexxii	Methylphenidate HCl Tab ER Osmotic Release (OSM)	63 MG	30	Tablets	30	DAYS			
61400020100490	Relexxii	Methylphenidate HCl Tab ER Osmotic Release (OSM) 72 MG	72 MG	30	Tablets	30	DAYS			
614000201003	Ritalin	methylphenidate hcl tab	10 MG; 20 MG; 5 MG	90	Tablets	30	DAYS			
61400020107010	Ritalin la	Methylphenidate HCl Cap ER 24HR 10 MG (LA)	10 MG	30	Capsules	30	DAYS			
61400020107020	Ritalin la	Methylphenidate HCl Cap ER 24HR 20 MG (LA)	20 MG	30	Capsules	30	DAYS			
61400020107030	Ritalin la	Methylphenidate HCl Cap ER 24HR 30 MG (LA)	30 MG	30	Capsules	30	DAYS			
61400020107040	Ritalin la	Methylphenidate HCl Cap ER 24HR 40 MG (LA)	40 MG	30	Capsules	30	DAYS			
61354015100110	Strattera	Atomoxetine HCl Cap 10 MG (Base Equiv)	10 MG	60	Capsules	30	DAYS			
61354015100180	Strattera	Atomoxetine HCl Cap 100 MG (Base Equiv)	100 MG	30	Capsules	30	DAYS			
61354015100118	Strattera	Atomoxetine HCl Cap 18 MG (Base Equiv)	18 MG	60	Capsules	30	DAYS			
61354015100125	Strattera	Atomoxetine HCl Cap 25 MG (Base Equiv)	25 MG	60	Capsules	30	DAYS			
61354015100140	Strattera	Atomoxetine HCl Cap 40 MG (Base Equiv)	40 MG	60	Capsules	30	DAYS			
61354015100160	Strattera	Atomoxetine HCl Cap 60 MG (Base Equiv)	60 MG	30	Capsules	30	DAYS			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
61354015100170	Strattera	Atomoxetine HCl Cap 80 MG (Base Equiv)	80 MG	30	Capsules	30	DAYS			
611000251001	Vyvanse	lisdexamfetamine dimesylate cap	10 MG; 20 MG; 30 MG; 40 MG; 50 MG; 60 MG; 70 MG	30	Capsules	30	DAYS			
611000251005	Vyvanse	lisdexamfetamine dimesylate chew tab	10 MG; 20 MG; 30 MG; 40 MG; 50 MG; 60 MG	30	Tablets	30	DAYS			
61100020005910	Xelstrym	Dextroamphetamine TD Patch	4.5 MG/9HR	30	Patches	30	DAYS			
61100020005920	Xelstrym	Dextroamphetamine TD Patch	9 MG/9HR	30	Patches	30	DAYS			
61100020005930	Xelstrym	Dextroamphetamine TD Patch	13.5 MG/9HR	30	Patches	30	DAYS			
61100020005940	Xelstrym	Dextroamphetamine TD Patch	18 MG/9HR	30	Patches	30	DAYS			
61100020100310	Zenzedi	Dextroamphetamine Sulfate Tab 10 MG	10 MG	180	Tablets	30	DAYS			
61100020100315	Zenzedi	Dextroamphetamine Sulfate Tab 15 MG	15 MG	90	Tablets	30	DAYS			
61100020100303	Zenzedi	Dextroamphetamine Sulfate Tab 2.5 MG	2.5 MG	90	Tablets	30	DAYS			
61100020100330	Zenzedi	Dextroamphetamine Sulfate Tab 20 MG	20 MG	90	Tablets	30	DAYS			
61100020100350	Zenzedi	Dextroamphetamine Sulfate Tab 30 MG	30 MG	60	Tablets	30	DAYS			
61100020100305	Zenzedi	Dextroamphetamine Sulfate Tab 5 MG	5 MG	90	Tablets	30	DAYS			
61100020100308	Zenzedi	Dextroamphetamine Sulfate Tab 7.5 MG	7.5 MG	90	Tablets	30	DAYS			

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL Standalone	**Evaluation** Quantities above the program quantity limit for the **Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) is greater than the program quantity limit AND ONE of the following: A. BOTH of the following:

Module	Clinical Criteria for Approval
	1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval**: 12 months

• Program Summary: ATTR Amyloidosis

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
6270104010E520	Tegsedi	Inotersen Sod Subcutaneous Pref Syr 284 MG/1.5ML (Base Eq)	284 MG/1.5 ML	4	Syringes	28	DAYS			
40550080000120	Vyndamax	Tafamidis Cap 61 MG	61 MG	30	Capsules	30	DAYS			
40550080200120	Vyndaqel	Tafamidis Meglumine (Cardiac) Cap 20 MG	20 MG	120	Capsules	30	DAYS			
6270102510D520	Wainua	eplontersen sodium subcutaneous soln auto-inj	45 MG/0.8 ML	1	Pen	30	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has ONE of the following: A. ALL of the following: 1. A diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis confirmed by testing (e.g., genetic testing, biopsy) **AND** 2. The requested agent is FDA approved for use in polyneuropathy of hereditary transthyretin-mediated amyloidosis **AND** 3. The patient has clinical manifestations of polyneuropathy (e.g., neuropathic pain, altered sensation, numbness, tingling, impaired balance, motor disability) **OR** B. ALL of the following:

Module	Clinical Criteria for Approval
	1. A diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis confirmed by testing [e.g., stannous pyrophosphate (PYP) scanning, monoclonal antibody studies, biopsy, scintigraphy, genetic testing (TTR genotyping)] **AND** 2. The requested agent is FDA approved for use in cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis **AND** 3. The patient has clinical manifestations of cardiomyopathy (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema) **OR** C. The patient has another FDA approved indication for the requested agent and route of administration **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient has NOT received a liver transplant **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, geneticist, neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient will NOT be using the requested agent in combination with another agent targeted in this program, Onpattro (patisiran), OR Amvuttra (vutrisiran) for the requested indication **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, geneticist, neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient has NOT received a liver transplant **AND** 5. The patient will NOT be using the requested agent in combination with another agent targeted in this program, Onpattro (patisiran), OR Amvuttra (vutrisiran) for the requested indication **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**

Module	Clinical Criteria for Approval
	C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of Approval:** 12 months

• Program Summary: Atypical Antipsychotics – Extended Maintenance Agents

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☑ Step Therapy ☐ Coverage / Formulary Exception

TARGET AGENT(S)	Prerequisite Agents
Abilify Asimtufii® (aripiprazole) **Abilify Maintena**® (aripiprazole) **Aristada**® (aripiprazole) **Aristada Initio**® (aripiprazole)	Any oral brand or generic: Abilify Abilify Mycite Abilify ODT Abilify solution aripiprazole
Invega Hafyera™ (paliperidone)	Invega Sustenna Invega Trinza
Invega Sustenna® (paliperidone)	Any oral brand or generic: Invega ER paliperidone ER
Invega Trinza® (paliperidone)	Invega Sustenna
Perseris™ (risperidone) **Risperdal Consta**® (risperidone)[a] **Rykindo**® (risperidone ER) **Uzedy™** (risperidone ER)	Any oral brand or generic: Risperdal Risperdal solution risperidone risperidone ODT
Zyprexa® **Relprevv™** (olanzapine)	Any oral brand or generic: olanzapine Zyprexa Zyprexa Zydis

a – available as generic; generic is a target

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Target Agent(s) will be approved when ONE of the following is met:

1. Information has been provided that indicates the patient is currently being treated with the requested agent within the past 180 days
   OR
2. The prescriber states the patient is currently being treated with the requested agent with the past 180 days AND is at risk if therapy is changed
   OR
3. The patient is currently being treated with the requested agent as indicated by ALL of the following:
   A. A statement by the prescriber that the patient is currently taking the requested agent
      AND
   B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
      AND
   C. The prescriber states that a change in therapy is expected to be ineffective or cause harm
   OR
4. The patient's medication history includes prerequisite agent use, intolerance, or hypersensitivity
   OR

5. BOTH of the following:
    A. The prescriber has stated that the patient has tried the prerequisite agent
    AND
    B. The prerequisite agent was discontinued due to lack of effectiveness or an adverse event

OR

6. The patient has an FDA labeled contraindication to ALL prerequisite agents that is not expected to occur with the requested agent

OR

7. The prescriber has provided documentation that ALL prerequisite agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

Length of Approval: 12 months

NOTE: If Quantity Limit applies, please refer to Quantity Limit documents.

• Program Summary: Baclofen

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
75100010001825	Fleqsuvy	Baclofen Susp	25 MG/5ML	480	mLs	30	DAYS			
75100010003010	Lyvispah	Baclofen Granules Packet	5 MG	120	Packets	30	DAYS			
75100010003020	Lyvispah	Baclofen Granules Packet	10 MG	120	Packets	30	DAYS			
75100010003030	Lyvispah	Baclofen Granules Packet	20 MG	120	Packets	30	DAYS			
75100010002070	Ozobax	Baclofen Oral Soln 5 MG/5ML	5 MG/5ML	2400	mLs	30	DAYS			
75100010002075	Ozobax ds	baclofen oral soln	10 MG/5ML	1200	mLs	30	DAYS			

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when BOTH of the following are met: 1. ONE of the following: A. The patient has a diagnosis of spasticity resulting from multiple sclerosis (MS) AND BOTH of the following: 1. The requested agent will be used for at least ONE of the following: A. Flexor spasms and concomitant pain **OR** B. Clonus **OR** C. Muscular rigidity **AND** 2. ONE of the following: A. BOTH of the following:

Module	Clinical Criteria for Approval
	1. ONE of the following: A. The patient has an intolerance or hypersensitivity to generic baclofen tablets that is not expected to occur with the requested agent **OR** B. The patient has an FDA labeled contraindication to generic baclofen tablets that is not expected to occur with the requested agent **OR** C. The prescriber has provided information to support use of the requested agent over generic baclofen tablets **OR** D. BOTH of the following: 1. The prescriber has stated that the patient has tried to generic baclofen tablets **AND** 2. Generic baclofen tablets were discontinued due to lack of effectiveness or an adverse event **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that generic baclofen tablets cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to another muscle relaxant (e.g., dantrolene, tizanidine) used for spasticity related to multiple sclerosis **OR** B. The patient has an intolerance or hypersensitivity to ALL muscle relaxants used for spasticity related to multiple sclerosis **OR** C. The patient has an FDA labeled contraindication to ALL muscle relaxants used for spasticity related to multiple sclerosis **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL muscle

Module	Clinical Criteria for Approval
	relaxants used for spasticity related to multiple sclerosis cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The prescriber has provided information on why the patient is unable to use a solid dosage form (e.g., difficulty swallowing tablets or capsules, feeding tube) **OR** B. The patient has a diagnosis of spasticity related to spinal cord injury or other spinal cord disease AND ONE of the following: 1. BOTH of the following: A. ONE of the following: 1. The patient has an intolerance or hypersensitivity to generic baclofen tablets that is not expected to occur with the requested agent **OR** 2. The patient has an FDA labeled contraindication to generic baclofen tablets that is not expected to occur with the requested agent **OR** 3. The prescriber has provided information to support use of the requested agent over generic baclofen tablets **OR** 4. BOTH of the following: A. The prescriber has stated that the patient has tried to generic baclofen tablets **AND** B. Generic baclofen tablets were discontinued due to lack of effectiveness or an adverse event **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that generic baclofen tablets cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. ONE of the following: 1. The patient has tried and had an inadequate response another muscle relaxant (e.g., dantrolene, pregabalin, tizanidine) used for spasticity related to spinal cord injuries or other spinal diseases **OR** 2. The patient has an intolerance, or hypersensitivity to ALL muscle relaxants used for spasticity related to spinal cord injuries or other spinal cord diseases **OR** 3. The patient has an FDA labeled contraindication to ALL muscle relaxants used for spasticity related to spinal cord injuries or other spinal cord diseases **OR**

Module	Clinical Criteria for Approval
	4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL muscle relaxants used for spasticity related to spinal cord injuries or other spinal cord diseases cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 2. The prescriber has provided information on why the patient is unable to use a solid dosage form (e.g., difficulty swallowing tablets or capsules, feeding tube) **AND** 2. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent (e.g., decreased spasms) **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher

Module	Clinical Criteria for Approval
	strength that does NOT exceed the program quantity limit **Length of Approval:** Initial: 6 months, Renewal:12 months

• Program Summary: Biologic Immunomodulators

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6627001507F810	Abrilada	adalimumab-afzb prefilled syringe kit	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001507F820	Abrilada	adalimumab-afzb prefilled syringe kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001507F520	Abrilada 1-pen kit; Abrilada 2-pen kit	adalimumab-afzb auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS				
6650007000E5	Actemra	tocilizumab subcutaneous soln prefilled syringe	162 MG/0.9ML	4	Syringes	28	DAYS				
6650007000D5	Actemra actpen	tocilizumab subcutaneous soln auto-injector	162 MG/0.9ML	4	Pens	28	DAYS				
6627001510D517	Amjevita	adalimumab-atto soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				
6627001510D520	Amjevita	adalimumab-atto soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS				
6627001510D537	Amjevita	adalimumab-atto soln auto-injector	80 MG/0.8ML	2	Pens	28	DAYS				
6627001510E505	Amjevita	adalimumab-atto soln prefilled syringe	10 MG/0.2ML	2	Syringes	28	DAYS				
6627001510E508	Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.2ML	2	Syringes	28	DAYS				
6627001510E510	Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001510E517	Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001510E520	Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS				
9025051800D520	Bimzelx	bimekizumab-bkzx subcutaneous soln auto-injector	160 MG/ML	2	Pens	56	DAYS				
9025051800E520	Bimzelx	bimekizumab-bkzx subcutaneous soln prefilled syr	160 MG/ML	2	Syringes	56	DAYS				
525050201064	Cimzia	certolizumab pegol for	200 MG	2	Kits	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		inj kit									
5250502010F840	Cimzia	Certolizumab Pegol Prefilled Syringe Kit	200 MG/ML	2	Kits	28	DAYS				
5250502010F860	Cimzia starter kit	Certolizumab Pegol Prefilled Syringe Kit	200 MG/ML	1	Kit	180	DAYS				
9025057500E530	Cosentyx	Secukinumab Subcutaneous Pref Syr 150 MG/ML (300 MG Dose)	150 MG/ML	2	Syringes	28	DAYS				
9025057500E510	Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe	75 MG/0.5ML	1	Syringe	28	DAYS				
9025057500E520	Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe 150 MG/ML	150 MG/ML	1	Syringe	28	DAYS				
9025057500D530	Cosentyx sensoready pen	Secukinumab Subcutaneous Auto-inj 150 MG/ML (300 MG Dose)	150 MG/ML	2	Pens	28	DAYS				
9025057500D520	Cosentyx sensoready pen	Secukinumab Subcutaneous Soln Auto-injector 150 MG/ML	150 MG/ML	1	Pen	28	DAYS				
9025057500D550	Cosentyx unoready	secukinumab subcutaneous soln auto-injector	300 MG/2ML	1	Pen	28	DAYS				
6627001505F520	Cyltezo	adalimumab-adbm auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS	00597037597; 00597054522			
6627001505F805	Cyltezo	adalimumab-adbm prefilled syringe kit	10 MG/0.2ML	2	Syringes	28	DAYS				
6627001505F810	Cyltezo	adalimumab-adbm prefilled syringe kit	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001505F820	Cyltezo	adalimumab-adbm prefilled syringe kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001505F520	Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00597037516; 00597054566			
6627001505F520	Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00597037523; 00597054544			
662900300021	Enbrel	etanercept for subcutaneous inj	25 MG	8	Vials	28	DAYS				
66290030002015	Enbrel	Etanercept Subcutaneous Inj 25 mg/0.5ml	25 MG/0.5ML	8	Vials	28	DAYS				
6629003000E525	Enbrel	Etanercept Subcutaneous Soln Prefilled Syringe 25 MG/0.5ML	25 MG/0.5ML	4	Syringes	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6629003000E530	Enbrel	Etanercept Subcutaneous Soln Prefilled Syringe 50 MG/ML	50 MG/ML	4	Syringes	28	DAYS				
6629003000E2	Enbrel mini	etanercept subcutaneous solution cartridge	50 MG/ML	4	Cartridges	28	DAYS				
6629003000D5	Enbrel sureclick	etanercept subcutaneous solution auto-injector	50 MG/ML	4	Pens	28	DAYS				
5250308000D220	Entyvio	vedolizumab soln pen-injector	108 MG/0.68ML	2	Pens	28	DAYS				
6627001520E510	Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001520E520	Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001520D510	Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				
6627001520D520	Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS				
6627001535F520	Hulio	adalimumab-fkjp auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS				
6627001535F810	Hulio	adalimumab-fkjp prefilled syringe kit	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001535F820	Hulio	adalimumab-fkjp prefilled syringe kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001500F804	Humira	Adalimumab Prefilled Syringe Kit 10 MG/0.1ML	10 MG/0.1ML	2	Syringes	28	DAYS				
6627001500F809	Humira	Adalimumab Prefilled Syringe Kit 20 MG/0.2ML	20 MG/0.2ML	2	Syringes	28	DAYS				
6627001500F830	Humira	Adalimumab Prefilled Syringe Kit 40 MG/0.4ML	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001500F820	Humira	Adalimumab Prefilled Syringe Kit 40 MG/0.8ML	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001500F840	Humira pediatric crohns d	Adalimumab Prefilled Syringe Kit 80 MG/0.8ML	80 MG/0.8ML	1	Kit	180	DAYS				
6627001500F880	Humira pediatric crohns d	Adalimumab Prefilled Syringe Kit 80 MG/0.8ML & 40 MG/0.4ML	80 MG/0.8ML & 40MG/0.4ML	1	Kit	180	DAYS				
6627001500F440	Humira pen	adalimumab pen-injector kit	80 MG/0.8ML	2	Pens	28	DAYS	00074012402			
6627001500F430	Humira pen	Adalimumab Pen-	40 MG/0.4ML	2	Pens	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		injector Kit 40 MG/0.4ML									
6627001500F420	Humira pen ; Humira pen-cd/uc/hs start	Adalimumab Pen-injector Kit ; adalimumab pen-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00074433906; 50090448700			
6627001500F420	Humira pen ; Humira pen-ps/uv starter	Adalimumab Pen-injector Kit ; adalimumab pen-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00074433907; 50090448700			
6627001500F440	Humira pen-cd/uc/hs start	adalimumab pen-injector kit	80 MG/0.8ML	1	Kit	180	DAYS	00074012403			
6627001500F440	Humira pen-pediatric uc s	adalimumab pen-injector kit	80 MG/0.8ML	4	Pens	180	DAYS	00074012404			
6627001500F450	Humira pen-ps/uv starter	Adalimumab Pen-injector Kit 80 MG/0.8ML & 40 MG/0.4ML	80 MG/0.8ML & 40MG/0.4ML	1	Kit	180	DAYS				
6627001504D515	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				
6627001504D515	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				
6627001504D520	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS				
6627001504E508	Hyrimoz	adalimumab-adaz soln prefilled syringe	10 MG/0.1 ML	2	Syringes	28	DAYS				
6627001504E513	Hyrimoz	adalimumab-adaz soln prefilled syringe	20 MG/0.2ML	2	Syringes	28	DAYS				
6627001504E515	Hyrimoz	adalimumab-adaz soln prefilled syringe	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001504E520	Hyrimoz	adalimumab-adaz soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001504D540	Hyrimoz ; Hyrimoz sensoready pens	adalimumab-adaz soln auto-injector	80 MG/0.8ML	2	Pens	28	DAYS	61314045420; 83457010701; 83457011301			
6627001504D540	Hyrimoz crohn's disease a; Hyrimoz sensoready pens	adalimumab-adaz soln auto-injector	80 MG/0.8ML	1	Starter Kit	180	DAYS	61314045436; 83457010701; 83457011301			
6627001504E560	Hyrimoz pediatric crohn's	adalimumab-adaz soln prefilled syr	80 MG/0.8ML & 40MG/0.4ML	2	Syringes	180	DAYS				
6627001504E540	Hyrimoz pediatric crohns	adalimumab-adaz soln prefilled syringe	80 MG/0.8ML	3	Syringes	180	DAYS				
6627001504D560	Hyrimoz plaque psoriasis	adalimumab-adaz soln auto-injector	80 MG/0.8ML & 40MG/0.4ML	1.6	Starter Kit	180	DAYS				
6627001502F540	Idacio	adalimumab-aacf auto-	40 MG/0.8ML	2	Pens	28	DAYS	65219055408;			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		injector kit						65219061299			
6627001502F840	Idacio	adalimumab-aacf prefilled syringe kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001502F540	Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	65219055428; 65219061299			
6627001502F540	Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	65219055438; 65219061299			
6650006000E5	Kevzara	sarilumab subcutaneous soln prefilled syringe	150 MG/1.14ML; 200 MG/1.14ML	2	Syringes	28	DAYS				
6650006000D5	Kevzara	sarilumab subcutaneous solution auto-injector	150 MG/1.14ML; 200 MG/1.14ML	2	Pens	28	DAYS				
6626001000E5	Kineret	anakinra subcutaneous soln prefilled syringe	100 MG/0.67ML	28	Syringes	28	DAYS				
90731060100120	Litfulo	ritlecitinib tosylate cap	50 MG	28	Capsules	28	DAYS				
666030100003	Olumiant	baricitinib tab	1 MG; 2 MG; 4 MG	30	Tablets	30	DAYS				
5250405040D520	Omvoh	mirikizumab-mrkz subcutaneous soln auto-injector	100 MG/ML	2	Pens	28	DAYS				
6640001000E520	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 125 MG/ML	125 MG/ML	4	Syringes	28	DAYS				
6640001000E510	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 50 MG/0.4ML	50 MG/0.4ML	4	Syringes	28	DAYS				
6640001000E515	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 87.5 MG/0.7ML	87.5 MG/0.7ML	4	Syringes	28	DAYS				
6640001000D5	Orencia clickject	abatacept subcutaneous soln auto-injector	125 MG/ML	4	Syringes	28	DAYS				
66603072007530	Rinvoq	Upadacitinib Tab ER	30 MG	30	Tablets	30	DAYS				
66603072007540	Rinvoq	Upadacitinib Tab ER	45 MG	84	Tablets	365	DAYS				
66603072007520	Rinvoq	Upadacitinib Tab ER 24HR 15 MG	15 MG	30	Tablets	30	DAYS				
9025052000E5	Siliq	brodalumab subcutaneous soln prefilled syringe	210 MG/1.5ML	2	Syringes	28	DAYS				
6627004000D540	Simponi	Golimumab Subcutaneous Soln	100 MG/ML	1	Syringe	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		Auto-injector 100 MG/ML									
6627004000D520	Simponi	Golimumab Subcutaneous Soln Auto-injector 50 MG/0.5ML	50 MG/0.5ML	1	Syringe	28	DAYS				
6627004000E540	Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 100 MG/ML	100 MG/ML	1	Syringe	28	DAYS				
6627004000E520	Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 50 MG/0.5ML	50 MG/0.5ML	1	Syringe	28	DAYS				
9025057070F8	Skyrizi	risankizumab-rzaa sol prefilled syringe	75 MG/0.83ML	1	Box	84	DAYS				
9025057070E5	Skyrizi	risankizumab-rzaa soln prefilled syringe	150 MG/ML	1	Injection Device	84	DAYS				
5250406070E210	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	180 MG/1.2ML	1	Cartridges	56	DAY				
5250406070E220	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	360 MG/2.4ML	1	Cartridges	56	DAYS				
9025057070D5	Skyrizi pen	risankizumab-rzaa soln auto-injector	150 MG/ML	1	Pen	84	DAYS				
90250524000320	Sotyktu	Deucravacitinib Tab	6 MG	30	Tablets	30	DAYS				
90250585002020	Stelara	Ustekinumab Inj 45 MG/0.5ML	45 MG/0.5ML	1	Vial	84	DAYS				
9025058500E520	Stelara	Ustekinumab Soln Prefilled Syringe 45 MG/0.5ML	45 MG/0.5ML	1	Syringe	84	DAYS				
9025058500E540	Stelara	Ustekinumab Soln Prefilled Syringe 90 MG/ML	90 MG/ML	1	Syringe	56	DAYS				
9025055400D5	Taltz	ixekizumab subcutaneous soln auto-injector	80 MG/ML	1	Syringe	28	DAYS				
9025055400E5	Taltz	ixekizumab subcutaneous soln prefilled syringe	80 MG/ML	1	Syringe	28	DAYS				
9025054200D2	Tremfya	guselkumab soln pen-injector	100 MG/ML	1	Pen	56	DAYS				
9025054200E5	Tremfya	guselkumab soln prefilled syringe	100 MG/ML	1	Syringe	56	DAYS				
52504525100350	Velsipity	etrasimod arginine tab	2 MG	30	Tablets	30	DAYS				
66603065102020	Xeljanz	Tofacitinib Citrate Oral Soln	1 MG/ML	240	mLs	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
66603065100330	Xeljanz	Tofacitinib Citrate Tab 10 MG (Base Equivalent)	10 MG	240	Tablets	365	DAYS				
66603065100320	Xeljanz	Tofacitinib Citrate Tab 5 MG (Base Equivalent)	5 MG	60	Tablets	30	DAYS				
66603065107530	Xeljanz xr	Tofacitinib Citrate Tab ER 24HR 11 MG (Base Equivalent)	11 MG	30	Tablets	30	DAYS				
66603065107550	Xeljanz xr	Tofacitinib Citrate Tab ER 24HR 22 MG (Base Equivalent)	22 MG	120	Tablets	365	DAYS				
6627001503F560	Yuflyma	adalimumab-aaty auto-injector kit	80 MG/0.8ML	2	Pens	28	DAYS	72606002304			
6627001503F530	Yuflyma 1-pen kit; Yuflyma 2-pen kit	adalimumab-aaty auto-injector kit	40 MG/0.4ML	2	Pens	28	DAYS				
6627001503F830	Yuflyma 2-syringe kit	adalimumab-aaty prefilled syringe kit	40 MG/0.4ML	1	Kit	28	DAYS				
6627001503F560	Yuflyma cd/uc/hs starter	adalimumab-aaty auto-injector kit	80 MG/0.8ML	1	Kit	180	DAYS	72606002307			
6627001509D240	Yusimry	adalimumab-aqvh soln pen-injector	40 MG/0.8ML	2	Pens	28	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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<tr><td>Option A - FlexRx, GenRx, BasicRx, and KeyRx</td><td>Step Table
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<tr><td colspan="7">Rheumatoid Disorders</td></tr>
<tr><td>Ankylosing Spondylitis (AS)</td><td>SQ: Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Cosentyx, Enbrel, Hadlima, Humira</td><td>Oral: Rinvoq, Xeljanz, Xeljanz XR</td><td>N/A</td><td>SQ: Cimzia, Simponi, Taltz</td><td>N/A</td><td>SQ: Abrilada**, Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Cyltezo**, Hulio**,</td></tr>
</table></td></tr>
</table>

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							Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
	Nonradiographic Axial Spondyloarthritis (nr-axSpA)	SQ: Cimzia, Cosentyx	Oral: Rinvoq	N/A	SQ: Taltz	N/A	N/A
	Polyarticular Juvenile Idiopathic Arthritis (PJIA)	SQ: Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Enbrel, Hadlima, Humira	Oral: Xeljanz	SQ: Actemra (Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Hadlima, or Humira are required Step 1 agents)	N/A	SQ: Orencia	SQ: Abrilada**, Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
	Psoriatic Arthritis (PsA)	SQ: Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Cosentyx, Enbrel, Hadlima, Humira, Skyrizi, Stelara, Tremfya Oral: Otezla	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Orencia, Simponi, Taltz	N/A	SQ: Abrilada**, Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
	Rheumatoid Arthritis	SQ: Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Enbrel, Hadlima, Humira	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Actemra (Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Hadlima, or Humira are required Step 1 agents)	Oral: Olumiant SQ: Cimzia, Kevzara, Kineret, Orencia, Simponi	N/A	SQ: Abrilada**, Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
	Dermatological Disorder						

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	Hidradenitis Suppurativa (HS)	SQ: Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL , Cosentyx, Hadlima, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
	Psoriasis (PS)	SQ: Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Cosentyx, Enbrel, Hadlima, Humira, Skyrizi, Stelara, Tremfya Oral: Otezla	N/A	N/A	SQ: Cimzia, Ilumya	N/A	SQ: Abrilada**, Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Bimzelx, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Siliq, Taltz, Yuflyma**, Yusimry** Oral: Sotyktu
	Inflammatory Bowel Disease						
	Crohn's Disease	SQ: Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Hadlima, Humira, Skyrizi, Stelara	Oral: Rinvoq	N/A	SQ: Cimzia (Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Hadlima, or Humira are required Step 1 agents)	N/A	SQ: Abrilada**, Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
	Ulcerative Colitis	SQ: Amjevita 10 mg/0.2 mL, Amjevita 20	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Amjevita 10 mg/0.2 mL,	N/A	Zeposia (Amjevita 10 mg/0.2 mL,	SQ: Abrilada**, Amjevita 20

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		mg/0.4 mL, Amjevita 40 mg/0.8 mL, Hadlima, Humira, Stelara		Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Hadlima, or Humira are required Step 1 agents)		Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Hadlima, Humira, Rinvoq, Stelara, OR Xeljanz / Xeljanz XR are required Step 1 agents)	mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Cyltezo**, Entyvio, Hulio**, Hyrimoz**, Idacio**, Omvoh, Yuflyma**, Yusimry** Oral: Velsipity
	Other						
	Uveitis	SQ: Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Hadlima, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
	Indications Without Prerequisite Biologic Immunomodulators Required						
	Alopecia Areata Atopic Dermatitis Deficiency of IL-1 Receptor Antagonist (DIRA) Enthesitis Related Arthritis (ERA) Giant Cell Arteritis (GCA) Neonatal-	N/A	N/A	N/A	N/A	N/A	N/A

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Onset Multisystem Inflammatory Disease (NOMID) Systemic Juvenile Idiopathic Arthritis (SJIA) Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)						

*Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product

**Note: Amjevita (one of: 10 mg/0.2 mL, 20 mg/0.4 mL, 40 mg/0.8 mL), Hadlima, and Humira are required Step 1 agents

Note: Branded generic available for Hulio and Hyrimoz and are included as a target at same step level in this program

Initial Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. The request is NOT for use of Olumiant in the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) *NOTE: This indication is not covered under the pharmacy benefit **AND**
2. If the request is for use in Alopecia Areata and Alopecia Areata is NOT restricted from coverage under the patient's benefit **AND**
3. ONE of the following:
   A. The requested agent is eligible for continuation of therapy AND ONE of the following:

Agents Eligible for Continuation of Therapy
All target agents EXCEPT the following are eligible for continuation of therapy
Abrilada
Amjevita 20 mg/0.2 mL
Amjevita 40 mg/0.4 mL
Amjevita 80 mg/0.8 mL
Cyltezo, Adalimumab-adbm
Entyvio
Hulio, Adalimumab-fkjp

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	Hyrimoz, Adalimumab-adaz Idacio, Adalimumab-aacf Omvoh Yusimry 1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. ALL of the following: 1. The patient has an FDA labeled indication or an indication supported in compendia for the requested agent and route of administration AND **ONE** of the following: A. The patient has a diagnosis of moderately to severely active rheumatoid arthritis (RA) AND BOTH of the following: 1. ONE of the following: A. The patient has tried and had an inadequate response to maximally tolerated methotrexate (e.g., titrated to 25 mg weekly) for at least 3-months **OR** B. The patient has tried and had an inadequate response to another conventional agent (i.e., hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA for at least 3-months **OR** C. The patient has an intolerance or hypersensitivity to ONE of the following conventional agents (i.e., maximally tolerated methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** D. The patient has an FDA labeled contraindication to ALL of the following conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** E. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of RA **OR** F. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** G. The prescriber has provided documentation that ALL conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. If the request is for Simponi, ONE of the following: A. The patient will be taking the requested agent in combination

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	with methotrexate **OR** B. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to methotrexate **OR** B. The patient has a diagnosis of active psoriatic arthritis (PsA) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA for at least 3-months **OR** 2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of PsA **OR** 3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PsA **OR** 4. The patient has severe active PsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR** 5. The patient has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** 6. The patient's medication history indicates use of another biologic immunomodulator agent OR Otezla that is FDA labeled or supported in compendia for the treatment of PsA **OR** 7. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 8. The prescriber has provided documentation that ALL conventional agents (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has a diagnosis of moderate to severe plaque psoriasis (PS) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS for at least 3-months **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PS **OR** 3. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of PS **OR** 4. The patient has severe active PS (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp,

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	face, or genitals], intractable pruritus, serious emotional consequences) **OR** 5. The patient has concomitant severe psoriatic arthritis (PsA) (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR** 6. The patient's medication history indicates use of another biologic immunomodulator agent OR Otezla that is FDA labeled or supported in compendia for the treatment of PS **OR** 7. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 8. The prescriber has provided documentation that ALL conventional agents (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. The patient has a diagnosis of moderately to severely active Crohn's disease (CD) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD for at least 3-months **OR** 2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of CD **OR** 3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of CD **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of CD **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL conventional agents (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the

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	treatment of CD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** E. The patient has a diagnosis of moderately to severely active ulcerative colitis (UC) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC for at least 3-months **OR** 2. The patient has severely active ulcerative colitis **OR** 3. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of UC **OR** 4. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of UC **OR** 5. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of UC **OR** 6. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 7. The prescriber has provided documentation that ALL conventional agents (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** F. The patient has a diagnosis of non-infectious intermediate uveitis, posterior uveitis, or panuveitis AND ONE of the following: 1. BOTH of the following: A. ONE of the following: 1. The patient has tried and had an inadequate response to oral corticosteroids used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis for a minimum of 2 weeks **OR** 2. The patient has tried and had an inadequate response to periocular or intravitreal corticosteroid injections in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 3. The patient has an intolerance or hypersensitivity to oral corticosteroids OR periocular or intravitreal

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	corticosteroid injections used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 4. The patient has an FDA labeled contraindication to BOTH oral corticosteroids and periocular/intravitreal corticosteroids **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that BOTH oral corticosteroids and periocular/intravitreal corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional systemic agent (i.e., azathioprine, mycophenolate, methotrexate, cyclosporine, tacrolimus) used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis for at least 3-months **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional systemic agent used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 3. The patient has an FDA labeled contraindication to ALL conventional systemic agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or

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	cause harm **OR** 5. The prescriber has provided documentation that ALL conventional systemic agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 2. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** G. The patient has a diagnosis of giant cell arteritis (GCA) AND ONE of the following: 1. The patient has tried and had an inadequate response to systemic corticosteroids (e.g., prednisone, methylprednisolone) used in the treatment of GCA for at least 7-10 days **OR** 2. The patient has an intolerance or hypersensitivity to systemic corticosteroids used in the treatment of GCA **OR** 3. The patient has an FDA labeled contraindication to ALL systemic corticosteroids **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of GCA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL systemic corticosteroids (e.g., prednisone, methylprednisolone) used in the treatment of GCA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** H. The patient has a diagnosis of active ankylosing spondylitis (AS) AND ONE of the following: 1. The patient has tried and had an inadequate response to two different NSAIDs used in the treatment of AS for at least a 4-week total trial **OR** 2. The patient has an intolerance or hypersensitivity to two different NSAIDs used in the treatment of AS **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of AS **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in

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	compendia for the treatment of AS **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of AS cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** I. The patient has a diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) AND ONE of the following: 1. The patient has tried and had an inadequate response to two different NSAIDs used in the treatment of nr-axSpA for at least a 4-week total trial **OR** 2. The patient has an intolerance or hypersensitivity to two different NSAIDs used in the treatment of nr-axSpA **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of nr-axSpA **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of nr-axSpA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of nr-axSpA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** J. The patient has a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., methotrexate, leflunomide) used in the treatment of PJIA for at least 3-months **OR** 2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of PJIA **OR** 3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PJIA **OR**

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	4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of PJIA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL conventional agents (i.e., methotrexate, leflunomide) used in the treatment of PJIA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** K. The patient has a diagnosis of moderate to severe hidradenitis suppurativa (HS) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., oral tetracyclines [doxycycline, minocycline, tetracycline]; oral contraceptives [females only]; metformin [females only]; finasteride [females only]; spironolactone [females only]; intralesional corticosteroids [triamcinolone]; clindamycin in combination with rifampin; combination of rifampin, moxifloxacin, and metronidazole; cyclosporine, oral retinoids) used in the treatment of HS for at least 3-months **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of HS **OR** 3. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of HS **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of HS **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL conventional agents (i.e., oral tetracyclines [doxycycline, minocycline, tetracycline]; oral contraceptives [females only]; metformin [females only]; finasteride [females only]; spironolactone [females only]; intralesional corticosteroids [triamcinolone]; clindamycin in combination with rifampin; combination of rifampin, moxifloxacin, and metronidazole; cyclosporine, oral retinoids) used in the treatment of HS cannot be

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	used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** L. BOTH of the following: 1. The patient has a diagnosis of systemic sclerosis associated interstitial lung disease (SSc-ILD) **AND** 2. The patient's diagnosis has been confirmed on high-resolution computed tomography (HRCT) or chest radiography scans **OR** M. The patient has a diagnosis of active enthesitis related arthritis (ERA) and ONE of the following: 1. The patient has tried and had an inadequate response to two different NSAIDs used in the treatment of ERA for at least a 4-week total trial **OR** 2. The patient has an intolerance or hypersensitivity to two different NSAIDs used in the treatment of ERA **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of ERA **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of ERA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of ERA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** N. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following: 1. ONE of the following: A. The patient has at least 10% body surface area involvement **OR** B. The patient has involvement of the palms and/or soles of the feet **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to at least a mid- potency topical steroid used in the treatment of AD for a minimum of 4 weeks **AND** a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD for a minimum of 6 weeks **OR** B. The patient has an intolerance or hypersensitivity to at least a mid- potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR**

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	C. The patient has an FDA labeled contraindication to ALL mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. ONE of the following**:** A. The patient has tried and had an inadequate response to a systemic immunosuppressant, including a biologic, used in the treatment of AD for a minimum of 3 months **OR** B. The patient has an intolerance or hypersensitivity to therapy with systemic immunosuppressants, including a biologic, used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL systemic immunosuppressants, including biologics, used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL systemic immunosuppressants, including biologics, used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The prescriber has documented the patient's baseline pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **AND** 5. BOTH of the following: A. The patient is currently treated with topical emollients and practicing good skin care **AND**

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	B. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent **OR** O. BOTH of the following: 1. The patient has a diagnosis of severe alopecia areata (AA) **AND** 2. The patient has at least 50% scalp hair loss that has lasted 6 months or more **OR** P. The patient has a diagnosis of polymyalgia rheumatica (PMR) AND ONE of the following: 1. The patient has tried and had an inadequate response to systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR for a minimum of 8 weeks **OR** 2. The patient is currently treated with systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone and cannot tolerate a corticosteroid taper **OR** 3. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 4. The prescriber has provided documentation that ALL systemic corticosteroids used in the treatment of PMR cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** Q. The patient has a diagnosis not mentioned previously **AND** 2. ONE of the following (reference Step Table): A. The requested indication does NOT require any prerequisite biologic immunomodulator agents **OR** B. The requested agent is a Step 1a agent for the requested indication **OR** C. If the requested agent is a Step 1b agent for the requested indication, then ONE of the following: 1. The patient has tried and had an inadequate response to ONE Tumor Necrosis Factor (TNF) inhibitor for the requested indication for at least 3-months (See Step 1a for preferred TNF inhibitors) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to therapy with a TNF inhibitor for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL TNF inhibitors for the requested indication **OR** 4. BOTH of the following: A. The prescriber has provided information indicating why ALL TNF inhibitors are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR**

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	5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL TNF inhibitors for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. If the requested agent is a Step 2 agent for the requested indication, then ONE of the following: 1. The patient has tried and had an inadequate response to ONE of the required Step 1 agents for the requested indication for at least 3-months (See Step 2) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE of the required Step 1 agents for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL required Step 1 agents for the requested indication **OR** 4. BOTH of the following: A. The prescriber has provided information indicating why ALL of the required Step 1 agents are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL required Step 1 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** E. If the requested agent is a Step 3a agent for the requested indication, then ONE of the following (chart notes required): 1. The patient has tried and had an inadequate response to TWO of the Step 1 agents for the requested indication for at least 3-months (See Step 3a) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or

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	its excipients, not to the route of administration or hypersensitivity to TWO of the Step 1 agents for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL of the Step 1 agents for the requested indication **OR** 4. BOTH of the following: A. The prescriber has provided information indicating why ALL of the Step 1 agents are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL of the Step 1 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** F. If the requested agent is a Step 3b agent for the requested indication, then ONE of the following (chart notes required): 1. The patient has tried and had an inadequate response to TWO agents from Step 1 and/or Step 2 for the requested indication for at least 3-months (See Step 3b) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to TWO agents from Step 1 and/or Step 2 for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL of the Step 1 AND Step 2 agents for the requested indication **OR** 4. BOTH of the following: A. The prescriber has provided information indicating why ALL of the Step 1 AND Step 2 agents are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL of the Step 1 AND Step 2 agents for the requested indication cannot be used due to a

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	documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** G. If the requested agent is a Step 3c agent for the requested indication, then ONE of the following (chart notes required): 1. The patient has tried and had an inadequate response to THREE of the Step 1 agents for the requested indication for at least 3-months (See Step 3c) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to THREE of the Step 1 agents for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL of the Step 1 agents for the requested indication **OR** 4. BOTH of the following: A. The prescriber has provided information indicating why ALL of the Step 1 agents are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL of the Step 1 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. If Cosentyx 300 mg every 4 weeks is requested as maintenance dosing, ONE of the following: A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis **OR** B. The patient has a diagnosis of hidradenitis suppurativa **OR** C. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks for at least 3-months **AND** 4. If Entyvio is requested for the treatment of ulcerative colitis, the patient has received at least 2 doses of Entyvio intravenous therapy **AND** 5. If Omvoh is requested for the treatment of ulcerative colitis, the patient has received Omvoh IV for induction therapy **AND** 6. If Skyrizi is requested for the treatment of Crohn's disease, the patient received Skyrizi IV for induction therapy **AND** 7. If Stelara is requested for the treatment of Crohn's disease or ulcerative colitis, the patient received Stelara IV for induction therapy **AND** 4. If the patient has an FDA approved indication, then ONE of the following:

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	A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 5. If Stelara 90 mg is requested, ONE of the following: A. The patient has a diagnosis of psoriasis AND weighs >100kg **OR** B. The patient has a dual diagnosis of psoriasis AND psoriatic arthritis AND the patient is >100kg **OR** C. The patient has a diagnosis of Crohn's disease or ulcerative colitis **AND** 6. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND** 7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or has consulted with a specialist in the area of the patient's diagnosis **AND** 8. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, i.e., clinical trials, phase III studies, guidelines required) **AND** 9. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 10. The patient has been tested for latent tuberculosis (TB) when required by the prescribing information for the requested agent AND if positive the patient has begun therapy for latent TB **Length of Approval:** 12 months for all agents EXCEPT adalimumab containing products for ulcerative colitis (UC), Rinvoq for atopic dermatitis (AD), Siliq for plaque psoriasis (PS), Xeljanz and Xeljanz XR for induction therapy for UC, and the agents with indications that require loading doses for new starts. NOTE: For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of the 12 months. Adalimumab containing products for UC may be approved for 12 weeks, Rinvoq for AD may be approved for 6 months, Siliq for PS may be approved for 16 weeks, and Xeljanz and Xeljanz XR for UC may be approved for 16 weeks. **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The request is NOT for use of Olumiant or Actemra in the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) *NOTE: This indication is not covered under the pharmacy benefit **AND** 2. The request is for use in Alopecia Areata and Alopecia Areata is NOT restricted from coverage under the patient's benefit **AND** 3. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (*please note Stelara renewal must be for the same strength as the initial approval) **AND** 4. ONE of the following:

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	A. The patient has a diagnosis of moderate to severe atopic dermatitis AND BOTH of the following: 1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following: A. Affected body surface area **OR** B. Flares **OR** C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **AND** 2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has a diagnosis of polymyalgia rheumatica AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. If the requested agent is Kevzara, the patient does NOT have any of the following: A. Neutropenia (ANC less than 1,000 per mm^3 at the end of the dosing interval) **AND** B. Thrombocytopenia (platelet count is less than 100,000 per mm^3) **AND** C. AST or ALT elevations 3 times the upper limit of normal **OR** C. The patient has a diagnosis other than moderate to severe atopic dermatitis or polymyalgia rheumatica AND the patient has had clinical benefit with the requested agent **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, i.e., clinical trials, phase III studies, guidelines required) **AND** 7. If Cosentyx 300 mg every 4 weeks is requested as maintenance dosing, ONE of the following: A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis **OR** B. The patient has a diagnosis of hidradenitis suppurativa **OR** C. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks for at least 3-months **AND** 8. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND** 9. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Option B - Focus Rx	**Step Table**

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	Disease State	**Step 1**		**Step 2 (Directed to ONE step 1 agent)**	**Step 3a (Directed to TWO step 1 agents)**	**Step 3b (Directed to TWO agents from step 1 and/or step 2)**	**Step 3c*** (Directed to THREE step 1 agents)**
		Step 1a	**Step 1b (Directed to ONE TNF inhibitor) NOTE: Please see Step 1a for preferred TNF inhibitors**				
	Rheumatoid Disorders						
	Ankylosing Spondylitis (AS)	SQ: Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Cosentyx, Cyltezo, Enbrel, Humira	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Simponi, Taltz	N/A	SQ: Abrilada**, Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
	Nonradiographic Axial Spondyloarthritis (nr-axSpA)	SQ: Cimzia, Cosentyx	Oral: Rinvoq	N/A	SQ: Taltz	N/A	N/A
	Polyarticular Juvenile Idiopathic Arthritis (PJIA)	SQ: Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Cyltezo, Enbrel, Humira	Oral: Xeljanz	SQ: Actemra (Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Cyltezo, or Humira are required Step 1 agents)	N/A	SQ: Orencia	SQ: Abrilada**, Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
	Psoriatic Arthritis (PsA)	SQ: Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Cosentyx, Cyltezo, Enbrel, Humira,	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Orencia, Simponi, Taltz	N/A	SQ: Abrilada**, Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Hadlima**, Hulio**,

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		Skyrizi, Stelara, Tremfya Oral: Otezla					Hyrimoz**, Idacio**, Yusimry**
	Rheumatoid Arthritis	SQ: Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Enbrel, Cyltezo, Humira	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Actemra (Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Cyltezo, or Humira are required Step 1 agents)	Oral: Olumiant SQ: Cimzia, Kevzara, Kineret, Orencia, Simponi	N/A	SQ: Abrilada**, Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
	Dermatological Disorder						
	Hidradenitis Suppurativa (HS)	SQ: Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Cosentyx, Cyltezo, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
	Psoriasis (PS)	SQ: Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Cosentyx, Cyltezo, Enbrel, Humira, Skyrizi, Stelara, Tremfya Oral: Otezla	N/A	N/A	SQ: Cimzia, Ilumya	N/A	SQ: Abrilada**, Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Siliq, Taltz, Yusimry** Oral: Sotyktu
	Inflammatory Bowel Disease						
	Crohn's Disease	SQ: Amjevita 10 mg/0.2 mL,	Oral: Rinvoq	N/A	SQ: Cimzia (Amjevita 10	N/A	SQ: Abrilada**,

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		Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Cyltezo, Humira, Skyrizi, Stelara			mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Cyltezo, or Humira are required Step 1 agents)		Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
	Ulcerative Colitis	SQ: Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Cyltezo, Humira, Stelara	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Cyltezo, or Humira are required Step 1 agents)	N/A	Zeposia (Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Cyltezo, Humira, Rinvoq, Stelara, OR Xeljanz / Xeljanz XR are required Step agents)	SQ: Abrilada**, Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Entyvio, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
	Other						
	Uveitis	SQ: Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Cyltezo, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
	Indications Without Prerequisite Biologic Immunomodulators Required						
	Alopecia Areata Atopic Dermatitis Deficiency of IL-1 Receptor Antagonist	N/A	N/A	N/A	N/A	N/A	N/A

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(DIRA) Enthesitis Related Arthritis (ERA) Giant Cell Arteritis (GCA) Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Systemic Juvenile Idiopathic Arthritis (SJIA) Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)						

*Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product

**Note: Amjevita (one of 10 mg/0.2 mL, 20 mg/0.4 mL, 40 mg/0.8 mL), Cyltezo, and Humira are required Step 1 agents

Note: branded generic available for Hulio and Hyrimoz and are a target at same step level in this this program

Initial Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. The request is NOT for use of Olumiant in the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) *NOTE: This indication is not covered under the pharmacy benefit **AND**
2. If the request is for use in Alopecia Areata and Alopecia Areata is NOT restricted from coverage under the patient's benefit **AND**
3. ONE of the following:
   A. The requested agent is eligible for continuation of therapy AND ONE of the following:

Agents Eligible for Continuation of Therapy
All target agents EXCEPT the following are eligible for continuation of therapy
Abrilada
Amjevita 20 mg/0.2 mL

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Amjevita 40 mg/0.4 mL
Amjevita 80 mg/0.8 mL
Entyvio
Hadlima
Hulio, Adalimumab-fkjp
Hyrimoz, Adalimumab-adaz
Idacio, Adalimumab-aacf
Omvoh
Yuflyma
Yusimry

1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**
2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR**

B. ALL of the following:
1. The patient has an FDA labeled indication or an indication supported in compendia for the requested agent and route of administration AND **ONE** of the following:
A. The patient has a diagnosis of moderately to severely active rheumatoid arthritis (RA) AND BOTH of the following:
1. ONE of the following:
A. The patient has tried and had an inadequate response to maximally tolerated methotrexate (e.g., titrated to 25 mg weekly) for at least 3-months **OR**
B. The patient has tried and had an inadequate response to another conventional agent (i.e., hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA for at least 3-months **OR**
C. The patient has an intolerance or hypersensitivity to ONE of the following conventional agents (i.e., maximally tolerated methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR**
D. The patient has an FDA labeled contraindication to ALL of the following conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR**
E. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of RA **OR**
F. The patient is currently being treated with the requested agent as indicated by ALL of the following:
1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND**
3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
G. The prescriber has provided documentation that ALL conventional agents (i.e., methotrexate, hydroxychloroquine,

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	leflunomide, sulfasalazine) used in the treatment of RA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. If the request is for Simponi, ONE of the following: A. The patient will be taking the requested agent in combination with methotrexate **OR** B. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to methotrexate **OR** B. The patient has a diagnosis of active psoriatic arthritis (PsA) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA for at least 3-months **OR** 2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of PsA **OR** 3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PsA **OR** 4. The patient has severe active PsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR** 5. The patient has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** 6. The patient's medication history indicates use of another biologic immunomodulator agent OR Otezla that is FDA labeled or supported in compendia for the treatment of PsA **OR** 7. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 8. The prescriber has provided documentation that ALL conventional agents (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has a diagnosis of moderate to severe plaque psoriasis (PS) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA

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	[phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS for at least 3-months **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PS **OR** 3. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of PS **OR** 4. The patient has severe active PS (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** 5. The patient has concomitant severe psoriatic arthritis (PsA) (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR** 6. The patient's medication history indicates use of another biologic immunomodulator agent OR Otezla that is FDA labeled or supported in compendia for the treatment of PS **OR** 7. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 8. The prescriber has provided documentation that ALL conventional agents (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. The patient has a diagnosis of moderately to severely active Crohn's disease (CD) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD for at least 3-months **OR** 2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of CD **OR** 3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of CD **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of CD **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND**

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	B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL conventional agents (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** E. The patient has a diagnosis of moderately to severely active ulcerative colitis (UC) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC for at least 3-months **OR** 2. The patient has severely active ulcerative colitis **OR** 3. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of UC **OR** 4. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of UC **OR** 5. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of UC **OR** 6. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 7. The prescriber has provided documentation that ALL conventional agents (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** F. The patient has a diagnosis of non-infectious intermediate uveitis, posterior uveitis, or panuveitis AND ONE of the following: 1. BOTH of the following: A. ONE of the following: 1. The patient has tried and had an inadequate response to oral corticosteroids used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis for a minimum of 2

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	weeks **OR** 2. The patient has tried and had an inadequate response to periocular or intravitreal corticosteroid injections in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 3. The patient has an intolerance or hypersensitivity to oral corticosteroids OR periocular or intravitreal corticosteroid injections used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 4. The patient has an FDA labeled contraindication to BOTH oral corticosteroids and periocular/intravitreal corticosteroids **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that BOTH oral corticosteroids and periocular/intravitreal corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional systemic agent (i.e., azathioprine, mycophenolate, methotrexate, cyclosporine, tacrolimus) used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis for at least 3-months **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional systemic agent used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 3. The patient has an FDA labeled contraindication to ALL conventional systemic agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the

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	patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL conventional systemic agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 2. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** G. The patient has a diagnosis of giant cell arteritis (GCA) AND ONE of the following: 1. The patient has tried and had an inadequate response to systemic corticosteroids (e.g., prednisone, methylprednisolone) used in the treatment of GCA for at least 7-10 days **OR** 2. The patient has an intolerance or hypersensitivity to systemic corticosteroids used in the treatment of GCA **OR** 3. The patient has an FDA labeled contraindication to ALL systemic corticosteroids **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of GCA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL systemic corticosteroids (e.g., prednisone, methylprednisolone) used in the treatment of GCA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** H. The patient has a diagnosis of active ankylosing spondylitis (AS) AND ONE of the following:

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	1. The patient has tried and had an inadequate response to two different NSAIDs used in the treatment of AS for at least a 4-week total trial **OR** 2. The patient has an intolerance or hypersensitivity to two different NSAIDs used in the treatment of AS **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of AS **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of AS **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of AS cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** I. The patient has a diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) AND ONE of the following: 1. The patient has tried and had an inadequate response to two different NSAIDs used in the treatment of nr-axSpA for at least a 4-week total trial **OR** 2. The patient has an intolerance or hypersensitivity to two different NSAIDs used in the treatment of nr-axSpA **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of nr-axSpA **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of nr-axSpA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of nr-axSpA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** J. The patient has a diagnosis of moderately to severely active polyarticular

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	juvenile idiopathic arthritis (PJIA) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., methotrexate, leflunomide) used in the treatment of PJIA for at least 3-months **OR** 2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of PJIA **OR** 3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PJIA **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of PJIA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL conventional agents (i.e., methotrexate, leflunomide) used in the treatment of PJIA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** K. The patient has a diagnosis of moderate to severe hidradenitis suppurativa (HS) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., oral tetracyclines [doxycycline, minocycline, tetracycline]; oral contraceptives [females only]; metformin [females only]; finasteride [females only]; spironolactone [females only]; intralesional corticosteroids [triamcinolone]; clindamycin in combination with rifampin; combination of rifampin, moxifloxacin, and metronidazole; cyclosporine, oral retinoids) used in the treatment of HS for at least 3-months **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of HS **OR** 3. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of HS **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of HS **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to

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	be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL conventional agents (i.e., oral tetracyclines [doxycycline, minocycline, tetracycline]; oral contraceptives [females only]; metformin [females only]; finasteride [females only]; spironolactone [females only]; intralesional corticosteroids [triamcinolone]; clindamycin in combination with rifampin; combination of rifampin, moxifloxacin, and metronidazole; cyclosporine, oral retinoids) used in the treatment of HS cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** L. BOTH of the following: 1. The patient has a diagnosis of systemic sclerosis associated interstitial lung disease (SSc-ILD) **AND** 2. The patient's diagnosis has been confirmed on high-resolution computed tomography (HRCT) or chest radiography scans **OR** M. The patient has a diagnosis of active enthesitis related arthritis (ERA) and ONE of the following: 1. The patient has tried and had an inadequate response to two different NSAIDs used in the treatment of ERA for at least a 4-week total trial **OR** 2. The patient has an intolerance or hypersensitivity to two different NSAIDs used in the treatment of ERA **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of ERA **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of ERA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of ERA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** N. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following: 1. ONE of the following: A. The patient has at least 10% body surface area involvement **OR** B. The patient has involvement of the palms and/or soles of the feet **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to at

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	least a mid- potency topical steroid used in the treatment of AD for a minimum of 4 weeks **AND** a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD for a minimum of 6 weeks **OR** B. The patient has an intolerance or hypersensitivity to at least a mid- potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. ONE of the following**:** A. The patient has tried and had an inadequate response to a systemic immunosuppressant, including a biologic, used in the treatment of AD for a minimum of 3 months **OR** B. The patient has an intolerance or hypersensitivity to therapy with systemic immunosuppressants, including a biologic, used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL systemic immunosuppressants, including biologics, used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL systemic immunosuppressants, including biologics, used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or

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	maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The prescriber has documented the patient's baseline pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **AND** 5. BOTH of the following: A. The patient is currently treated with topical emollients and practicing good skin care **AND** B. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent **OR** O. BOTH of the following: 1. The patient has a diagnosis of severe alopecia areata (AA) **AND** 2. The patient has at least 50% scalp hair loss that has lasted 6 months or more **OR** P. The patient has a diagnosis of polymyalgia rheumatica (PMR) AND ONE of the following: 1. The patient has tried and had an inadequate response to systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR for a minimum of 8 weeks **OR** 2. The patient is currently treated with systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone and cannot tolerate a corticosteroid taper **OR** 3. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 4. The prescriber has provided documentation that ALL systemic corticosteroids used in the treatment of PMR cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** Q. The patient has a diagnosis not mentioned previously **AND** 2. ONE of the following (reference Step Table): A. The requested indication does NOT require any prerequisite biologic immunomodulator agents **OR** B. The requested agent is a Step 1a agent for the requested indication **OR** C. If the requested agent is a Step 1b agent for the requested indication, then ONE of the following: 1. The patient has tried and had an inadequate response to ONE Tumor Necrosis Factor (TNF) inhibitor for the requested indication for at least 3-months (See Step 1a for preferred TNF inhibitors) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to therapy with a TNF inhibitor for the requested indication **OR**

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	3. The patient has an FDA labeled contraindication to ALL TNF inhibitors for the requested indication **OR** 4. BOTH of the following: A. The prescriber has provided information indicating why ALL TNF inhibitors are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL TNF inhibitors for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. If the requested agent is a Step 2 agent for the requested indication, then ONE of the following: 1. The patient has tried and had an inadequate response to ONE of the required Step 1 agents for the requested indication for at least 3-months (See Step 2) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE of the required Step 1 agents for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL required Step 1 agents for the requested indication **OR** 4. BOTH of the following: A. The prescriber has provided information indicating why ALL of the required Step 1 agents are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL required Step 1 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or

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	maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** E. If the requested agent is a Step 3a agent for the requested indication, then ONE of the following (chart notes required): 1. The patient has tried and had an inadequate response to TWO of the Step 1 agents for the requested indication for at least 3-months (See Step 3a) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration or hypersensitivity to TWO of the Step 1 agents for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL of the Step 1 agents for the requested indication **OR** 4. BOTH of the following: A. The prescriber has provided information indicating why ALL of the Step 1 agents are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL of the Step 1 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** F. If the requested agent is a Step 3b agent for the requested indication, then ONE of the following (chart notes required): 1. The patient has tried and had an inadequate response to TWO agents from Step 1 and/or Step 2 for the requested indication for at least 3-months (See Step 3b) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to TWO agents from Step 1 and/or Step 2 for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL of the Step 1 AND Step 2 agents for the requested indication **OR** 4. BOTH of the following: A. The prescriber has provided information indicating why ALL of the Step 1 AND Step 2 agents are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently

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	taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL of the Step 1 AND Step 2 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** G. If the requested agent is a Step 3c agent for the requested indication, then ONE of the following (chart notes required): 1. The patient has tried and had an inadequate response to THREE of the Step 1 agents for the requested indication for at least 3-months (See Step 3c) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to THREE of the Step 1 agents for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL of the Step 1 agents for the requested indication **OR** 4. BOTH of the following: A. The prescriber has provided information indicating why ALL of the Step 1 agents are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL of the Step 1 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. If Cosentyx 300 mg every 4 weeks is requested as maintenance dosing, ONE of the following: A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis **OR** B. The patient has a diagnosis of hidradenitis suppurativa **OR** C. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks for at least 3-months **AND** 4. If Entyvio is requested for the treatment of ulcerative colitis, the patient has received at

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	least 2 doses of Entyvio intravenous therapy **AND** 5. If Omvoh is requested for the treatment of ulcerative colitis, the patient received Omvoh IV for induction therapy **AND** 6. If Skyrizi is requested for the treatment of Crohn's disease, the patient received Skyrizi IV for induction therapy **AND** 7. If Stelara is requested for the treatment of Crohn's disease or ulcerative colitis, the patient received Stelara IV for induction therapy **AND** 4. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 5. If Stelara 90 mg is requested, ONE of the following: A. The patient has a diagnosis of psoriasis AND weighs >100kg **OR** B. The patient has a dual diagnosis of psoriasis AND psoriatic arthritis AND the patient is >100kg **OR** C. The patient has a diagnosis of Crohn's disease or ulcerative colitis **AND** 6. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND** 7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or has consulted with a specialist in the area of the patient's diagnosis **AND** 8. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, i.e., clinical trials, phase III studies, guidelines required) **AND** 9. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 10. The patient has been tested for latent tuberculosis (TB) when required by the prescribing information for the requested agent AND if positive the patient has begun therapy for latent TB **Length of Approval:** 12 months for all agents EXCEPT adalimumab containing products for ulcerative colitis (UC), Rinvoq for atopic dermatitis (AD), Siliq for plaque psoriasis (PS), Xeljanz and Xeljanz XR for induction therapy for UC, and the agents with indications that require loading doses for new starts. NOTE: For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of the 12 months. Adalimumab containing products for UC may be approved for 12 weeks, Rinvoq for AD may be approved for 6 months, Siliq for PS may be approved for 16 weeks, and Xeljanz and Xeljanz XR for UC may be approved for 16 weeks. **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The request is NOT for use of Olumiant or Actemra in the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation,

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	or extracorporeal membrane oxygenation (ECMO) *NOTE: This indication is not covered under the pharmacy benefit **AND** 2. The request is for use in Alopecia Areata and Alopecia Areata is NOT restricted from coverage under the patient's benefit **AND** 3. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (*please note Stelara renewal must be for the same strength as the initial approval) **AND** 4. ONE of the following: A. The patient has a diagnosis of moderate to severe atopic dermatitis AND BOTH of the following: 1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following: A. Affected body surface area **OR** B. Flares **OR** C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **AND** 2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has a diagnosis of polymyalgia rheumatica AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. If the requested agent is Kevzara, the patient does NOT have any of the following: A. Neutropenia (ANC less than 1,000 per mm^3 at the end of the dosing interval) **AND** B. Thrombocytopenia (platelet count is less than 100,000 per mm^3) **AND** C. AST or ALT elevations 3 times the upper limit of normal **OR** C. The patient has a diagnosis other than moderate to severe atopic dermatitis or polymyalgia rheumatica AND the patient has had clinical benefit with the requested agent **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, i.e., clinical trials, phase III studies, guidelines required) **AND** 7. If Cosentyx 300 mg every 4 weeks is requested as maintenance dosing, ONE of the following: A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis **OR** B. The patient has a diagnosis of hidradenitis suppurativa **OR** C. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks for at least 3-months **AND** 8. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND** 9. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months

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	**NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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QL All Program Type	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. The requested agent is Xeljanz/Xeljanz XR for a diagnosis of ulcerative colitis, AND BOTH of the following: 1. The prescriber has provided information in support of therapy for the dose exceeding the quantity limit [e.g., patient has lost response to the FDA labeled maintenance dose (i.e., 5 mg twice daily or 11 mg once daily) during maintenance treatment; requires restart of induction therapy] (medical records required **AND** 2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit **OR** B. The requested agent is Xeljanz oral solution for a diagnosis of polyarticular course juvenile idiopathic arthritis, AND ONE of the following: 1. BOTH of the following: A. The requested quantity (dose) does not exceed the maximum FDA labeled dose (i.e., 5 mg twice daily) NOR the maximum compendia supported dose **AND** B. The prescriber has provided information stating why the patient cannot take Xeljanz 5 mg tablets **OR** 2. The requested quantity (dose) exceeds the maximum FDA labeled dose but does NOT exceed the maximum compendia supported dose for the requested indication **OR** 3. BOTH of the following: A. The requested quantity (dose) exceeds the maximum FDA labeled dose AND the maximum compendia supported dose for the requested indication **AND** B. The prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required) **OR** C. The requested agent is NOT Xeljanz/Xeljanz XR for a diagnosis of ulcerative colitis or polyarticular course juvenile idiopathic arthritis, AND ONE of the following: 1. The patient has an FDA labeled indication for the requested agent, AND ONE of the following: A. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose **AND** 2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does NOT exceed the program quantity limit **OR** B. ALL of the following: 1. The requested quantity (dose) exceeds the FDA maximum labeled dose **AND** 2. The patient has tried and had an inadequate response to at least

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	a 3 month trial of the maximum FDA labeled dose (medical records required) **AND** 3. ONE of the following: A. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum compendia supported dose for the requested indication **AND** 2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does NOT exceed the program quantity limit **OR** B. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose AND the maximum compendia supported dose for the requested indication **AND** 2. The prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required) **OR** 2. The patient has a compendia supported indication for the requested agent, AND ONE of the following: A. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum compendia supported dose for the requested indication **AND** 2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does NOT exceed the program quantity limit **OR** B. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum compendia supported dose for the requested indication **AND** 2. The prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required) **OR** 3. The patient does NOT have an FDA labeled indication NOR a compendia supported indication for the requested agent AND BOTH of the following: A. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit **AND** B. The prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required) **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** **Initial Approval with PA:** 12 months for all agents EXCEPT adalimumab containing products for ulcerative colitis (UC), Rinvoq for atopic dermatitis (AD), Siliq for plaque psoriasis (PS), Xeljanz and Xeljanz XR for induction therapy for UC, and the agents with indications that require loading doses for new starts. NOTE: For

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	agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of the 12 months. Adalimumab containing products for UC may be approved for 12 weeks, Rinvoq for AD may be approved for 6 months, Siliq for PS may be approved for 16 weeks, and Xeljanz and Xeljanz XR for UC may be approved for 16 weeks. **Renewal Approval with PA:** 12 months **Standalone QL approval:** 12 months or through the remainder of an existing authorization, whichever is shorter **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable.

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly
Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)
Cibinqo (abrocitinib)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Litfulo (ritlecitinib)
Nucala (mepolizumab)

Contraindicated as Concomitant Therapy
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tysabri (natalizumab)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)
Zymfentra (infliximab-dyyb)

• Program Summary: Cibinqo (abrocitinib)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
90272005000320	Cibinqo	Abrocitinib Tab	50 MG	30	Tablets	30	DAYS			09-01-2022
90272005000325	Cibinqo	Abrocitinib Tab	100 MG	30	Tablets	30	DAYS			09-01-2022
90272005000330	Cibinqo	Abrocitinib Tab	200 MG	30	Tablets	30	DAYS			09-01-2022

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** B. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** C. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following: 1. ONE of the following: A. The patient has at least 10% body surface area involvement **OR** B. The patient has involvement of body sites that are difficult to treat with prolonged topical corticosteroid therapy (e.g., hands, feet, face, neck, scalp, genitals/groin, skin folds) **OR** C. The patient has an Eczema Area and Severity Index (EASI) score of greater than or equal to 16 **OR** D. The patient has an investigator Global Assessment (IGA) score of greater than or equal to 3 **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to at least a mid- potency topical steroid used in the treatment of AD **OR** B. The patient has an intolerance or hypersensitivity to at least a mid- potency topical steroid used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL mid-, high-, and super-potency topical steroids used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL mid-, high-, and super-potency topical steroids used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR** B. The patient has an intolerance or hypersensitivity to a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL topical calcineurin inhibitors used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following:

Module	Clinical Criteria for Approval
	1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL topical calcineurin inhibitors used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. ONE of the following**:** A. The patient has tried and had an inadequate response to a systemic immunosuppressant, including a biologic, used in the treatment of AD **OR** B. The patient has an intolerance or hypersensitivity to therapy with systemic immunosuppressants, including a biologic, used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL systemic immunosuppressants, including biologics, used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL systemic immunosuppressants, including biologics, used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 5. The prescriber documented the patient's baseline (prior to therapy with the requested agent) pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **AND** 6. BOTH of the following: A. The patient is currently treated with topical emollients and practicing good skin care **AND** B. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent **OR** D. The patient has another FDA approved indication for the requested agent and route of administration **OR** E. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient has been tested for latent tuberculosis (TB) AND if positive the patient has begun therapy for latent TB **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, allergist,

Module	Clinical Criteria for Approval
	immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval**: 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. ONE of the following: A. The patient has a diagnosis of moderate-to-severe atopic dermatitis AND BOTH of the following: 1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following: A. Affected body surface area **OR** B. Flares **OR** C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **OR** D. A decrease in the Eczema Area and Severity Index (EASI) score **OR** E. A decrease in the Investigator Global Assessment (IGA) score **AND** 2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has a diagnosis other than moderate-to-severe atopic dermatitis AND has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent

Module	Clinical Criteria for Approval
	Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval**: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **Length of Approval**: Initial - 6 months Renewal - 12 months

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly
Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)
Cibinqo (abrocitinib)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)

Contraindicated as Concomitant Therapy
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Litfulo (ritlecitinib)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tysabri (natalizumab)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)
Zymfentra (infliximab-dyyb)

• Program Summary: Coverage Exception with Quantity Limit - Commercial

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☑ Coverage / Formulary Exception

This program should not be used as formulary exception criteria. Ascensia products are the preferred glucose test strip products.

Anti-obesity agents on coverage delay must use the Anti-Obesity Formulary Exception criteria for FlexRx Closed, FlexRx Open, GenRx Closed, and GenRx Open.

This criterion does not apply to FocusRx or KeyRx (see appropriate program).

Objective

These criteria apply to any request for agents that are included in the clients Lockout/Excluded Agents list and is not otherwise excluded from coverage under the member's pharmacy benefit.

EXCEPTION CRITERIA FOR APPROVAL

A coverage exception will be granted when ALL of the following are met:

1. The request is NOT for a drug/drug class/medical condition that is restricted to coverage under the medical benefit (Medical Benefit Agents are pharmacy benefit exclusions and non-reviewable; they should be directed to the plan)

Examples of Agents Restricted to Coverage on the Medical Benefit
Insulin Pumps and Insulin Pump Supplies
Route of Administration which is excluded from coverage under the pharmacy benefit

AND

2. ONE of the following:
   - A. ALL of the following:
     - i. The requested agent is in an Affordable Care Act (ACA) Preventive Care category
       AND
     - ii. The member's benefit includes ACA Preventive Care for the category requested
       AND
     - iii. ONE of the following:
       - a. The requested agent is a contraception agent **AND** the following:
         1. The prescriber has provided information stating that the requested contraceptive agent is medically necessary
            AND
         2. The requested agent is being used for contraception

       OR

       - b. BOTH of the following:
         1. If the requested agent is a brand product with an available formulary generic equivalent, then ONE of the following:
            - A. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent
              OR
            - B. The patient has an intolerance or hypersensitivity to a formulary generic equivalent agent that is not expected to occur with the requested agent
              OR
            - C. The patient has an FDA labeled contraindication to ALL formulary generic equivalent agent(s) that is not expected to occur with the requested agent

            AND
         2. ONE of the following:
            - A. The requested agent is an aspirin agent **AND** ALL of the following:
              - i. The requested agent is the 81 mg strength aspirin
                AND

ii. The prescriber has provided information stating that the requested aspirin agent is medically necessary
AND
iii. The patient is pregnant, at high risk of preeclampsia, and using the requested agent after 12 weeks of gestation

OR

B. The requested agent is a bowel prep agent **AND** ALL of the following:
i. The prescriber has provided information stating that the requested bowel prep agent is medically necessary
AND
ii. The prescriber has indicated the requested agent will be used for the preparation of colorectal cancer screening using fecal occult blood testing, sigmoidoscopy, or colonoscopy
AND
iii. The patient is 45 years of age or over

OR

C. The requested agent is a breast cancer primary prevention agent **AND** ALL of the following:
i. The prescriber has provided information stating that the requested breast cancer primary prevention agent is medically necessary
AND
ii. The requested agent is tamoxifen, raloxifene, or aromatase inhibitor (anastrozole, exemestane, letrozole)
AND
iii. The patient is 35 years of age or over
AND
iv. The agent is requested for the primary prevention of breast cancer

OR

D. The requested agent is a fluoride supplement **AND** ALL of the following:
i. The prescriber has provided information stating that the requested fluoride supplement is medically necessary
AND
ii. The patient is 6 months to 16 years of age

OR

E. The requested agent is a folic acid agent **AND** ALL of the following:
i. The prescriber has provided information stating that the requested folic acid supplement is medically necessary
AND
ii. The requested folic acid supplement contains 0.4-0.8 mg of folic acid
AND
iii. The requested folic acid supplement is to be used in support of pregnancy

OR

F. The requested agent is an HIV infection pre-exposure prophylaxis (PrEP) agent **AND** ALL of the following:
i. The prescriber has provided information stating that the requested PrEP agent is medically necessary compared to other available PrEP agents
AND
ii. The requested agent is being used for PrEP
AND
iii. ONE of the following:
a. The requested PrEP agent is ONE of the following:

1. Tenofovir disoproxil fumarate and emtricitabine combination ingredient agent
   OR
2. Tenofovir disoproxil fumarate single ingredient agent
   OR
3. Tenofovir alafenamide and emtricitabine combination ingredient agent

OR

b. The prescriber has provided information stating that a tenofovir disoproxil fumarate and emtricitabine combination ingredient agent, tenofovir disoproxil fumarate single ingredient agent, or tenofovir alafenamide and emtricitabine combination ingredient agent is contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

AND

iv. The patient is at high risk of HIV infection

AND

v. The patient has recently tested negative for HIV

OR

G. The requested agent is an infant eye ointment **AND** ALL of the following:
   i. The prescriber has provided information stating that the requested infant eye ointment is medically necessary
   AND
   ii. The patient is 3 months of age or younger
   AND
   iii. The requested agent is requested for the prevention of gonococcal ophthalmia neonatorum

OR

H. The requested agent is an iron supplement **AND** ALL of the following:
   i. The prescriber has provided information stating that the requested iron supplement is medically necessary
   AND
   ii. The patient is under 12 months of age
   AND
   iii. The patient is at increased risk for iron deficiency anemia

OR

I. The requested agent is a statin **AND** ALL of the following:
   i. The prescriber has provided information stating that the requested statin is medically necessary
   AND
   ii. The requested agent is for use in ONE of the following low to moderate daily statin regimen (with up to the highest dosage strength as noted):
      a. Atorvastatin 10-20 mg per day (20 mg tablet)
      b. Fluvastatin 20-80 mg per day (40 mg capsule)
      c. Fluvastatin ER 80 mg per day (80 mg tablet)
      d. Lovastatin 20-40 mg per day (40 mg tablet)
      e. Lovastatin ER 20-40 mg per day (40 mg tablet)
      f. Pitavastatin 1-4 mg per day (4 mg tablet)
      g. Pravastatin 10-80 mg per day (80 mg tablet)
      h. Rosuvastatin 5-10 mg per day (10 mg tablet)

i. Simvastatin 10-40 mg per day (40 mg tablet, 40 mg/5 mL suspension)

AND

iii. The requested statin is for use in the primary prevention of cardiovascular disease (CVD)

AND

iv. The patient is 40-75 years of age (inclusive)

AND

v. The patient has at least one of the following risk factors:
   a. Dyslipidemia
   b. Diabetes
   c. Hypertension
   d. Smoking

AND

vi. The patient has a calculated 10-year risk of a cardiovascular event of 10% or greater per the American College of Cardiology and American Heart Association's Atherosclerotic Cardiovascular Disease (ASCVD) calculator

OR

J. The requested agent is a tobacco cessation agent **AND** ALL of the following:
   i. The patient is a non-pregnant adult

   AND

   ii. The prescriber has provided information stating that the requested tobacco cessation agent is medically necessary

OR

K. The requested agent is a vaccine **AND** ALL of the following:
   i. The prescriber has provided information stating that the requested vaccine is medically necessary

   AND

   ii. The requested vaccine will be used per the recommendations of the Advisory Committee on Immunization Practices/CDC

OR

B. ALL of the following:
   i. ONE of the following:
      a. The requested agent is in an ACA Preventive Care category AND did NOT meet the preventive service requirements

      OR

      b. BOTH of the following:
         1. ONE of the following:
            A. The requested agent is NOT in an ACA Preventive Care category

            OR

            B. The member's benefit does NOT include ACA Preventive Care for the category requested

         AND

         2. The request is NOT for a drug/drug class/medical condition which are excluded from coverage under the pharmacy benefit

Examples of Agents Excluded from Coverage on the Pharmacy Benefit
Brand for Generic*   Agents with the following reject message: #NDC NOT COVERED, USE XXX#
Bulk Powders*   (Defined as those products containing the third-party restriction code of B (BULK CHEMICALS) in the product file in RxClaim)
Clinic Packs*   (Y in the Clinic Pack field)

Examples of Agents Excluded from Coverage on the Pharmacy Benefit
Cosmetic Alteration* (Defined as those products containing the third-party restriction code of C (COSMETIC ALTERATION DRUGS) in the product file in RxClaim)
Infertility Agents* (Defined as those products containing the third-party restriction code 7 (FERTILITY DRUGS) in the product file in RxClaim) (only when not covered in BET AND is being requested for treatment of infertility)
Institutional Packs* Those that contain any one of the following modifier codes in the product file in RXClaims i. MODIFIER AAAD31 INSTITUTIONAL/HOSP. PACK ii. MODIFIER BBAD9A INSTITUTIONAL iii. MODIFIER TTAAJQ INSTITUTIONAL iv. MODIFIER TTAA5V INSTITUTIONAL USE ONLY v. MODIFIER AAAB9A HOSPITAL PACK vi. MODIFIER AAADQQ HUD (HOSPITAL UNIT DOSE) vii. MODIFER AAAD6T HOSPITAL USE ONLY
Non-FDA Approved Agents* (Refer to all tiers on Formulary ID 220 or reject messaging of 'Non-FDA Approved Drug')
Repackagers (not including Veterans Administration and Department of Defense Claims)* (Defined as indicated as Y in Repkg code field in the product file in RxClaim)
Over-The-Counter Medications* (not including glucose test strips, insulin, ACA required drugs, lancets, syringes) (Defined as indicated by O or P in the Rx-OTC indicator code field in the Product file in RxClaim)
Sexual Dysfunction Agents* (Defined as those products (e.g., Addyi, Viagra, Cialis 10 mg and 20 mg, Levitra, Staxyn, Caverject, Edex, Muse) containing the third-party restriction V (IMPOTENCE AGENTS) in the product file in RxClaim (only when not covered in BET AND is being requested for treatment of sexual dysfunction))
Weight Loss Agents* (Defined as those products containing the third-party restriction code 8 (ANOREXIC, ANTI-OBESITY) in the product file in RxClaim) (only when not covered in BET AND is being requested for treatment of weight loss)
Other

*Category specific denial reasons apply

AND

ii. ONE of the following:
   a. The requested agent is a CGM/Sensor/Transmitter/Receiver AND ONE of the following:
      1. Patient has a visual impairment
         OR
      2. Patient uses an insulin pump that is only compatible with one specific CGM/sensor/transmitter/receiver
         OR
      3. Patient has a physical or a mental disability

   OR

   b. The requested agent is a glucose cartridge, test strip, or all-in-one glucose meter system AND ONE of the following:
      1. Patient has visual impairment
         OR
      2. Patient uses an insulin pump OR continuous glucose monitor that is not accommodated with a preferred glucose cartridge, test strip, or all-in-one glucose meter system
         OR
      3. Patient has a physical or a mental disability

   OR

c. The requested agent is a rapid, regular, Humalog 50/50, Mix, or NPH insulin agent and ONE of the following:
    1. BOTH of the following:
        A. The requested agent is a rapid insulin
        AND
        B. There is information that the patient is currently using an insulin pump that has an incompatibility with the preferred rapid insulin agent that is not expected to occur with the requested agent
    OR
    2. The request is for Humalog Mix 50/50 AND ONE of the following:
        A. The patient is currently using Humalog Mix 50/50 AND the prescriber states the patient is at risk if switched to a different insulin
        OR
        B. The patient has tried and failed a preferred insulin mix (e.g., Novolin, Novolog)
    OR
    3. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to the preferred insulin agents (e.g., Novolin, Novolog) of the same type (rapid or regular, mix or NPH) that is not expected to occur with the requested agent
    OR
    4. There is information that the patient has a physical or a mental disability that would prevent him/her from using a preferred insulin agent
    OR
    5. The patient is pregnant

OR

d. The requested agent is a long-acting insulin agent and the following:
    1. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to the preferred insulin agents (e.g., Semglee, Insulin glargine-yfgn) of the same type (long-acting) that is not expected to occur with the requested agent

OR

e. The requested agent is Cialis/tadalafil 2.5 and 5 mg AND BOTH of the following:
    1. The requested agent is be used for a diagnosis of benign prostatic hyperplasia
    AND
    2. The requested quantity is equal to or less than 30 tablets per month

OR

f. The requested agent is a Self-Administered Contraceptive Agent AND the agent is being prescribed for an allowable diagnosis

Allowable Diagnoses
Acne vulgaris
Amenorrhea
Dysfunctional uterine bleeding
Dysmenorrhea
Endometriosis
Fibroid Uterus
Hyperandrogenism
Irregular menses (menorrhagia, oligomenorrhea, and hypermenorrhea)
Menstrual migraine
Perimenopausal symptoms
Polycystic ovarian syndrome
Premenstrual dysphoric disorder (PMDD)
Premenstrual syndrome
Treatment to reduce the risk of osteoporosis, ovarian cancer, colorectal cancer, and endometrial cancer, especially in women with a family history of these disorders

OR

g. The requested agent is Auvi-Q 0.1 mg AND the patient weighs 7.5 to 15 kg (16.5 to 33 pounds)

OR

h. BOTH of the following:
    1. The requested agent is for ONE of the following:
        A. Weight loss agent that will not be used for weight loss
        OR
        B. Infertility agent that will not be used for infertility
        OR
        C. Coverage Delay Agent

    AND

    2. BOTH of the following:
        A. ONE of the following:
            i. The patient has an FDA labeled indication for the requested agent
            OR
            ii. The patient has an indication supported in AHFS, DrugDex with 1 or 2a level of evidence, or NCCN with 1 or 2a level of evidence (for oncology agents also accept NCCN Compendium™ level of evidence 2B, DrugDex 2B, Wolters Kluwer Lexi-Drugs level A, and Clinical Pharmacology) for the requested agent
            OR
            iii. The patient has a diagnosis of Gender Identity Disorder (GID) or gender dysphoria and clinical guidelines support therapy with the requested agent

        AND

        B. ONE of the following:
            i. The requested agent has formulary alternatives (any formulary tier) for the diagnosis being treated by the requested agent AND BOTH of the following:
                a. If the requested agent is a brand product with an available formulary generic equivalent AND ONE of the following:
                    1. The patient has tried and failed one or more available formulary generic equivalents to the requested agent
                    OR
                    2. The prescriber has provided information stating that ALL available formulary (any formulary tier) generic equivalents to the requested agent are contraindicated, are likely to be less effective, or will cause an adverse reaction or other harm for the patient

                AND

                b. ONE of the following:
                    1. The patient has tried and failed at least three formulary alternatives (any formulary tier), if available, for the diagnosis being treated with the requested agent
                    OR
                    2. The prescriber has provided information stating that ALL available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

OR

ii. The requested agent does NOT have formulary (any formulary tier) alternatives for the diagnosis being treated with the requested agent
OR
iii. The prescriber stated that the patient is currently stabilized on for a minimum of 90 days the requested agent and switching could potentially cause harm or a health risk (starting on samples is not approvable)

AND

iii. If the requested agent is a biologic immunomodulator agent, Otezla, or Zeposia, the patient will NOT be using the requested agent in combination with another biologic immunomodulator agent, Otezla, or Zeposia

AND

3. ONE of the following:
    A. The requested agent is not subject to an existing quantity limit program
    OR
    B. The requested agent is subject to an existing quantity limit program and ONE of the following:
        i. The requested quantity (dose) does NOT exceed the program quantity limit
        OR
        ii. Information has been provided that fulfills the criteria listed under the "Allowed exceptions/diagnoses" (if applicable)
        OR
        iii. The requested quantity (dose) is greater than the program quantity limit and ONE of the following:
            a. BOTH of the following:
                1. The requested agent does not have a maximum FDA labeled dose for the requested indication
                AND
                2. The prescriber has provided information in support of therapy with a higher dose for the requested indication

            OR

            b. BOTH of the following:
                1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
                AND
                2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

            OR

            c. BOTH of the following:
                1. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
                AND
                2. The prescriber has provided information in support of therapy with a higher dose for the requested indication

ACA Length of Approval:

- Aspirin 81 mg:
    - Preeclampsia in pregnancy: 9 months
- Infant eye appointment: 3 months
- All other indications: 12 months
- Apply $0 copay if ACA criteria met

Coverage Exception Length of Approval: 12 months

• Program Summary: Daybue (abrocitinib)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
74653075002020	Daybue	trofinetide oral soln	200 MG/ML	8	Bottles	30	DAYS		05-18-2023	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy**: Daybue 1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. BOTH of the following: 1. The patient has a diagnosis of classic/typical Rett syndrome (RTT) **AND** 2. The patient has a disease-causing mutation in the MECP2 gene **AND** 2. If the patient has an FDA approved indicatqion, then ONE of the following**:** A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient's weight is 9 kg or greater **AND** 4. The prescriber has assessed baseline status (prior to therapy with the requested agent) of the patient's RTT symptoms (e.g., speech patterns, hand movements, gait, growth, muscle tone, seizures, breathing patterns, quality of sleep) **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., geneticist, neurologist, pediatrician) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent (e.g., speech patterns, hand movements, gait, growth, muscle tone, seizures, breathing patterns, quality of sleep) **AND**

Module	Clinical Criteria for Approval
	3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., geneticist, neurologist, pediatrician) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval:** Initial: 3 months; Renewal: 12 months

• Program Summary: Dipeptidyl Peptidase-4 Inhibitors (DPP-4) and Combinations

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☑ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
279925027003	Janumet	sitagliptin-metformin hcl tab	50-1000 MG; 50-500 MG	60	Tablets	30	DAYS			
27992502707530	Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 50-1000 MG	50-1000 MG	60	Tablets	30	DAYS			
27992502707520	Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 50-500 MG	50-500 MG	30	Tablets	30	DAYS			
275500701003	Januvia	sitagliptin phosphate tab	100 MG; 25 MG; 50 MG	30	Tablets	30	DAYS			
279925024003	Jentadueto	linagliptin-metformin hcl tab	2.5-1000 MG;	60	Tablets	30	DAYS			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
			2.5-500 MG; 2.5-850 MG							
27992502407520	Jentadueto xr	Linagliptin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS			
27992502407530	Jentadueto xr	Linagliptin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	30	Tablets	30	DAYS			
279925021003	Kazano	alogliptin-metformin hcl tab	12.5-1000 MG; 12.5-500 MG	30	Tablets	30	DAYS			
27992502607520	Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS			
27992502607540	Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	30	Tablets	30	DAYS			
27992502607530	Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 5-500 MG	5-500 MG	30	Tablets	30	DAYS			
275500101003	Nesina	alogliptin benzoate tab	12.5 MG; 25 MG; 6.25 MG	30	Tablets	30	DAYS			
275500651003	Onglyza	saxagliptin hcl tab	2.5 MG; 5 MG	30	Tablets	30	DAYS			
279940021003	Oseni	alogliptin-pioglitazone tab	12.5-15 MG; 12.5-30 MG; 12.5-45 MG; 25-15 MG; 25-30 MG; 25-45 MG	30	Tablets	30	DAYS			
27550050000320	Tradjenta	Linagliptin Tab 5 MG	5 MG	30	Tablets	30	DAYS			
27550070000320	Zituvio	sitagliptin tab	25 MG	30	Tablets	30	DAYS			
27550070000330	Zituvio	sitagliptin tab	50 MG	30	Tablets	30	DAYS			
27550070000340	Zituvio	sitagliptin tab	100 MG	30	Tablets	30	DAYS			

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
1-Step Through Preferred	**Preferred Agents**: **Januvia** (sitagliptin); **Janumet** (sitagliptin/metformin); **Janumet XR** (sitagliptin/metformin extended-release) **Non-preferred Agents**: **Alogliptin**; **Alogliptin/metformin**; **Alogliptin/pioglitazone**; **Jentadueto** (linagliptin/metformin)

Module	Clinical Criteria for Approval
	Jentadueto XR (linagliptin/metformin ER) **Kazano** (alogliptin/metformin) **Kombiglyze XR** (saxagliptin/metformin ER)* **Nesina** (alogliptin) **Onglyza** (saxagliptin)* **Oseni** (alogliptin/pioglitazone) **Tradjenta** (linagliptin) **Zituvio** (sitagliptin)

* available as generic; not a prerequisite or target in the step therapy program

Target Agent(s) will be approved when ONE of the following is met:

1. The patient is currently being treated with the requested agent as indicated by ALL of the following:
   A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
   B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
   C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
2. The patient's medication history includes use of one or more of the following: Januvia, Janumet, Janumet XR **OR**
3. BOTH of the following:
   A. The prescriber has stated that the patient has tried Januvia, Janumet, or Janumet XR **AND**
   B. Januvia, Janumet, or Janumet XR was discontinued due to lack of effectiveness or an adverse event **OR**
4. The patient has an intolerance or hypersensitivity to sitagliptin **OR**
5. The patient has an FDA labeled contraindication to sitagliptin that is not expected to occur with the requested agent **OR**
6. The prescriber has provided documentation that sitagliptin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

Length of Approval: 12 months

NOTE: If Quantity Limit program also applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL Standalone	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND**

Module	Clinical Criteria for Approval
	2. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• Program Summary: Factor VIII and von Willebrand Factor

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
851000102521	Advate; Kovaltry	antihemophilic factor recomb (rahf-pfm) for inj	1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 4000 UNIT; 500 UNIT	Dependent on patient weight and number of doses			
851000104021	Adynovate	antihemophilic factor recomb pegylated for inj	1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 500 UNIT; 750 UNIT	Dependent on patient weight and number of doses			
851000105564	Afstyla	antihemophilic fact rcmb single chain for inj kit	1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 2500 UNIT; 3000 UNIT; 500 UNIT	Dependent on patient weight and number of doses			
851000151021	Alphanate; Humate-p	antihemophilic factor/vwf (human) for inj	1000 UNIT; 1000-2400 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 250-600 UNIT; 500 UNIT; 500-1200 UNIT	Dependent on patient weight and number of doses			
851000103121	Altuviiio	antihemophilic fact rcmb fc-vwf-xten-ehtl for inj	1000 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 4000 UNIT; 500 UNIT; 750 UNIT	Dependent on patient weight and number of doses			
851000103021	Eloctate	antihemophilic	1000 UNIT;	Dependent on patient weight and number of			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		factor rcmb (bdd-rfviiifc) for inj	1500 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 4000 UNIT; 500 UNIT; 5000 UNIT; 6000 UNIT; 750 UNIT	doses			
851000103521	Esperoct	antihemophilic factor recomb glycopeg-exei for inj	1000 UNIT; 1500 UNIT; 2000 UNIT; 3000 UNIT; 500 UNIT	Dependent on patient weight and number of doses			
851000100021	Hemofil m; Koate; Koate-dvi	antihemophilic factor (human) for inj	1000 UNIT; 1700 UNIT; 250 UNIT; 500 UNIT	Dependent on patient weight and number of doses			
851000104121	Jivi	antihemophil fact rcmb(bdd-rfviii peg-aucl) for inj; antihemophil fact rcmb(bdd-rfviii peg-aucl) for inj	1000 UNIT; 2000 UNIT; 3000 UNIT; 500 UNIT	Dependent on patient weight and number of doses			
851000102064	Kogenate fs	antihemophilic factor recomb (rfviii) for inj kit	1000 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 500 UNIT	Dependent on patient weight and number of doses			
851000103321	Novoeight	antihemophilic fact rcmb (bd trunc-rfviii) for inj	1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 500 UNIT	Dependent on patient weight and number of doses			
851000102264	Nuwiq	antihemophil fact rcmb (bdd-rfviii,sim) for inj kit; antihemophil fact rcmb(bdd-rfviii,sim) for inj kit	1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 2500 UNIT; 3000 UNIT; 4000 UNIT; 500 UNIT	Dependent on patient weight and number of doses			
851000102221	Nuwiq	antihemophilic fact rcmb (bdd-rfviii,sim) for inj ; antihemophilic factor rcmb (bdd-rfviii,sim) for inj	1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 2500 UNIT; 3000 UNIT; 4000 UNIT; 500 UNIT	Dependent on patient weight and number of doses			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
851000102021	Recombinate	antihemophilic factor recomb (rfviii) for inj	1241 -1800 UNIT; 1801 -2400 UNIT; 220 -400 UNIT; 401 -800 UNIT; 801 -1240 UNIT	Dependent on patient weight and number of doses			
851000702021	Vonvendi	von willebrand factor (recombinant) for inj	1300 UNIT; 650 UNIT	Dependent on patient weight and number of doses			
851000151064	Wilate	antihemophilic factor/vwf (human) for inj	1000-1000 UNIT; 500-500 UNIT	Dependent on patient weight and number of doses			
851000102664	Xyntha; Xyntha solofuse	antihemophil fact rcmb (bdd-rfviii,mor) for inj kit; antihemophil fact rcmb(bdd-rfviii,mor) for inj kit	1000 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 500 UNIT	Dependent on patient weight and number of doses			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Effective until 10/31/24 for:** **Those with an original PA date prior to 11/1/23 seeking reauthorization AND that have not started a new plan year** **Preferred and Non-Preferred Agents to be determined by client**

Preferred Agents for Hemophilia A	Non-Preferred Agents for Hemophilia A
Advate Adynovate Afstyla Eloctate Esperoct Jivi Kogenate FS Kovaltry NovoEight Nuwiq Recombinate	None

Module	Clinical Criteria for Approval

Vonvendi Wilate Xyntha/Xyntha solofuse Alphanate Altuviiio Hemofil-M Humate-P Koāte	

Preferred Agents for von Willebrand disease	**Non-Preferred Agents for von Willebrand disease**
Vonvendi Wilate Alphanate Humate-P	None

Target Agent(s) will be approved when ALL of the following are met:

1. ONE of the following:
   A. The requested agent is eligible for continuation of therapy AND ONE of the following:

Agents Eligible for Continuation of Therapy
All target agents are eligible for continuation of therapy

      1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**
      2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR**

   B. The patient has a diagnosis of hemophilia A (also known as Factor VIII deficiency or classic hemophilia) AND ONE of the following:
      1. The patient is currently experiencing a bleed AND BOTH of the following:
         A. The patient is out of medication **AND**
         B. The patient needs to receive a ONE TIME emergency supply of medication **OR**
      2. BOTH of the following:
         A. The requested agent is being used for ONE of the following:
            1. Prophylaxis AND the patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **OR**
            2. As a component of Immune Tolerance Therapy (ITT)/Immune Tolerance Induction (ITI) AND BOTH of the following:
               A. The patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **AND**
               B. ONE of the following: (medical records required)
                  1. The patient has NOT had more than 33 months of ITT/ITI therapy **OR**
                  2. Information has been provided supporting the continued use of ITT/ITI therapy (i.e., the patient has had a greater than or equal to 20% decrease in inhibitor level over the last 6 months and needs further treatment to eradicate inhibitors) **OR**
            3. On-demand use for bleeds **OR**
            4. Peri-operative management of bleeding **AND**
         B. If the client has a preferred agent(s), then ONE of the following:

Module	Clinical Criteria for Approval
	1. The requested agent is a preferred agent **OR** 2. The patient has tried and had an inadequate response to ALL of the preferred agent(s) for the requested indication **OR** 3. The patient has an intolerance or hypersensitivity to ALL of the preferred agent(s) for the requested indication **OR** 4. The patient has an FDA labeled contraindication to ALL preferred agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation the preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has a diagnosis of von Willebrand disease (VWD) AND ALL of the following: 1. ONE of the following: A. The patient is currently experiencing a bleed AND BOTH of the following: 1. The patient is out of medication **AND** 2. The patient needs to receive a ONE TIME emergency supply of medication **OR** B. The patient has type 1, 2A, 2M or 2N VWD AND ONE of the following: 1. The patient has tried and had an inadequate response to desmopressin (e.g., DDAVP injection, Stimate nasal spray) **OR** 2. The patient did not respond to a DDAVP trial with 1 and 4 hour post infusion bloodwork **OR** 3. The patient has an intolerance or hypersensitivity to desmopressin **OR** 4. The patient has an FDA labeled contraindication to desmopressin **OR** 5. The prescriber has provided information supporting why the patient cannot use desmopressin (e.g., shortage in marketplace) **OR** 6. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 7. The prescriber has provided documentation desmopressin (e.g., DDAVP injection, Stimate nasal spray) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has type 2B or 3 VWD **AND**

Module	Clinical Criteria for Approval
	2. The requested agent will be used for ONE of the following: A. Prophylaxis AND ONE of the following: 1. The requested agent is Vonvendi AND ONE of the following: A. The patient has severe Type 3 VWD **OR** B. The patient has another subtype of VWD AND the subtype is FDA approved for prophylaxis use **OR** 2. The requested agent is NOT Vonvendi **OR** B. On-demand use for bleeds **OR** C. Peri-operative management of bleeding **AND** 3. If the client has a preferred agent(s), then ONE of the following: A. The requested agent is a preferred agent **OR** B. The patient has tried and had an inadequate response to ALL of the preferred agent(s) for the requested indication **OR** C. The patient has an intolerance or hypersensitivity to ALL of the preferred agent(s) for the requested indication **OR** D. The patient has an FDA labeled contraindication to ALL preferred agents for the requested indication **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation the preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. If the patient has an FDA approved indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following: A. The patient will NOT be using the requested agent in combination with a nonsteroidal anti-inflammatory agent (NSAID) (e.g., aspirin, ibuprofen) other than cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib) NOTE: for the purposes of this criteria COX-2 inhibitors will be accepted for concomitant use **OR** B. The prescriber has provided information in support of using an NSAID for this patient **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 6. The prescriber must provide the actual prescribed dose with ALL of the following: A. Patient's weight **AND** B. Intended use/regimen: (e.g., prophylaxis, ITT/ITI, on-demand, peri-operative) **AND** C. If the patient has a diagnosis of hemophilia A BOTH of the following: 1. Severity of the factor deficiency (i.e., severe is less than 1% factor activity, moderate is greater than or equal to 1 to less than or equal to 5% factor activity, mild is greater than 5 to 40% factor activity) **AND** 2. Inhibitor status **AND**

Module	Clinical Criteria for Approval
	7. ONE of the following: A. The patient will NOT be using the requested agent in combination with another agent in the same category (e.g., Factor VIII agents, Factor VIII and von Willebrand Factor combination agents) included in this program **OR** B. Information has been provided supporting the use of more than one unique agent in the same category (medical records required) **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** One time emergency use: up to 2 weeks Peri-operative dosing: 1 time per request On-demand: up to 3 months Prophylaxis: up to 6 months ITT/ITI: up to 6 months NOTE: If Quantity Limit applies, please see Quantity Limit criteria **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (if current request is for ONE TIME emergency use or if patient ONLY has previous approval(s) for emergency use, must use Initial Evaluation) **AND** 2. If the patient is using the requested agent for prophylaxis, then ONE of the following: A. The patient has a diagnosis of hemophilia A AND the patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **OR** B. The patient has another diagnosis **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following: A. The patient will NOT be using the requested agent in combination with a nonsteroidal anti-inflammatory agent (NSAID) (e.g., aspirin, ibuprofen) other than cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib) NOTE: for the purposes of this criteria COX-2 inhibitors will be accepted for concomitant use **OR** B. The prescriber has provided information in support of using an NSAID for this patient **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 6. The prescriber must provide the actual prescribed dose with ALL of the following: A. Patient's weight **AND** B. Intended use/regimen: (e.g., prophylaxis, ITT/ITI, on-demand, peri-operative) **AND** C. If the patient has a diagnosis of hemophilia A BOTH of the following: 1. Severity of the factor deficiency (i.e., severe is less than 1% factor activity, moderate is greater than or equal to 1 to less than or equal to 5% factor activity, mild is greater than 5 to 40% factor activity) **AND** 2. Inhibitor status **AND** 7. ONE of the following: A. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have greater than 5 on-demand doses on hand **OR** B. The prescriber has provided information in support of the patient having more than 5 on-demand doses on hand **AND** 8. ONE of the following: A. The patient will NOT be using the requested agent in combination with another agent in the same category (e.g., Factor VIII agents, Factor VIII and von Willebrand Factor combination agents) included in this program **OR**

Module	Clinical Criteria for Approval

B. Information has been provided supporting the use of more than one unique agent in the same category (medical records required) **AND**

9. If the patient is using Immune Tolerance Therapy (ITT)/Immune Tolerance Induction (ITI), then ONE of the following:
   A. The patient has NOT had more than 33 months of ITT/ITI therapy **OR**
   B. Information has been provided supporting the continued use of ITT/ITI therapy (i.e., the patient has had a greater than or equal to 20% decrease in inhibitor level over the last 6 months and needs further treatment to eradicate inhibitors) (medical records required)

Length of Approval: Peri-operative: 1 time per request On-demand: up to 3 months Prophylaxis: up to 12 months ITT/ITI: up to 6 months, or up to a total of 33 months of ITT/ITI therapy, or requested duration, whichever is shortest

NOTE: If Quantity Limit applies, please see Quantity Limit criteria

Initial Evaluation

Effective 11/1/23 for:
Those who were approved through criteria after 11/1/23
Those who have started a new plan year since last authorization

Preferred and Non-Preferred Agents to be determined by client

Preferred Agents for Hemophilia A	Non-Preferred Agents for Hemophilia A
Advate Adynovate Afstyla Eloctate Esperoct Jivi Kogenate FS Kovaltry NovoEight Nuwiq Recombinate Vonvendi Wilate Xyntha/Xyntha solofuse Alphanate Altuviiio Hemofil-M Humate-P Koāte	None

Preferred Agents for von Willebrand disease	Non-Preferred Agents for von Willebrand disease
Vonvendi Wilate Alphanate Humate-P	None

Module	Clinical Criteria for Approval
	Target Agent(s) will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. The patient has a diagnosis of hemophilia A (also known as Factor VIII deficiency or classic hemophilia) AND ONE of the following: 1. The patient is currently experiencing a bleed AND BOTH of the following: A. The patient is out of medication **AND** B. The patient needs to receive a ONE TIME emergency supply of medication **OR** 2. ALL of the following: A. The requested agent is FDA approved or compendia supported for a diagnosis of hemophilia A **AND** B. The requested agent is being used for ONE of the following: 1. Prophylaxis AND the patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **OR** 2. As a component of Immune Tolerance Therapy (ITT)/Immune Tolerance Induction (ITI) AND BOTH of the following: A. The patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **AND** B. ONE of the following: (medical records required) 1. The patient has NOT had more than 33 months of ITT/ITI therapy **OR** 2. Information has been provided supporting the continued use of ITT/ITI therapy (i.e., the patient has had a greater than or equal to 20% decrease in inhibitor level over the last 6 months and needs further treatment to eradicate inhibitors) **OR** 3. On-demand use for bleeds **OR** 4. Peri-operative management of bleeding **AND** C. If the client has a preferred agent(s), then ONE of the following: 1. The requested agent is a preferred agent **OR** 2. The patient has tried and had an inadequate response to ALL of the preferred agent(s) for the requested indication **OR** 3. The patient has an intolerance or hypersensitivity to ALL of the preferred agent(s) for the requested indication **OR** 4. The patient has an FDA labeled contraindication to ALL preferred agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**

Module	Clinical Criteria for Approval
	C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation the preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has a diagnosis of von Willebrand disease (VWD) AND ALL of the following: 1. The requested agent is FDA approved or compendia supported for a diagnosis of von Willebrand disease **AND** 2. ONE of the following: A. The patient is currently experiencing a bleed AND BOTH of the following: 1. The patient is out of medication **AND** 2. The patient needs to receive a ONE TIME emergency supply of medication **OR** B. The patient has type 1, 2A, 2M or 2N VWD AND ONE of the following: 1. The patient has tried and had an inadequate response to desmopressin (e.g., DDAVP injection, Stimate nasal spray) **OR** 2. The patient did not respond to a DDAVP trial with 1 and 4 hour post infusion bloodwork **OR** 3. The patient has an intolerance or hypersensitivity to desmopressin **OR** 4. The patient has an FDA labeled contraindication to desmopressin **OR** 5. The prescriber has provided information supporting why the patient cannot use desmopressin (e.g., shortage in marketplace) **OR** 6. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 7. The prescriber has provided documentation desmopressin (e.g., DDAVP injection, Stimate nasal spray) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has type 2B or 3 VWD **AND** 3. The requested agent will be used for ONE of the following: A. Prophylaxis AND ONE of the following: 1. The requested agent is Vonvendi AND ONE of the following: A. The patient has severe Type 3 VWD **OR** B. The patient has another subtype of VWD AND the subtype is FDA approved for prophylaxis use **OR** 2. The requested agent is NOT Vonvendi **OR** B. On-demand use for bleeds **OR** C. Peri-operative management of bleeding **AND**

Module	Clinical Criteria for Approval
	4. If the client has a preferred agent(s), then ONE of the following: A. The requested agent is a preferred agent **OR** B. The patient has tried and had an inadequate response to ALL of the preferred agent(s) for the requested indication **OR** C. The patient has an intolerance or hypersensitivity to ALL of the preferred agent(s) for the requested indication **OR** D. The patient has an FDA labeled contraindication to ALL preferred agents for the requested indication **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation the preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. If the patient has an FDA approved indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following: A. The patient will NOT be using the requested agent in combination with a nonsteroidal anti-inflammatory agent (NSAID) (e.g., aspirin, ibuprofen) other than cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib) NOTE: for the purposes of this criteria COX-2 inhibitors will be accepted for concomitant use **OR** B. The prescriber has provided information in support of using an NSAID for this patient **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 6. The prescriber must provide the actual prescribed dose with ALL of the following: A. Patient's weight **AND** B. Intended use/regimen: (e.g., prophylaxis, ITT/ITI, on-demand, peri-operative) **AND** C. If the patient has a diagnosis of hemophilia A BOTH of the following: 1. Severity of the factor deficiency (i.e., severe is less than 1% factor activity, moderate is greater than or equal to 1 to less than or equal to 5% factor activity, mild is greater than 5 to 40% factor activity) **AND** 2. Inhibitor status **AND** 7. ONE of the following: A. The patient will NOT be using the requested agent in combination with another agent in the same category (e.g., Factor VIII agents, Factor VIII and von Willebrand Factor combination agents) included in this program **OR** B. Information has been provided supporting the use of more than one unique agent in the same category (medical records required) **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence

Module	Clinical Criteria for Approval
	Length of Approval: One time emergency use: up to 2 weeks Peri-operative dosing: 1 time per request On-demand: up to 3 months Prophylaxis: up to 6 months ITT/ITI: up to 6 months NOTE: If Quantity Limit applies, please see Quantity Limit criteria **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (if current request is for ONE TIME emergency use or if patient ONLY has previous approval(s) for emergency use, must use Initial Evaluation) **AND** 2. If the patient is using the requested agent for prophylaxis, then ONE of the following: A. The patient has a diagnosis of hemophilia A AND the patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **OR** B. The patient has another diagnosis **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following: A. The patient will NOT be using the requested agent in combination with a nonsteroidal anti-inflammatory agent (NSAID) (e.g., aspirin, ibuprofen) other than cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib) NOTE: for the purposes of this criteria COX-2 inhibitors will be accepted for concomitant use **OR** B. The prescriber has provided information in support of using an NSAID for this patient **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 6. The prescriber must provide the actual prescribed dose with ALL of the following: A. Patient's weight **AND** B. Intended use/regimen: (e.g., prophylaxis, ITT/ITI, on-demand, peri-operative) **AND** C. If the patient has a diagnosis of hemophilia A BOTH of the following: 1. Severity of the factor deficiency (i.e., severe is less than 1% factor activity, moderate is greater than or equal to 1 to less than or equal to 5% factor activity, mild is greater than 5 to 40% factor activity) **AND** 2. Inhibitor status **AND** 7. ONE of the following: A. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have greater than 5 on-demand doses on hand **OR** B. The prescriber has provided information in support of the patient having more than 5 on-demand doses on hand **AND** 8. ONE of the following: A. The patient will NOT be using the requested agent in combination with another agent in the same category (e.g., Factor VIII agents, Factor VIII and von Willebrand Factor combination agents) included in this program **OR** B. Information has been provided supporting the use of more than one unique agent in the same category (medical records required) **AND** 9. If the patient is using Immune Tolerance Therapy (ITT)/Immune Tolerance Induction (ITI), then ONE of the following: A. The patient has NOT had more than 33 months of ITT/ITI therapy **OR** B. Information has been provided supporting the continued use of ITT/ITI therapy (i.e., the patient has had a greater than or equal to 20% decrease in inhibitor level over the last 6 months and needs further treatment to eradicate inhibitors) (medical records required)

Module	Clinical Criteria for Approval
	Length of Approval: Peri-operative: 1 time per request On-demand: up to 3 months Prophylaxis: up to 12 months ITT/ITI: up to 6 months, or up to a total of 33 months of ITT/ITI therapy, or requested duration, whichever is shortest NOTE: If Quantity Limit applies, please see Quantity Limit criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the requested agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit defined by BOTH of the following: A. The requested dose is within the FDA labeled dosing **AND** B. The requested quantity (number of doses) is appropriate based on intended use (e.g., prophylaxis, ITT/ITI, on-demand, peri-operative) **OR** 2. The prescriber has provided clinical reasoning for exceeding the defined program quantity limit (dose and/or number of doses) (medical records required) **Length of Approval:** Peri-operative: 1 time per request; On-demand: up to 3 months; Prophylaxis: up to 12 months; ITT/ITI: up to 6 months, or up to a total of 33 months of ITT/ITI therapy, or requested duration, whichever is shortest

• Program Summary: Glucagon-like peptide-1 Agonists (GLP-1)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMITS

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
2717005600D230	Adlyxin	Lixisenatide Soln Pen-injector 20 MCG/0.2ML (100 MCG/ML)	20 MCG/0.2ML	2	Pens	28	DAYS			
2717005600F420	Adlyxin starter pack	Lixisenatide Pen-inj Starter Kit 10 MCG/0.2ML & 20 MCG/0.2ML	10 & 20 MCG/0.2ML	2	Pens	180	DAYS			
2717002000D420	Bydureon bcise	Exenatide Extended Release Susp Auto-Injector 2 MG/0.85ML	2 MG/0.85ML	4	Pens	28	DAYS			
2717002000D240	Byetta	Exenatide Soln Pen-injector 10 MCG/0.04ML	10 MCG/0.04ML	1	Pen	30	DAYS			
2717002000D220	Byetta	Exenatide Soln Pen-injector 5 MCG/0.02ML	5 MCG/0.02ML	1	Pen	30	DAYS			
2717308000D210	Mounjaro	Tirzepatide Soln Pen-injector	2.5 MG/0.5ML	4	Pens	28	DAYS			
2717308000D215	Mounjaro	Tirzepatide Soln Pen-injector	5 MG/0.5ML	4	Pens	28	DAYS			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
2717308000D220	Mounjaro	Tirzepatide Soln Pen-injector	7.5 MG/0.5ML	4	Pens	28	DAYS			
2717308000D225	Mounjaro	Tirzepatide Soln Pen-injector	10 MG/0.5ML	4	Pens	28	DAYS			
2717308000D230	Mounjaro	Tirzepatide Soln Pen-injector	12.5 MG/0.5ML	4	Pens	28	DAYS			
2717308000D235	Mounjaro	Tirzepatide Soln Pen-injector	15 MG/0.5ML	4	Pens	28	DAYS			
2717007000D221	Ozempic	Semaglutide Soln Pen-inj	2 MG/3ML	1	Pen	28	DAYS			
2717007000D225	Ozempic	Semaglutide Soln Pen-inj	8 MG/3ML	1	Pen	28	DAYS			
2717007000D222	Ozempic	Semaglutide Soln Pen-inj	4 MG/3ML	1	Pen	28	DAYS			
2717007000D210	Ozempic	Semaglutide Soln Pen-inj 0.25 or 0.5 MG/DOSE (2 MG/1.5ML)	2 MG/1.5ML	1	Pen	28	DAYS			
2717007000D220	Ozempic	Semaglutide Soln Pen-inj 1 MG/DOSE (2 MG/1.5ML)	2 MG/1.5ML	2	Pens	28	DAYS			
27170070000330	Rybelsus	Semaglutide Tab 14 MG	14 MG	30	Tablets	30	DAYS			
27170070000310	Rybelsus	Semaglutide Tab 3 MG	3 MG	30	Tablets	180	DAYS			
27170070000320	Rybelsus	Semaglutide Tab 7 MG	7 MG	30	Tablets	30	DAYS			
2717001500D240	Trulicity	Dulaglutide Soln Pen-injector	3 MG/0.5ML	4	Pens	28	DAYS			
2717001500D250	Trulicity	Dulaglutide Soln Pen-injector	4.5 MG/0.5ML	4	Pens	28	DAYS			
2717001500D220	Trulicity	Dulaglutide Soln Pen-injector 0.75 MG/0.5ML	0.75 MG/0.5ML	4	Pens	28	DAYS			
2717001500D230	Trulicity	Dulaglutide Soln Pen-injector 1.5 MG/0.5ML	1.5 MG/0.5ML	4	Pens	28	DAYS			
2717005000D220	Victoza	Liraglutide Soln Pen-injector 18 MG/3ML (6 MG/ML)	18 MG/3ML	3	Pens	30	DAYS			

ADDITIONAL QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
2717005600D230	Adlyxin	Lixisenatide Soln Pen-injector 20 MCG/0.2ML (100 MCG/ML)	20 MCG/0.2ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717005600F420	Adlyxin starter pack	Lixisenatide Pen-inj Starter Kit 10 MCG/0.2ML & 20	10 & 20 MCG/0.2ML	The patient has a diagnosis of type 2 diabetes mellitus			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		MCG/0.2ML					
2717002000D420	Bydureon bcise	Exenatide Extended Release Susp Auto-Injector 2 MG/0.85ML	2 MG/0.85ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717002000D240	Byetta	Exenatide Soln Pen-injector 10 MCG/0.04ML	10 MCG/0.04ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717002000D220	Byetta	Exenatide Soln Pen-injector 5 MCG/0.02ML	5 MCG/0.02ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717308000D210	Mounjaro	Tirzepatide Soln Pen-injector	2.5 MG/0.5ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717308000D215	Mounjaro	Tirzepatide Soln Pen-injector	5 MG/0.5ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717308000D220	Mounjaro	Tirzepatide Soln Pen-injector	7.5 MG/0.5ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717308000D225	Mounjaro	Tirzepatide Soln Pen-injector	10 MG/0.5ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717308000D230	Mounjaro	Tirzepatide Soln Pen-injector	12.5 MG/0.5ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717308000D235	Mounjaro	Tirzepatide Soln Pen-injector	15 MG/0.5ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717007000D221	Ozempic	Semaglutide Soln Pen-inj	2 MG/3ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717007000D225	Ozempic	Semaglutide Soln Pen-inj	8 MG/3ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717007000D222	Ozempic	Semaglutide Soln Pen-inj	4 MG/3ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717007000D210	Ozempic	Semaglutide Soln Pen-inj 0.25 or 0.5 MG/DOSE (2 MG/1.5ML)	2 MG/1.5ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717007000D220	Ozempic	Semaglutide Soln Pen-inj 1 MG/DOSE (2 MG/1.5ML)	2 MG/1.5ML	The patient has a diagnosis of type 2 diabetes mellitus			
27170070000330	Rybelsus	Semaglutide Tab 14 MG	14 MG	The patient has a diagnosis of type 2 diabetes mellitus			
27170070000310	Rybelsus	Semaglutide Tab 3 MG	3 MG	The patient has a diagnosis of type 2 diabetes mellitus			
27170070000320	Rybelsus	Semaglutide Tab 7 MG	7 MG	The patient has a diagnosis of type 2 diabetes mellitus			
2717001500D240	Trulicity	Dulaglutide Soln Pen-injector	3 MG/0.5ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717001500D250	Trulicity	Dulaglutide Soln Pen-injector	4.5 MG/0.5ML	The patient has a diagnosis of type 2 diabetes mellitus			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
2717001500D220	Trulicity	Dulaglutide Soln Pen-injector 0.75 MG/0.5ML	0.75 MG/0.5ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717001500D230	Trulicity	Dulaglutide Soln Pen-injector 1.5 MG/0.5ML	1.5 MG/0.5ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717005000D220	Victoza	Liraglutide Soln Pen-injector 18 MG/3ML (6 MG/ML)	18 MG/3ML	The patient has a diagnosis of type 2 diabetes mellitus			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
CoT with Dx check	

Preferred Target Agent(s)	Non-Preferred Target Agent(s)
Bydureon (exenatide) **Mounjaro** (tirzepatide) **Ozempic** (semaglutide) **Rybelsus** (semaglutide) **Trulicity** (dulaglutide)	**Adlyxin** (lixisenatide) **Byetta** (exenatide) **Victoza** (liraglutide)

Target Agent(s) will be approved when BOTH of the following are met:

1. The patient has a diagnosis of type 2 diabetes **AND**
2. ONE of the following:
   - A. If the requested agent is a preferred GLP-1 or GLP-1/GIP, then ONE of the following:

Agents Eligible for Continuation of Therapy
Ozempic, Rybelsus, Trulicity, Mounjaro, Bydureon

     1. Information has been provided that indicates the patient has been treated with a preferred agent (starting on samples is not approvable) within the past 90 days **OR**
     2. The prescriber states the patient has been treated with a preferred agent within the past 90 days (starting on samples is not approvable) AND is at risk if therapy with a preferred agent is discontinued **OR**
   - B. BOTH of the following:
     1. ONE of the following:
        - A. The patient has tried and had an inadequate response to an agent containing metformin or insulin **OR**
        - B. The patient has an intolerance or hypersensitivity to metformin or insulin **OR**
        - C. The patient has an FDA labeled contraindication to BOTH metformin AND insulin **OR**
        - D. The patient has a diagnosis of type 2 diabetes with/or at high risk for atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease **OR**
        - E. The patient is currently being treated with the requested agent as indicated by ALL of the following:
          1. A statement by the prescriber that the patient is currently taking the requested agent **AND**

Module	Clinical Criteria for Approval
	2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that metformin and insulin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. ONE of the following: A. The requested agent is a preferred GLP-1 or GLP-1/GIP **OR** B. The agent is a non-preferred GLP-1 and ONE of the following: 1. TWO of the following: A. The patient has tried and had an inadequate response, has an intolerance, has a hypersensitivity, or has an FDA labeled contraindication to semaglutide (Ozempic OR Rybelsus) **OR** B. The patient has tried and had an inadequate response, has an intolerance, has a hypersensitivity, or has an FDA labeled contraindication to dulaglutide (Trulicity) **OR** C. The patient has tried and had an inadequate response, has a hypersensitivity, or has an FDA labeled contraindication to tirzepatide (Mounjaro) **OR** 2. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 3. The prescriber has provided documentation that semaglutide (Ozempic OR Rybelsus), dulaglutide (Trulicity), AND tirzepatide (Mounjaro) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval:** 12 months NOTE: If Quantity Limit program also applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval:** 12 months

• Program Summary: Gonadotropin Hormones

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMITS

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
30090025106420	Cetrotide	Cetrorelix Acetate For Inj Kit 0.25 MG	0.25 MG	5	Kits	30	DAYS			
30062030102020	Follistim aq	Follitropin Beta Inj 300 Unit/0.36ML	300 UNT/0.36ML	15	Cartridges	30	DAYS			
30062030102030	Follistim aq	Follitropin Beta Inj 600 Unit/0.72ML	600 UNT/0.72ML	8	Cartridges	30	DAYS			
30062030102040	Follistim aq	Follitropin Beta Inj 900 Unit/1.08ML	900 UNT/1.08ML	5	Cartridges	30	DAYS			
3009004010E520	Fyremadel	Ganirelix Acetate Soln Prefilled Syringe 250 MCG/0.5ML	250 MCG/0.5ML	5	Syringes	30	DAYS			
30062030052150	Gonal-f	Follitropin Alfa For Inj 1050 Unit	1050 UNIT	4	Syringes	30	DAYS			
30062030052140	Gonal-f	Follitropin Alfa For Inj 450 Unit	450 UNIT	10	Syringes	30	DAYS			
30062030052115	Gonal-f rff	Follitropin Alfa For Subcutaneous Inj 75 Unit	75 UNIT	20	Syringes	30	DAYS			
3006203005D220	Gonal-f rff rediject	Follitropin Alfa	300	15	Pens	30	DAYS			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		Subcutaneous Soln Pen-inj	UNIT/0.5ML							
3006203005D225	Gonal-f rff rediject	Follitropin Alfa Subcutaneous Soln Pen-inj	450 UNT/0.75ML	10	Pens	30	DAYS			
3006203005D240	Gonal-f rff rediject	Follitropin Alfa Subcutaneous Soln Pen-inj	900 UNIT/1.5ML	5	Pens	30	DAYS			
30062050002175	Menopur	Menotropins For Subcutaneous Inj 75 Unit	75 UNIT	60	Vials	30	DAYS			
30062020002130	Novarel	Chorionic Gonadotropin For IM Inj 5000 Unit	5000 UNIT	4	Vials	30	DAYS			
30062020002140	Novarel ; Pregnyl ; Pregnyl w/diluent benzyl	Chorionic Gonadotropin For IM Inj 10000 Unit	10000 UNIT	2	Vials	30	DAYS			
30062022052220	Ovidrel	Choriogonadotropin Alfa Inj 250 MCG/0.5ML	250 MCG/0.5ML	2	Syringes	30	DAYS			

ADDITIONAL QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
30062030102020	Follistim aq	Follitropin Beta Inj 300 Unit/0.36ML	300 UNT/0.36ML	Each cartridge is billed as 0.420 mL			
30062030102030	Follistim aq	Follitropin Beta Inj 600 Unit/0.72ML	600 UNT/0.72ML	Each cartridge is billed as 0.780 mL			
30062030102040	Follistim aq	Follitropin Beta Inj 900 Unit/1.08ML	900 UNT/1.08ML	Each cartridge is billed as 1.170 mL			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Follicle Stimulating Hormone	**Follicle Stimulating Hormone Evaluation** **Follistim AQ and Gonal-F** will be approved when ALL of the following are met: 1. The patient's benefit plan covers agents for infertility **AND** 2. ONE of the following: A. The requested agent will be used for ovulation induction AND ONE of the following: 1. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy A. Information has been provided that indicates the patient has been treated with the requested agent within the past 90 days **OR** B. The prescriber states the patient has been treated with the requested agent

Module	Clinical Criteria for Approval

within the past 90 days AND is at risk if therapy is changed **OR**

2. ALL of the following:
   A. ONE of the following:
      1. The patient has tried and had an inadequate response to clomiphene citrate **OR**
      2. The patient has an intolerance or hypersensitivity to clomiphene citrate **OR**
      3. The patient has an FDA labeled contraindication to clomiphene citrate **OR**
      4. The patient is currently being treated with the requested agent as indicated by ALL of the following:
         A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
         B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
         C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
      5. The prescriber has provided documentation that clomiphene citrate cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
   B. The patient is NOT pregnant **AND**
   C. The patient does NOT have primary ovarian failure **AND**
   D. The patient will receive human chorionic gonadotropin (hCG) following completion of the requested agent unless there are risks present for ovarian hyperstimulation syndrome (OHSS) **AND**
   E. ONE of the following:

Preferred Target Agents	Non-Preferred Target Agents
Follistim AQ (follitropin beta)	Gonal F Kit (follitropin alfa) Gonal F RFF (follitropin alfa) Gonal F RFF Pen (follitropin alfa)

      1. The requested agent is a preferred agent **OR**
      2. The patient has tried and had an inadequate response to ONE of the preferred agent(s) **OR**
      3. The patient has an intolerance or hypersensitivity to ONE of the preferred agent(s) that is NOT expected to occur with the requested agent **OR**
      4. The patient has an FDA labeled contraindication to ALL of the preferred agent(s) that is NOT expected to occur with the requested agent **OR**
      5. The patient is currently being treated with the requested agent as indicated by ALL of the following:
         A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
         B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
         C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
      6. The prescriber has provided documentation ALL of the preferred

Module	Clinical Criteria for Approval

agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

B. The requested agent will be used for the development of multiple follicles as part of an assisted reproductive technology (ART) [e.g., invitro fertilization (IVF), gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), tubal embryo transfer (TET), cryopreservation, intracytoplasmic sperm injection (ICSI)] AND ONE of the following:

1. The requested agent is eligible for continuation of therapy AND ONE of the following:

Agents Eligible for Continuation of Therapy
All target agents are eligible for continuation of therapy

   A. Information has been provided that indicates the patient has been treated with the requested agent within the past 90 days **OR**
   B. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR**

2. ALL of the following:
   A. The patient is NOT pregnant **AND**
   B. The patient does NOT have primary ovarian failure **AND**
   C. The patient will receive human chorionic gonadotropin (hCG) following completion of the requested agent unless there are risks present for ovarian hyperstimulation syndrome (OHSS) **AND**
   D. ONE of the following:

Preferred Target Agents	Non-Preferred Target Agents
Follistim AQ (follitropin beta)	Gonal F Kit (follitropin alfa) Gonal F RFF (follitropin alfa) Gonal F RFF Pen (follitropin alfa)

      1. The requested agent is a preferred agent **OR**
      2. The patient has tried and had an inadequate response to ONE of the preferred agent(s) **OR**
      3. The patient has an intolerance or hypersensitivity to ONE of the preferred agent(s) that is NOT expected to occur with the requested agent **OR**
      4. The patient has an FDA labeled contraindication to ALL of the preferred agent(s) that is NOT expected to occur with the requested agent **OR**
      5. The patient is currently being treated with the requested agent as indicated by ALL of the following:
         A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
         B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
         C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
      6. The prescriber has provided documentation ALL of the preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td></td><td>
OR
C. The requested agent will be used for hypogonadotropic hypogonadism AND ALL of the following:
1. The requested agent is Follistim AQ or Gonal-F AND
2. The patient does not have primary testicular failure AND
3. The requested agent will be used in combination with human chorionic gonadotropin (hCG) AND
4. The requested agent will not be started until the patient’s serum testosterone level is at normal levels AND
5. ONE of the following:
<table>
<tr><th>Preferred Target Agents</th><th>Non-Preferred Target Agents</th></tr>
<tr><td>Follistim AQ (follitropin beta)</td><td>Gonal F Kit (follitropin alfa)
Gonal F RFF (follitropin alfa)
Gonal F RFF Pen (follitropin alfa)</td></tr>
</table>
A. The requested agent is a preferred agent OR
B. The patient has tried and had an inadequate response to ONE of the preferred agent(s) OR
C. The patient has an intolerance or hypersensitivity to ONE of the preferred agent(s) that is NOT expected to occur with the requested agent OR
D. The patient has an FDA labeled contraindication to ALL of the preferred agent(s) that is NOT expected to occur with the requested agent OR
E. The patient is currently being treated with the requested agent as indicated by ALL of the following:
1. A statement by the prescriber that the patient is currently taking the requested agent AND
2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent AND
3. The prescriber states that a change in therapy is expected to be ineffective or cause harm OR
F. The prescriber has provided documentation ALL of the preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm AND
3. The patient has undergone a complete medical and endocrinologic evaluation AND
4. The fertility status of the patient’s partner has been evaluated (if applicable) AND
5. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of approval: 3 months for ART or ovulation induction
6 months for hypogonadotropic hypogonadism

NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents</td></tr>
<tr><td>Gonadotropin Releasing Hormone (GnRH) Analogs</td><td>
Gonadotropin Releasing Hormone (GnRH) Analogs Evaluation

Cetrotide and Ganirelix acetate will be approved when ALL of the following are met:
1. The patient’s benefit plan covers agents for infertility AND
2. ONE of the following:
A. The requested agent is eligible for continuation of therapy AND ONE of the following:
<table>
<tr><th>Agents Eligible for Continuation of Therapy</th></tr>
</table>
</td></tr>
</table>

Module	Clinical Criteria for Approval
	All target agents are eligible for continuation of therapy 1. Information has been provided that indicates the patient has been treated with the requested agent within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR** B. ALL of the following: 1. The patient is undergoing ovarian stimulation **AND** 2. The patient is NOT pregnant **AND** 3. The patient has undergone a complete medical and endocrinologic evaluation **AND** 4. The fertility status of the patient's partner has been evaluated (if applicable) **AND** 5. The patient will receive human chorionic gonadotropin (hCG) following completion of the requested agent unless there are risks present for ovarian hyper-stimulation syndrome (OHSS) **AND** 6. ONE of the following: **Preferred Target Agents**: Ganirelix acetate*; *generic available and included as preferred in this program **Non-Preferred Target Agents**: Cetrotide (cetrorelix acetate) A. The requested agent is a preferred agent **OR** B. The patient has tried and had an inadequate response to ONE of the preferred agent(s) **OR** C. The patient has an intolerance or hypersensitivity to ONE of the preferred agent(s) that is NOT expected to occur with the requested agent **OR** D. The patient has an FDA labeled contraindication to ALL of the preferred agent(s) that is NOT expected to occur with the requested agent **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that ALL of the preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 3 months NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents
Human Chorionic Gonadotropin Evaluation	**Human Chorionic Gonadotropin Evaluation** **Novarel, Ovidrel, Pregnyl, and Chorionic gonadotropin** will be approved when BOTH of the following are met: 1. ONE of the following: A. The requested agent will be used for a diagnosis of cryptorchidism AND ALL of the following:

Module	Clinical Criteria for Approval

1. The requested agent is Novarel, Pregnyl, or hCG **AND**
2. The diagnosis is not due to an anatomical obstruction **AND**
3. The patient is prepubertal **AND**
4. ONE of the following:
    A. The patient has had surgery to correct the cryptorchidism **OR**
    B. The patient will have surgery to correct the cryptorchidism after using the requested agent **OR**
    C. The patient is unable to have surgery to correct the cryptorchidism **OR**

B. The requested agent will be used for a diagnosis of hypogonadotropic hypogonadism AND BOTH of the following:
1. The requested agent is Novarel, Pregnyl, or hCG **AND**
2. ONE of the following:
    A. The patient is not currently receiving treatment for the diagnosis AND has ONE of the following pretreatment levels
        1. Total serum testosterone level that is below the testing laboratory's normal range or is less than 300 ng/dL **OR**
        2. Free serum testosterone level that is below the testing laboratory's normal range **OR**
    B. The patient is currently receiving treatment for the diagnosis AND has ONE of the following current levels:
        1. Total serum testosterone level that is within OR below the testing laboratory's normal range OR is less than 300 ng/dL **OR**
        2. Free serum testosterone level is within OR below the testing laboratory's normal range **OR**

C. The requested agent will be used for the development of multiple follicles as part of an assisted reproductive technology (ART) [e.g., invitro fertilization (IVF), gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), tubal embryo transfer (TET), cryopreservation, intracytoplasmic sperm injection (ICSI)] OR for ovulation induction AND BOTH of the following:
1. The patient's benefit plan covers agents for infertility **AND**
2. ONE of the following:
    A. The requested agent is eligible for continuation of therapy AND ONE of the following:

Agents Eligible for Continuation of Therapy
Ovidrel (chorionic gonadotropin) Pregnyl (chorionic gonadotropin)

        1. Information has been provided that indicates the patient has been treated with the requested agent within the past 90 days **OR**
        2. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR**
    B. ALL of the following:
        1. The patient is NOT pregnant **AND**
        2. The patient does NOT have primary ovarian failure **AND**
        3. The patient will receive follicle stimulating hormone (FSH) OR clomiphene before the requested agent unless there are risks present for ovarian hyperstimulation syndrome (OHSS) **AND**
        4. The patient has undergone a complete medical and endocrinologic evaluation **AND**
        5. The fertility status of the partner been evaluated (if applicable) **AND**
        6. ONE of the following:

Module	Clinical Criteria for Approval

Preferred Target Agents	Non-Preferred Target Agents
Ovidrel (chorionic gonadotropin) Pregnyl (chorionic gonadotropin) (50090-5923-**, 00052-0315-**)	Chorionic gonadotropin (63323-0030-**) Novarel (chorionic gonadotropin) (55566-1501-**, 55566-1502-**)

A. The requested agent is a preferred agent **OR**
B. The patient has tried and had an inadequate response to ONE of the preferred agent(s) **OR**
C. The patient has an intolerance or hypersensitivity to ONE preferred agent(s) that is NOT expected to occur with the requested agent **OR**
D. The patient has an FDA labeled contraindication to ALL of the preferred agent(s) that is NOT expected to occur with the requested agent **OR**
E. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
    2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
    3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
F. The prescriber has provided documentation that ALL of the preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

2. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 3 months for ovulation induction or ART
6 months for hypogonadotropic hypogonadism
3 months for cryptorchidism

NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents

Menotropins	**Menotropins Evaluation** **Menopur** will be approved when ALL of the following are met: 1. The patient's benefit plan covers agents for infertility **AND** 2. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following:

Agents Eligible for Continuation of Therapy
All target agents are eligible for continuation of therapy

1. Information has been provided that indicates the patient has been treated with the requested agent within the past 90 days **OR**

Module	Clinical Criteria for Approval
	2. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR** B. ALL of the following: 1. The requested agent will be used for the development of multiple follicles as part of an assisted reproductive technology (ART) [e.g., invitro fertilization (IVF), gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), tubal embryo transfer (TET), cryopreservation, intracytoplasmic sperm injection (ICSI) **AND** 2. The patient is NOT pregnant **AND** 3. The patient does NOT have primary ovarian failure **AND** 4. The patient will receive human chorionic gonadotropin (hCG) following completion of the requested agent unless there are risks present for ovarian hyperstimulation syndrome (OHSS) **AND** 5. The patient has undergone a complete medical and endocrinologic evaluation **AND** 6. The fertility status of the patient's partner has been evaluated (if applicable) **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 3 months NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when the following is met: 1. ONE of the following: A. The requested quantity (dose) does NOT exceed the program quantity limit **OR** B. ALL of the following: 1. The requested quantity (dose) is greater than the program quantity limit **AND** 2. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 3. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** C. ALL of the following: 1. The requested quantity (dose) is greater than the program quantity limit **AND** 2. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** 3. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of approval:** 3 months for ART or ovulation induction 6 months for hypogonadotropic hypogonadism

• Program Summary: Growth Hormone

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☐ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	3010	Genotropin; Genotropin miniquick; Humatrope; Ngenla; Norditropin flexpro; Nutropin aq nuspin 10; Nutropin aq nuspin 20; Nutropin aq nuspin 5; Omnitrope; Saizen; Saizenprep reconstitution; Serostim; Skytrofa; Sogroya; Zomacton; Zorbtive	lonapegsomatropin-tcgd for subcutaneous inj cart; lonapegsomatropin-tcgd for subcutaneous inj cartridge; somapacitan-beco solution pen-injector; somatrogon-ghla solution pen-injector; somatropin (non-refrigerated) for inj; somatropin (non-refrigerated) for subcutaneous inj; somatropin for inj; somatropin for inj cartridge; somatropin for subcutaneous inj; somatropin for subcutaneous inj cartridge; somatropin for subcutaneous inj prefilled syr; somatropin solution cartridge; somatropin solution pen-injector	0.2 MG; 0.4 MG; 0.6 MG; 0.8 MG; 1 MG; 1.2 MG; 1.4 MG; 1.6 MG; 1.8 MG; 10 MG; 10 MG/1.5ML; 10 MG/2ML; 11 MG; 12 MG; 13.3 MG; 15 MG/1.5ML; 2 MG; 20 MG/2ML; 24 MG; 24 MG/1.2ML; 3 MG; 3.6 MG; 30 MG/3ML; 4 MG; 4.3 MG; 5 MG; 5 MG/1.5ML; 5 MG/2ML; 5.2 MG; 5.8 MG; 6 MG; 6.3 MG; 60 MG/1.2ML; 7.6 MG; 8.8 MG; 9.1 MG	M; N; O; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Adults: Long and Short Acting Growth Hormone with Preferred Exception	**TARGET AGENT(S)**

Formulation	Preferred Target Agent(s)	Non-Preferred Target Agent(s)
	Preferred and non-preferred target agents - to be determined by client	Preferred and non-preferred target agents - to be determined by client
Short - Acting Agents	**Genotropin, Genotropin Mini Quick** (somatropin) **Omnitrope** (somatropin)	**Humatrope** (somatropin) **Norditropin FlexPro** (somatropin) **Nutropin AQ, NuSpin** (somatropin) **Saizen, Saizenprep** (somatropin) **Serostim** (somatropin)

Module	Clinical Criteria for Approval

		Zomacton (somatropin) **Zorbtive** (somatropin)
Long - Acting Agents	**Skytrofa** (lonapegsomatropin-tcgd)	**Ngenla** (somatrogon-ghla) **Sogroya** (somapacitan-beco)

Adults – Initial Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. The patient is an adult (as defined by the prescriber) **AND**
2. The patient has ONE of the following diagnoses:
    A. The patient has a diagnosis of AIDS wasting/cachexia AND ALL of the following:
        1. The requested agent is a short-acting growth hormone (GH) **AND**
        2. The patient is currently treated with antiretroviral therapy **AND**
        3. The patient will continue antiretroviral therapy in combination with the requested agent **AND**
        4. BOTH of the following:
            A. ONE of the following:
                1. The patient has had weight loss that meets ONE of the following:
                    A. 10% unintentional weight loss over 12 months **OR**
                    B. 7.5% unintentional weight loss over 6 months **OR**
                2. The patient has a body cell mass (BCM) loss greater than or equal to 5% within 6 months **OR**
                3. The patient's sex is male and has BCM less than 35% of total body weight and body mass index (BMI) less than 27 kg/m^2 **OR**
                4. The patient's sex is female and has BCM less than 23% of total body weight and BMI less than 27 kg/m^2 **OR**
                5. The prescriber has provided information that the patient's BCM less than 35% or less than 23% and BMI less than 27 kg/m^2 are medically appropriate for diagnosing AIDS wasting/cachexia for the patient's sex **OR**
                6. The patient's BMI is less than 20 kg/m^2 **AND**
            B. All other causes of weight loss have been ruled out **OR**
    B. The patient has a diagnosis of short bowel syndrome (SBS) AND BOTH of the following:
        1. The requested agent is a short-acting GH **AND**
        2. The patient is receiving specialized nutritional support **OR**
    C. The patient has a diagnosis of growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone AND ONE of the following:
        1. The patient had a diagnosis of childhood-onset growth hormone deficiency AND has failed at least one growth hormone (GH) stimulation test as an adult **OR**
        2. The patient has a low insulin-like growth factor-1 (IGF-1) level AND ONE of the following:
            A. Organic hypothalamic-pituitary disease **OR**
            B. Pituitary structural lesion or trauma **OR**
            C. The patient has panhypopituitarism or multiple (greater than or equal to 3) pituitary hormone deficiency **OR**
        3. The patient has an established causal genetic mutation OR hypothalamic-

Module	Clinical Criteria for Approval
	pituitary structural defect other than ectopic posterior pituitary **OR** 4. The patient has failed at least two growth hormone (GH) stimulation tests as an adult **OR** 5. The patient has failed at least one GH stimulation test as an adult AND the patient has an organic pituitary disease **OR** D. The patient has another FDA approved indication for the requested agent and route of administration **OR** E. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 3. The request is for a long-acting GH agent AND if the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication **AND** 7. ONE of the following: A. The request is for a short-acting GH agent AND if the client has preferred agent(s), then ONE of the following: 1. BOTH of the following: A. The request is for a preferred agent **AND** B. The preferred agent is supported in FDA labeling for the requested indication **OR** 2. If the request is for a nonpreferred agent, then BOTH of the following: A. The nonpreferred agent is supported in FDA labeling for the requested indication **AND** B. ONE of the following: 1. The preferred agent(s) are not supported in FDA labeling for the requested indication **OR** 2. ONE of the following: A. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to a preferred agent that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** B. The prescriber has provided information to support the efficacy of the requested nonpreferred agent over a preferred agent for the intended diagnosis (medical record required) **OR** C. The patient's medication history includes use of a preferred agent **OR** D. BOTH of the following: 1. The prescriber has stated that the patient has tried a preferred agent **AND** 2. The preferred agent was discontinued due to lack of effectiveness or an adverse event **OR** E. The patient is currently being treated with the

Module	Clinical Criteria for Approval
	requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that the preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The request is for a long-acting GH agent AND if the client has preferred agent(s), then ALL of the following: 1. The requested agent is FDA approved for the requested indication **AND** 2. ONE of the following: A. The preferred short-acting GH agent(s) are NOT FDA approved for the requested indication **OR** B. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a preferred short-acting GH agent that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** C. The prescriber has provided information to support the efficacy of the requested nonpreferred agent over a preferred short-acting GH agent for the intended diagnosis (medical record required) **OR** D. The patient's medication history includes use of a preferred short-acting GH agent **OR** E. BOTH of the following: 1. The prescriber has stated that the patient has tried a preferred short-acting GH agent **AND** 2. The preferred short-acting GH agent was discontinued due to lack of effectiveness or an adverse event **OR** F. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** G. The prescriber has provided documentation that the preferred short-acting GH agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an

Module	Clinical Criteria for Approval

adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

3. ONE of the following:
   - A. The requested agent is a preferred agent **OR**
   - B. The preferred agent(s) are NOT FDA approved for the requested indication **OR**
   - C. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a preferred long-acting GH agent that is not expected to occur with the requested nonpreferred agent (medical record required) **OR**
   - D. The prescriber has provided information to support the efficacy of the requested nonpreferred agent over a preferred long-acting GH agent for the intended diagnosis (medical record required) **OR**
   - E. The patient's medication history includes use of a preferred long-acting GH agent **OR**
   - F. BOTH of the following:
     1. The prescriber has stated that the patient has tried a preferred long-acting GH agent **AND**
     2. The preferred long-acting GH agent was discontinued due to lack of effectiveness or an adverse event **OR**
   - G. The patient is currently being treated with the requested agent as indicated by ALL of the following:
     1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
     2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
     3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
   - H. The prescriber has provided documentation that the preferred long-acting GH agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

Compendia Allowed: AHFS or DrugDex 1 or 2a level of evidence

Length of Approval:

SBS	4 weeks
AIDS wasting/cachexia	12 weeks
All other indications	12 months

Effective 4/1/24 for:

Those who were approved through initial criteria after 4/1/24

Those who have started a new plan year since last authorization

Adults – Renewal Evaluation

Module	Clinical Criteria for Approval
	Target Growth Hormone Agent(s) will be approved when ALL of the following are met: 1. The patient has been approved for therapy with GH previously through the plan's prior authorization process **AND** 2. The patient is an adult (as defined by the prescriber) **AND** 3. ONE of the following: A. The request is for a short-acting GH agent AND if the client has preferred agent(s), then ONE of the following: 1. BOTH of the following: A. The request is for a preferred agent **AND** B. The preferred agent is supported in FDA labeling for the requested indication **OR** 2. If the request is for a nonpreferred agent, then BOTH of the following: A. The nonpreferred agent is supported in FDA labeling for the requested indication **AND** B. ONE of the following: 1. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a preferred agent that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 2. The prescriber has provided information to support the efficacy of the requested nonpreferred agent over a preferred agent for the intended diagnosis (medical record required) **OR** 3. The patient's medication history includes use of a preferred agent **OR** 4. BOTH of the following: A. The prescriber has stated that the patient has tried a preferred agent **AND** B. The preferred agent was discontinued due to lack of effectiveness or an adverse event **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that the preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The request is for a long-acting growth hormone agent AND if the client has preferred agent(s), then ALL of the following: 1. The requested agent is FDA approved for the requested indication **AND** 2. ONE of the following: A. The preferred short-acting agent(s) are NOT supported in FDA labeling for the requested indication **OR**

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	B. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a preferred short-acting GH agent that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** C. The prescriber has provided information to support the efficacy of the requested nonpreferred agent over a preferred short-acting GH agent for the intended diagnosis (medical record required) **OR** D. The patient's medication history includes use of a preferred short-acting GH agent **OR** E. BOTH of the following: 1. The prescriber has stated that the patient has tried a preferred short-acting GH agent **AND** 2. The preferred short-acting GH agent was discontinued due to lack of effectiveness or an adverse event **OR** F. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** G. The prescriber has provided documentation that the preferred short-acting GH agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. ONE of the following: A. The requested agent is a preferred agent **OR** B. The preferred agent(s) are NOT FDA approved for the requested indication **OR** C. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a preferred long-acting GH agent that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** D. The prescriber has provided information to support the efficacy of the requested nonpreferred agent over a preferred long-acting GH agent for the intended diagnosis (medical record required) **OR** E. The patient's medication history includes use of a preferred long-acting GH agent **OR** F. BOTH of the following: 1. The prescriber has stated that the patient has tried a preferred long-acting GH agent **AND** 2. The preferred long-acting GH agent was discontinued due to lack of effectiveness or an adverse event **OR** G. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently

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receiving a positive therapeutic outcome on requested agent **AND**

3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

H. The prescriber has provided documentation that the preferred long-acting GH agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

4. ONE of the following:
   - A. The patient has a diagnosis of short bowel syndrome (SBS) AND has had clinical benefit with the requested agent **OR**
   - B. The patient has a diagnosis of AIDS wasting/cachexia AND ALL of the following:
     1. The patient is currently treated with antiretroviral therapy **AND**
     2. The patient will continue antiretroviral therapy in combination with the requested agent **AND**
     3. The patient has had clinical benefit with the requested agent (i.e., an increase in weight or weight stabilization) **OR**
   - C. The patient has growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone AND BOTH of the following:
     1. The patient's IGF-I level has been evaluated to confirm the appropriateness of the current dose **AND**
     2. The patient has had clinical benefit with the requested agent (i.e., body composition, hip-to-waist ratio, cardiovascular health, bone mineral density, serum cholesterol, physical strength, or quality of life) **OR**
   - D. The patient has a diagnosis other than SBS, AIDS wasting/cachexia, GHD, or growth failure due to inadequate secretion of endogenous growth hormone AND has had clinical benefit with the requested agent **AND**
5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or has consulted with a specialist in the area of the patient's diagnosis **AND**
7. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication **AND**
8. The patient is being monitored for adverse effects of GH

Compendia Allowed: AHFS or DrugDex 1 or 2a level of evidence

Length of Approval:

SBS	4 weeks
AIDS wasting/cachexia	12 weeks
All other indications	12 months

Effective until 3/31/25 for:

Those with an original PA date 4/1/24 – 3/31/25 seeking reauthorization AND that have not started a new plan year

Adults – Renewal Evaluation

Target Growth Hormone Agent(s) will be approved when ALL of the following are met:

Module	Clinical Criteria for Approval
	1. The patient has been approved for therapy with GH previously through the plan's prior authorization process **AND** 2. The patient is an adult (as defined by the prescriber) **AND** 3. ONE of the following: A. If the request is for a short acting GH agent, then ONE of the following: 1. BOTH of the following: A. The request is for a preferred agent **AND** B. The preferred agent is supported in FDA labeling for the requested indication **OR** 2. If the request is for a nonpreferred agent, then BOTH of the following: A. The nonpreferred agent is supported in FDA labeling for the requested indication **AND** B. ONE of the following: 1. The preferred agents are not supported in FDA labeling for the requested indication **OR** 2. ONE of the following: A. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a preferred agent that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** B. The prescriber has provided information to support the efficacy of the requested nonpreferred agent over a preferred agent for the intended diagnosis (medical record required) **OR** C. The patient's medication history includes use of a preferred agent **OR** D. BOTH of the following: 1. The prescriber has stated that the patient has tried a preferred agent **AND** 2. The preferred agent was discontinued due to lack of effectiveness or an adverse event **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that the preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in

Module	Clinical Criteria for Approval
	performing daily activities or cause physical or mental harm **OR** B. If the request is for a long acting GH agent, then BOTH of the following: 1. The nonpreferred agent is supported in FDA labeling for the requested indication **AND** 2. ONE of the following: A. The preferred short acting GH agents are not supported in FDA labeling for the requested indication **OR** B. ONE of the following: 1. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a preferred short acting GH agent that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 2. The prescriber has provided information to support the efficacy of the requested nonpreferred agent over a preferred short acting GH agent for the intended diagnosis (medical record required) **OR** 3. The patient's medication history includes use of a preferred short acting GH agent **OR** 4. BOTH of the following: A. The prescriber has stated that the patient has tried a preferred short acting GH agent **AND** B. The preferred short acting GH agent was discontinued due to lack of effectiveness or an adverse event **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that the preferred short acting GH agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. ONE of the following: A. The patient has a diagnosis of short bowel syndrome (SBS) AND has had clinical benefit with the requested agent **OR** B. The patient has a diagnosis of AIDS wasting/cachexia AND ALL of the following: 1. The patient is currently treated with antiretroviral therapy **AND** 2. The patient will continue antiretroviral therapy in combination with the requested agent **AND** 3. The patient has had clinical benefit with the requested agent (i.e., an increase in weight or weight stabilization) **OR** C. The patient has growth hormone deficiency (GHD) or growth failure due to

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td></td><td>
inadequate secretion of endogenous growth hormone AND BOTH of the following:
1. The patient's IGF-I level has been evaluated to confirm the appropriateness of the current dose AND
2. The patient has had clinical benefit with the requested agent (i.e., body composition, hip-to-waist ratio, cardiovascular health, bone mineral density, serum cholesterol, physical strength, or quality of life) OR
D. The patient has a diagnosis other than SBS, AIDS wasting/cachexia, GHD, or growth failure due to inadequate secretion of endogenous growth hormone AND has had clinical benefit with the requested agent AND
5. The patient does NOT have any FDA labeled contraindications to the requested agent AND
6. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., endocrinologist) or has consulted with a specialist in the area of the patient’s diagnosis AND
7. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication AND
8. The patient is being monitored for adverse effects of GH

Compendia Allowed: AHFS or DrugDex 1 or 2a level of evidence

Length of Approval:

<table>
<tr><td>SBS</td><td>4 weeks</td></tr>
<tr><td>AIDS wasting/cachexia</td><td>12 weeks</td></tr>
<tr><td>All other indications</td><td>12 months</td></tr>
</table>
</td></tr>
<tr><td>Children: Long-Acting Growth Hormone with Preferred Exception</td><td>
TARGET AGENT(S)

<table>
<tr><th>Formulation</th><th>Preferred Target Agent(s)</th><th>Non-Preferred Target Agent(s)</th></tr>
<tr><td></td><td>Preferred and non-preferred target agents - to be determined by client</td><td>Preferred and non-preferred target agents - to be determined by client</td></tr>
<tr><td>Short-Acting Agent(s)</td><td>Genotropin, Genotropin Mini Quick (somatropin)
Omnitrope (somatropin)</td><td>Humatrope (somatropin)
Norditropin FlexPro (somatropin)
Nutropin AQ NuSpin (somatropin)
Saizen,
Saizenprep (somatropin)
Serostim (somatropin)
Zomacton (somatropin)
Zorbtive (somatropin)</td></tr>
<tr><td>Long-Acting Agent(s)</td><td>Skytrofa (lonapegsomatropin-tcgd)</td><td>Ngenla (somatrogon-ghla)
Sogroya (somapacitan-beco)</td></tr>
</table>

Children – Initial Evaluation

Target Agent(s) will be approved when ALL of the following are met:
1. ONE of the following
A. The patient has a diagnosis of growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone AND ONE of the
</td></tr>
</table>

Module	Clinical Criteria for Approval
	following: 1. The patient has extreme short stature (e.g., height less than or equal to -3 SD), normal nutrition, significantly reduced IGF-1 and IGFBP-3 (e.g., less than -2 SD), and delayed bone age **OR** 2. BOTH of the following: A. The patient has ONE of the following: 1. Height more than 2 SD below the mean for age and sex **OR** 2. Height more than 1.5 SD below the midparental height **OR** 3. A decrease in height SD of more than 0.5 over one year in children greater than 2 years of age **OR** 4. Height velocity (HV) more than 2 SD below the mean over one year or more than 1.5 SD sustained over two years **OR** 5. Height-for-age curve that has deviated downward across two major height percentile curves (e.g., from above the 25th percentile to below the 10th percentile) **OR** 6. BOTH of the following: A. The patient's age is 2-4 years **AND** B. The patient has a HV less than 5.5 cm/year (less than 2.2 inches/year) **OR** 7. BOTH of the following: A. The patient's age is 4-6 years **AND** B. The patient has a HV less than 5 cm/year (less than 2 inches/year) **OR** 8. The patient's age is 6 years to puberty AND ONE of the following: A. The patient's sex is male and HV is less than 4 cm/year (less than 1.6 inches/year) **OR** B. The patient's sex is female and HV is less than 4.5 cm/year (less than 1.8 inches/year) **AND** B. ONE of the following: 1. The patient has failed at least 2 growth hormone (GH) stimulation tests (e.g., peak GH value of less than 10 mcg/L after stimulation, or otherwise considered abnormal as determined by testing lab) **OR** 2. The patient has failed at least 1 GH stimulation test (e.g., peak GH value of less than 10 mcg/L after stimulation, or otherwise considered abnormal as determined by testing lab) AND ONE of the following: A. Pathology of the central nervous system **OR** B. History of irradiation **OR** C. Other pituitary hormone defects (e.g., multiple pituitary hormone deficiency [MPHD]) **OR** D. A genetic defect **OR** 3. The patient has a pituitary abnormality and a known deficit of at least one other pituitary hormone **OR** B. The patient has another FDA approved indication for the requested agent and route of administration **OR** C. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. The patient is a child (as defined by the prescriber) **AND** 3. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested

Module	Clinical Criteria for Approval
	agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 4. If the client has preferred agent(s), then ALL of the following: A. The requested agent is FDA approved for the requested indication **AND** B. ONE of the following: 1. The preferred short-acting GH agent(s) are NOT FDA approved for the requested indication **OR** 2. The patient has an intolerance, hypersensitivity or FDA labeled contraindication to a preferred short-acting growth hormone that is not expected to occur with the requested nonpreferred agent (medical records required) **OR** 3. BOTH of the following: A. The prescriber has stated that the patient has tried a preferred short-acting GH **AND** B. The preferred short-acting GH was discontinued due to lack of effectiveness or an adverse event **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that the preferred short-acting GH agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** C. ONE of the following: 1. The requested agent is a preferred agent **OR** 2. The preferred agent(s) are NOT FDA approved for the requested indication **OR** 3. The patient has an intolerance, hypersensitivity or FDA labeled contraindication to a preferred long-acting growth hormone that is not expected to occur with the requested nonpreferred agent (medical records required) **OR** 4. BOTH of the following: A. The prescriber has stated that the patient has tried a preferred long-acting GH **AND** B. The preferred long-acting GH was discontinued due to lack of effectiveness or an adverse event **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that the preferred long-acting

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	GH agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or has consulted with a specialist in the area of the patient's diagnosis **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 7. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication **Compendia Allowed:** AHFS or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months **Children – Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for therapy with GH through the plan's prior authorization process **AND** 2. The patient is a child (as defined by the prescriber) **AND** 3. If the client has preferred agent(s), then ALL of the following: A. The requested agent is FDA approved for the requested indication **AND** B. ONE of the following: 1. The preferred short-acting GH agent(s) are NOT FDA approved for the requested indication **OR** 2. The patient has an intolerance, hypersensitivity or FDA labeled contraindication to a preferred short-acting growth hormone that is not expected to occur with the requested nonpreferred agent (medical records required) **OR** 3. BOTH of the following: A. The prescriber has stated that the patient has tried a preferred short-acting GH **AND** B. The preferred short-acting GH was discontinued due to lack of effectiveness or an adverse event **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that the preferred short-acting GH agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** C. ONE of the following: 1. The requested agent is a preferred GH agent **OR** 2. The preferred GH agent(s) are NOT FDA approved for the requested indication **OR** 3. The patient has an intolerance, hypersensitivity or FDA labeled

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contraindication to a preferred long-acting growth hormone that is not expected to occur with the requested nonpreferred agent (medical records required) OR
4. BOTH of the following:
A. The prescriber has stated that the patient has tried a preferred long-acting GH AND
B. The preferred long-acting GH was discontinued due to lack of effectiveness or an adverse event OR
5. The patient is currently being treated with the requested agent as indicated by ALL of the following:
A. A statement by the prescriber that the patient is currently taking the requested agent AND
B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent AND
C. The prescriber states that a change in therapy is expected to be ineffective or cause harm OR
6. The prescriber has provided documentation that the preferred long-acting GH agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm AND
4. ONE of the following:
A. The patient has a diagnosis of growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone AND BOTH of the following:
1. The patient does NOT have closed epiphyses AND
2. The patient’s height has increased greater than or equal to 2 cm over the previous year with GH therapy OR
B. The patient has a diagnosis other than GHD or growth failure due to inadequate secretion of endogenous growth hormone AND has had clinical benefit with the requested agent AND
5. The patient is being monitored for adverse effects of GH AND
6. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., endocrinologist) or has consulted with a specialist in the area of the patient’s diagnosis AND
7. The patient does NOT have any FDA labeled contraindications to the requested agent AND
8. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication

Compendia Allowed: AHFS or DrugDex 1 or 2a level of evidence

Length of Approval: 12 months
</td></tr>
<tr><td>Children: Short-Acting Growth Hormone with Preferred Exception</td><td>
TARGET AGENT(S)

<table>
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Module	Clinical Criteria for Approval

		Nutropin AQ NuSpin (somatropin) **Saizen,** **Saizenprep** (somatropin) **Serostim** (somatropin) **Zomacton** (somatropin) **Zorbtive** (somatropin)

Children – Initial Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. The patient is a child (as defined by the prescriber) **AND**
2. The patient has ONE of the following diagnoses:
    - A. ALL of the following:
        1. The patient is a newborn (less than or equal to 4 months of age) with hypoglycemia **AND**
        2. The patient has a serum growth hormone (GH) concentration less than or equal to 5 mcg/L **AND**
        3. ONE of the following:
            - A. Congenital pituitary abnormality (e.g., ectopic posterior pituitary and pituitary hypoplasia with abnormal stalk) **OR**
            - B. Deficiency of at least one additional pituitary hormone **OR**
    - B. ALL of the following:
        1. The patient is a newborn (less than or equal to 4 months of age) with hypoglycemia **AND**
        2. The patient has a growth hormone (GH) concentration less than 20 mcg/L **AND**
        3. The patient does not have a known metabolic disorder **AND**
        4. The patient has a reduced IGFBP-3 level (e.g., less than -2 SD) **OR**
    - C. The patient has a diagnosis of Turner syndrome **OR**
    - D. The patient has a diagnosis of Noonan syndrome **OR**
    - E. The patient has a diagnosis of Prader-Willi syndrome **OR**
    - F. The patient has a diagnosis of SHOX gene deficiency **OR**
    - G. The patient has a diagnosis of short bowel syndrome (SBS) AND is receiving specialized nutritional support AND ONE of the following:
        1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
        2. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **OR**
    - H. The patient has a diagnosis of panhypopituitarism or has deficiencies in at least 3 or more pituitary axes AND serum IGF-I levels below the age- and sex-appropriate reference range when off GH therapy **OR**
    - I. The patient has a diagnosis of chronic renal insufficiency and BOTH of the following:
        1. The patient's height velocity (HV) for age is less than -1.88 standard deviations (SD) OR HV for age is less than the third percentile **AND**
        2. Other etiologies for growth impairment have been addressed **OR**
    - J. The patient has a diagnosis of small for gestational age (SGA) and ALL of the following:
        1. The patient is 2 years of age or older **AND**
        2. The patient has a documented birth weight and/or birth length that is 2 or more standard deviations (SD) below the mean for gestational age **AND**
        3. At 24 months of age, the patient failed to manifest catch-up growth

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	evidenced by a height that remains 2 or more standard deviations (SD) below the mean for age and sex OR K. The patient has a diagnosis of idiopathic short stature (ISS) AND ALL of the following: 1. The patient has a height less than or equal to -2.25 SD below the corresponding mean height for age and sex **AND** 2. The patient has open epiphyses **AND** 3. ONE of the following: A. The patient has a predicted adult height that is below the normal range AND ONE of the following: 1. The patient's sex is male and predicted adult height is less than 63 inches **OR** 2. The patient's sex is female and predicted adult height is less than 59 inches **OR** B. The patient is more than 2 SD below their mid-parental target height **AND** 4. BOTH of the following: A. The patient has been evaluated for constitutional delay of growth and puberty (CDGP) **AND** B. The patient does NOT have a diagnosis of CDGP **OR** L. The patient has a diagnosis of growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone AND ONE of the following: 1. The patient has extreme short stature (e.g., height less than or equal to -3 SD), normal nutrition, significantly reduced IGF-1 and IGFBP-3 (e.g., less than -2 SD), and delayed bone age **OR** 2. BOTH of the following: A. The patient has ONE of the following: 1. Height more than 2 SD below the mean for age and sex **OR** 2. Height more than 1.5 SD below the midparental height **OR** 3. A decrease in height SD of more than 0.5 over one year in children greater than 2 years of age **OR** 4. Height velocity (HV) more than 2 SD below the mean over one year or more than 1.5 SD sustained over two years **OR** 5. Height-for-age curve that has deviated downward across two major height percentile curves (e.g., from above the 25th percentile to below the 10th percentile) **OR** 6. BOTH of the following: A. The patient's age is 2-4 years **AND** B. The patient has a HV less than 5.5 cm/year (less than 2.2 inches/year) **OR** 7. BOTH of the following: A. The patient's age is 4-6 years **AND** B. The patient has a HV less than 5 cm/year (less than 2 inches/year) **OR** 8. The patient's age is 6 years to puberty AND ONE of the following: A. The patient's sex is male and HV is less than 4 cm/year (less than 1.6 inches/year) **OR** B. The patient's sex is female and HV is less than 4.5 cm/year (less than 1.8 inches/year) **AND** B. ONE of the following: 1. The patient has failed at least 2 GH stimulation tests (e.g.,

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	peak GH value of less than 10 mcg/L after stimulation, or otherwise considered abnormal as determined by testing lab) **OR** 2. The patient has failed at least 1 GH stimulation test (e.g., peak GH value of less than 10 mcg/L after stimulation, or otherwise considered abnormal as determined by testing lab) AND ONE of the following: A. Pathology of the central nervous system **OR** B. History of irradiation OR C. Other pituitary hormone defects (e.g., multiple pituitary hormone deficiency [MPHD]) **OR** D. A genetic defect **OR** 3. The patient has a pituitary abnormality and a known deficit of at least one other pituitary hormone **AND** M. The patient has another FDA approved indication for the requested agent and route of administration **OR** N. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication **AND** 6. If the client has preferred agent(s), then ONE of the following: A. BOTH of the following: 1. The request is for a preferred agent **AND** 2. The preferred agent(s) are supported in FDA labeling for the requested indication **OR** B. The request is for a nonpreferred agent and BOTH of the following: 1. The nonpreferred agent is supported in FDA labeling for the requested indication **AND** 2. ONE of the following: A. The preferred agent(s) are NOT supported in FDA labeling for the requested indication **OR** B. ONE of the following: 1. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to a preferred agent that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 2. The prescriber has provided information to support the efficacy of a requested nonpreferred agent over ALL preferred agent(s) for the intended diagnosis (medical record required) **OR** 3. The patient's medication history includes use of a preferred agent **OR** 4. BOTH of the following: A. The prescriber has stated that the patient has tried a preferred agent **AND** B. The preferred agent was discontinued due to lack of effectiveness or an adverse event **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following:

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	A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that the preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Compendia Allowed:** AHFS or DrugDex 1 or 2a level of evidence **Length of Approval:** 4 weeks for SBS 12 months for all other indications **Effective 4/1/24 for:** **Those who were approved through initial criteria after 4/1/24** **Those who have started a new plan year since last authorization** **Children – Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for therapy with GH through the plan's prior authorization process **AND** 2. The patient is a child (as defined by the prescriber) **AND** 3. If the client has preferred agent(s), then ONE of the following: A. BOTH of the following: 1. The request is for a preferred agent **AND** 2. The preferred agent(s) are supported in FDA labeling for the requested indication **OR** B. The request is for a nonpreferred agent and BOTH of the following: 1. The nonpreferred agent is supported in FDA labeling for the requested indication **AND** 2. ONE of the following: A. The preferred agent(s) are NOT supported in FDA labeling for the requested indication **OR** B. ONE of the following: 1. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to a preferred agent that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 2. The prescriber has provided information to support the efficacy of a requested nonpreferred agent over the preferred agent for the intended diagnosis (medical record required) **OR** 3. The patient's medication history includes use of a

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	preferred agent **OR** 4. BOTH of the following: A. The prescriber has stated that the patient has tried a preferred agent **AND** B. The preferred agent was discontinued due to lack of effectiveness or an adverse event **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that the preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. ONE of the following: A. The patient has a diagnosis of short bowel syndrome (SBS) AND has had clinical benefit with the requested agent AND ONE of the following: 1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** 2. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **OR** B. The patient has a diagnosis of ISS and BOTH of the following: 1. Height has increased greater than or equal to 2 cm over the previous year with GH therapy **AND** 2. Bone age is less than 16 years in patients with a sex of male and 15 years in patients with a sex of female AND the patient has open epiphyses **OR** C. The patient has a diagnosis of growth hormone deficiency (GHD), growth failure due to inadequate secretion of endogenous growth hormone, short stature disorder (i.e., Noonan's syndrome, SHOX deficiency, Turner syndrome, small for gestational age), or renal function impairment with growth failure AND BOTH of the following: 1. The patient does NOT have closed epiphyses **AND** 2. The patient's height has increased greater than or equal to 2 cm over the previous year with GH therapy **OR** D. The patient has a diagnosis of Prader-Willi syndrome AND has had clinical benefit with the requested agent **OR** E. The patient has a diagnosis other than SBS, ISS, GHD, growth failure due to inadequate secretion of endogenous growth hormone, short stature disorder (i.e., Noonan's syndrome, SHOX deficiency, Turner syndrome, small for gestational age), or renal function impairment with growth failure, and Prader-Willi AND has had clinical benefit with the requested agent **AND** 5. The patient is being monitored for adverse effects of GH **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or has consulted with a specialist in the area of the patient's diagnosis **AND**

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	8. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication **Compendia Allowed:** AHFS or DrugDex 1 or 2a level of evidence **Length of Approval:** 4 weeks for SBS 12 months for all other indications **Effective until 3/31/25 for:** **Those with an original PA date 4/1/23 – 3/31/24 seeking reauthorization AND that have not started a new plan year** **Children – Renewal Evaluation** **Target Short-Acting Growth Hormone Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for therapy with GH through the plan's prior authorization process **AND** 2. The patient is a child (as defined by the prescriber) **AND** 3. If the client has preferred agent(s), then ONE of the following: 1. BOTH of the following: A. The request is for a preferred agent **AND** B. The preferred agent is supported in FDA labeling for the requested indication **OR** 2. The request is for a nonpreferred agent and BOTH of the following: A. The nonpreferred agent is supported in FDA labeling for the requested indication **AND** B. ONE of the following: 1. The preferred agents are not supported in FDA labeling for the requested indication **OR** 2. ONE of the following: A. The preferred agents are not supported in FDA labeling for the requested indication **OR** B. ONE of the following: 1. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a preferred agent that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 2. The prescriber has provided information to support the efficacy of a requested nonpreferred agent over the preferred agent for the intended diagnosis (medical record required) **OR** 3. The patient's medication history includes use of a preferred agent **OR** 4. BOTH of the following: A. The prescriber has stated that the patient has tried a preferred agent **AND** B. The preferred agent was discontinued due to lack of effectiveness or an adverse event **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the

Module	Clinical Criteria for Approval
	following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that the preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. ONE of the following: 1. The patient has a diagnosis of short bowel syndrome (SBS) AND has had clinical benefit with the requested agent AND ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **OR** 2. The patient has a diagnosis of ISS and BOTH of the following: A. Growth velocity is greater than 2 cm/year **AND** B. Bone age is less than 16 years in patients with a sex of male and 15 years in patients with a sex of female AND the patient has open epiphyses **OR** 3. The patient has a diagnosis of growth hormone deficiency (GHD), growth failure due to inadequate secretion of endogenous growth hormone, short stature disorder (i.e., Noonan's syndrome, SHOX deficiency, Turner syndrome, small for gestational age), or renal function impairment with growth failure AND BOTH of the following: A. The patient does NOT have closed epiphyses **AND** B. The patient's height has increased or height velocity has improved since initiation or last GH approval **OR** 4. The patient has a diagnosis of Prader-Willi syndrome AND has had clinical benefit with the requested agent **OR** 5. The patient has a diagnosis other than SBS, ISS, GHD, growth failure due to inadequate secretion of endogenous growth hormone, short stature disorder (i.e., Noonan's syndrome, SHOX deficiency, Turner syndrome, small for gestational age), or renal function impairment with growth failure, and Prader-Willi AND has had clinical benefit with the requested agent **AND** 5. The patient is being monitored for adverse effects of GH **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or has consulted with a specialist in the area of the patient's diagnosis **AND** 8. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication **Compendia Allowed:** AHFS or DrugDex 1 or 2a level of evidence

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	Length of Approval: 4 weeks for SBS 12 months for other indications

• Program Summary: Hemlibra (emicizumab-kxwh)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
85105030202060	Hemlibra	emicizumab-kxwh subcutaneous soln	300 MG/2ML	Determined by patient weight and dosing interval* *See Hemlibra weight based approvable quantities chart for guidance			
85105030202030	Hemlibra	Emicizumab-kxwh Subcutaneous Soln 105 MG/0.7ML (150 MG/ML)	105 MG/0.7ML	Determined by patient weight and dosing interval* *See Hemlibra weight based approvable quantities chart for guidance			
85105030202040	Hemlibra	Emicizumab-kxwh Subcutaneous Soln 150 MG/ML	150 MG/ML	Determined by patient weight and dosing interval* *See Hemlibra weight based approvable quantities chart for guidance			
85105030202010	Hemlibra	Emicizumab-kxwh Subcutaneous Soln 30 MG/ML	30 MG/ML	Determined by patient weight and dosing interval* *See Hemlibra weight based approvable quantities chart for guidance			
85105030202020	Hemlibra	Emicizumab-kxwh Subcutaneous Soln 60 MG/0.4ML (150 MG/ML)	60 MG/0.4ML	Determined by patient weight and dosing interval* *See Hemlibra weight based approvable quantities chart for guidance			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** Hemlibra (emicizumab-kxwh) 1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**

Module	Clinical Criteria for Approval
	2. The prescriber states the patient has been treated with the requested agent within the past 90 days (starting on samples is not approvable) AND is at risk if therapy is changed **OR** B. The patient has a diagnosis of hemophilia A with or without inhibitors **AND** 2. The requested agent will be used as prophylaxis to prevent or reduce the frequency of bleeding episodes **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient will NOT be using the requested agent in combination with any of the following while on maintenance dosing with the requested agent: A. Prophylaxis with a Factor VIIa product (e.g., NovoSeven RT) **OR** B. Prophylaxis with a Factor VIII product (e.g., Advate, Adynovate, Eloctate, Nuwiq, Recombinate, Xyntha) **OR** C. Prophylaxis with a bypassing agent (e.g., Feiba, NovoSeven) **OR** D. Immune tolerance therapy (ITT) (immune tolerance induction [ITI]) **AND** 5. If the patient is receiving Feiba [activated prothrombin complex concentrate (aPCC)] for breakthrough bleeds, BOTH of the following: A. The patient will be monitored for thrombotic microangiopathy and thromboembolism **AND** B. The prescriber has counseled the patient on the maximum dosages of Feiba to be used (i.e., no more than 100 u/kg/24 hours) **AND** 6. ONE of the following: A. The patient will NOT be using the requested agent in combination with a nonsteroidal anti-inflammatory agent (NSAID) (e.g., aspirin, ibuprofen) other than cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib) NOTE: for the purposes of this criteria COX-2 inhibitors will be accepted for concomitant use **OR** B. The prescriber has provided information in support of using an NSAID for this patient **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 8. The requested quantity (dose) is within the FDA labeled dosing based on the patient's weight and dosing interval **Length of Approval:** 1 month for induction therapy 6 months for maintenance therapy (or remainder of 6 months if requesting induction therapy and maintenance therapy) NOTE: If Quantity Limit applies, please see Quantity Limit criteria **Renewal Evaluation** **Target Agent(s**) will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. ONE of the following: A. The patient has shown clinical benefit since starting the requested agent (i.e., less breakthrough bleeds as reported in the treatment log and/or chart notes) (medical records including treatment log and/or chart notes required) **OR** B. The prescriber has provided information supporting the continued use of the requested agent (medical record required) **AND** 3. If the patient is receiving Feiba [activated prothrombin complex concentrate (aPCC)] for breakthrough bleeds, the patient will be monitored for thrombotic microangiopathy and thromboembolism **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**

Module	Clinical Criteria for Approval
	5. The patient will NOT be using the requested agent in combination with any of the following: A. Prophylaxis with a Factor VIIa product (e.g., NovoSeven RT) **OR** B. Prophylaxis with a Factor VIII product (e.g., Advate, Adynovate, Eloctate, Nuwiq, Recombinate, Xyntha) **OR** C. Prophylaxis with a bypassing agent (e.g., Feiba, NovoSeven) OR D. Immune tolerance therapy (ITT) (immune tolerance induction [ITI]) **AND** 6. ONE of the following: A. The patient will NOT be using the requested agent in combination with a nonsteroidal anti-inflammatory agent (NSAID) (e.g., aspirin, ibuprofen) other than cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib) NOTE: for the purposes of this criteria COX-2 inhibitors will be accepted for concomitant use **OR** B. The prescriber has provided information in support of using an NSAID for this patient **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 8. The requested quantity (dose) is within the FDA labeled dosing based on the patient's weight and dosing interval **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please see Quantity Limit criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Quantity Limit for Target Agent(s)** will be approved when ONE of the following is met: 1. The patient is requesting induction therapy only **OR** 2. The patient is requesting induction therapy and maintenance therapy and the requested quantity (dose) for maintenance therapy does not exceed the program quantity limit (see Hemlibra Weight-Based Approvable Quantities chart) **OR** 3. The patient is requesting maintenance therapy only and the requested quantity (dose) does not exceed the program quantity limit (see the Hemlibra Weight-Based Approvable Quantities chart) **Length of Approval:** 1 month for induction therapy 6 months for maintenance therapy (or remainder of 6 months if requesting induction therapy and maintenance therapy) **Renewal Evaluation** **Quantity Limit for the Target Agent(s)** will be approved when the requested quantity (dose) for maintenance therapy does not exceed the program quantity limit (see the Hemlibra Weight-Based Approvable Quantities chart) **Length of Approval:** 12 months **Hemlibra Weight-Based Approvable Quantities (maintenance dosing)**

Weight (kg)	Dosing Schedule	30 mg/1 mL vials	60 mg/0.4 mL vials	105 mg/0.7 mL vials	150 mg/1 mL vials	300 mg/2 mL vial
less than or equal to 5 kg	1.5 mg/kg	4 mL (4	0	0	0	0

Module	Clinical Criteria for Approval						
		every week	vials)/28 days				
	less than or equal to 5 kg	3 mg/kg every 2 weeks	2 mL (2 vials)/28 days	0	0	0	0
	less than or equal to 5	6 mg/kg every 4 weeks	1 mL (1 vial)/28 days	0	0	0	0
	greater than 5 and less than or equal to 10 kg	1.5 mg/kg every week	4 mL (4 vials)/28 days	0	0	0	0
	greater than 5 and less than or equal to 10 kg	3 mg/kg every 2 weeks	2 mL (2 vials)/28 days	0	0	0	0
	greater than 5 and less than or equal to 10 kg	6 mg/kg every 4 weeks	0	0.4 mL (1 vial)/28 days	0	0	0
	greater than 10 and less than or equal to 15 kg	1.5 mg/kg every week	4 mL (4 vials)/28 days	0	0	0	0
	greater than 10 and less than or equal to 15 kg	3mg/kg every 2 weeks	0	0.8 mL (2 vials)/28 days	0	0	0
	greater than 10 and less than or equal to 15 kg	6 mg/kg every 4 weeks	1 mL (1 vial)/28 days	0.4 mL (1 vial)/28 days	0	0	0
	greater than 15 and less than or equal to 20 kg	1.5 mg/kg every week	4 mL (4 vials)/28 days	0	0	0	0
	greater than 15 and less than or equal to 20 kg	3 mg/kg every 2 weeks	0	0.8 mL (2 vials)/28 days	0	0	0
	greater than 15 and less than or equal to 20 kg	6 mg/kg every 4 weeks	0	0.8 mL (2 vials)/28 days	0	0	0
	greater than 20 and less than or equal to 25 kg	1.5 mg/kg every week	0	1.6 mL (4 vials)/28 days	0	0	0
	greater than 20 and less than or equal to 25 kg	3 mg/kg every 2 weeks	2 mL (2 vials)/28 days	0.8 mL (2 vials)/28 days	0	0	0
	greater than 20 and less than or equal to 25 kg	6 mg/kg every 4 weeks	0	0	0	1 mL (1 vial)/28 days	0
	greater than 25 and less than or equal to 30 kg	1.5 mg/kg once every week	0	1.6 mL (4 vials)/28 days	0	0	0
	greater than 25 and less than or equal to 30 kg	3mg/kg every 2 weeks	2 mL (2 vials)/28 days	0.8 mL (2 vials)/28 days	0	0	0
	greater than 25 and less than or equal to 30 kg	6 mg/kg every 4 weeks	0	1.2 mL (3 vials)/28 days	0	0	0
	greater than 30 and less	1.5 mg/kg once	0	1.6 mL (4	0	0	0

Module	Clinical Criteria for Approval						
	than or equal to 35 kg	every week		vials)/28 days			
	greater than 30 and less than or equal to 35 kg	3mg/kg every 2 weeks	0	0	1.4 mL (2 vials)/28 days	0	0
	greater than 30 and less than or equal to 35 kg	6 mg/kg every 4 weeks	0	0	1.4 mL (2 vials)/28 days	0	0
	greater than 35 and less than or equal to 40 kg	1.5 mg/kg once every week	0	1.6 mL (4 vials)/28 days	0	0	0
	greater than 35 and less than or equal to 40 kg	3 mg/kg every 2 weeks	0	1.6 mL (4 vials)/28 days	0	0	0
	greater than 35 and less than or equal to 40 kg	6 mg/kg every 4 weeks	0	1.6 mL (4 vials)/28 days	0	0	0
	greater than 40 and less than or equal to 45 kg	1.5 mg/kg once every week	4 mL (4 vials)/28 days	1.6 mL (4 vials)/28 days	0	0	0
	greater than 40 and less than or equal to 45 kg	3 mg/kg every 2 weeks	2 mL (2 vials)/28 days	0	1.4 mL (2 vials)/28 days	0	0
	greater than 40 and less than or equal to 45 kg	6 mg/kg every 4 weeks	0	0.8 mL (2 vials)/28 days	0	1 mL (1 vial)/28 days	0
	greater than 45 and less than or equal to 50 kg	1.5 mg/kg once every week	4 mL (4 vials)/28 days	1.6 mL (4 vials)/28 days	0	0	0
	greater than 45 and less than or equal to 50 kg	3 mg/kg every 2 weeks	0	0	0	2 mL (2 vials)/28 days	0
	greater than 45 and less than or equal to 50 kg	6 mg/kg every 4 weeks	0	0	0	0	2 mL (1 vial)/28 days
	greater than 50 and less than or equal to 55 kg	1.5 mg/kg once every week	4 mL (4 vials)/28 days	1.6 mL (4 vials)/28 days	0	0	0
	greater than 50 and less than or equal to 55 kg	3 mg/kg every 2 weeks	0	0.8 mL (2 vials)/28 days	1.4 mL (2 vials)/28 days	0	0
	greater than 50 and less than or equal to 55 kg	6 mg/kg every 4 weeks	0	0.8 mL (2 vials)/28 days	1.4 mL (2 vials)/28 days	0	0
	greater than 55 and less than or equal to 60 kg	1.5 mg/kg once every week	4 mL (4 vials)/28 days	1.6 mL (4 vials)/28 days	0	0	0
	greater than 55 and less	3 mg/kg every	0	2.4 mL (6	0	0	0

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	than or equal to 60 kg	2 weeks		vials)/28 days			
	greater than 55 and less than or equal to 60 kg	6 mg/kg every 4 weeks	0	0.4 mL (1 vial)/28 days	0	0	2 mL (1 vial/28 days)
	greater than 60 and less than or equal to 65 kg	1.5 mg/kg once every week	0	0	2.8 mL (4 vials)/28 days	0	0
	greater than 60 and less than or equal to 65 kg	3 mg/kg every 2 weeks	2 mL (2 vials)/28 days	0.8 mL (2 vials)/28 days	1.4 mL (2 vials)/28 days	0	0
	greater than 60 and less than or equal to 65 kg	6 mg/kg every 4 weeks	0	1.6 mL (4 vials)/28 days	0	1 mL (1 vial)/28 days	0
	greater than 65 and less than or equal to 70 kg	1.5 mg/kg once every week	0	0	2.8 mL (4 vials)/28 days	0	0
	greater than 65 and less than or equal to 70 kg	3 mg/kg every 2 weeks	0	0	2.8 mL (4 vials)/28 days	0	0
	greater than 65 and less than or equal to 70 kg	6 mg/kg every 4 weeks	0	0.8 mL (2 vials)/28 days	0	0	2 mL (1 vial)/28 days
	greater than 70 and less than or equal to 75 kg	1.5 mg/kg once every week	0	3.2 mL (8 vials)/28 days	0	0	0
	greater than 70 and less than or equal to 75 kg	3 mg/kg every 2 weeks	0	1.6mL (4 vials)/28 days	1.4 mL (2 vials)/28 days	0	0
	greater than 70 and less than or equal to 75 kg	6 mg/kg every 4 weeks	0	0	0	3 mL (3 vials)/28 days	0
	greater than 75 and less than or equal to 80 kg	1.5 mg/kg once every week	0	3.2 mL (8 vials)/28 days	0	0	0
	greater than 75 and less than or equal to 80 kg	3 mg/kg every 2 weeks	0	3.2 mL (8 vials)/28 days	0	0	0
	greater than 75 and less than or equal to 80 kg	6 mg/kg every 4 weeks	0	0.4 mL (1 vial)/28 days	2.8 mL (4 vials)/28 days	0	0
	greater than 80 and less than or equal to 85 kg	1.5 mg/kg once every week	4 mL (4 vials)/28 days	0	2.8 mL (4 vials)/28 days	0	0
	greater than 80 and less than or equal to 85 kg	3 mg/kg every 2 weeks	0	0	1.4 mL (2 vials)/28 days	2 mL (2 vials)/28 days	0
	greater than 80 and less	6 mg/kg every	0	0.4 mL (1		3 mL	0

Module	Clinical Criteria for Approval						
	than or equal to 85 kg	4 weeks		vial)/28 days		(3 vials)/28 days	
	greater than 85 and less than or equal to 90 kg	1.5 mg/kg once every week	4 mL (4 vials)/28 days	0	2.8 mL (4 vials)/28 days	0	0
	greater than 85 and less than or equal to 90 kg	3 mg/kg every 2 weeks	0	1.6 mL (4 vials)/28 days	0	2 mL (2 vials)/28 days	0
	greater than 85 and less than or equal to 90 kg	6 mg/kg every 4 weeks	0	0.8 mL (2 vials)/28 days	2.8 mL (4 vials)/28 days	0	0
	greater than 90 and less than or equal to 95 kg	1.5 mg/kg once every week	0	0	0	4 mL (4 vials)/28 days	0
	greater than 90 and less than or equal to 95 kg	3 mg/kg every 2 weeks	0	2.4 mL (6 vials)/28 days	1.4 mL (2 vials)/28 days	0	0
	greater than 90 and less than or equal to 95 kg	6 mg/kg every 4 weeks	0	0	2.8 mL (4 vials)/28 days	1 mL (1 vial)/28 days	0
	greater than 95 and less than or equal to 100 kg	1.5 mg/kg once every week	0	0	0	4 mL (4 vials)/28 days	0
	greater than 95 and less than or equal to 100 kg	3 mg/kg every 2 weeks	0	0	0	0	4 mL (2 vials)/28 days
	greater than 95 and less than or equal to 100 kg	6 mg/kg every 4 weeks	0	0	0	0	4 mL (2 vials)/28 days
	greater than 100 and less than or equal to105 kg	1.5 mg/kg once every week	0	1.6 mL (4 vials)/28 days	2.8 mL (4 vials)/28 days	0	0
	greater than 100 and less than or equal to 105 kg	3 mg/kg every 2 weeks	0	0	4.2 mL (6 vials)/28 days	0	0
	greater than 100 and less than or equal to 105 kg	6 mg/kg every 4 weeks	0	0	4.2 mL (6 vials)/28 days	0	0
	greater than 105 and less than or equal to 110 kg	1.5 mg/kg once every week	0	1.6 mL (4 vials)/28 days	2.8 mL (4 vials)/28 days	0	0
	greater than 105 and less than or equal to 110 kg	3 mg/kg every 2 weeks	0	1.6 mL (4 vials)/28 days	2.8 mL (4 vials)/28 days	0	0
	greater than 105 and less than or equal to 110 kg	6 mg/kg every 4 weeks	0	0.4 mL (1 vial)/28 days	0	0	4 mL (2 vials/28 days)
	greater than 110 and less	1.5 mg/kg once	0	4.8 mL (12	0	0	0

Module	Clinical Criteria for Approval						
	than or equal to 115 kg	every week		vials)/28 days			
	greater than 110 and less than or equal to 115 kg	3 mg/kg every 2 weeks	0	3.2 mL (8 vials)/28 days	1.4 mL (2 vials)/28 days	0	0
	greater than 110 and less than or equal to 115 kg	6 mg/kg every 4 weeks	0	0.4 mL (1 vial)/28 days	4.2 mL (6 vials)/28 days	0	0
	greater than 115 and less than or equal to 120 kg	1.5 mg/kg once every week	0	4.8 mL (12 vials)/28 days	0	0	0
	greater than 115 and ≤less than or equal to120 kg	3 mg/kg every 2 weeks	0	0.8 mL (2 vials)/28 days	0	0	4 mL (2 vials)/28 days
	greater than 115 and less than or equal to 120 kg	6 mg/kg every 4 weeks	0	0.8 mL (2 vials)/28 days	0	0	4 mL (2 vials)/28 days
	greater than 120 and less than or equal to 125 kg	1.5 mg/kg once every week	4 mL (4 vials)/28 days	1.6 mL (4 vials)/28 days	2.8 mL (4 vials)/28 days	0	0
	greater than 120 and less than or equal to 125 kg	3 mg/kg every 2 weeks	0	0.8 mL (2 vials)/28 days	4.2 mL (6 vials)/28 days	0	0
	greater than 120 and less than or equal to 125 kg	6 mg/kg every 4 weeks	0	0	0	5 mL (5 vials)/28 days	0
	greater than 125 and less than or equal to130 kg	1.5 mg/kg once every week	4 mL (4 vials)/28 days	1.6 mL (4 vials)/28 days	2.8 mL (4 vials)/28 days	0	0
	greater than 125 and less than or equal to 130 kg	3 mg/kg every 2 weeks	0	3.2 mL (8 vials)/28 days	0	0	2 mL (1 vial)/28 days
	greater than 125 and less than or equal to 130 kg	6 mg/kg every 4 weeks	0	1.2 mL (3 vials)/28 days	0	0	4 mL (2 vials)/28 days
	greater than 130 and less than or equal to 135 kg	1.5 mg/kg once every week	0	0	5.6 mL (8 vials)/28 days	0	0
	greater than 130 and less than or equal to 135 kg	3 mg/kg every 2 weeks	0	0	1.4 mL (2 vials)/28 days	0	4 mL (2 vials)/28 days
	greater than 130 and less than or equal to 135 kg	6 mg/kg every 4 weeks	0	0.4 mL (1 vial)/28 days	0	5 mL (5 vials)/28 days	0
	greater than 135 and less than or equal to 140 kg	1.5 mg/kg once every week	0	0	5.6 mL (8 vials)/28 days	0	0
	greater than 135 and less	3 mg/kg every	0	1.6 mL (4	0	0	4 mL

Module	Clinical Criteria for Approval						
	than or equal to 140 kg	2 weeks		vials)/28 days			(2 vials)/28 days
	greater than 135 and less than or equal to 140 kg	6 mg/kg every 4 weeks	0	0	5.6 mL (8 vials)/28 days	0	0
	greater than 140 and less than or equal to 145 kg	1.5 mg/kg once every week	0	3.2 mL (8 vials)/28 days	2.8 mL (4 vials)/28 days	0	0
	greater than 140 and less than or equal to 145 kg	3 mg/kg every 2 weeks	0	1.6 mL (4 vials)/28 days	4.2 mL (6 vials)/28 days	0	0
	greater than 140 and less than or equal to 145 kg	6 mg/kg every 4 weeks	0	0.8 mL (2 vials)/28 days		5 mL (5 vials)/28 days	0
	greater than 145 and less than or equal to 150 kg	1.5 mg/kg once every week	0	3.2 mL (8 vials)/28 days	2.8 mL (4 vials)/28 days	0	0
	greater than 145 and less than or equal to 150 kg	3 mg/kg every 2 weeks	0	0	0	6 mL (6 vials)/28 days	0
	greater than 145 and less than or equal to 150 kg	6 mg/kg every 4 weeks	0	0	0	0	6 mL (3 vials)/28 days
	greater than 150 and less than or equal to 155 kg	1.5 mg/kg once every week	4 mL (4 vials)/28 days	0	5.6 mL (8 vials)/28 days	0	0
	greater than 150 and less than or equal to 155 kg	3 mg/kg every 2 weeks	0	0.8 mL (2 vials)/28 days	1.4 mL (2 vials)/28 days	0	4 mL (2 vials)/28 days
	greater than 150 and less than or equal to 155 kg	6 mg/kg every 4 weeks	1 mL (1 vial)/28 days	0	0	0	6 mL (3 vials)/28 days
	greater than 155 and less than or equal to 160 kg	1.5 mg/kg once every week	4 mL (4 vials)/28 days	0	5.6 mL (8 vials)/28 days	0	0
	greater than 155 and less than or equal to 160 kg	3 mg/kg every 2 weeks	2 mL (2 vials)/28 days	0	0	6 mL (6 vials)/28 days	0
	greater than 155 and less than or equal to 160 kg	6 mg/kg every 4 weeks	0	0.4 mL (1 vial)/28 days	0	0	6 mL (3 vials)/28 days
	greater than 160 and less than or equal to 165 kg	1.5 mg/kg once every week	0	0	2.8 mL (4 vials)/28 days	4 mL (4 vials)/28 days	0
	greater than 160 and less than or equal to 165 kg	3 mg/kg every 2 weeks	0	2.4 mL (6 vials)/28 days	4.2 mL (6 vials)/28 days	0	0
	greater than 160 and less	6 mg/kg every	1 mL (1	0	1.4 mL (2	5 mL	0

Module	Clinical Criteria for Approval						
	than or equal to 165 kg	4 weeks	vial)/28 days		vials)/28 days	(5 vials)/28 days	
	greater than 165 and less than or equal to 170 kg	1.5 mg/kg once every week	0	0	2.8 mL (4 vials)/28 days	4 mL (4 vials)/28 days	0
	greater than 165 and less than or equal to 170 kg	3 mg/kg every 2 weeks	0	0.8 mL (2 vials)/28 days	0	6 mL (6 vials)/28 days	0
	greater than 165 and less than or equal to 170 kg	6 mg/kg every 4 weeks	0	0.4 mL (1 vial)/28 days	1.4 mL (2 vials)/28 days	5 mL (5 vials)/28 days	0
	greater than 170 and less than or equal to 175 kg	1.5 mg/kg once every week	0	2.4 mL (4 vials)/28 days	5.6 mL (8 vials)/28 days	0	0
	greater than 170 and less than or equal to 175 kg	3 mg/kg every 2 weeks	0	0.8 mL (2 vials)/28 days	4.2 mL (6 vials)/28 days	2 mL (2 vials)/28 days	0
	greater than 170 and less than or equal to 175 kg	6 mg/kg every 4 weeks	0	0	0	7 mL (7 vials)/28 days	0
	greater than 175 and less than or equal to 180 kg	1.5 mg/kg once every week	0	2.4 mL (4 vials)/28 days	5.6 mL (8 vials)/28 days	0	0
	greater than 175 and less than or equal to 180 kg	3 mg/kg every 2 weeks	2 mL (2 vials)/28 days	0	2.8 mL (4 vials)/28 days	0	4 mL (2 vials)/28 days
	greater than 175 and less than or equal to 180 kg	6 mg/kg every 4 weeks	1 mL (1 vial)/28 days	0	0	7 mL (7 vials)/28 days	0
	greater than 180 and less than or equal to 185 kg	1.5 mg/kg once every week	4 mL (4 vials)/28 days	0	2.8mL (4 vials)/28 days	4 mL (4 vials)/28 days	0
	greater than 180 and less than or equal to 185 kg	3 mg/kg every 2 weeks	0	0	1.4 mL (2 vials)/28 days	6 mL (6 vials)/28 days	0
	greater than 180 and less than or equal to 185 kg	6 mg/kg every 4 weeks	0	0.4 mL (1 vial)/28 days	0	7 mL (7 vials)/28 days	0
	greater than 185 and less than or equal to 190 kg	1.5 mg/kg once every week	4 mL (4 vials)/28 days	0	2.8mL (4 vials)/28 days	4 mL (4 vials)/28 days	0
	greater than 185 and less than or equal to 190 kg	3 mg/kg every 2 weeks	0	0.8 mL (2 vials)/28 days	2.8 mL (4 vials)/28 days	0	4 mL (2 vials)/28 days
	greater than 185 and less than or equal to 190 kg	6 mg/kg every 4 weeks	1 mL (1 vial)/28 days	0	1.4 mL (2 vials)/28 days	0	6 mL (3 vials)/28 days
	greater than 190 and less	1.5 mg/kg once	0	0	0	0	8 mL (4

Module	Clinical Criteria for Approval

than or equal to 195 kg	every week					vials)/28 days
greater than 190 and less than or equal to 195 kg	3 mg/kg every 2 weeks	2 mL (2 vials)/28 days	0	1.4 mL (2 vials)/28 days	6 mL (6 vials)/28 days	0
greater than 190 and less than or equal to 195 kg	6 mg/kg every 4 weeks	0	0.4 mL (1 vial)/28 days	1.4 mL (2 vials)/28 days	0	6 mL (3 vials)/28 days
greater than 195 and less than or equal to 200 kg	1.5 mg/kg once every week	0	0	0	0	8 mL (4 vials)/28 days
greater than 195 and less than or equal to 200 kg	3 mg/kg every 2 weeks	0	0	0	0	8 mL (4 vials)/28 days
greater than 195 and less than or equal to 200 kg	6 mg/kg every 4 weeks	0	0	0	0	8 mL (4 vials)/28 days
greater than 200 kg	Approve quantity requested if appropriate for patient weight and dosing interval					

The 60 mg, 105 mg, 150 mg, and/or 300 mg vials are the same concentration (150 mg/mL) and may be combined for dosing

The 30 mg vials (30mg/mL) should NOT be combined in the same injection with the 60 mg, 105 mg, 150 mg, or 300 mg vials and should be given as a separate injection

• Program Summary: Insulin Combination Agents (Soliqua, Xultophy)

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☑ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
2799100235D2	Soliqua 100/33	insulin glargine-lixisenatide sol pen-inj	100-33 UNIT-MCG/ML	6	Pens	30	DAYS			
2799100225D2	Xultophy 100/3.6	insulin degludec-liraglutide sol pen-inj	100-3.6 UNIT-MG/ML	5	Pens	30	DAYS			

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

TARGET AGENT(S)	PREREQUISITE AGENT(S)
Soliqua **Xultophy**	Any agent containing: metformin or insulin

Module	Clinical Criteria for Approval
	PRIOR AUTHORIZATION CRITERIA FOR APPROVAL **Target Agent(s)** will be approved when ONE of the following is met: 1. Information has been provided that indicates the patient has been treated with the requested agent within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR** 3. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 4. The patient's medication history includes use of an agent containing insulin or an agent containing metformin **OR** 5. BOTH of the following: A. The prescriber has stated that the patient has tried an agent containing insulin or an agent containing metformin **AND** B. Insulin or an agent containing metformin was discontinued due to lack of effectiveness or an adverse event **OR** 6. The patient has an intolerance or hypersensitivity to metformin or insulin that is not expected to occur with the requested agent **OR** 7. The patient has an FDA labeled contraindication to BOTH metformin AND insulin that is not expected to occur with the requested agent **OR** 8. The patient has a diagnosis of type 2 diabetes with/or at high risk for atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease **OR** 9. The prescriber has provided documentation that BOTH insulins and metformin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval:** 12 months NOTE: If Quantity Limit program also applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the

Module	Clinical Criteria for Approval
	requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• Program Summary: Insulin Pumps

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
97201030506400	Omnipod 5 g6 intro kit (gen 5)	*insulin infusion disposable pump kit***		1	Kit	720	DAYS	08508300001		
97201030506300	Omnipod 5 g6 pods (gen 5); Omnipod classic pods (gen 3; Omnipod dash pods (gen 4)	*Insulin Infusion Disposable Pump Supplies***		30	Pods	30	DAYS			
97201030506400	Omnipod classic pdm start (gen 3)	*insulin infusion disposable pump kit***		1	Kit	720	DAYS	08508114002		
97201030506400	Omnipod dash intro kit (gen 4)	*insulin infusion disposable pump kit***		1	Kit	720	DAYS	08508200032		
97201030506400	Omnipod dash pdm kit (gen 4)	*insulin infusion disposable pump kit***		1	Kit	720	DAYS	08508200000		
97201030506410	Omnipod go 10 units/day	*insulin infusion disposable pump kit	10 UNIT/24 HR	30	Systems	30	DAYS			
97201030506415	Omnipod go 15 units/day	*insulin infusion disposable pump kit	15 UNIT/24 HR	30	Systems	30	DAYS			
97201030506420	Omnipod go 20 units/day	*insulin infusion disposable pump kit	20 UNIT/24 HR	30	Systems	30	DAYS	08508400020		
97201030506425	Omnipod go 25 units/day	*insulin infusion disposable pump kit	25 UNIT/24 HR	30	Systems	30	DAYS			
97201030506430	Omnipod go 30 units/day	*insulin infusion disposable pump kit	30 UNIT/24 HR	30	Systems	30	DAYS	08508400030		
97201030506435	Omnipod go 35 units/day	*insulin infusion disposable pump kit	35 UNIT/24 HR	30	Systems	30	DAYS			
97201030506440	Omnipod go 40	*insulin infusion	40	30	Systems	30	DAYS	08508400040		

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
	units/day	disposable pump kit	UNIT/24 HR							
97201030506400	V-go 20	*insulin infusion disposable pump kit		1	Kit	30	DAYS	08560940003		
97201030506400	V-go 30	*insulin infusion disposable pump kit		1	Kit	30	DAYS	08560940002		
97201030506400	V-go 40	*insulin infusion disposable pump kit		1	Kit	30	DAYS	08560940001		

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL Standalone	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: 1. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **OR** 2. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months

• Program Summary: Interleukin-4 (IL-4) Inhibitor

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
9027302000D215	Dupixent	Dupilumab Subcutaneous Soln Pen-injector	200 MG/1.14 ML	2	Pens	28	DAYS			
9027302000D220	Dupixent	Dupilumab Subcutaneous Soln Pen-injector 300 MG/2ML	300 MG/2ML	4	Pens	28	DAYS			
9027302000E510	Dupixent	Dupilumab Subcutaneous Soln Prefilled Syringe	100 MG/0.67 ML	2	Syringes	28	DAYS			
9027302000E515	Dupixent	Dupilumab Subcutaneous Soln Prefilled Syringe 200 MG/1.14ML	200 MG/1.14 ML	2	Syringes	28	DAYS			
9027302000E520	Dupixent	Dupilumab Subcutaneous Soln Prefilled Syringe 300 MG/2ML	300 MG/2ML	4	Syringes	28	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following: 1. ONE of the following: A. The patient has at least 10% body surface area involvement **OR** B. The patient has involvement of body sites that are difficult to treat with prolonged topical corticosteroid therapy (e.g., hands, feet, face, neck, scalp, genitals/groin, skin folds) **OR** C. The patient has an Eczema Area and Severity Index (EASI) score of greater than

Module	Clinical Criteria for Approval
	or equal to 16 **OR** D. The patient has an Investigator Global Assessment (IGA) score of greater than or equal to 3 **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to an oral systemic immunosuppressant (e.g., methotrexate, azathioprine, mycophenolate mofetil, cyclosporine) **OR** B. The patient has an intolerance or hypersensitivity to an oral systemic immunosuppressant **OR** C. The patient has tried and had an inadequate response to BOTH at least a mid-potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) **OR** D. The patient has an intolerance or hypersensitivity to BOTH at least a mid-potency topical steroid AND a topical calcineurin inhibitor **OR** E. The patient has an FDA labeled contraindication to ALL oral systemic immunosuppressants, mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors **OR** F. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** G. The prescriber has provided documentation that ALL oral systemic immunosuppressants, mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The prescriber has assessed the patient's baseline (prior to therapy with the requested agent) pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **AND** 4. The patient will be using standard maintenance therapy (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** C. The patient has a diagnosis of moderate to severe asthma AND BOTH of the following: 1. ONE of the following: A. The patient has eosinophilic type asthma AND ONE of the following: 1. The patient has a baseline (prior to therapy with the requested agent) blood eosinophilic count of 150 cells/microliter or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **OR** 2. The patient has a fraction of exhaled nitric oxide (FeNO) of 20 parts per billion or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **OR** 3. The patient has sputum eosinophils 2% or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **OR** B. The patient has oral corticosteroid dependent type asthma **AND** 2. The patient has a history of uncontrolled asthma while on asthma control therapy as demonstrated by ONE of the following: A. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months **OR**

Module	Clinical Criteria for Approval
	B. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months **OR** C. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered **OR** D. The patient has baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted **OR** D. The patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND ALL of the following: 1. The patient has at least TWO of the following symptoms consistent with chronic rhinosinusitis (CRS): A. Nasal discharge (rhinorrhea or post-nasal drainage) B. Nasal obstruction or congestion C. Loss or decreased sense of smell (hyposmia) D. Facial pressure or pain AND 2. The patient has had symptoms consistent with chronic rhinosinusitis (CRS) for at least 12 consecutive weeks AND 3. There is information indicating the patient's diagnosis was confirmed by ONE of the following: A. Anterior rhinoscopy or endoscopy **OR** B. Computed tomography (CT) of the sinuses **AND** 4. ONE of the following: A. ONE of the following: 1. The patient had an inadequate response to sinonasal surgery **OR** 2. The patient is NOT a candidate for sinonasal surgery **OR** B. ONE of the following: 1. The patient has tried and had an inadequate response to oral systemic corticosteroids **OR** 2. The patient has an intolerance or hypersensitivity to therapy with oral systemic corticosteroids **OR** 3. The patient has an FDA labeled contraindication to ALL oral systemic corticosteroids **AND** 5. ONE of the following: A. The patient has tried and had an inadequate response to intranasal corticosteroids (e.g., fluticasone, Sinuva) **OR** B. The patient has an intolerance or hypersensitivity to therapy with intranasal corticosteroids (e.g., fluticasone, Sinuva) **OR** C. The patient has an FDA labeled contraindication to ALL intranasal corticosteroids **OR** E. The patient has a diagnosis of eosinophilic esophagitis (EoE) AND BOTH of the following: 1. The patient's diagnosis was confirmed by ALL of the following: A. Chronic symptoms of esophageal dysfunction **AND** B. Greater than or equal to 15 eosinophils per high-power field on esophageal biopsy **AND** C. Other causes that may be responsible for or contributing to symptoms and esophageal eosinophilia have been ruled out **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to ONE standard corticosteroid therapy for EoE (i.e., budesonide suspension, fluticasone MDI swallowed) **OR** B. The patient has an intolerance or hypersensitivity to standard corticosteroid therapy for EoE **OR** C. The patient has an FDA labeled contraindication to standard corticosteroid

Module	Clinical Criteria for Approval
	therapy for EoE **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL standard corticosteroid therapy for EoE cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** F. The patient has a diagnosis of prurigo nodularis (PN) and BOTH of the following: 1. The patient has ALL of the following features associated with PN: A. Presence of firm, nodular lesions **AND** B. Pruritus that has lasted for at least 6 weeks **AND** C. History and/or signs of repeated scratching, picking, or rubbing **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to at least a mid-potency topical steroid **OR** B. The patient has an intolerance or hypersensitivity to therapy with at least a mid-potency topical steroid **OR** C. The patient has an FDA labeled contraindication to ALL mid-, high-, and super-potency topical steroids **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL mid-, high-, and super-potency topical steroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** G. The patient has another FDA approved indication for the requested agent and route of administration **OR** H. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP), BOTH of the following: A. The patient is currently treated with standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) **AND** B. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **AND** 3. If the patient has moderate to severe asthma, ALL of the following: A. ONE of the following: 1. The patient is NOT currently being treated with the requested agent AND is currently

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	treated with a maximally tolerated inhaled corticosteroid **OR** 2. The patient is currently being treated with the requested agent AND ONE of the following: A. Is currently treated with an inhaled corticosteroid that is adequately dosed to control symptoms **OR** B. Is currently treated with a maximally tolerated inhaled corticosteroid **OR** 3. The patient has an intolerance or hypersensitivity to inhaled corticosteroid therapy **OR** 4. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids **AND** B. ONE of the following: 1. The patient is currently being treated with ONE of the following: A. A long-acting beta-2 agonist (LABA) **OR** B. A leukotriene receptor antagonist (LTRA) **OR** C. Long-acting muscarinic antagonist (LAMA) **OR** D. Theophylline **OR** 2. The patient has an intolerance or hypersensitivity to therapy with a LABA, LTRA, LAMA, or theophylline **OR** 3. The patient has an FDA labeled contraindication to ALL long-acting beta-2 agonists (LABA) AND long-acting muscarinic antagonists (LAMA) **AND** C. The patient will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **AND** 4. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., atopic dermatitis -dermatologist, allergist, immunologist; asthma -allergist, immunologist, pulmonologist; CRSwNP -otolaryngologist, allergist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. ONE of the following: A. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND BOTH of the

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	following: 1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following: A. Affected body surface area **OR** B. Flares **OR** C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **OR** D. A decrease in the Eczema Area and Severity Index (EASI) score **OR** E. A decrease in the Investigator Global Assessment (IGA) score **AND** 2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has a diagnosis of moderate to severe asthma AND BOTH of the following: 1. The patient has had improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following: A. The patient has had an increase in percent predicted Forced Expiratory Volume (FEV_1) **OR** B. The patient has had a decrease in the dose of inhaled corticosteroids required to control the patient's asthma **OR** C. The patient has had a decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma **OR** D. The patient has had a decrease in number of hospitalizations, need for mechanical ventilation, or visits to urgent care or emergency room due to exacerbations of asthma **AND** 2. The patient is currently treated and is compliant with asthma control therapy [e.g., inhaled corticosteroids, ICS/long-acting beta-2 agonist (LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), theophylline] **OR** C. The patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **OR** D. The patient has a diagnosis other than moderate-to-severe atopic dermatitis (AD), moderate to severe asthma, or chronic rhinosinusitis with nasal polyposis (CRSwNP) AND has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., atopic dermatitis -dermatologist, allergist, immunologist; asthma -allergist, immunologist, pulmonologist; CRSwNP -otolaryngologist, allergist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 5. The patient does NOT have an FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

Module	Clinical Criteria for Approval
	Length of Approval: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limits for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose, or the compendia supported dose, for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval**: 6 months for Initial; 12 months for Renewal

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly
Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)
Cibinqo (abrocitinib)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)

Contraindicated as Concomitant Therapy
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Litfulo (ritlecitinib)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tysabri (natalizumab)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)
Zymfentra (infliximab-dyyb)

• Program Summary: Interstitial Lung Disease (ILD)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
45550060000333		Pirfenidone Tab 534MG	534 MG	21	Tablets	180	DAYS			
45550060000120	Esbriet	Pirfenidone Cap 267 MG	267 MG	180	Capsules	30	DAYS			
45550060000325	Esbriet	Pirfenidone Tab 267 MG	267; 267 MG	180	Tablets	30	DAYS			
45550060000345	Esbriet	Pirfenidone Tab 801 MG	801; 801 MG	90	Tablets	30	DAYS			
45554050200120	Ofev	Nintedanib Esylate Cap 100 MG (Base Equivalent)	100 MG	60	Capsules	30	DAYS			
45554050200130	Ofev	Nintedanib Esylate Cap 150 MG (Base Equivalent)	150 MG	60	Capsules	30	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of idiopathic pulmonary fibrosis (IPF) AND BOTH of the following: 1. Other known causes of interstitial lung disease (ILD) have been excluded (e.g., domestic and occupational environmental exposures, connective tissue diseases, drug toxicities, alternative diagnoses, etc) **AND** 2. ONE of the following: A. The patient had a high-resolution computed tomography (HRCT) scan with results showing a pattern for usual interstitial pneumonia (UIP) **OR** B. The patient had a surgical lung biopsy with pathology confirming UIP **OR** C. The patient had a HRCT scan with results showing a pattern for probable UIP AND a surgical lung biopsy with pathology indicating probable UIP **OR** B. The patient has a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) AND ALL of the following: 1. The requested agent is Ofev **AND** 2. The patient's diagnosis has been confirmed on high-resolution computed tomography (HRCT) or chest radiography scans **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to ONE conventional agent (i.e., mycophenolate mofetil, cyclophosphamide, azathioprine) **OR** B. The patient has an intolerance or hypersensitivity to ONE conventional agent **OR** C. The patient has an FDA labeled contraindication to ALL conventional agents **OR** D. The prescriber has provided documentation that ALL conventional agents

Module	Clinical Criteria for Approval
	cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** C. The patient has a diagnosis of chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype AND ALL of the following: 1. The requested agent is Ofev **AND** 2. The patient has greater than 10% fibrotic features on HRCT **AND** 3. The patient presented with clinical signs of progression, defined by at least ONE of the following: A. FVC decline greater than or equal to 10% **OR** B. FVC decline greater than or equal to 5% and less than 10% with worsening symptoms or imaging **OR** C. Worsening symptoms and worsening imaging within the past 24 months **AND** 4. The patient has an FVC greater than or equal to 45% of predicted **AND** 5. The patient has a diffusion capacity of the lungs for carbon monoxide (DLCO) between 30% to less than 80% of predicted **AND** 6. The patient does NOT meet any of the following: A. A diagnosis of IPF B. Relevant airway obstructions (i.e., pre-bronchodilator FEV1/FVC less than 0.7) C. Significant pulmonary hypertension D. Greater than 1.5 times the upper limit of normal for ALT, AST, or bilirubin E. Known risk or predisposition to bleeding F. Receiving full dose anticoagulation treatment G. Recent history of MI or stroke **AND** 7. The patient has another FDA approved indication for the requested agent **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., pathologist, pulmonologist, radiologist, rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient will NOT be using the requested agent in combination with another agent included in this prior authorization program **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., pathologist, pulmonologist, radiologist, rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's

Module	Clinical Criteria for Approval
	diagnosis **AND** 4. The patient will NOT be using the requested agent in combination with another agent included in this prior authorization program **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval:** 12 months

● Program Summary: Jynarque

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
30454060000320	Jynarque	tolvaptan tab	15 MG	60	Tablets	30	DAYS	59148008213		
30454060000330	Jynarque	tolvaptan tab	30 MG	30	Tablets	30	DAYS	59148008313		
3045406000B710	Jynarque	Tolvaptan Tab Therapy Pack 15 MG	15 MG	56	Tablets	28	DAYS			
3045406000B720	Jynarque	Tolvaptan Tab Therapy Pack 30 & 15 MG	30 & 15 MG	56	Tablets	28	DAYS			
3045406000B725	Jynarque	Tolvaptan Tab Therapy Pack 45 & 15 MG	45 & 15 MG	56	Tablets	28	DAYS			
3045406000B735	Jynarque	Tolvaptan Tab Therapy Pack 60 & 30 MG	60 & 30 MG	56	Tablets	28	DAYS			
3045406000B745	Jynarque	Tolvaptan Tab Therapy Pack 90 & 30 MG	90 & 30 MG	56	Tablets	28	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of autosomal dominant polycystic kidney disease (ADPKD) and BOTH of the following: A. The patient does not have stage 5 chronic kidney disease (CKD) **AND** B. The patient is not on dialysis **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient will NOT be using the requested agent in combination with another tolvaptan agent **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient will NOT be using the requested agent in combination with another tolvaptan agent **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of Approval:** 12 months

• Program Summary: Kerendia

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
30354030000310	Kerendia	Finerenone Tab	10 MG	30	Tablets	30	DAYS			
30354030000320	Kerendia	Finerenone Tab	20 MG	30	Tablets	30	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** B. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR** C. The patient has a diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes and BOTH of the following: 1. ONE of the following: A. The patient will be using an agent containing an angiotensin-receptor enzyme inhibitor (ACEi) (e.g., lisinopril, captopril) or an agent containing an angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan) at a maximally tolerated dose in combination with the requested agent **OR** B. The patient has an intolerance or hypersensitivity to an agent containing an angiotensin-receptor enzyme inhibitor (ACEi) AND an agent containing an angiotensin II receptor blocker (ARB) **OR** C. The patient has an FDA labeled contraindication to ALL agents containing an angiotensin-receptor enzyme inhibitor (ACEi) AND ALL agents containing an angiotensin II receptor blocker (ARB) **OR** D. The patient's medication history includes use of an agent containing an angiotensin-receptor enzyme inhibitor (ACEi) OR an agent containing an angiotensin II receptor blocker (ARB) in the past 999 days **OR** E. BOTH of the following: 1. The prescriber has stated that the patient has tried maximally tolerated therapy on an angiotensin-receptor enzyme inhibitor (ACEi) or an agent containing an angiotensin II receptor blocker (ARB) **AND** 2. Maximally tolerated therapy on an angiotensin-receptor enzyme inhibitor (ACEi) or an agent containing an angiotensin II receptor blocker (ARB) was discontinued due to lack of effectiveness or an adverse event **OR** F. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**

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	3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** G. The prescriber has provided documentation that ALL agents containing an angiotensin-receptor enzyme inhibitor (ACEi) AND ALL agents containing an angiotensin II receptor blocker (ARB) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. ONE of the following: A. The patient will be using an agent containing a sodium glucose transport protein 2 (SGLT2) inhibitor that is indicated for use in patients with chronic kidney disease (i.e., canagliflozin, dapagliflozin) in combination with the requested agent **OR** B. The patient has an intolerance or hypersensitivity to an agent containing a sodium glucose transport protein 2 (SGLT2) inhibitor that is indicated for use in patients with chronic kidney disease (i.e., canagliflozin, dapagliflozin) **OR** C. The patient has an FDA labeled contraindication to ALL agents containing a sodium glucose transport protein 2 (SGLT2) inhibitor that is indicated for use in patients with chronic kidney disease (i.e., canagliflozin, dapagliflozin) **OR** D. The patient has chronic kidney disease and is at increased risk for cardiovascular events or chronic kidney disease progression **OR** E. The patient's medication history includes use of an agent containing a sodium glucose transport protein 2 (SGLT2) inhibitor that is indicated for use in patients with chronic kidney disease (i.e., canagliflozin, dapagliflozin) in the past 999 days **OR** F. BOTH of the following: 1. The prescriber has stated that the patient has tried an agent containing a sodium glucose transport protein 2 (SGLT2) inhibitor that is indicated for use in patients with chronic kidney disease (i.e., canagliflozin, dapagliflozin) **AND** 2. The agent containing a sodium glucose transport protein 2 (SGLT2) inhibitor that is indicated for use in patients with chronic kidney disease (i.e., canagliflozin, dapagliflozin)was discontinued due to lack of effectiveness or an adverse event **OR** G. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** H. The prescriber has provided documentation that ALL agents containing a sodium glucose transport protein 2 (SGLT2) inhibitor indicated for use in patients with chronic kidney disease (i.e., canagliflozin, dapagliflozin) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. The patient has another FDA approved indication for the requested agent and route of administration **OR**

Module	Clinical Criteria for Approval
	E. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. The patient's serum potassium is less than or equal to 5.0 mEq/L **AND** 3. The patient's estimated glomerular filtration rate (eGFR) is greater than or equal to 25 mL/min/1.73m^2 **AND** 4. The patient's urine albumin-to-creatinine ratio (UACR) is greater than or equal to 30 mg/g **AND** 5. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 4 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval:** Initial: 4 months; Renewal: 12 months

• Program Summary: Lupus

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
9942201500D5	Benlysta	belimumab subcutaneous solution auto-injector	200 MG/ML	4	Syringes	28	DAYS			
9942201500E5	Benlysta	belimumab subcutaneous solution prefilled syringe	200 MG/ML	4	Syringes	28	DAYS			
994020800001	Lupkynis	voclosporin cap	7.9 MG	180	Capsules	30	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. The patient has a diagnosis of active systemic lupus erythematosus (SLE) disease WITHOUT active Lupus Nephritis AND BOTH of the following: 1. The requested agent is FDA approved for SLE **AND** 2. BOTH of the following: A. ONE of the following: 1. The patient has tried and had an inadequate response to hydroxychloroquine **OR** 2. The patient has an intolerance or hypersensitivity to hydroxychloroquine **OR** 3. The patient has an FDA labeled contraindication to hydroxychloroquine **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is

Module	Clinical Criteria for Approval
	expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that hydroxychloroquine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. ONE of the following: 1. The patient has tried and had an inadequate response to corticosteroids OR immunosuppressives (i.e., azathioprine, methotrexate, oral cyclophosphamide, mycophenolate) **OR** 2. The patient has an intolerance or hypersensitivity to therapy with corticosteroids OR immunosuppressives (i.e., azathioprine, methotrexate, oral cyclophosphamide, mycophenolate) **OR** 3. The patient has an FDA labeled contraindication to ALL corticosteroids AND immunosuppressives (i.e., azathioprine, methotrexate, oral cyclophosphamide, mycophenolate) **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL corticosteroids AND immunosuppressives (i.e., azathioprine, methotrexate, oral cyclophosphamide, mycophenolate) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has a diagnosis of active lupus nephritis (LN) AND BOTH of the following: 1. The requested agent is FDA approved for lupus nephritis **AND** 2. The patient has Class III, IV, or V lupus nephritis confirmed via kidney biopsy **OR** D. The patient has another FDA approved indication for the requested agent **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent and route of administration **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication and route of administration **AND** 3. ONE of the following: A. The patient has a diagnosis of active systemic lupus erythematosus (SLE) disease WITHOUT active Lupus Nephritis AND BOTH of the following: 1. The patient is currently treated with standard SLE therapy (i.e.,

Module	Clinical Criteria for Approval
	corticosteroids, hydroxychloroquine, azathioprine, methotrexate, oral cyclophosphamide, mycophenolate) **AND** 2. The patient will continue standard SLE therapy (i.e., corticosteroids, hydroxychloroquine, azathioprine, methotrexate, oral cyclophosphamide, mycophenolate) in combination with the requested agent **OR** B. The patient has a diagnosis of active lupus nephritis AND the patient will be using the requested agent with background immunosuppressive lupus nephritis therapy (e.g., corticosteroids with mycophenolate or for Benlysta corticosteroids with mycophenolate or IV cyclophosphamide) **OR** C. The patient has another FDA approved indication for the requested agent **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist, nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have severe active central nervous system lupus **AND** 6. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agents **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 7. If the requested agent is Lupkynis, the patient will NOT be using the requested agent in combination with cyclophosphamide **AND** 8. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months ***NOTE:** Approve Benlysta subcutaneous loading dose for 1 month, then maintenance dose can be approved for the remainder of 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. ONE of the following: A. The patient has a diagnosis of active systemic lupus erythematosus (SLE) disease WITHOUT active Lupus Nephritis AND ALL of the following: 1. The requested agent is FDA approved for SLE **AND** 2. The patient will continue standard SLE therapy (i.e., corticosteroids, hydroxychloroquine, azathioprine, methotrexate, oral cyclophosphamide, mycophenolate) **AND** 3. The patient has had clinical benefit with the requested agent **OR** B. The patient has a diagnosis of active lupus nephritis (LN) AND ALL of the following: 1. The requested agent is FDA approved for lupus nephritis **AND** 2. The patient will continue background lupus nephritis therapy (e.g., corticosteroids with mycophenolate or for Benlysta corticosteroids with

Module	Clinical Criteria for Approval
	mycophenolate or IV cyclophosphamide) **AND** 3. The patient has had clinical benefit with the requested agent **OR** C. The patient has another FDA approved indication for the requested agent AND has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist, nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have severe active central nervous system lupus **AND** 5. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agents **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 6. If the requested agent is Lupkynis, the patient will NOT be using the requested agent in combination with cyclophosphamide **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **Length of Approval**: 12 months

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly
Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)

Contraindicated as Concomitant Therapy
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)
Cibinqo (abrocitinib)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Litfulo (ritlecitinib)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tysabri (natalizumab)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)

Contraindicated as Concomitant Therapy
Xeljanz XR (tofacitinib extended release) Xolair (omalizumab) Yuflyma (adalimumab-aaty) Yusimry (adalimumab-aqvh) Zeposia (ozanimod) Zymfentra (infliximab-dyyb)

• Program Summary: Ophthalmic Immunomodulators

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
86720020002040	Cequa	Cyclosporine (Ophth) Soln 0.09% (PF)	0.09 %	60	Vials	30	DAYS			04-01-2016
86720020001630	Cyclosporine in klarity ; Verkazia	Cyclosporine (Ophth) Emulsion 0.1%	0.1 %	120	Vials	30	DAYS			04-04-2022
86720020001620	Restasis	cyclosporine (ophth) emulsion	0.05 %	60	Vials	30	DAYS	00023916330; 00023916360; 00378876058; 00378876091; 10702080803; 10702080806; 50090124200; 50090447600; 60505620201; 60505620202; 68180021430; 68180021460		04-01-2019
86720020001620	Restasis ; Restasis multidose	cyclosporine (ophth) emulsion	0.05 %	1	Bottle	30	DAYS	00023530105; 50090447600		04-01-2019
86720020002043	Vevye	cyclosporine (ophth) soln	0.1 %	1	Bottle	30	DAYS			
86734050002020	Xiidra	Lifitegrast Ophth Soln 5%	5 %	60	Vials	30	DAYS			01-01-2017

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Restasis (cyclosporine ophthalmic emulsion)** will be approved when ALL of the following are met: 1. ONE of the following: A. ALL of the following: 1. The patient has a diagnosis of dry eye disease (i.e., dry eye syndrome, keratoconjunctivitis sicca [e.g., Sjögren's Syndrome]) **AND** 2. The patient will NOT be using the requested agent in combination with punctal plug(s) **AND** 3. ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient has previously tried or is currently using aqueous enhancements (e.g., artificial tears, gels, ointments [target agents not included]) **OR** B. The patient has an intolerance or hypersensitivity to aqueous enhancements (e.g., artificial tears, gels, ointments [target agents not included]) **OR** C. The patient has an FDA labeled contraindication to ALL aqueous enhancements **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL aqueous enhancements cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has another FDA approved indication for the requested agent **AND** 2. The patient will NOT be using the requested agent in combination with another ophthalmic immunomodulator agent (e.g., Restasis, Cequa, Xiidra, Verkazia, Vevye) or Tyrvaya **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Initial Evaluation** **Cequa (cyclosporine), Xiidra (lifitegrast), Vevye (cyclosporine)** will be approved when ALL of the following are met: 1. ONE of the following: A. BOTH of the following: 1. The patient has a diagnosis of dry eye disease (i.e., dry eye syndrome, keratoconjunctivitis sicca [e.g., Sjögren's Syndrome]) **AND** 2. ONE of the following: A. The patient has previously tried or is currently using aqueous enhancements (e.g., artificial tears, gels, ointments [target agents not included]) **OR** B. The patient has an intolerance or hypersensitivity to aqueous enhancements (e.g., artificial tears, gels, ointments [target agents not included]) **OR** C. The patient has an FDA labeled contraindication to ALL aqueous enhancements **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND**

Module	Clinical Criteria for Approval
	3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL aqueous enhancements cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has another FDA approved indication for the requested agent **AND** 2. The patient will NOT be using the requested agent in combination with another ophthalmic immunomodulator agent (e.g., Restasis, Cequa, Xiidra, Verkazia, Vevye) or Tyrvaya **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** Cequa (cyclosporine), Xiidra (lifitegrast) Vevye (cyclosporine) - 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Initial Evaluation** **Verkazia (cyclosporine)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of vernal keratoconjunctivitis (VKC) AND BOTH of the following: 1. ONE of the following: A. The patient has tried and had an inadequate response to combination of a topical ophthalmic mast cell stabilizer AND an antihistamine used in the treatment of VKC **OR** B. The patient has an intolerance or hypersensitivity to combination of a topical ophthalmic mast cell stabilizer AND an antihistamine used in the treatment of VKC **OR** C. The patient has an FDA labeled contraindication to ALL topical ophthalmic mast cell stabilizers AND antihistamines **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL topical ophthalmic mast cell stabilizers AND antihistamines cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to a topical ophthalmic corticosteroid used in the treatment of VKC **OR** B. The patient has an intolerance or hypersensitivity to topical ophthalmic corticosteroid therapy **OR** C. The patient has an FDA labeled contraindication to ALL topical ophthalmic corticosteroids **OR** D. The patient is currently being treated with the requested agent as indicated by

Module	Clinical Criteria for Approval
	ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL topical ophthalmic corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. The patient has another FDA approved indication for the requested agent **AND** 2. The patient will NOT be using the requested agent in combination with another ophthalmic immunomodulator agent (e.g., Restasis, Cequa, Xiidra, Verkazia, Vevye) or Tyrvaya **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 4 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient will NOT be using the requested agent in combination with another ophthalmic immunomodulator agent (e.g., Restasis, Cequa, Xiidra, Verkazia, Vevye) or Tyrvaya **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. BOTH of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **Length of Approval**: Initial - Cequa, Xiidra, Vevye - 3 months, Verkazia - 4 months, Restasis/cyclosporine - 6 months Renewal - 12 months

• Program Summary: Opioids Immediate Release (IR) New To Therapy with Daily QL

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

OBJECTIVE

The program will check if a patient is new to opioid therapy as defined as having no prior opioid use in the past 120 days. If the patient is new to therapy, the patient will be restricted to <50 MME per day and ≤7 days of therapy. The program will allow for exceptions for uses beyond these limits based on program requirements. The program will also check for appropriate age for requests for products containing tramadol, dihydrocodeine, and codeine. Requests for these agents will be limited to patients 12 years of age and older, and patients 12 to 18 years will be restricted from use for post-operative pain management following a tonsillectomy and/or adenoidectomy. (program applies to all Multi-Source Codes [M, N, O, Y])

TARGET AGENT(S) FOR NEW TO THERAPY[b]

SINGLE INGREDIENT AGENT(S)				
Brand (generic)	**GPI**	**Daily Quantity Limit**	**Quantity Equaling <50 MME/day**	**Age Limit**
butorphanol[a]				
10 mg/mL nasal spray	65200020102050	0.25 mL	See note*	NA
Codeine				
15 mg tablet	65100020200305	6 tablets	22 tablets	≥18 years
30 mg tablet[a]	65100020200310	6 tablets	11 tablets	≥18 years
60 mg tablet	65100020200315	6 tablets	5 tablets	≥18 years
Dilaudid (hydromorphone)[a]				
2 mg tablet	65100035100310	6 tablets	5 tablets	NA
4 mg tablet	65100035100320	6 tablets	3 tablets	NA
8 mg tablet	65100035100330	6 tablets	1 tablet	NA
1 mg/mL liquid	65100035100920	48 mL	10 mL	NA
Levorphanol[a]				
2 mg tablet	65100040100305	4 tablets	2 tablets	NA
3 mg tablet	65100040100310	4 tablets	1 tablet	NA
Meperidine				
50 mg tablet	65100045100305	12 tablets	10 tablets	NA
50 mg/5 mL solution	65100045102060	60 mL	50 mL	NA
Dolophine (methadone)[a]				
5 mg tablet	65100050100305	3 tablets	3 tablets	NA
10 mg tablet	65100050100310	3 tablets	1 tablet	NA
Methadose, Methadone[a]				
40 mg soluble tablet	65100050107320	3 tablets	see note*	NA
5 mg/5 mL solution	65100050102010	30 mL	11 mL	NA
10 mg/5 mL solution	65100050102015	15 mL	6 mL	NA
10 mg/mL concentrate	65100050101310	3 mL	1 mL	NA
Morphine sulfate				
15 mg tablet[a]	65100055100310	12 tablets	3 tablets	NA
30 mg tablet[a]	65100055100315	6 tablets	1 tablet	NA
10 mg/5 mL solution	65100055102065	90 mL	25 mL	NA
20 mg/5 mL solution[a]	65100055102070	45 mL	12 mL	NA
20 mg/mL concentrate[a]	65100055102090	9 mL	2 mL	NA
Oxaydo, Roxybond, Roxicodone (oxycodone)				
5 mg capsule[a]	65100075100110	12 capsules	6 capsules	NA
5 mg tablet[a]	65100075100310	12 tablets	6 tablets	NA
5 mg tablet	6510007510A530	12 tablets	6 tablets	NA

7.5 mg tablet	65100075100315	6 tablets	4 tablets	NA
10 mg tablet[a]	65100075100320	6 tablets	3 tablets	NA
15 mg tablet[a]	65100075100325	6 tablets	2 tablets	NA
15 mg tablet	6510007510A540	6 tablets	2 tablets	NA
20 mg tablet[a]	65100075100330	6 tablets	1 tablet	NA
30 mg tablet[a]	65100075100340	6 tablets	1 tablet	NA
30 mg tablet	6510007510A560	6 tablets	1 tablet	NA
5 mg/5 mL solution[a]	65100075102005	180 mL	33 mL	NA
20 mg/mL concentrate[a]	65100075101320	9 mL	1 mL	NA
Opana (oxymorphone)[a]				
5 mg tablet	65100080100305	6 tablets	3 tablets	NA
10 mg tablet	65100080100310	6 tablets	1 tablet	NA
Nucynta (tapentadol)				
50 mg tablet	65100091100320	6 tablets	2 tablets	NA
75 mg tablet	65100091100330	6 tablets	1 tablet	NA
100 mg tablet	65100091100340	6 tablets	1 tablet	NA
Qdolo, Ultram, Tramadol				
25 mg tablet	65100095100310	8 tablets	10 tablets	≥18 years
50 mg tablet[a]	65100095100320	8 tablets	5 tablets	≥18 years
100 mg tablet	65100095100340	4 tablets	3 tablets	≥18 years
5 mg/mL solution	65100095102005	80 mL	50 mL	≥18 years
COMBINATION INGREDIENT AGENT(S)				
Apadaz, Benzhydrocodone/acetaminophen				
4.08/325 mg tablet	65990002020310	12 tablets	11 tablets[‡]	NA
6.12/325 mg tablet	65990002020320	12 tablets	7 tablets[‡]	NA
8.16/325 mg tablet	65990002020330	12 tablets	6 tablets[‡]	NA
Tylenol w/Codeine (acetaminophen/codeine)[a]				
120 mg/12 mg/5 mL solution	65991002052020	90 mL	138 mL[‡]	≥18 years
300 mg/15 mg tablet	65991002050310	12 tablets	22 tablets[‡]	≥18 years
300 mg/30 mg tablet	65991002050315	12 tablets	11 tablets[‡]	≥18 years
300 mg/60 mg tablet	65991002050320	6 tablets	5 tablets[‡]	≥18 years
Fioricet w/Codeine (butalbital/acetaminophen/caffeine/codeine)[a]				
50 mg/300 mg/40 mg/30 mg capsule	65991004100113	6 capsules	11 capsules[‡]	≥18 years
50 mg/325 mg/40 mg/30 mg capsule	65991004100115	6 capsules	11 capsules[‡]	≥18 years
Fiorinal w/Codeine (butalbital/aspirin/caffeine/codeine)[a]				
50 mg/325 mg/40 mg/30 mg capsule	65991004300115	6 capsules	11 capsules[‡]	≥18 years
Trezix, Acetaminophen/caffeine/dihydrocodeine				
320.5 mg/30 mg/16 mg capsule	65991303050115	10 capsules	12 capsules[‡]	≥18 years
325 mg/30 mg/16 mg tablet	65991303050320	10 tablets	12 tablets[‡]	≥18 years
Lortab, Norco, Hydrocodone/acetaminophen				
5 mg/300 mg tablet[a]	65991702100309	8 tablets	10 tablets[‡]	NA
5 mg/325 mg tablet[a]	65991702100356	8 tablets	10 tablets[‡]	NA
7.5 mg/300 mg tablet[a]	65991702100322	6 tablets	6 tablets[‡]	NA
7.5 mg/325 mg tablet[a]	65991702100358	6 tablets	6 tablets[‡]	NA
10 mg/300 mg tablet[a]	65991702100375	6 tablets	5 tablets[‡]	NA

10 mg/325 mg tablet[a]	65991702100305	6 tablets	5 tablets‡	NA
7.5 mg/325 mg/15 mL solution[a]	65991702102015	90 mL	100 mL‡	NA
10 mg/300 mg/15 mL solution	65991702102024	67.5 mL	74 mL‡	NA
10 mg/325 mg/15 mL solution	65991702102025	90 mL	74 mL‡	NA
Hydrocodone/Ibuprofen				
5 mg/200 mg tablet	65991702500315	5 tablets	10 tablets‡	NA
7.5 mg/200 mg tablet[a]	65991702500320	5 tablets	6 tablets‡	NA
10 mg/200 mg tablet[a]	65991702500330	5 tablets	5 tablets‡	NA
Percocet, Prolate, Oxycodone/acetaminophen, Nalocet, Primlev				
2.5 mg/300 mg tablet	65990002200303	12 tablets	13 tablets‡	NA
2.5 mg/325 mg tablet[a]	65990002200305	12 tablets	13 tablets‡	NA
5 mg/300 mg tablet	65990002200308	12 tablets	6 tablets‡	NA
5 mg/325 mg tablet[a]	65990002200310	12 tablets	6 tablets‡	NA
7.5 mg/300 mg tablet	65990002200325	8 tablets	4 tablets‡	NA
7.5 mg/325 mg tablet[a]	65990002200327	8 tablets	4 tablets‡	NA
10 mg/300 mg tablet	65990002200333	6 tablets	3 tablets‡	NA
10 mg/325 mg tablet[a]	65990002200335	6 tablets	3 tablets‡	NA
10 mg/300 mg/5 mL solution	65990002202020	30 mL	15 mL‡	NA
5 mg/325 mg/5 mL solution	65990002202005	60 mL	30 mL‡	NA
Oxycodone/Aspirin				
4.8355 mg/325 mg tablet	65990002220340	12 tablets	6 tablets‡	NA
Oxycodone/Ibuprofen				
5 mg/400 mg tablet	65990002260320	4 tablets	6 tablets‡	NA
pentazocine/naloxone[a]				
50 mg/0.5 mg tablet	65200040300310	12 tablets	2 tablets‡	NA
Seglentis (celecoxib/tramadol)				
56 mg/44 mg tablet	65995002100320	4 tablets	13 tablets‡	≥18 years
Ultracet (tramadol/acetaminophen)[a]				
37.5 mg/325 mg tablet	65995002200320	8 tablets	7 tablets	≥18 years

a - generic available

b - all target agents are subject to a ≤ 7 days of therapy and <50 morphine milligram equivalents per day if no prior opioid or oncology claims are found in the past 120 days

* - product minimum dosage strength surpasses 50 MME

‡ - quantity for being under 50 MME per day may exceed dosing limit of other ingredients in the combination product

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Target Agent(s) will be approved when ONE of the following is met:

1. The request exceeds the 7 day supply limit and/or the 50 morphine milligram equivalent per day limit AND ALL of the following:
    A. If the requested agent contains acetaminophen, then the requested dose of acetaminophen does NOT exceed 4 g/day
    AND
    B. If the requested agent contains tramadol, dihydrocodeine, OR codeine, then ONE of the following:
        i. The patient is 12 to less than 18 years of age AND the requested agent will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy

OR

ii. The patient is 18 years of age or over

AND

C. ONE of the following:

i. The requested quantity (dose) does NOT exceed the program daily quantity limit AND ONE of the following:

a. There is information that the patient is NOT new to opioid therapy in the past 120 days

OR

b. The prescriber states the patient is NOT new to opioid therapy AND is at risk if therapy is changed

OR

c. The patient has a claim for an oncology agent in the past 120 days

OR

d. BOTH of the following:

1. ONE of the following:

A. The patient has a diagnosis of chronic cancer pain due to an active malignancy

OR

B. The patient is eligible for hospice OR palliative care

OR

C. The patient has a diagnosis of sickle cell disease

OR

D. The patient is undergoing treatment of non-cancer pain and ALL of the following:

i. The prescriber has provided information in support of use of immediate-release single or combination opioids for an extended duration (>7 days) and/or greater than a 50 morphine milligram equivalents (MME) per day

AND

ii. A formal, consultative evaluation which includes BOTH of the following was conducted:

a. Diagnosis

AND

b. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy

AND

iii. A patient-specific pain management plan is on file for the patient

AND

iv. The prescriber has reviewed the patient's records in the state's prescribing drug monitoring program (PDMP) **AND** has determined that the opioid dosage and combinations within the patient's records do NOT indicate the patient is at high risk for overdose

AND

2. ONE of the following:

A. The patient is not concurrently using buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment

OR

B. The prescriber has provided information in support of use of opioids with buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment

OR

ii. The requested quantity (dose) is greater than the program daily quantity limit AND ALL of the following:

a. ONE of the following:
    1. There is information that the patient is NOT new to opioid therapy in the past 120 days
       OR
    2. The prescriber states the patient is NOT new to opioid therapy AND is at risk if therapy is changed
       OR
    3. The patient has a claim for an oncology agent in the past 120 days
       OR
    4. The prescriber has provided information in support of use of immediate-release single or combination opioids for an extended duration (>7 days) and/or greater than a 50 morphine milligram equivalents (MME) per day

   AND

b. ONE of the following:
    1. The patient has a diagnosis of chronic cancer pain due to an active malignancy
       OR
    2. The patient is eligible for hospice OR palliative care
       OR
    3. The patient has a diagnosis of sickle cell disease
       OR
    4. The patient is undergoing treatment of non-cancer pain and ALL of the following:
        A. A formal, consultative evaluation which includes BOTH of the following was conducted:
            i. Diagnosis
               AND
            ii. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy
        AND
        B. A patient-specific pain management plan is on file for the patient
           AND
        C. The prescriber has reviewed the patient's records in the state's prescription drug monitoring program (PDMP) **AND** has determined that the opioid dosages and combinations within the patient's records do NOT indicate the patient is at high risk for overdose

   AND

c. ONE of the following:
    1. The patient is not concurrently using buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment
       OR
    2. The prescriber has provided information in support of use of opioids with buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment

   AND

d. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
   AND
e. The prescriber has provided information in support of therapy with a higher dose for the requested indication

OR

2. The request does NOT exceed the 7 day supply limit nor the 50 morphine milligram equivalent per day limit; but the requested dose is greater than the program quantity daily limit AND ALL of the following:
    A. ONE of the following:
        i. The patient has a diagnosis of chronic cancer pain due to an active malignancy

OR

ii. The patient is eligible for hospice OR palliative care

OR

iii. The patient has a diagnosis of sickle cell disease

OR

iv. The patient is undergoing treatment of non-cancer pain and ALL of the following:

a. A formal, consultative evaluation which includes BOTH of the following was conducted:

1. Diagnosis

AND

2. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy

AND

b. A patient-specific pain management plan is on file for the patient

AND

c. The prescriber has reviewed the patient's records in the state's prescription drug monitoring program (PDMP) **AND** has determined that the opioid dosages and combinations within the patient's records do NOT indicate the patient is at high risk for overdose

AND

B. ONE of the following:

i. The patient is not concurrently using buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment

OR

ii. The prescriber has provided information in support of use of opioids with buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment

AND

C. If the requested agent contains acetaminophen, then the requested dose of acetaminophen does NOT exceed 4 g/day

AND

D. If the requested agent contains tramadol, dihydrocodeine, OR codeine, then ONE of the following:

i. The patient is 12 to less than 18 years of age AND the requested agent will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy

OR

ii. The patient is 18 years of age or over

AND

E. BOTH of the following:

i. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

AND

ii. The prescriber has provided information in support of therapy with a higher dose for the requested indication

OR

3. The request does NOT exceed the 7 day supply limit nor the 50 morphine milligram equivalent per day limit nor the program quantity daily limit AND the requested agent contains tramadol, dihydrocodeine, OR codeine, then ONE of the following:

A. The patient is 12 to less than 18 years of age AND the requested agent will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy

OR

B. The patient is 18 years of age or over

Length of Approval: 6 months

• Program Summary: Opzelura (ruxolitinib)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
90272060503720	Opzelura	Ruxolitinib Phosphate Cream	1.5 %	1	Tube	30	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Target Agent(s) will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of mild to moderate atopic dermatitis AND ALL of the following: 1. The patient's affected body surface area (BSA) is less than or equal to 20% **AND** 2. The patient is NOT immunocompromised **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to at least a low-potency topical corticosteroid **OR** B. The patient has an intolerance or hypersensitivity to therapy with a topical corticosteroid **OR** C. The patient has an FDA labeled contraindication to ALL topical corticosteroids **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL topical corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. ONE of the following: A. The patient has tried and had an inadequate response to a topical calcineurin inhibitor **OR** B. The patient has an intolerance or hypersensitivity to therapy with a topical calcineurin inhibitor **OR** C. The patient has an FDA labeled contraindication to ALL topical calcineurin inhibitors **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**

Module	Clinical Criteria for Approval
	3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL topical calcineurin inhibitors cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 5. The patient will be using standard maintenance therapy (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has a diagnosis of nonsegmental vitiligo AND ALL of the following: 1. Vitiligo is NOT restricted from coverage under the patient's benefit **AND** 2. The patient's affected body surface area (BSA) is less than or equal to 10% **AND** 3. ONE of the following: A. The patient has vitiligo impacting areas other than the face, neck, or groin AND ONE of the following: 1. The patient has tried and had an inadequate response to at least a potent topical corticosteroid **OR** 2. The patient has an intolerance or hypersensitivity to therapy with a potent topical corticosteroid **OR** 3. The patient has an FDA labeled contraindication to ALL potent topical corticosteroids **OR** 4. The prescriber has provided information indicating why the patient cannot use at least a potent topical corticosteroid for the treatment of vitiligo **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL potent topical corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has vitiligo on the face, neck, or groin AND ONE of the following: 1. The patient has tried and had an inadequate response to at least a potent topical corticosteroid OR a topical calcineurin inhibitor **OR** 2. The patient has an intolerance or hypersensitivity to therapy with a potent topical corticosteroid OR a topical calcineurin inhibitor **OR** 3. The patient has an FDA labeled contraindication to ALL potent topical corticosteroids AND topical calcineurin inhibitors **OR** 4. The prescriber has provided information indicating why the patient cannot use at least a potent topical corticosteroid OR a topical calcineurin inhibitor for the treatment of vitiligo **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently

Module	Clinical Criteria for Approval
	taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL potent topical corticosteroids AND topical calcineurin inhibitors cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has another FDA approved indication for the requested agent **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 3 months for atopic dermatitis and 6 months for nonsegmental vitiligo NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the

Module	Clinical Criteria for Approval
	requested indication **Length of Approval**: 3 months for atopic dermatitis and 6 months for nonsegmental vitiligo

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly
Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)
Cibinqo (abrocitinib)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Litfulo (ritlecitinib)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)

Contraindicated as Concomitant Therapy
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tysabri (natalizumab)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)
Zymfentra (infliximab-dyyb)

● Program Summary: Oral Non-Steroidal Anti-Inflammatory Drugs (NSAID)

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☐ Quantity Limit ☑ Step Therapy ☐ Coverage / Formulary Exception

TARGET AGENT(S) (brands only)

Anaprox DS® (naproxen)[a]
Arthrotec® (diclofenac/misoprostol)[a]
Cambia® (diclofenac)
Celebrex® (celecoxib)[a]
Coxanto™ (oxaprozin)
Daypro® (oxaprozin)[a]
Diclofenac[b]
EC-Naprosyn® (naproxen)[a]
Feldene® (piroxicam)[a]
Fenoprofen[b]
Fenortho™ (fenoprofen)
Flurbiprofen[b]
Indocin® (indomethacin)
Indomethacin[a]
Ketoprofen
Ketoprofen ER[b]
Lodine® (etodolac)[a]
Meclofenamate[b]
Mobic® (meloxicam)[a]
Nalfon® (fenoprofen)[a]
Naprelan CR® (naproxen ER)[a]
Naprosyn® (naproxen)[a]
Qmiiz ODT™ (meloxicam)
Relafen DS™ (nabumetone)
Tivorbex® (indomethacin)
Tolmetin[b]
Vivlodex® (meloxicam)[a]

Zipsor® (diclofenac)[a]
Zorvolex®

a – Available as a generic; included as a prerequisite in the step therapy program
b – Branded generic product(s) available; targeted in the step therapy program

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Target Agent will be approved when ONE of the following is met:

1. The patient is currently being treated with the requested agent as indicated by ALL of the following:
   A. A statement by the prescriber that the patient is currently taking the requested agent
   AND
   B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
   AND
   C. The prescriber states that a change in therapy is expected to be ineffective or cause harm

   OR
2. The patient's medication history includes use of at least two prescription strength generic oral NSAIDs within the past 999 days

   OR
3. BOTH of the following:
   A. The prescriber has stated that the patient has tried at least two prescription strength generic oral NSAID agents
   AND
   B. Prescription strength generic oral NSAID agents were discontinued due to lack of effectiveness or an adverse event

   OR
4. The patient has an intolerance or hypersensitivity to at least two prescription strength generic oral NSAIDs

   OR
5. The patient has an FDA labeled contraindication to ALL prescription strength generic oral NSAIDs

   OR
6. The prescriber has provided documentation that ALL prescription strength generic oral NSAID agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

Length of Approval: 12 months

● Program Summary: Pancreatic Enzymes

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☐ Quantity Limit ☑ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY STEP THERAPY

Final Module	Target Agent GPI	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status	Effective Date	Targeted NDCs When Exclusions Exist
	51200024006703	Pancreaze	Pancrelipase (Lip-Prot-Amyl) DR Cap	2600-8800 UNIT	M; N; O; Y	N				
	51200024006781	Pancreaze	Pancrelipase (Lip-Prot-Amyl) DR Cap	37000-97300 UNIT	M; N; O; Y	N				
	51200024006734	Pancreaze	Pancrelipase (Lip-Prot-Amyl) DR Cap 10500-35500-61500 Unit	10500-35500 UNIT	M; N; O; Y	N				
	51200024006750	Pancreaze	Pancrelipase (Lip-	16800-	M; N; O; Y	N				

Final Module	Target Agent GPI	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status	Effective Date	Targeted NDCs When Exclusions Exist
			Prot-Amyl) DR Cap 16800-56800-98400 Unit	56800 UNIT						
	51200024006754	Pancreaze	Pancrelipase (Lip-Prot-Amyl) DR Cap 21000-54700-83900 Unit	21000-54700 UNIT	M; N; O; Y	N				
	51200024006710	Pancreaze	Pancrelipase (Lip-Prot-Amyl) DR Cap 4200-14200-24600 Unit	4200-14200 UNIT	M; N; O; Y	N				
	51200024006749	Pertzye	Pancrelipase (Lip-Prot-Amyl) DR Cap 16000-57500-60500 Unit	16000-57500 UNIT	M; N; O; Y	N				
	51200024006762	Pertzye	Pancrelipase (Lip-Prot-Amyl) DR Cap 24000-86250-90750 Unit	24000-86250 UNIT	M; N; O; Y	N				
	51200024006709	Pertzye	Pancrelipase (Lip-Prot-Amyl) DR Cap 4000-14375-15125 Unit	4000-14375 UNIT	M; N; O; Y	N				
	51200024006725	Pertzye	Pancrelipase (Lip-Prot-Amyl) DR Cap 8000-28750-30250 Unit	8000-28750 UNIT	M; N; O; Y	N				
	512000240003	Viokace	pancrelipase (lip-prot-amyl) tab	10440-39150 UNIT; 20880-78300 UNIT	M; N; O; Y	N				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

TARGET AGENT(S)	PREREQUISITE AGENT(S)
Pancreaze Pertzye Viokace	Creon Zenpep

Target Agent(s) will be approved when ONE of the following is met:

1. The requested agent is eligible for continuation of therapy AND ONE of the following:

Agents Eligible for Continuation of Therapy
All target agents are eligible for continuation of therapy

   A. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**
   B. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR**

Module	Clinical Criteria for Approval
	2. The patient's medication history includes both Creon and Zenpep as indicated by ONE of the following: A. Evidence of a paid claim(s) **OR** B. The prescriber has stated that the patient has tried both Creon and Zenpep AND both Creon and Zenpep were discontinued due to lack of effectiveness or an adverse event **OR** 3. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 4. The prescriber has provided documentation that both Creon and Zenpep cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval:** 12 months

● Program Summary: Parathyroid Hormone Analog for Osteoporosis

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
3004407000D221		Teriparatide (Recombinant) Soln Pen-inj 620 MCG/2.48ML	620 MCG/2.48ML	1	Pen	28	DAYS			
3004407000D220	Forteo	Teriparatide (Recombinant) Soln Pen-inj 600 MCG/2.4ML	600 MCG/2.4ML	1	Pen	28	DAYS			
3004400500D230	Tymlos	Abaloparatide Subcutaneous Soln Pen-injector 3120 MCG/1.56ML	3120 MCG/1.56ML	1	Pen	30	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Forteo preferred	**Preferred Agent (Forteo)** will be approved when ALL of the following are met: 1. ONE of the following: A. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** B. The prescriber states that the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** C. The patient has a diagnosis of osteoporosis and ALL of the following: 1. ONE of the following: A. The patient's sex is male and ONE of the following: 1. The patient's age is 50 years or over **OR**

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	2. The prescriber has provided information that the requested agent is medically appropriate for the patient's age and sex **OR** B. The patient's sex is female and ONE of the following: 1. The patient is postmenopausal **OR** 2. The prescriber has provided information that the requested agent is medically appropriate for the patient's sex and menopause status **AND** 2. The patient's diagnosis was confirmed by ONE of the following: A. A fragility fracture in the hip or spine **OR** B. A T-score of -2.5 or lower **OR** C. A T-score of -1.0 to -2.5 and ONE of the following: 1. A fragility fracture of a proximal humerus, pelvis, or distal forearm **OR** 2. A FRAX 10-year probability for major osteoporotic fracture of greater than or equal to 20% **OR** 3. A FRAX 10-year probability of hip fracture of greater than or equal to 3% **AND** 3. ONE of the following: A. The patient is at a very high fracture risk as defined by ONE of the following: 1. Patient had a recent fracture (within the past 12 months) **OR** 2. Patient had fractures while on FDA approved osteoporosis therapy **OR** 3. Patient has had multiple fractures **OR** 4. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) **OR** 5. Patient has a very low T-score (less than -3.0) **OR** 6. Patient is at high risk for falls or has a history of injurious falls **OR** 7. Patient has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm **OR** B. ONE of the following: 1. The patient has tried and had an inadequate response to a bisphosphonate (medical records required) **OR** 2. The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required) **OR** 3. The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required) **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation ALL bisphosphonates cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. The patient has a diagnosis of glucocorticoid-induced osteoporosis and ALL of the following: 1. The patient is either initiating or currently taking glucocorticoids in a daily dosage

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	equivalent to 5 mg or higher of prednisone **AND** 2. The patient's expected current course of therapy of glucocorticoids is for a period of at least 3 months **AND** 3. The patient's diagnosis was confirmed by ONE of the following: A. A fragility fracture in the hip or spine **OR** B. A T-score of -2.5 or lower **OR** C. A T-score of -1.0 to -2.5 and ONE of the following: 1. A fragility fracture of a proximal humerus, pelvis, or distal forearm **OR** 2. A FRAX 10-year probability for major osteoporotic fracture of greater than or equal to 20% **OR** 3. A FRAX or the 10-year probability of hip fracture of greater than or equal to 3% **AND** 4. ONE of the following: A. The patient is at a very high fracture risk as defined by ONE of the following: 1. Patient had a recent fracture (within the past 12 months) **OR** 2. Patient had fractures while on FDA approved osteoporosis therapy **OR** 3. Patient has had multiple fractures **OR** 4. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) **OR** 5. Patient has a very low T-score (less than -3.0) **OR** 6. Patient is at high risk for falls or has a history of injurious falls **OR** 7. Patient has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm **OR** 5. ONE of the following: A. The patient has tried and had an inadequate response to a bisphosphonate (medical records required) **OR** B. The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required) **OR** C. The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required) **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation ALL bisphosphonates cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient will NOT be using the requested agent in combination with a bisphosphonate, denosumab (e.g., Prolia, Xgeva), romosozumab-aqqg or another parathyroid hormone analog (e.g., abaloparatide) **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. ONE of the following: A. The patient has never received treatment with a parathyroid hormone analog (Teriparatide, Forteo, and Tymlos) **OR** B. The patient has been previously treated with parathyroid hormone analog(s) and ONE of the

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	following: 1. The total duration of treatment with Forteo (teriparatide), Teriparatide, and Tymlos (abaloparatide) has NOT exceeded 24 months in lifetime **OR** 2. BOTH of the following: A. The patient has received 24 months or more of parathyroid hormone analog treatment in their lifetime, and is at high risk for fracture (e.g., shown by T-score, FRAX score, continued use of glucocorticoids at a daily equivalent of 5 mg of prednisone or higher) **AND** B. The patient was previously treated with Forteo **Length of approval:** Approve for up to 2 years for new Forteo starts or patients new to the plan's Prior Authorization process. Approve for 1 year if patient has already had 2 years of Forteo in lifetime and is at high risk. Only one parathyroid hormone analog will be approved for use at a time. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Teriparatide through preferred	**Non-Preferred Agent(s) Teriparatide** will be approved when ALL of the following are met: 1. ONE of the following: A. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** B. The prescriber states that the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** C. The patient has a diagnosis of osteoporosis AND ALL of the following: 1. ONE of the following: A. The patient's sex is male and ONE of the following: 1. The patient's age is 50 years or over **OR** 2. The prescriber has provided information that the requested agent is medically appropriate for the patient's age and sex **OR** B. The patient's sex is female and ONE of the following: 1. The patient is postmenopausal **OR** 2. The prescriber has provided information that the requested agent is medically appropriate for the patient's sex and menopause status **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to BOTH of the preferred agents (Forteo AND Tymlos) **OR** B. The patient has an intolerance or hypersensitivity to BOTH of the preferred agents (Forteo AND Tymlos) that is not expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to BOTH of the preferred agent (Forteo AND Tymlos) that is not expected to occur with the requested agent **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation BOTH Forteo AND Tymlos cannot be used due to a documented medical condition or comorbid condition that is

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	likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The patient's diagnosis was confirmed by ONE of the following: A. A fragility fracture in the hip or spine **OR** B. A T-score of -2.5 or lower **OR** C. A T-score of -1.0 to -2.5 and ONE of the following: 1. A fragility fracture of a proximal humerus, pelvis, or distal forearm **OR** 2. A FRAX 10-year probability for major osteoporotic fracture of greater than or equal to 20% **OR** 3. A FRAX 10-year probability of hip fracture of greater than or equal to 3% **AND** 4. ONE of the following: A. The patient is at a very high fracture risk as defined by ONE of the following: 1. Patient had a recent fracture (within the past 12 months) **OR** 2. Patient had fractures while on FDA approved osteoporosis therapy **OR** 3. Patient has had multiple fractures **OR** 4. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) **OR** 5. Patient has a very low T-score (less than -3.0) **OR** 6. Patient is at high risk for falls or has a history of injurious falls **OR** 7. Patient has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm **OR** B. ONE of the following: 1. The patient has tried and had an inadequate response to a bisphosphonate (medical records required) **OR** 2. The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required) **OR** 3. The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required) **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL bisphosphonates cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. The patient has a diagnosis of glucocorticoid-induced osteoporosis AND ALL of the following: 1. ONE of the following: A. The patient has tried and had an inadequate response to a preferred agent (Forteo) **OR** B. The patient has an intolerance or hypersensitivity to the preferred agent (Forteo) that is not expected to occur with the requested agent **OR**

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	C. The patient has an FDA labeled contraindication to the preferred agent (Forteo) that is not expected to occur with the requested agent **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that the preferred agent (Forteo) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient is either initiating or currently taking glucocorticoids in a daily dosage equivalent to 5 mg or higher of prednisone **AND** 3. The patient's expected current course of therapy of glucocorticoids is for a period of at least 3 months **AND** 4. The patient's diagnosis was confirmed by ONE of the following: A. A fragility fracture in the hip or spine **OR** B. A T-score of -2.5 or lower **OR** C. A T-score of -1.0 to -2.5 and ONE of the following: 1. A fragility fracture of a proximal humerus, pelvis, or distal forearm **OR** 2. A FRAX 10-year probability for major osteoporotic fracture of greater than or equal to 20% **OR** 3. A FRAX 10-year probability of hip fracture of greater than or equal to 3% **AND** 5. ONE of the following: A. The patient is at a very high fracture risk as defined by ONE of the following: 1. Patient had a recent fracture (within the past 12 months) **OR** 2. Patient had fractures while on FDA approved osteoporosis therapy **OR** 3. Patient has had multiple fractures **OR** 4. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) **OR** 5. Patient has a very low T-score (less than -3.0) **OR** 6. Patient is at high risk for falls or has a history of injurious falls **OR** 7. Patient has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm **OR** B. ONE of the following: 1. The patient has tried and had an inadequate response to a bisphosphonate (medical records required) **OR** 2. The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required) **OR** 3. The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required) **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently

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	receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL bisphosphonates cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient will NOT be using the requested agent in combination with a bisphosphonate, denosumab (e.g., Prolia, Xgeva), romosozumab-aqqg or another parathyroid hormone analog (e.g., abaloparatide) **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. ONE of the following: A. The patient has never received treatment with a parathyroid hormone analog (Teriparatide, Forteo, and Tymlos) **OR** B. The patient has been previously treated with parathyroid hormone analog(s) AND the total duration of treatment with Forteo (teriparatide), Teriparatide, and Tymlos (abaloparatide) has NOT exceeded 24 months in lifetime **Length of approval:** up to a total of 2 years of treatment in lifetime between Teriparatide and Tymlos (abaloparatide). Only one parathyroid hormone analog will be approved for use at a time. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Tymlos - through preferred	**Preferred Agent (Tymlos)** will be approved when ALL of the following are met: 1. ONE of the following: A. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** B. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** C. The patient has a diagnosis of osteoporosis AND ALL of the following: 1. ONE of the following: A. The patient's sex is male and ONE of the following: 1. The patient's age is 50 years or over **OR** 2. The prescriber has provided information that the requested agent is medically appropriate for the patient's age and sex **OR** B. The patient's sex is female and ONE of the following: 1. The patient is postmenopausal **OR** 2. The prescriber has provided information that the requested agent is medically appropriate for the patient's sex and menopause status **AND** 2. The patient's diagnosis was confirmed by ONE of the following: A. A fragility fracture in the hip or spine **OR** B. A T-score of -2.5 or lower **OR** C. A T-score of -1.0 to -2.5 and ONE of the following: 1. A fragility fracture of a proximal humerus, pelvis, or distal forearm **OR** 2. a FRAX 10-year probability for major osteoporotic fracture of greater than or equal to 20% **OR** 3. a FRAX 10-year probability of hip fracture of greater than or equal to 3% **AND**

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	3. ONE of the following: A. The patient is at a very high fracture risk as defined by ONE of the following: 1. Patient had a recent fracture (within the past 12 months) **OR** 2. Patient had fractures while on FDA approved osteoporosis therapy **OR** 3. Patient has had multiple fractures **OR** 4. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) **OR** 5. Patient a very low T-score (less than -3.0) **OR** 6. Patient is at high risk for falls or has a history of injurious falls **OR** 7. Patient has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm **OR** B. ONE of the following: 1. The patient has tried and had an inadequate response to a bisphosphonate (medical records required) **OR** 2. The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required) **OR** 3. The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required) **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL bisphosphonates cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient will NOT be using the requested agent in combination with a bisphosphonate, denosumab (e.g., Prolia, Xgeva), romosozumab-aqqg, or another parathyroid hormone analog (e.g., teriparatide) therapy **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. The total duration of treatment with Forteo (teriparatide), Teriparatide, and Tymlos (abaloparatide) has NOT exceeded 2 years in lifetime **Length of approval:** For those who have had less than 2 years of treatment in lifetime between Teriparatide, and Tymlos (abaloparatide), approve for the remainder of the 2 years of therapy remaining. Only one parathyroid hormone analog will be approved for use at a time. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA Forteo preferred	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **Length of approval:** Approve for up to 2 years for new Forteo starts or patients new to the plan's Prior Authorization process. Approve for 1 year if patient has already had 2 years of Forteo in lifetime and is at high risk. Only one parathyroid hormone analog will be approved for use at a time.
QL with PA Teriparatide through preferred	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **Length of approval:** up to a total of 2 years of treatment in lifetime between Teriparatide and Tymlos (abaloparatide). Only one parathyroid hormone analog will be approved for use at a time.
QL with PA Tymlos	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **Length of approval:** For those who have had less than 2 years of treatment in lifetime between Teriparatide and Tymlos (abaloparatide), approve for the remainder of the 2 years of therapy remaining. Only one parathyroid hormone analog will be approved for use at a time.

• Program Summary: Proton Pump Inhibitors (PPIs)

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☑ Step Therapy ☐ Coverage / Formulary Exception

For the **GenRx Closed** formulary, step therapy will target Nexium suspension packets. Any generic PPI except omeprazole/sodium bicarbonate can serve as a prerequisite.

For the **GenRx Open, Health Insurance Marketplace & KeyRx** formularies, step therapy will target ALL brand PPIs and generic omeprazole/sodium bicarbonate. Any generic PPI except omeprazole/sodium bicarbonate can serve as a prerequisite.

For the **FlexRx Closed** formulary, step therapy will target Nexium suspension packets. Any generic PPI except omeprazole/sodium bicarbonate can serve as a prerequisite.

For the **FlexRx Open** formulary, step therapy will target ALL brand PPIs and generic omeprazole/sodium bicarbonate. Any generic PPI except omeprazole/sodium bicarbonate can serve as a prerequisite.

TARGET AGENT(S)[a]
Aciphex® (rabeprazole)
Aciphex® Sprinkle™ (rabeprazole)
Dexilant® (dexlansoprazole)
Dexlansoprazole
Esomeprazole Strontium
Konvomep™ (Omeprazole/sodium bicarbonate)
Nexium® (esomeprazole)
Prevacid® (lansoprazole)
Prevacid® SoluTab™ (lansoprazole)
Prilosec® (omeprazole)
Protonix® (pantoprazole)
Rabeprazole Sprinkle
Voquezna® (vonoprazan)
Zegerid® (omeprazole/sodium bicarbonate)
a - see formulary specific information

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Target Agent(s) will be approved when ONE of the following is met:

1. The patient's medication history includes use of a prescription strength prerequisite agent
   OR
2. The patient has an intolerance or hypersensitivity to a prescription strength prerequisite agent
   OR
3. The patient has an FDA labeled contraindication to ALL prescription strength prerequisite agent
   OR
4. BOTH of the following:
   A. The prescriber has stated that the patient has tried a prescription strength prerequisite agent
      AND
   B. The prescription strength prerequisite agent was discontinued due to lack of effectiveness or an adverse event
   OR
5. The patient is currently being treated with the requested agent as indicated by ALL of the following:
   A. A statement by the prescriber that the patient is currently taking the requested agent
      AND
   B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
      AND
   C. The prescriber states that a change in therapy is expected to be ineffective or cause harm

OR

6. The prescriber has provided documentation that ALL prescription strength prerequisite agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

Length of Approval: 12 months

NOTE: If Quantity Limit applies, please refer to Quantity Limit document.

• Program Summary: Rapid to Intermediate Acting Insulin

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
27104005	Admelog; Admelog solostar; Humalog; Humalog junior kwikpen; Humalog kwikpen; Humalog tempo pen; Lyumjev; Lyumjev kwikpen; Lyumjev tempo pen	insulin lispro inj soln; insulin lispro soln cartridge; insulin lispro soln pen-inj w/transmitter port; insulin lispro soln pen-injector; insulin lispro-aabc inj; insulin lispro-aabc soln pen-inj; insulin lispro-aabc soln pen-inj w/transmit port; insulin lispro-aabc soln pen-injector	100 UNIT/ML; 200 UNIT/ML	100	mLs	30	DAYS			
27104004	Apidra; Apidra solostar	insulin glulisine inj; insulin glulisine soln pen-injector inj	100 UNIT/ML	100	mLs	30	DAYS			
27104002	Fiasp; Fiasp flextouch; Fiasp penfill; Fiasp pumpcart; Novolog; Novolog flexpen; Novolog flexpen relion; Novolog penfill; Novolog relion	insulin aspart (with niacinamide) inj; insulin aspart (with niacinamide) sol pen-inj; insulin aspart (with niacinamide) soln cartridge; insulin aspart inj soln; insulin aspart soln cartridge; insulin aspart soln pen-injector	100 UNIT/ML	100	mLs	30	DAYS			
27104080	Humalog mix 50/50; Humalog mix 50/50 kwikpen; Humalog mix 75/25;	insulin lispro prot & lispro inj; insulin lispro prot & lispro sus pen-inj; insulin	(50-50) 100 UNIT/ML; (75-25) 100 UNIT/ML	100	mLs	30	DAYS			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
	Humalog mix 75/25 kwikpen	lispro protamine & lispro inj								
27104090	Humulin 70/30; Humulin 70/30 kwikpen; Novolin 70/30; Novolin 70/30 flexpen; Novolin 70/30 flexpen relion; Novolin 70/30 relion	insulin nph & regular susp pen-inj; insulin nph isophane & regular human inj	(70-30) 100 UNIT/ML	100	mLs	30	DAYS			
27104020	Humulin n; Humulin n kwikpen; Novolin n; Novolin n flexpen; Novolin n flexpen relion; Novolin n relion	insulin nph (human) (isophane) inj; insulin nph (human) (isophane) susp pen-injector	100 UNIT/ML	100	mLs	30	DAYS			
271040100020	Humulin r; Humulin r u-500 (concentrate); Novolin r; Novolin r relion	insulin regular (human) inj	100 UNIT/ML; 500 UNIT/ML	100	mLs	30	DAYS			
2710401000D2	Humulin r u-500 kwikpen; Novolin r flexpen; Novolin r flexpen relion	insulin regular (human) soln pen-injector	100 UNIT/ML; 500 UNIT/ML	100	mLs	30	DAYS			
27104070	Novolog mix 70/30; Novolog mix 70/30 prefill; Novolog mix 70/30 relion	insulin aspart prot & aspart (human) inj; insulin aspart prot & aspart sus pen-inj	(70-30) 100 UNIT/ML	100	mLs	30	DAYS			

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL Standalone	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program

Module	Clinical Criteria for Approval
	quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months

• Program Summary: Risdiplam (fka Evrydsi)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
74706560002120	Evrysdi	Risdiplam For Soln	0.75 MG/ML	240	mLs	30	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of Spinal Muscular Atrophy (SMA) type 1, 2, or 3 **AND** 2. The patient's diagnosis was confirmed by genetic testing confirming the mutation or deletion of genes in chromosome 5q (medical records required) **AND** 3. The patient has had at least ONE of the following baseline (prior to starting therapy with the requested agent) functional assessments based on patient age and motor ability: A. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) B. Hammersmith Infant Neurological Examination (HINE-2) C. Hammersmith Functional Motor Scale-Expanded (HFMSE) D. Six-minute walk test (6MWT) E. Bayley Scales of Infant and Toddler Development (BSID) F. Motor Function Measurement score (MFM32) G. Revised Upper Limb Module (RULM) test **AND** 4. The patient does NOT require invasive ventilation or tracheostomy **AND** 5. The patient has not received gene therapy for the requested indication (e.g., Zolgensma [onasemnogene abeparvovec-xioi]) **AND** 6. If the patient has used Spinraza (nusinersen) in the last four months, they will complete a four-month washout period between the last Spinraza (nusinersen) dose and the initiation of therapy with the requested agent **AND** 7. The patient will NOT be using the requested agent in combination with Spinraza (nusinersen) **AND** 8. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, geneticist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 9. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months

Module	Clinical Criteria for Approval
	NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had improvements or stabilization from baseline (prior to starting therapy with the requested agent) with the requested agent as indicated by one of the following functional assessments based on patient age and motor ability: A. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) B. Hammersmith Infant Neurological Examination (HINE-2) C. Hammersmith Functional Motor Scale-Expanded (HFMSE) D. Six-minute walk test (6MWT) E. Bayley Scales of Infant and Toddler Development (BSID) F. Motor Function Measurement score (MFM32) G. Revised Upper Limb Module (RULM) test **AND** 3. The patient does NOT require invasive ventilation or tracheostomy **AND** 4. The patient has not received gene therapy for the requested indication (e.g., Zolgensma [onasemnogene abeparvovec-xioi]) **AND** 5. The patient will NOT be using the requested agent in combination with Spinraza (nusinersen) **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, geneticist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of Approval:** 12 months

• Program Summary: Samsca (tolvaptan)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
30454060000320	Samsca	tolvaptan tab	15 MG	30	Tablets	365	DAYS	31722086803; 31722086831; 49884076852; 49884076854; 59148002050; 60505431700; 60505470400; 60505470402; 67877063502; 67877063533; 72205013011		
30454060000330	Samsca	tolvaptan tab	30 MG	60	Tablets	365	Days	31722086903; 49884077052; 49884077054; 59148002150; 60505431800; 60505470500; 60505470501; 67877063602; 67877063633; 72205013111		

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The requested agent was initiated (or re-initiated) in the hospital **AND** 2. Prior to initiating the requested agent, the patient has/had a diagnosis of clinically significant hypervolemic or euvolemic hyponatremia defined by one of the following: A. serum sodium less than 125 mEq/L **OR** B. serum sodium greater than or equal to 125 mEq/L and has symptomatic hyponatremia that has resisted correction with fluid restriction **AND** 3. The patient does NOT have underlying liver disease, including cirrhosis **AND** 4. Medications known to cause hyponatremia (e.g., antidepressants [SSRIs, tricyclics, MAOIs, venlafaxine], anticonvulsants [carbamazepine, oxcarbazepine, sodium valproate, lamotrigine], antipsychotics [phenothiazines, butyrophenones], anticancer [vinca alkaloids, platinum compounds, ifosfamide, melphalan, cyclophosphamide, methotrexate, pentostatin], antidiabetic [chlorpropamide, tolbutamide], vasopressin analogues [desmopressin, oxytocin, terlipressin, vasopressin], miscellaneous [amiodarone, clofibrate, interferon, NSAIDs, levamisole, linezolid, monoclonal antibodies, nicotine, opiates, PPIs]) have been evaluated and discontinued when appropriate **AND** 5. The patient will NOT be using the requested agent in combination with another tolvaptan agent for the requested indication **AND** 6. The patient does not have any FDA labeled contraindications to the requested agent **AND** 7. The patient has not already received 30 days of therapy with the requested agent for the current

Module	Clinical Criteria for Approval
	hospitalization **Length of Approval:** 30 tablets/365 days of the 15 mg tablets 60 tablets/365 days of the 30 mg tablets NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Evaluation** **Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose and/or duration of therapy) does NOT exceed the program quantity limit **OR** 2. BOTH of the following: A. The requested quantity (dose and/or duration of therapy) is greater than the program quantity limit **AND** B. The patient has had an additional hospitalization for hyponatremia for initiation of the requested agent **Length of Approval:** 30 tablets/365 days of the 15 mg tablets 60 tablets/365 days of the 30 mg tablets

● Program Summary: Self-Administered Oncology Agents

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
21406010200310		Abiraterone Acetate Tab 125 MG		120	Tablets	30	DAYS				
2156006000B730		Selinexor Tab Therapy Pack 20 MG (100 MG Once Weekly)		20	Tablets	28	DAYS				
2156006000B712		Selinexor Tab Therapy Pack 20 MG (40 MG Once Weekly)		8	Tablets	28	DAYS				
2156006000B715		Selinexor Tab Therapy Pack 20 MG (40 MG Twice Weekly)		16	Tablets	28	DAYS				
2156006000B750		Selinexor Tab Therapy Pack 20 MG (60 MG Once Weekly)		12	Tablets	28	DAYS				
2156006000B740		Selinexor Tab Therapy Pack 20 MG (80 MG Once Weekly)		16	Tablets	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
215325300003	Afinitor	everolimus tab	10 MG; 2.5 MG; 5 MG; 7.5 MG	30	Tablets	30	DAYS				
21532530007310	Afinitor disperz	Everolimus Tab for Oral Susp 2 MG	2 MG	60	Tablets	30	DAYS				
21532530007320	Afinitor disperz	Everolimus Tab for Oral Susp 3 MG	3 MG	90	Tablets	30	DAYS				
21532530007340	Afinitor disperz	Everolimus Tab for Oral Susp 5 MG	5 MG	60	Tablets	30	DAYS				
21409902120320	Akeega	niraparib tosylate-abiraterone acetate tab	50-500 MG	60	Tablets	30	DAYS				
21409902120330	Akeega	niraparib tosylate-abiraterone acetate tab	100-500 MG	60	Tablets	30	DAYS				
215305071001	Alecensa	alectinib hcl cap	150 MG	240	Capsules	30	DAYS				
21530510000330	Alunbrig	Brigatinib Tab	30 MG	120	Tablets	30	DAYS				
21530510000350	Alunbrig	Brigatinib Tab	90 MG	30	Tablets	30	DAYS				
21530510000365	Alunbrig	Brigatinib Tab	180 MG	30	Tablets	30	DAYS				
2153051000B720	Alunbrig	Brigatinib Tab Initiation Therapy Pack	90 & 180 MG	30	Tablets	180	DAYS				
21533865000120	Augtyro	repotrectinib cap	40 MG	240	Capsules	30	DAYS				
214900090003	Ayvakit	avapritinib tab	100 MG; 200 MG; 25 MG; 300 MG; 50 MG	30	Tablets	30	DAYS				
21532225000325	Balversa	erdafitinib tab	4 MG	60	Tablets	30	DAYS				
21532225000320	Balversa	Erdafitinib Tab 3 MG	3 MG	90	Tablets	30	DAYS				
21532225000330	Balversa	Erdafitinib Tab 5 MG	5 MG	30	Tablets	30	DAYS				
2170007750E520	Besremi	Ropeginterferon alfa-	500 MCG/ML	2	Syringes	28	DAYS				
21531812000120	Bosulif	bosutinib cap	50 MG	30	Capsules	30	DAYS				
21531812000130	Bosulif	bosutinib cap	100 MG	150	Capsules	30	DAYS				
21531812000320	Bosulif	Bosutinib Tab	100 MG	90	Tablets	30	DAYS				
21531812000327	Bosulif	Bosutinib Tab	400 MG	30	Tablets	30	DAYS				
21531812000340	Bosulif	Bosutinib Tab	500 MG	30	Tablets	30	DAYS				
215320400001	Braftovi	encorafenib cap	75 MG	180	Capsules	30	DAYS				
21532195000120	Brukinsa	zanubrutinib cap	80 MG	120	Capsules	30	DAYS				
21533010100320	Cabometyx	Cabozantinib S-Malate Tab	20 MG	30	Tablets	30	DAYS				
21533010100330	Cabometyx	Cabozantinib S-Malate Tab	40 MG	30	Tablets	30	DAYS				
21533010100340	Cabometyx	Cabozantinib S-Malate Tab	60 MG	30	Tablets	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
215321030001	Calquence	acalabrutinib cap	100 MG	60	Capsules	30	DAYS				
215321035003	Calquence	acalabrutinib maleate tab	100 MG	60	Tablets	30	DAYS				
21533085000320	Caprelsa	Vandetanib Tab	100 MG	60	Tablets	30	DAYS				
21533085000340	Caprelsa	Vandetanib Tab	300 MG	30	Tablets	30	DAYS				
21533010106470	Cometriq	Cabozantinib S-Mal Cap	80 & 20 MG	1	Carton	28	DAYS				
21533010106480	Cometriq	Cabozantinib S-Mal Cap	3 x 20 MG & 80 MG	1	Carton	28	DAYS				
21533010106460	Cometriq	Cabozantinib S-Malate Cap	20 MG	1	Carton	28	DAYS				
215380300001	Copiktra	duvelisib cap	15 MG; 25 MG	56	Capsules	28	DAYS				
215335302003	Cotellic	cobimetinib fumarate tab	20 MG	63	Tablets	28	DAYS				
21370030300335	Daurismo	Glasdegib Maleate Tab 100 MG (Base Equivalent)	100 MG	30	Tablets	30	DAYS				
21370030300320	Daurismo	Glasdegib Maleate Tab 25 MG (Base Equivalent)	25 MG	60	Tablets	30	DAYS				
21370070000120	Erivedge	Vismodegib Cap 150 MG	150 MG	30	Capsules	30	DAYS				
21402410000360	Erleada	apalutamide tab	240 MG	30	Tablets	30	DAYS				
21402410000320	Erleada	Apalutamide Tab 60 MG	60 MG	120	Tablets	30	DAYS				
21360050600120	Exkivity	Mobocertinib Succinate Cap	40 MG	120	Capsules	30	DAYS				
215315501001	Farydak	panobinostat lactate cap	10 MG; 15 MG; 20 MG	6	Capsules	21	DAYS				
21533076250120	Fotivda	Tivozanib HCl Cap	0.89 MG	21	Capsules	28	DAYS				
21533076250130	Fotivda	Tivozanib HCl Cap	1.34 MG	21	Capsules	28	DAYS				
21335035000120	Fruzaqla	fruquintinib cap	1 MG	84	Capsules	28	DAYS				
21335035000140	Fruzaqla	fruquintinib cap	5 MG	21	Capsules	28	DAYS				
215357500001	Gavreto	pralsetinib cap	100 MG	120	Capsules	30	DAYS				
213600061003	Gilotrif	afatinib dimaleate tab	20 MG; 30 MG; 40 MG	30	Tablets	30	DAYS				
21531835100320	Gleevec	Imatinib Mesylate Tab	100 MG	90	Tablets	30	DAYS				
21531835100340	Gleevec	Imatinib Mesylate Tab	400 MG	60	Tablets	30	DAYS				
21531060000130	Ibrance	Palbociclib Cap 100 MG	100 MG	21	Capsules	28	DAYS				
21531060000140	Ibrance	Palbociclib Cap 125 MG	125 MG	21	Capsules	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
21531060000120	Ibrance	Palbociclib Cap 75 MG	75 MG	21	Capsules	28	DAYS				
21531060000330	Ibrance	Palbociclib Tab 100 MG	100 MG	21	Tablets	28	DAYS				
21531060000340	Ibrance	Palbociclib Tab 125 MG	125 MG	21	Tablets	28	DAYS				
21531060000320	Ibrance	Palbociclib Tab 75 MG	75 MG	21	Tablets	28	DAYS				
21531875100315	Iclusig	Ponatinib HCl Tab	10 MG	30	Tablets	30	DAYS				
21531875100320	Iclusig	Ponatinib HCl Tab	15 MG	30	Tablets	30	DAYS				
21531875100330	Iclusig	Ponatinib HCl Tab	30 MG	30	Tablets	30	DAYS				
21531875100340	Iclusig	Ponatinib HCl Tab	45 MG	30	Tablets	30	DAYS				
21535030200340	Idhifa	Enasidenib Mesylate Tab 100 MG (Base Equivalent)	100 MG	30	Tablets	30	DAYS				
21535030200320	Idhifa	Enasidenib Mesylate Tab 50 MG (Base Equivalent)	50 MG	30	Tablets	30	DAYS				
21532133000110	Imbruvica	Ibrutinib Cap	70 MG	30	Capsules	30	DAYS				
21532133000120	Imbruvica	ibrutinib cap	140 MG	90	Capsules	30	DAYS				
21532133001820	Imbruvica	Ibrutinib Oral Susp	70 MG/ML	216	mLs	30	DAYS				
215321330003	Imbruvica	ibrutinib tab	140 MG; 280 MG; 420 MG; 560 MG	30	Tablets	30	DAYS				
21335013000320	Inlyta	Axitinib Tab	1 MG	180	Tablets	30	DAYS				
21335013000340	Inlyta	Axitinib Tab	5 MG	120	Tablets	30	DAYS				
219900022503	Inqovi	decitabine-cedazuridine tab	35-100 MG	5	Tablets	28	DAYS				
21537520200120	Inrebic	Fedratinib HCl Cap 100 MG	100 MG	120	Capsules	30	DAYS				
213600300003	Iressa	gefitinib tab	250 MG	30	Tablets	30	DAYS				
21757220300320	Iwilfin	eflornithine hcl tab	192 MG	240	Tablets	30	DAYS				
215375602003	Jakafi	ruxolitinib phosphate tab	10 MG; 15 MG; 20 MG; 25 MG; 5 MG	60	Tablets	30	DAYS				
21532165000320	Jaypirca	pirtobrutinib tab	50 MG	30	Tablets	30	DAYS				
21532165000330	Jaypirca	pirtobrutinib tab	100 MG	60	Tablets	30	DAYS				
2153107050B720	Kisqali	Ribociclib Succinate Tab Pack 200 MG Daily Dose	200 MG	21	Tablets	28	DAYS				
2153107050B740	Kisqali	Ribociclib Succinate Tab Pack 400 MG Daily Dose (200 MG Tab)	200 MG	42	Tablets	28	DAYS				
2153107050B760	Kisqali	Ribociclib Succinate Tab Pack 600 MG Daily Dose (200 MG Tab)	200 MG	63	Tablets	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
2199000260B730	Kisqali femara 200 dose	Ribociclib 200 MG Dose (200 MG Tab) & Letrozole 2.5 MG TBPK	200 & 2.5 MG	49	Tablets	28	DAYS				
2199000260B740	Kisqali femara 400 dose	Ribociclib 400 MG Dose (200 MG Tab) & Letrozole 2.5 MG TBPK	200 & 2.5 MG	70	Tablets	28	DAYS				
2199000260B760	Kisqali femara 600 dose	Ribociclib 600 MG Dose (200 MG Tab) & Letrozole 2.5 MG TBPK	200 & 2.5 MG	91	Tablets	28	DAYS				
21533565500110	Koselugo	Selumetinib Sulfate Cap 10 MG	10 MG	240	Capsules	30	DAYS				
21533565500125	Koselugo	Selumetinib Sulfate Cap 25 MG	25 MG	120	Capsules	30	DAYS				
21532410000320	Krazati	Adagrasib Tab	200 MG	180	Tablets	30	DAYS				
2133505420B220	Lenvima 10 mg daily dose	Lenvatinib Cap Therapy Pack	10 MG	30	Capsules	30	DAYS				
2133505420B223	Lenvima 12mg daily dose	Lenvatinib Cap Therapy Pack	4 MG	90	Capsules	30	DAYS				
2133505420B240	Lenvima 14 mg daily dose	Lenvatinib Cap Therapy Pack	10 & 4 MG	60	Capsules	30	DAYS				
2133505420B244	Lenvima 18 mg daily dose	Lenvatinib Cap Ther Pack	10 MG & 2 x 4 MG	90	Capsules	30	DAYS				
2133505420B230	Lenvima 20 mg daily dose	Lenvatinib Cap Therapy Pack	10 MG	60	Capsules	30	DAYS				
2133505420B250	Lenvima 24 mg daily dose	Lenvatinib Cap Ther Pack	2 x 10 MG & 4 MG	90	Capsules	30	DAYS				
2133505420B210	Lenvima 4 mg daily dose	Lenvatinib Cap Therapy Pack	4 MG	30	Capsules	30	DAYS				
2133505420B215	Lenvima 8 mg daily dose	Lenvatinib Cap Therapy Pack	4 MG	60	Capsules	30	DAYS				
21990002750320	Lonsurf	Trifluridine-Tipiracil Tab 15-6.14 MG	15-6.14 MG	60	Tablets	28	DAYS				
21990002750330	Lonsurf	Trifluridine-Tipiracil Tab 20-8.19 MG	20-8.19 MG	80	Tablets	28	DAYS				
21530556000320	Lorbrena	Lorlatinib Tab	25 MG	90	Tablets	30	DAYS				
21530556000330	Lorbrena	Lorlatinib Tab	100 MG	30	Tablets	30	DAYS				
21532480000340	Lumakras	sotorasib tab	320 MG	90	Tablets	30	DAYS				
21532480000320	Lumakras	Sotorasib Tab	120 MG	240	Tablets	30	DAYS				
215355600003	Lynparza	olaparib tab	100 MG; 150 MG	120	Tablets	30	DAYS				
2153222800B720	Lytgobi	Futibatinib Tab Therapy Pack	4 MG	84	Tablets	28	DAYS				
2153222800B725	Lytgobi	Futibatinib Tab Therapy Pack	4 MG	112	Tablets	28	DAYS				
2153222800B730	Lytgobi	Futibatinib Tab Therapy Pack	4 MG	140	Tablets	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
21533570102120	Mekinist	trametinib dimethyl sulfoxide for soln	0.05 MG/ML	1170	mLs	28	DAYS				
21533570100310	Mekinist	Trametinib Dimethyl Sulfoxide Tab 0.5 MG (Base Equivalent)	0.5 MG	90	Tablets	30	DAYS				
21533570100330	Mekinist	Trametinib Dimethyl Sulfoxide Tab 2 MG (Base Equivalent)	2 MG	30	Tablets	30	DAYS				
215335200003	Mektovi	binimetinib tab	15 MG	180	Tablets	30	DAYS				
21533035100320	Nerlynx	Neratinib Maleate Tab	40 MG	180	Tablets	30	DAYS				
21533060400320	Nexavar	Sorafenib Tosylate Tab 200 MG (Base Equivalent)	200 MG	120	Tablets	30	DAYS				
215360451001	Ninlaro	ixazomib citrate cap	2.3 MG; 3 MG; 4 MG	3	Capsules	28	DAYS				
21402425000320	Nubeqa	Darolutamide Tab 300 MG	300 MG	120	Tablets	30	DAYS				
213700602001	Odomzo	sonidegib phosphate cap	200 MG	30	Capsules	30	DAYS				
21532350200320	Ogsiveo	nirogacestat hydrobromide tab	50 MG	180	Tablets	30	DAYS				
21537540300320	Ojjaara	momelotinib dihydrochloride tab	100 MG	30	Tablets	30	DAYS				
21537540300330	Ojjaara	momelotinib dihydrochloride tab	150 MG	30	Tablets	30	DAYS				
21537540300340	Ojjaara	momelotinib dihydrochloride tab	200 MG	30	Tablets	30	DAYS				
213000030003	Onureg	azacitidine tab	200 MG; 300 MG	14	Tablets	28	DAYS				
214055700003	Orgovyx	relugolix tab	120 MG	30	Tablets	30	DAYS				
21403720100320	Orserdu	elacestrant hydrochloride tab	86 MG	90	Tablets	30	DAYS				
21403720100340	Orserdu	elacestrant hydrochloride tab	345 MG	30	Tablets	30	DAYS				
21532260000340	Pemazyre	Pemigatinib Tab 13.5 MG	13.5 MG	14	Tablets	21	DAYS				
21532260000320	Pemazyre	Pemigatinib Tab 4.5 MG	4.5 MG	14	Tablets	21	DAYS				
21532260000330	Pemazyre	Pemigatinib Tab 9 MG	9 MG	14	Tablets	21	DAYS				
2153801000B720	Piqray 200mg daily dose	Alpelisib Tab Therapy Pack 200 MG Daily Dose	200 MG	28	Tablets	28	DAYS				
2153801000B725	Piqray 250mg daily dose	Alpelisib Tab Pack 250 MG Daily Dose (200 MG & 50 MG Tabs)	200 & 50 MG	56	Tablets	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
2153801000B730	Piqray 300mg daily dose	Alpelisib Tab Pack 300 MG Daily Dose (2x150 MG Tab)	150 MG	56	Tablets	28	DAYS				
214500800001	Pomalyst	pomalidomide cap	1 MG; 2 MG; 3 MG; 4 MG	21	Capsules	28	DAYS				
21533053000320	Qinlock	Ripretinib Tab	50 MG	90	Tablets	30	DAYS				
21535779000120	Retevmo	Selpercatinib Cap	40 MG	180	Capsules	30	DAYS				
21535779000140	Retevmo	Selpercatinib Cap	80 MG	120	Capsules	30	DAYS				
99394050000130	Revlimid	Lenalidomide Cap 10 MG	10 MG	30	Capsules	30	DAYS				
99394050000140	Revlimid	Lenalidomide Cap 15 MG	15 MG	21	Capsules	28	DAYS				
99394050000145	Revlimid	Lenalidomide Cap 20 MG	20 MG	21	Capsules	28	DAYS				
99394050000150	Revlimid	Lenalidomide Cap 25 MG	25 MG	21	Capsules	28	DAYS				
99394050000120	Revlimid	Lenalidomide Cap 5 MG	5 MG	30	Capsules	30	DAYS				
99394050000110	Revlimid	Lenalidomide Caps 2.5 MG	2.5 MG	30	Capsules	30	DAYS				
21534960000120	Rezlidhia	Olutasidenib Cap	150 MG	60	Capsules	30	DAYS				
21533820000120	Rozlytrek	Entrectinib Cap 100 MG	100 MG	30	Capsules	30	DAYS				
21533820000130	Rozlytrek	Entrectinib Cap 200 MG	200 MG	90	Capsules	30	DAYS				
21533820003020	Rozlytrek	entrectinib pellet pack	50 MG	336	Packets	28	DAYS				
21535570200320	Rubraca	Rucaparib Camsylate Tab 200 MG (Base Equivalent)	200 MG	120	Tablets	30	DAYS				
21535570200325	Rubraca	Rucaparib Camsylate Tab 250 MG (Base Equivalent)	250 MG	120	Tablets	30	DAYS				
21535570200330	Rubraca	Rucaparib Camsylate Tab 300 MG (Base Equivalent)	300 MG	120	Tablets	30	DAYS				
21533030000130	Rydapt	Midostaurin Cap 25 MG	25 MG	240	Capsules	30	DAYS				
21531806100320	Scemblix	Asciminib HCl Tab	20 MG	60	Tablets	30	DAYS				
21531806100340	Scemblix	Asciminib HCl Tab	40 MG	300	Tablets	30	DAYS				
21531820000320	Sprycel	Dasatinib Tab	20 MG	90	Tablets	30	DAYS				
21531820000340	Sprycel	Dasatinib Tab	50 MG	30	Tablets	30	DAYS				
21531820000350	Sprycel	Dasatinib Tab	70 MG	30	Tablets	30	DAYS				
21531820000354	Sprycel	Dasatinib Tab	80 MG	30	Tablets	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
21531820000360	Sprycel	Dasatinib Tab	100 MG	30	Tablets	30	DAYS				
21531820000380	Sprycel	Dasatinib Tab	140 MG	30	Tablets	30	DAYS				
2153305000	Stivarga	regorafenib tab	40 MG	84	Tablets	28	DAYS				
21533070300120	Sutent	Sunitinib Malate Cap 12.5 MG (Base Equivalent)	12.5 MG	90	Capsules	30	DAYS				
21533070300130	Sutent	Sunitinib Malate Cap 25 MG (Base Equivalent)	25 MG	30	Capsules	30	DAYS				
21533070300135	Sutent	Sunitinib Malate Cap 37.5 MG (Base Equivalent)	37.5 MG	30	Capsules	30	DAYS				
21533070300140	Sutent	Sunitinib Malate Cap 50 MG (Base Equivalent)	50 MG	30	Capsules	30	DAYS				
215337162003	Tabrecta	capmatinib hcl tab	150 MG; 200 MG	120	Tablets	30	DAYS				
215320251001	Tafinlar	dabrafenib mesylate cap	50 MG; 75 MG	120	Capsules	30	DAYS				
21532025107320	Tafinlar	dabrafenib mesylate tab for oral susp	10 MG	840	Tablets	28	DAYS				
213600682003	Tagrisso	osimertinib mesylate tab	40 MG; 80 MG	30	Tablets	30	DAYS				
21535580400105	Talzenna	talazoparib tosylate cap	0.1 MG	30	Capsules	30	DAYS				
21535580400112	Talzenna	talazoparib tosylate cap	0.35 MG	30	Capsules	30	DAYS				
21535580400114	Talzenna	Talazoparib Tosylate Cap	0.5 MG	30	Capsules	30	DAYS				
21535580400118	Talzenna	Talazoparib Tosylate Cap	0.75 MG	30	Capsules	30	DAYS				
21535580400110	Talzenna	Talazoparib Tosylate Cap 0.25 MG (Base Equivalent)	0.25 MG	90	Capsules	30	DAYS				
21535580400120	Talzenna	Talazoparib Tosylate Cap 1 MG (Base Equivalent)	1 MG	30	Capsules	30	DAYS				
21360025100320	Tarceva	Erlotinib HCl Tab	25 MG	60	Tablets	30	DAYS				
21360025100330	Tarceva	Erlotinib HCl Tab	100 MG	30	Tablets	30	DAYS				
21360025100360	Tarceva	Erlotinib HCl Tab	150 MG	30	Tablets	30	DAYS				
215318602001	Tasigna	nilotinib hcl cap	150 MG; 200 MG; 50 MG	120	Capsules	30	DAYS				
215336752003	Tazverik	tazemetostat hbr tab	200 MG	240	Tablets	30	DAYS				
21533773100320	Tepmetko	Tepotinib HCl Tab	225 MG	60	Tablets	30	DAYS				
99392070000130	Thalomid	Thalidomide Cap 100	100 MG	30	Tablets	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		MG									
99392070000135	Thalomid	Thalidomide Cap 150 MG	150 MG	60	Capsules	30	DAYS				
99392070000140	Thalomid	Thalidomide Cap 200 MG	200 MG	60	Capsules	30	DAYS				
99392070000120	Thalomid	Thalidomide Cap 50 MG	50 MG	30	Capsules	30	DAYS				
21534940000320	Tibsovo	Ivosidenib Tab 250 MG	250 MG	60	Tablets	30	DAYS				
21530320000320	Truqap	capivasertib tab	160 MG	64	Tablets	28	DAYS				
21530320000325	Truqap	capivasertib tab	200 MG	64	Tablets	28	DAYS				
2153223540B235	Truseltiq	Infigratinib Phos Cap Pack	100 & 25 MG	42	Capsules	28	DAYS				
2153223540B220	Truseltiq	infigratinib phos cap ther pack	25 MG	42	Capsules	28	DAYS				
2153223540B225	Truseltiq	Infigratinib Phos Cap Ther Pack	25 MG	63	Capsules	28	DAYS				
2153223540B230	Truseltiq	Infigratinib Phos Cap Ther Pack	100 MG	21	Capsules	28	DAYS				
21170080000320	Tukysa	Tucatinib Tab	50 MG	300	Tablets	30	DAYS				
21170080000340	Tukysa	Tucatinib Tab	150 MG	120	Tablets	30	DAYS				
21533045010110	Turalio	Pexidartinib HCl Cap	125 MG	120	Capsules	30	DAYS				
21533045010120	Turalio	Pexidartinib HCl Cap	200 MG	120	Capsules	30	DAYS				
21533026100320	Tykerb	Lapatinib Ditosylate Tab	250 MG	180	Tablets	30	DAYS				
21533047100320	Vanflyta	quizartinib dihydrochloride tab	17.7 MG	28	Tablets	28	DAYS				
21533047100325	Vanflyta	quizartinib dihydrochloride tab	26.5 MG	56	Tablets	28	DAYS				
21470080000320	Venclexta	Venetoclax Tab 10 MG	10 MG	60	Tablets	30	DAYS				
21470080000360	Venclexta	Venetoclax Tab 100 MG	100 MG	180	Tablets	30	DAYS				
21470080000340	Venclexta	Venetoclax Tab 50 MG	50 MG	30	Tablets	30	DAYS				
2147008000B720	Venclexta starting pack	Venetoclax Tab Therapy Starter Pack 10 & 50 & 100 MG	10 & 50 & 100 MG	1	Pack	180	DAYS				
215310100003	Verzenio	abemaciclib tab	100 MG; 150 MG; 200 MG; 50 MG	60	Tablets	30	DAYS				
21533835200150	Vitrakvi	Larotrectinib Sulfate Cap 100 MG (Base Equivalent)	100 MG	60	Capsules	30	DAYS				
21533835200120	Vitrakvi	Larotrectinib Sulfate Cap 25 MG (Base Equivalent)	25 MG	180	Capsules	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
21533835202020	Vitrakvi	Larotrectinib Sulfate Oral Soln 20 MG/ML (Base Equivalent)	20 MG/ML	300	mLs	30	DAYS				
213600190003	Vizimpro	dacomitinib tab	15 MG; 30 MG; 45 MG	30	Tablets	30	DAYS				
215375501001	Vonjo	pacritinib citrate cap	100 MG	120	Capsules	30	DAYS				
21533042100320	Votrient	Pazopanib HCl Tab	200 MG	120	Tablets	30	DAYS				
21421020000320	Welireg	Belzutifan Tab	40 MG	90	Tablets	30	DAYS				
215305170001	Xalkori	crizotinib cap	200 MG; 250 MG	120	Capsules	30	DAYS				
21530517006820	Xalkori	crizotinib cap sprinkle	20 MG	120	Capsules	30	DAYS				
21530517006830	Xalkori	crizotinib cap sprinkle	50 MG	120	Capsules	30	DAYS				
21530517006850	Xalkori	crizotinib cap sprinkle	150 MG	180	Capsules	30	DAYS				
21533020200320	Xospata	Gilteritinib Fumarate Tablet	40 MG	90	Tablets	30	DAYS				
2156006000B760	Xpovio	Selinexor Tab Therapy Pack	40 MG	4	Tablets	28	DAYS				
2156006000B765	Xpovio	Selinexor Tab Therapy Pack	40 MG	8	Tablets	28	DAYS				
2156006000B770	Xpovio	Selinexor Tab Therapy Pack	40 MG	8	Tablets	28	DAYS				
2156006000B775	Xpovio	Selinexor Tab Therapy Pack	50 MG	8	Tablets	28	DAYS				
2156006000B780	Xpovio	Selinexor Tab Therapy Pack	60 MG	4	Tablets	28	DAYS				
2156006000B755	Xpovio 60 mg twice weekly	Selinexor Tab Therapy Pack 20 MG (60 MG Twice Weekly)	20 MG	24	Tablets	28	DAYS				
2156006000B720	Xpovio 80 mg twice weekly	Selinexor Tab Therapy Pack 20 MG (80 MG Twice Weekly)	20 MG	32	Tablets	28	DAYS				
214024300001	Xtandi	enzalutamide cap	40 MG	120	Capsules	30	DAYS				
21402430000320	Xtandi	Enzalutamide Tab	40 MG	120	Tablets	30	DAYS				
21402430000340	Xtandi	Enzalutamide Tab	80 MG	60	Tablets	30	DAYS				
21406010250310	Yonsa	abiraterone acetate tab 125 mg	125 MG	120	Tablets	30	DAYS				
215355502001	Zejula	niraparib tosylate cap	100 MG	90	Capsules	30	DAYS				
215355502003	Zejula	niraparib tosylate tab	100 MG; 200 MG; 300 MG	30	Tablets	30	DAYS				
21532080000320	Zelboraf	Vemurafenib Tab ; vemurafenib tab	240 MG	240	Tablets	30	DAYS				
21531575000120	Zolinza	Vorinostat Cap 100 MG	100 MG	120	Capsules	30	DAYS				
215380400003	Zydelig	idelalisib tab	100 MG;	60	Tablets	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
			150 MG								
215305140003	Zykadia	ceritinib tab	150 MG	90	Tablets	30	DAYS				
21406010200320	Zytiga	Abiraterone Acetate Tab 250 MG	250 MG	120	Tablets	30	DAYS				
21406010200330	Zytiga	Abiraterone Acetate Tab 500 MG	500 MG	60	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA QL	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. Information has been provided that indicates the patient is currently being treated with the requested agent within the past 180 days **OR** B. The prescriber states the patient is being treated with the requested agent within the past 180 days AND is at risk if therapy is changed **OR** C. ALL of the following: 1. ONE of the following: A. The patient has an FDA approved indication for the requested agent **OR** B. The patient has an indication that is supported by compendia (NCCN Compendium level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) [i.e., this indication must be supported by ALL requirements in the compendia (e.g., performance status, disease severity, previous failures, monotherapy vs combination therapy, etc.)] for the requested agent **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. ONE of the following: A. The requested indication does NOT require specific genetic/diagnostic testing per FDA labeling or compendia (NCCN Compendium level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested agent **OR** B. The requested indication requires genetic/specific diagnostic testing per FDA labeling or compendia (NCCN Compendium level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested agent AND BOTH of the following: 1. Genetic/specific diagnostic testing has been completed **AND** 2. The results of the genetic/specific diagnostic testing indicate therapy with the requested agent is appropriate **AND** 4. ONE of the following: A. The requested agent is being used as monotherapy AND is approved for use as monotherapy in the FDA labeling or supported by compendia (NCCN Compendium level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the

Module	Clinical Criteria for Approval
	requested indication **OR** B. The requested agent will be used as combination therapy with all agent(s) and/or treatments (e.g., radiation) listed for concomitant use in the FDA labeling or compendia (NCCN Compendium level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested indication **AND** 5. ONE of the following: A. The requested agent will be used as a first-line agent AND is FDA labeled or supported by compendia (NCCN Compendium level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) as a first-line agent for the requested indication **OR** B. The patient has tried and had an inadequate response to the appropriate number and type(s) of prerequisite agent(s) listed in FDA labeling or compendia (NCCN Compendium level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested indication **OR** C. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to the appropriate number and type(s) of prerequisite agent(s) listed in the FDA labeling or compendia (NCCN Compendium level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested indication **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that the appropriate prerequisite agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient does not have any FDA labeled contraindications to the requested agent **AND** 3. The patient does not have any FDA labeled limitation(s) of use that is otherwise not supported in NCCN to the requested agent **Length of Approval:** Up to 3 months for dose titration requests and Vitrakvi; Up to 12 months for all other requests, approve starter packs and loading doses where appropriate and maintenance dose for the remainder of the authorization NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. ONE of the following: A. The requested agent is Vitrakvi AND the patient has experienced clinical benefit (i.e., partial response, complete response, or stable disease) with the requested agent **OR**

Module	Clinical Criteria for Approval
	B. The requested agent is NOT Vitrakvi **AND** 3. The patient does not have any FDA labeled contraindications to the requested agent **AND** 4. The patient does not have any FDA labeled limitation(s) of use that is otherwise not supported in NCCN to the requested agent **Length of Approval:** Up to 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. FDA Companion Diagnostics: https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: Up to 3 months for dose titration requests over the program quantity limit and Vitrakvi; Up to 12 months for all other requests, approve starter packs/loading doses where appropriate and maintenance doses for the remainder of the authorization

• Program Summary: Sodium-glucose Co-transporter (SGLT) Inhibitors and Combinations

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☑ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
27700010000320	Brenzavvy	bexagliflozin tab	20 MG	30	Tablets	30	DAYS			
277000402003	Farxiga	dapagliflozin propanediol tab	10 MG; 5 MG	30	Tablets	30	DAYS			
279965023003	Glyxambi	empagliflozin-linagliptin tab	10-5 MG; 25-5 MG	30	Tablets	30	DAYS			
40750010000320	Inpefa	sotagliflozin tab	200 MG	30	Tablets	30	DAYS			
40750010000340	Inpefa	sotagliflozin tab	400 MG	30	Tablets	30	DAYS			
279960022003	Invokamet	canagliflozin-metformin hcl tab	150-1000 MG; 150-500 MG; 50-1000 MG; 50-500 MG	60	Tablets	30	DAYS			
279960022075	Invokamet xr	canagliflozin-metformin hcl tab er	150-1000 MG; 150-500 MG; 50-1000 MG; 50-500 MG	60	Tablets	30	DAYS			
277000200003	Invokana	canagliflozin tab	100 MG; 300 MG	30	Tablets	30	DAYS			
277000500003	Jardiance	empagliflozin tab	10 MG; 25 MG	30	Tablets	30	DAYS			
27996502200330	Qtern	Dapagliflozin-Saxagliptin Tab 10-5 MG	10-5 MG	30	Tablets	30	DAYS			
27996502200320	Qtern	Dapagliflozin-Saxagliptin Tab 5-5 MG	5-5 MG	30	Tablets	30	DAYS			
27996002450320	Segluromet	Ertugliflozin-Metformin HCl Tab 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS			
27996002450310	Segluromet	Ertugliflozin-Metformin HCl Tab 2.5-500 MG	2.5-500 MG	120	Tablets	30	DAYS			
27996002450340	Segluromet	Ertugliflozin-Metformin HCl Tab 7.5-1000 MG	7.5-1000 MG	60	Tablets	30	DAYS			
27996002450330	Segluromet	Ertugliflozin-Metformin HCl Tab 7.5-500 MG	7.5-500 MG	60	Tablets	30	DAYS			
27700055200340	Steglatro	Ertugliflozin L-Pyroglutamic Acid Tab 15 MG (Base Equiv)	15 MG	30	Tablets	30	DAYS			
27700055200320	Steglatro	Ertugliflozin L-Pyroglutamic Acid	5 MG	60	Tablets	30	DAYS			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		Tab 5 MG (Base Equiv)								
27996502350330	Steglujan	Ertugliflozin-Sitagliptin Tab 15-100 MG	15-100 MG	30	Tablets	30	DAYS			
27996502350320	Steglujan	Ertugliflozin-Sitagliptin Tab 5-100 MG	5-100 MG	30	Tablets	30	DAYS			
279960024003	Synjardy	empagliflozin-metformin hcl tab	12.5-1000 MG; 12.5-500 MG; 5-1000 MG; 5-500 MG	60	Tablets	30	DAYS			
27996002407540	Synjardy xr	Empagliflozin-Metformin HCl Tab ER 24HR 10-1000 MG	10-1000 MG	60	Tablets	30	DAYS			
27996002407550	Synjardy xr	Empagliflozin-Metformin HCl Tab ER 24HR 12.5-1000 MG	12.5-1000 MG	60	Tablets	30	DAYS			
27996002407560	Synjardy xr	Empagliflozin-Metformin HCl Tab ER 24HR 25-1000 MG	25-1000 MG	30	Tablets	30	DAYS			
27996002407530	Synjardy xr	Empagliflozin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	60	Tablets	30	DAYS			
27996703407530	Trijardy xr	Empagliflozin-Linaglip-Metformin Tab ER 24HR 12.5-2.5-1000MG	12.5-2.5-1000 MG	60	Tablets	30	DAYS			
27996703407520	Trijardy xr	Empagliflozin-Linagliptin-Metformin Tab ER 24HR 10-5-1000 MG	10-5-1000 MG	30	Tablets	30	DAYS			
27996703407540	Trijardy xr	Empagliflozin-Linagliptin-Metformin Tab ER 24HR 25-5-1000 MG	25-5-1000 MG	30	Tablets	30	DAYS			
27996703407510	Trijardy xr	Empagliflozin-Linagliptin-Metformin Tab ER 24HR 5-2.5-1000MG	5-2.5-1000 MG	60	Tablets	30	DAYS			
27996002307525	Xigduo xr	Dapagliflozin-Metformin HCl Tab ER 24HR 10-1000 MG	10-1000 MG	30	Tablets	30	DAYS			
27996002307520	Xigduo xr	Dapagliflozin-Metformin HCl Tab ER 24HR 10-500 MG	10-500 MG	30	Tablets	30	DAYS			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
27996002307507	Xigduo xr	Dapagliflozin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS			
27996002307515	Xigduo xr	Dapagliflozin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	60	Tablets	30	DAYS			
27996002307510	Xigduo xr	Dapagliflozin-Metformin HCl Tab ER 24HR 5-500 MG	5-500 MG	30	Tablets	30	DAYS			

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
2-Step Edit: All Other Target Agents	**Target Agent(s)** **Brenzavvy** (bexagliflozin) **Invokana** (canagliflozin) **Invokamet** (canagliflozin/metformin) **Invokamet XR** (canagliflozin/metformin ER) **Inpefa** (sotagliflozin) **Segluromet** (ertugliflozin/metformin) **Steglatro** (ertugliflozin) **All Other Target Agent(s)** will be approved when BOTH of the following are met: 1. ONE of the following: A. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** B. The patient's medication history includes use of an agent containing dapagliflozin **OR** C. BOTH of the following: 1. The prescriber has stated that the patient has tried an agent containing dapagliflozin **AND** 2. The agent containing dapagliflozin was discontinued due to lack of effectiveness or an adverse event **OR** D. The patient has an intolerance or hypersensitivity to dapagliflozin **OR** E. The patient has an FDA labeled contraindication to dapagliflozin **OR** F. The prescriber has provided documentation that dapagliflozin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. ONE of the following: A. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** B. The patient's medication history includes use of an agent containing empagliflozin **OR** C. BOTH of the following: 1. The prescriber has stated that the patient has tried empagliflozin **AND** 2. Empagliflozin was discontinued due to lack of effectiveness or an adverse event **OR**

Module	Clinical Criteria for Approval
	D. The patient has an intolerance or hypersensitivity to empagliflozin **OR** E. The patient has an FDA labeled contraindication to empagliflozin **OR** F. The prescriber has provided documentation that empagliflozin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
2-Step Edit: Qtern, Steglujan	**Target Agent(s)** **Qtern** (dapagliflozin/saxagliptin) **Steglujan** (ertugliflozin/sitagliptin) **Target Agent(s)-Qtern, Steglujan** will be approved when ONE of the following is met: 1. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. The patient's medication history includes use of Glyxambi or Trijardy XR **OR** 3. BOTH of the following: A. The prescriber has stated that the patient has tried Glyxambi or Trijardy XR **AND** B. Glyxambi or Trijardy XR was discontinued due to lack of effectiveness or an adverse event **OR** 4. The patient has an intolerance or hypersensitivity to BOTH Glyxambi and Trijardy XR **OR** 5. The patient has an FDA labeled contraindication to BOTH Glyxambi and Trijardy XR **OR** 6. The prescriber has provided documentation that BOTH Glyxambi and Trijardy XR cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support why the requested quantity (dose)

Module	Clinical Criteria for Approval
	cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

● Program Summary: Statin

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☑ Step Therapy ☐ Coverage / Formulary Exception

Statin Step Therapy

TARGET AGENT(S)	PREREQUISITE AGENT(S)
Altoprev® (lovastatin extended release) **Atorvaliq®** (atorvastatin suspension) **Crestor®** (rosuvastatin)[a] **Ezetimibe/atorvastatin** **Ezetimibe/rosuvastatin** **Ezallor™ Sprinkle** (rosuvastatin) **Flolipid™** (simvastatin oral suspension) **Lescol XL®** (fluvastatin extended release)[a] **Lipitor®** (atorvastatin)[a] **Livalo®** (pitavastatin)[a] **Pravachol®** (pravastatin)[a] **Roszet™** (ezetimibe/rosuvastatin) **Simvastatin oral suspension 20 mg/5ml** **Vytorin®** (ezetimibe/simvastatin)[a] **Zocor®** (simvastatin)[a] **Zypitamag** (pitavastatin)	Any generic statin or stain combination

a - available as a generic

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Target Agent will be approved when ONE of the following is met:

1. The patient's medication history includes use of ONE prerequisite agent
   OR
2. The patient has an intolerance or hypersensitivity to a prerequisite agent
   OR
3. The patient has an FDA labeled contraindication to ALL prerequisite agents
   OR
4. BOTH of the following:
   A. The prescriber has stated that the patient has tried ONE prerequisite agent
      AND
   B. The prerequisite agent was discontinued due to lack of effectiveness or an adverse event
   OR
5. The patient is currently being treated with the requested agent as indicated by ALL of the following:
   A. A statement by the prescriber that the patient is currently taking the requested agent
      AND

B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
AND
C. The prescriber states that a change in therapy is expected to be ineffective or cause harm

OR

6. The prescriber has provided documentation that ALL prerequisite agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

Length of Approval: 12 months

NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria.

• Program Summary: Substrate Reduction Therapy

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
82700040600120	Cerdelga	Eliglustat Tartrate Cap 84 MG (Base Equivalent)	84 MG	60	Capsules	30	DAYS			
30907760000120	Opfolda	miglustat (gaa deficiency) cap	65 MG	8	Capsules	28	DAYS			
82700070000120	Yargesa; Zavesca	Miglustat Cap 100 MG	100 MG	90	Capsules	30	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Cerdelga, Zavesca	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of Gaucher disease type 1 (GD1) **AND** 2. If the patient has an FDA approved indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient does NOT have any neuronopathic symptoms indicative of Gaucher disease type 2 or type 3 [e.g., bulbar signs (e.g., stridor, strabismus, swallowing difficulty), pyramidal signs (e.g., opisthotonos, head retroflexion, spasticity, trismus), oculomotor apraxia, tonic-clonic seizures, myoclonic epilepsy, dementia, ataxia] **AND** 4. ONE of the following: A. The patient has baseline (prior to therapy for the requested indication) glucocerebrosidase enzyme activity of less than or equal to 15% of mean normal in fibroblasts, leukocytes, or other nucleated cells **OR** B. Genetic analysis confirmed two (2) pathogenic alleles in the glucocerebrosidase (*GBA*) gene **AND** 5. The prescriber has assessed baseline (prior to therapy for the requested indication) status of hemoglobin level, platelet count, liver volume, and spleen volume **AND** 6. The patient has at least ONE of the following clinical presentations at baseline (prior to therapy for the requested indication):

Module	Clinical Criteria for Approval

A. Anemia defined as mean hemoglobin (Hb) level below the testing laboratory's lower limit of the normal range based on age and gender **OR**
B. Thrombocytopenia (platelet count less than 100,000/microliter on at least 2 measurements) **OR**
C. Hepatomegaly **OR**
D. Splenomegaly **OR**
E. Growth failure (i.e., growth velocity is below the standard mean for age) **OR**
F. Evidence of bone disease with other causes ruled out **AND**

7. If the requested agent is Cerdelga or eliglustat, the patient is a CYP2D6 extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM), as detected by an FDA-cleared test for determining CYP2D6 genotype **AND**
8. If the requested agent is Zavesca or miglustat, enzyme replacement therapy (ERT) is NOT a therapeutic option (e.g., due to allergy, hypersensitivity, poor venous access, previous ERT failure) **AND**
9. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following:
   A. The patient's medication history includes use of the generic equivalent **OR**
   B. BOTH of the following:
      1. The prescriber has stated that the patient has tried the generic equivalent **AND**
      2. The generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**
   C. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**
   D. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR**
   E. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent **OR**

Brand	Generic Equivalent
Zavesca	miglustat

   F. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
      2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
      3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
   G. The prescriber has provided documentation that the generic equivalent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
10. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
11. The patient will NOT be using the requested agent in combination with another substrate reduction therapy agent (e.g., Cerdelga, Zavesca) for the requested indication **AND**
12. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 12 months

NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

Renewal Evaluation

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td></td><td>
Target Agent(s) will be approved when ALL of the following are met:
1. The patient has been previously approved for the requested agent through the plan’s Prior Authorization process AND
2. The patient has had improvements or stabilization with the requested agent as indicated by ONE of the following:
A. Spleen volume OR
B. Hemoglobin level OR
C. Liver volume OR
D. Platelet count (sufficient to decrease the risk of bleeding) OR
E. Growth OR
F. Bone pain or crisis AND
3. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following:
A. The patient's medication history includes use of the generic equivalent OR
B. BOTH of the following:
1. The prescriber has stated that the patient has tried the generic equivalent AND
2. The generic equivalent was discontinued due to lack of effectiveness or an adverse event OR
C. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent OR
D. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent OR
E. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent OR
<table>
<tr><th>Brand</th><th>Generic Equivalent</th></tr>
<tr><td>Zavesca</td><td>miglustat</td></tr>
</table>
F. The patient is currently being treated with the requested agent as indicated by ALL of the following:
1. A statement by the prescriber that the patient is currently taking the requested agent AND
2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent AND
3. The prescriber states that a change in therapy is expected to be ineffective or cause harm OR
G. The prescriber has provided documentation that the generic equivalent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm AND
4. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., endocrinologist, geneticist) or the prescriber has consulted with a specialist in the area of patient’s diagnosis AND
5. The patient will NOT be using the requested agent in combination with another substrate reduction therapy agent (e.g., Cerdelga, Zavesca) for the requested indication AND
6. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 12 months

NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
</td></tr>
<tr><td>Opfolda</td><td>Initial Evaluation

Opfolda will be approved when ALL of the following are met:</td></tr>
</table>

Module	Clinical Criteria for Approval
	1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: 1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** **Agents Eligible for Continuation of Therapy** Opfolda B. The patient has a diagnosis of late-onset Pompe disease (acid maltase deficiency [AMD]; glycogen storage disease type II [GSDII]) confirmed by at least ONE of the following: 1. Genetic analysis confirms biallelic mutation (two pathogenic variants) in the *GAA* gene **OR** 2. The patient has deficient acid alpha-glucosidase glycogen enzyme activity in dried blood spots, leukocytes, skin fibroblasts, and/or skeletal muscle tissue **AND** 2. The patient is not improving on their current enzyme replacement therapy (ERT) **AND** 3. The requested agent will be taken in combination with Pombiliti **AND** 4. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 5. The prescriber has assessed current status of the following: gross motor function (e.g., walking distance), pulmonary function (e.g., forced vital capacity [FVC]) **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval**: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria. **Renewal Evaluation** **Opfolda** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had improvements or stabilization with the requested agent as indicated by ONE of the following: A. Gross motor function (e.g., walking distance) **OR** B. Pulmonary function (e.g., forced vital capacity [FVC]) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval**: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: 12 months

• Program Summary: Sunosi (solriamfetol)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
61370070200340	Sunosi	Solriamfetol HCl Tab 150 MG (Base Equiv)	150 MG	30	Tablets	30	DAYS			
61370070200320	Sunosi	Solriamfetol HCl Tab 75 MG (Base Equiv)	75 MG	30	Tablets	30	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of excessive daytime sleepiness associated with obstructive sleep apnea (OSA) AND ALL of the following: 1. The underlying airway obstruction has been treated (e.g., continuous positive airway pressure [CPAP]) for at least 1-month prior to initiating therapy with the requested agent **AND** 2. The modalities to treat the underlying airway obstruction (e.g., continuous positive airway pressure [CPAP]) will be continued during treatment with the requested agent **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to armodafinil OR modafinil **OR** B. The patient has an intolerance or hypersensitivity to armodafinil OR

Module	Clinical Criteria for Approval
	modafinil **OR** C. The patient has an FDA labeled contraindication to BOTH armodafinil AND modafinil **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that BOTH armodafinil AND modafinil cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has a diagnosis of excessive daytime sleepiness associated with narcolepsy AND ONE of the following: 1. The patient has tried and had an inadequate response to armodafinil OR modafinil **OR** 2. The patient has an intolerance or hypersensitivity to armodafinil OR modafinil **OR** 3. The patient has an FDA labeled contraindication to BOTH armodafinil AND modafinil **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that BOTH armodafinil AND modafinil cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient will NOT be using the requested agent in combination with armodafinil OR modafinil for the requested indication **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, psychiatrist, pulmonologist, sleep disorder specialist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND**

Module	Clinical Criteria for Approval
	2. The patient has had clinical benefit with the requested agent **AND** 3. If the diagnosis is excessive daytime sleepiness associated with obstructive sleep apnea (OSA), the modalities to treat the underlying airway obstruction (e.g., continuous positive airway pressure [CPAP]) will be continued during treatment with the requested agent **AND** 4. The patient will NOT be using the requested agent in combination with armodafinil OR modafinil for the requested indication **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, psychiatrist, pulmonologist, sleep disorder specialist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose (for the requested indication) **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **Length of Approval:** 12 months

● Program Summary: Tezspire (tezepelumab-ekko)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
4460807525D520	Tezspire	tezepelumab-ekko subcutaneous soln auto-inj	210 MG/1.91 ML	1	Pen	28	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy

Module	Clinical Criteria for Approval
	1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. BOTH of the following: 1. The patient has a diagnosis of severe asthma **AND** 2. The patient has a history of uncontrolled asthma while on asthma control therapy as demonstrated by ONE of the following: A. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months **OR** B. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months **OR** C. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered **OR** D. The patient has baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted **OR** C. The patient has another FDA approved indication for the requested agent and route of administration **OR** D. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has a diagnosis of severe asthma, then ALL of the following: A. ONE of the following: 1. The patient is NOT currently being treated with the requested agent AND is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months **OR** 2. The patient is currently being treated with the requested agent AND ONE of the following: A. Is currently treated with an inhaled corticosteroid for at least 3 months that is adequately dosed to control symptoms **OR** B. Is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months **OR** 3. The patient has an intolerance or hypersensitivity to inhaled corticosteroid therapy **OR** 4. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids **AND** B. ONE of the following: 1. The patient is currently being treated for at least 3 months with ONE of the following: A. A long-acting beta-2 agonist (LABA) **OR** B. Long-acting muscarinic antagonist (LAMA) **OR** C. A leukotriene receptor antagonist (LTRA) **OR** D. Theophylline **OR** 2. The patient has an intolerance or hypersensitivity to therapy with long-acting beta-2 agonists (LABA), long-acting muscarinic antagonists (LAMA), leukotriene receptor antagonist (LTRA), or theophylline **OR** 3. The patient has an FDA labeled contraindication to ALL long-acting beta-2 agonists (LABA) AND long-acting muscarinic antagonists (LAMA) **OR** 4. The patient is currently treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL LABA and LAMA therapies cannot

Module	Clinical Criteria for Approval
	be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** C. The patient will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **AND** 3. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. ONE of the following: A. The patient has a diagnosis of severe asthma AND BOTH of the following: 1. The patient has had improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following: A. The patient has had an increase in percent predicted Forced Expiratory Volume (FEV1) **OR** B. The patient has had a decrease in the dose of inhaled corticosteroids required to control the patient's asthma **OR** C. The patient has had a decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma **OR** D. The patient has had a decrease in number of hospitalizations, need for mechanical ventilation, or visits to urgent care or emergency room due to exacerbations of asthma **AND** 2. The patient is currently treated and is compliant with asthma control therapy [e.g., inhaled corticosteroids, ICS/long-acting beta-2 agonist (ICS/LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), theophylline] **OR** B. The patient has another FDA approved indication for the requested agent and route of

Module	Clinical Criteria for Approval
	administration AND has had clinical benefit with the requested agent **OR** C. The patient has another indication that is supported in compendia for the requested agent and route of administration AND has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 5. The patient does NOT have an FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Evaluation **Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of approval:** Initial - 6 months; Renewal - 12 months

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly
Abrilada (adalimumab-afzb)
Actemra (tocilizumab)

Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)
Cibinqo (abrocitinib)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Litfulo (ritlecitinib)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)

Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tysabri (natalizumab)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)
Zymfentra (infliximab-dyyb)

• Program Summary: Topical Corticosteroids

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☑ Step Therapy ☐ Coverage / Formulary Exception

TARGET AGENT(S)
Super-high potency (group 1)
Betamethasone dipropionate augmented gel
Clobex® 0.05% (clobetasol propionate) lotion[a]
Clobex® 0.05% (clobetasol propionate) shampoo[a]
Clobex® 0.05% (clobetasol propionate) spray[a]
Cordran® 4 mcg/cm^2 (flurandrenolide) tape
Diprolene® 0.05% (betamethasone dipropionate augmented) ointment[a]
Halobetasol propionate 0.05% foam
Impeklo™ 0.05% (clobetasol propionate) lotion
Lexette™ 0.05% (halobetasol propionate) foam[a]
Olux® 0.05% (clobetasol propionate) foam[a]
Olux-E® 0.05% (clobetasol propionate) emulsion foam[a]
Temovate®0.05% (clobetasol propionate) cream[a]
Temovate®0.05% (clobetasol propionate) ointment[a]
Ultravate® 0.05% (halobetasol propionate) lotion
Vanos® 0.1% (fluocinonide) cream[a]

High potency (group 2)
Amcinonide 0.1% ointment
ApexiCon® E 0.05% (diflorasone diacetate) emollient cream
Bryhali™ 0.01% (halobetasol propionate) lotion
Diprolene® AF 0.05% (betamethasone dipropionate) cream[a]
Halog® 0.1% (halcinonide) cream[a]
Halog® 0.1% (halcinonide) ointment
Halog® 0.1% (halcinonide) solution
Impoyz™ 0.025% (clobetasol propionate) cream
Topicort® 0.05% (desoximetasone) gel[a]
Topicort® 0.25% (desoximetasone) cream[a]
Topicort® 0.25% (desoximetasone) ointment[a]

Topicort® 0.25% (desoximetasone) spray[a]

Mid-High potency (group 3)
Amcinonide 0.1% cream
Amcinonide 0.1% lotion
Diflorasone diacetate 0.05% cream
Luxiq® 0.12% (betamethasone valerate) foam[a]
Topicort® 0.05% (desoximetasone) cream[a]
Topicort® 0.05% (desoximetasone) ointment[a]

Medium potency (group 4)
Cloderm® 0.1% (clocortolone pivalate) cream[a]
Cordran® 0.05% (flurandrenolide) ointment[a]
Kenalog® 0.147 mg/gm (triamcinolone acetonide) spray[a]
Sernivo® 0.05% (betamethasone dipropionate) spray
Synalar® 0.025% (fluocinolone acetonide) ointment[a]

Lower-mid potency (group 5)
Cordran® 0.025% (flurandrenolide) cream
Cordran® 0.05% (flurandrenolide) cream[a]
Cordran® 0.05% (flurandrenolide) lotion[a]
Cutivate® 0.05% (fluticasone propionate) lotion
Desonate® 0.05% (desonide) gel[a]
Hydrocortisone butyrate 0.1% solution
Hydrocortisone butyrate 0.1% cream
Locoid® 0.1% (hydrocortisone butyrate) lotion[a]
Locoid® Lipocream 0.1% (hydrocortisone butyrate) cream
Pandel® 0.10% (hydrocortisone probutate) cream
Prednicarbate 0.1% ointment
Synalar® 0.025% (fluocinolone acetonide) cream[a]

Low potency (group 6)
Capex®® 0.01% (fluocinolone acetonide) shampoo
Derma-Smoothe® 0.01% (fluocinolone acetonide) body oil[a]
Derma-Smoothe® 0.01% (fluocinolone acetonide) scalp oil[a]
DesOwen® 0.05% (desonide) cream[a]
Synalar® 0.01% (fluocinolone acetonide) solution[a]
Tridesilon™ 0.05% (desonide) cream[a]
Verdeso® 0.05% (desonide) foam

Least potent (group 7)
Ala Scalp® 2% (hydrocortisone) lotion[a]
Texacort® 2.5% (hydrocortisone) solution
a – available as a generic; included as a prerequisite in the step therapy program

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Target Agent(s) will be approved when ONE of the following is met:
1. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    A. A statement by the prescriber that the patient is currently taking the requested agent
    AND
    B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
    AND

C. The prescriber states that a change in therapy is expected to be ineffective or cause harm

OR

2. The patient's medication history includes use of TWO generic topical corticosteroids within the same potency group as indicated by:
   A. Evidence of a paid claim(s)
      OR
   B. The prescriber has stated the patient has tried TWO generic topical corticosteroids within the same potency group AND the TWO generic topical corticosteroids were discontinued due to lack of effectiveness or an adverse event

OR

3. The patient has an intolerance or hypersensitivity to TWO generic topical corticosteroids within the same potency group

OR

4. The patient has an FDA labeled contraindication to ALL generic topical corticosteroids within the same potency group

OR

5. The prescriber has provided documentation that ALL generic topical corticosteroids within the same potency group cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

Length of Approval: 12 months

NOTE: If Quantity Limit applies, please refer to Quantity Limit document.

● Program Summary: Vascepa

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
39500035100110	Vascepa	Icosapent Ethyl Cap 0.5 GM	0.5 GM	240	Capsules	30	DAYS			10-01-2019
39500035100120	Vascepa	Icosapent Ethyl Cap 1 GM	1 GM	120	Capsules	30	DAYS			10-01-2019

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

PA

Target Agent(s)	Preferred Target Agent(s)
Target and preferred agents - to be determined by client	Target and preferred agents - to be determined by client
icosapent ethyl*	Vascepa

*generic available

Initial Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. ONE of the following:
   A. The patient has a pre-treatment triglyceride (TG) level of greater than or equal to 500 mg/dL **OR**
   B. The patient is using the requested agent to reduce the risk of myocardial infarction, stroke, coronary revascularization, or unstable angina requiring hospitalization AND ALL of the following:

Module	Clinical Criteria for Approval
	1. ONE of the following: A. The patient is on maximally tolerated statin therapy **OR** B. The patient has an intolerance or hypersensitivity to statin therapy **OR** C. The patient has an FDA labeled contraindication to ALL statins **AND** 2. The patient's triglyceride (TG) level is greater than or equal to 135 mg/dL **AND** 3. ONE of the following: A. The patient has established cardiovascular disease **OR** B. The patient has diabetes mellitus AND 2 or more additional risk factors for cardiovascular disease (e.g., hypertension, premature family history, chronic kidney disease) **OR** C. The patient has another FDA approved indication for the requested agent and route of administration **OR** D. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. If the client has preferred agent(s), then ONE of the following: A. The requested agent is a preferred agent **OR** B. The patient has an intolerance or hypersensitivity to the preferred agent(s) that is not expected to occur with the non-preferred agent **OR** C. The patient has an FDA labeled contraindication to the preferred agent(s) that is not expected to occur with the non-preferred agent **OR** D. The patient's medication history includes use of a preferred agent **OR** E. BOTH of the following: 1. The prescriber has stated that the patient has tried a preferred agent **AND** 2. The preferred agent was discontinued due to lack of effectiveness or an adverse event **OR** F. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** G. The prescriber has provided documentation that the preferred agent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met:

Module	Clinical Criteria for Approval
	1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. If the client has preferred agent(s), then ONE of the following: A. The requested agent is a preferred agent **OR** B. The patient has an intolerance or hypersensitivity to the preferred agent(s) that is not expected to occur with the non-preferred agent **OR** C. The patient has an FDA labeled contraindication to the preferred agent(s) that is not expected to occur with the non-preferred agent **OR** D. The patient's medication history includes use of a preferred agent **OR** E. BOTH of the following: 1. The prescriber has stated that the patient has tried a preferred agent **AND** 2. The preferred agent was discontinued due to lack of effectiveness or an adverse event **OR** F. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** G. The prescriber has provided documentation that the preferred agent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: 12 months

• Program Summary: Weight Loss Agents

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
61200010100305		Benzphetamine HCl Tab 25 MG	25 MG	90	Tablets	30	DAYS			
61200010100310		Benzphetamine HCl Tab 50 MG	50 MG	90	Tablets	30	DAYS			
61200020100305		Diethylpropion HCl Tab 25 MG	25 MG	90	Tablet	30	DAYS			
61200020107510		Diethylpropion HCl Tab ER 24HR 75 MG	75 MG	30	Tablets	30	DAYS			
61200050107010		Phendimetrazine Tartrate Cap ER 24HR 105 MG	105 MG	30	Capsules	30	DAYS			
61200050100305		Phendimetrazine Tartrate Tab 35 MG	35 MG	180	Tablets	30	DAYS			
61200070100110		Phentermine HCl Cap 15 MG	15 MG	30	Capsules	30	DAYS			
61200070100115		Phentermine HCl Cap 30 MG	30 MG	30	Capsules	30	DAYS			
61200070100120	Adipex-p	Phentermine HCl Cap 37.5 MG	37.5 MG	30	Capsules	30	DAYS			
61200070100310	Adipex-p	Phentermine HCl Tab 37.5 MG	37.5 MG	30	Tablets	30	DAYS			
61259902507420	Contrave	Naltrexone HCl-Bupropion HCl Tab ER 12HR 8-90 MG	8-90 MG	120	Tablets	30	DAYS			
61200070100305	Lomaira	Phentermine HCl Tab 8 MG	8 MG	90	Tablets	30	DAYS			
61209902307040	Qsymia	Phentermine HCl-Topiramate Cap ER 24HR 11.25-69 MG	11.25-69 MG	30	Capsules	30	DAYS			
61209902307050	Qsymia	Phentermine HCl-Topiramate Cap ER 24HR 15-92 MG	15-92 MG	30	Capsules	30	DAYS			
61209902307020	Qsymia	Phentermine HCl-Topiramate Cap ER 24HR 3.75-23 MG	3.75-23 MG	30	Capsules	30	DAYS			
61209902307030	Qsymia	Phentermine HCl-Topiramate Cap ER 24HR 7.5-46 MG	7.5-46 MG	30	Capsules	30	DAYS			
6125205000D220	Saxenda	Liraglutide (Weight Mngmt) Soln Pen-Inj 18 MG/3ML (6 MG/ML)	18 MG/3ML	15	mLs	30	DAYS			
6125207000D520	Wegovy	Semaglutide (Weight	0.25	8	Pens	180	DAYS			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		Mngmt) Soln Auto-Injector	MG/0.5 ML							
6125207000D525	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	0.5 MG/0.5 ML	8	Pens	180	DAYS			
6125207000D530	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	1 MG/0.5 ML	8	Pens	180	DAYS			
6125207000D535	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	1.7 MG/0.75 ML	4	Pens	28	DAYS			
6125207000D540	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	2.4 MG/0.75 ML	4	Pens	28	DAYS			
61253560000120	Xenical	Orlistat Cap 120 MG	120 MG	90	Capsules	30	DAYS			
6125258000D520	Zepbound	tirzepatide (weight mngmt) soln auto-injector	2.5 MG/0.5 ML	4	Pens	180	DAYS			
6125258000D525	Zepbound	tirzepatide (weight mngmt) soln auto-injector	5 MG/0.5 ML	4	Pens	28	DAYS			
6125258000D530	Zepbound	tirzepatide (weight mngmt) soln auto-injector	7.5 MG/0.5 ML	4	Pens	28	DAYS			
6125258000D535	Zepbound	tirzepatide (weight mngmt) soln auto-injector	10 MG/0.5 ML	4	Pens	28	DAYS			
6125258000D540	Zepbound	tirzepatide (weight mngmt) soln auto-injector	12.5 MG/0.5 ML	4	Pens	28	DAYS			
6125258000D545	Zepbound	tirzepatide (weight mngmt) soln auto-injector	15 MG/0.5 ML	4	Pens	28	DAYS			

ADDITIONAL QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
6125207000D520	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	0.25 MG/0.5ML	* - This strength is not approvable for maintenance dosing			
6125207000D525	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	0.5 MG/0.5ML	* - This strength is not approvable for maintenance dosing			
6125207000D530	Wegovy	Semaglutide (Weight	1 MG/0.5ML	* - This strength is not approvable for maintenance dosing			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		Mngmt) Soln Auto-Injector					
6125258000D520	Zepbound	tirzepatide (weight mngmt) soln auto-injector	2.5 MG/0.5ML	* - This strength is not approvable for maintenance dosing			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation (Patient new to therapy, new to Prime, or attempting a repeat weight loss course of therapy) **Target Agent(s)** will be approved when ALL the following are met: 1. ONE of the following: A. The patient is 17 years of age or over and ALL of the following: 1. ONE of the following: A. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 30 kg/m^2 OR a BMI greater than or equal to 25 kg/m^2 if the patient is of South Asian, Southeast Asian, or East Asian descent **OR** B. The patient has a BMI greater than or equal to 27 kg/m^2 with at least one weight-related comorbidity/risk factor/complication (e.g., diabetes, dyslipidemia, coronary artery disease) **AND** 2. The patient has been on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications for a minimum of 6 months prior to initiating therapy with the requested agent **AND** 3. The patient did not achieve a weight loss of 1 pound or more per week while on the weight loss regimen prior to initiating therapy with the requested agent **AND** 4. The patient is currently on and will continue a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **OR** B. The patient is 12 to 16 years of age and ALL of the following: 1. ONE of the following: A. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 95th percentile for age and gender **OR** B. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 30 kg/m^2 **OR** C. The patient has a BMI greater than or equal to 85th percentile for age and gender AND at least one severe weight-related comorbidity/risk factor/complication **AND** 2. The patient has been on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications for a minimum of 6 months prior to initiating therapy with the requested agent **AND** 3. The patient did not achieve a weight loss of 1 pound or more per week while on the weight loss regimen prior to initiating therapy with the requested agent **AND** 4. The patient is currently on and will continue a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **AND** 2. If the patient has an FDA approved indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**

Module	Clinical Criteria for Approval
	3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication **AND** 5. ONE of the following: A. The patient has not tried a targeted weight loss agent in the past 12 months **OR** B. The patient has tried a targeted weight loss agent for a previous course of therapy in the past 12 months AND the prescriber anticipates success with repeating therapy **AND** 6. ONE of the following: A. The requested agent is benzphetamine, diethylpropion, phendimetrazine, phentermine, or Zepbound **OR** B. The requested agent is Qsymia and ONE of the following: 1. The requested dose is 3.75mg/23mg **OR** 2. The patient is currently being treated with Qsymia, the requested dose is greater than 3.75 mg/23 mg AND ONE of the following: A. ONE of the following: 1. For adults, the patient has demonstrated and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of the requested agent) **OR** 2. For pediatric patients aged 12 years and older, the patient has experienced a reduction of at least 5% of baseline BMI (prior to initiation of the requested agent) **OR** B. The patient received less than 14 weeks of therapy **OR** C. The patient's dose is being titrated upward **OR** D. The patient has received less than 12 weeks (3 months) of therapy on the 15mg/92mg strength **OR** 3. The prescriber has provided information in support of therapy for the requested dose for this patient **OR** C. The requested agent is Contrave and ONE of the following 1. The patient is newly starting therapy **OR** 2. The patient is currently being treated and has received less than 16 weeks (4 months) of therapy **OR** 3. The patient has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of requested agent) **OR** D. The requested agent is Xenical (orlistat) and ONE of the following: 1. The patient is 12 to 16 years of age and ONE of the following: A. The patient is newly starting therapy **OR** B. The patient is currently being treated and has received less than 12 weeks (3 months) of therapy **OR** C. The patient has achieved and maintained a weight loss of greater than 4% from baseline (prior to initiation of requested agent) **OR** 2. The patient is 17 years of age or over and ONE of the following: A. The patient is newly starting therapy **OR** B. The patient is currently being treated and has received less than 12 weeks (3 months) of therapy **OR** C. The patient has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of requested agent) **OR** E. The requested agent is Saxenda and ALL of the following: 1. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND** 2. ONE of the following: A. The patient is 18 years of age or over and ONE of the following: 1. The patient is newly starting therapy **OR**

Module	Clinical Criteria for Approval
	2. The patient is currently being treated and has received less than 16 weeks (4 months) of therapy **OR** 3. The patient has achieved and maintained a weight loss of greater than or equal to 4% from baseline (prior to initiation of requested agent) **OR** B. The patient is pediatric (12 to less than 18 years of age) and BOTH of the following: 1. The requested agent is NOT being used to treat type 2 diabetes **AND** 2. ONE of the following: A. The patient is newly starting therapy **OR** B. The patient is currently being treated and has received less than 20 weeks (5 months) of therapy **OR** C. The patient has achieved and maintained a reduction in BMI of greater than or equal to 1% from baseline (prior to initiation of requested agent) **OR** F. The requested agent is Wegovy and ALL of the following: 1. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND** 2. The patient does NOT have a history of pancreatitis **AND** 3. ONE of the following: A. The patient is newly starting therapy **OR** B. The patient is currently being treated and has received less than 52 weeks (1 year) of therapy **OR** C. ONE of the following: 1. The patient is an adult AND has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of the requested agent) **OR** 2. The patient is pediatric (12 to less than 18 years of age) AND has achieved and maintained a reduction in BMI of at least 5% from baseline (prior to initiation of the requested agent) **Length of Approval:** • For Wegovy, Zepbound: 12 months • For Saxenda pediatric patients (age 12 to less than 18): 5 months • For Saxenda (adults) and Contrave: 4 months • For all other agents: 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** (Patient continuing a current weight loss course of therapy) **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient is currently on and will continue to be on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. For Saxenda only, BOTH of the following: A. The requested agent is NOT being used to treat type 2 diabetes in pediatric patients (12 to less than 18 years of age) **AND** B. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND**

Module	Clinical Criteria for Approval
	5. For Wegovy only, ALL of the following: A. The requested dose is 1.7 mg or 2.4 mg **AND** B. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND** C. The patient does NOT have a history of pancreatitis **AND** 6. The patient meets ONE of the following: A. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of requested agent) **OR** B. For Saxenda only, ONE of the following: 1. If the patient is 18 years of age or over, the patient has achieved and maintained a weight loss greater than or equal to 4% from baseline (prior to initiation of requested agent) **OR** 2. If the patient is pediatric (12 to less than 18 years of age), the patient has achieved and maintained a reduction in BMI of greater than or equal to 1% from baseline (prior to initiation of requested agent) **OR** C. For Qsymia only, ONE of the following: 1. For pediatric patients aged 12 years and older, the patient has achieved and maintained a reduction of at least 5% of baseline (prior to initiation of the requested agent) BMI **OR** 2. The patient has achieved and maintained a weight loss less than 5% from baseline (prior to initiation of requested agent) for adults, or a reduction in BMI less than 5% from baseline (prior to initiation of the requested agent) for pediatric patients aged 12 years or older, AND BOTH of the following: A. The patient's dose is being titrated upward (for the 3.75 mg/23 mg, 7.5 mg/46 mg or 11.25 mg/69 mg strengths only) **AND** B. The patient has received less than 12 weeks of therapy on the 15mg/92mg strength **OR** D. For Xenical (orlistat) only, ONE of the following: 1. The patient 12 to 16 years of age AND has achieved and maintained a weight loss greater than 4% from baseline (prior to initiation of requested agent) **OR** 2. The patient is 17 years of age or over AND has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of requested agent) **OR** E. For Wegovy only, ONE of the following: 1. The patient is 12 years of age and over AND has received less than 52 weeks of therapy on the maximum-tolerated dose (1.7 mg or 2.4 mg) **OR** 2. The patient is pediatric (12 to less than 18 years of age) **AND** has achieved and maintained a reduction in BMI of at least 5% from baseline (prior to initiation of the requested agent) **AND** 7. If the patient is 12 to less than 18 years of age, the current BMI is greater than 85th percentile for age and gender **AND** 8. The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication **Length of Approval:** • Qsymia: greater than or equal to 5% weight loss from baseline (adults); greater than or equal to 5% reduction in BMI from baseline (pediatrics): 12 months • Qsymia less than 5% weight loss from baseline (adults); less than 5% reduction in BMI from baseline (pediatrics): 3 months • All other agents: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: • Initial Approval: o For Wegovy, Zepbound: 12 months o For Saxenda pediatric patients (age 12 to less than 18): 5 months o For Saxenda (adults) and Contrave: 4 months o For all other agents: 3 months • Renewal Approval: o Qsymia: greater than or equal to 5% weight loss from baseline (adults); greater than or equal to 5% reduction in BMI from baseline (pediatrics): 12 months o Qsymia. less than 5% weight loss from baseline (adults); less than 5% reduction in BMI from baseline (pediatrics): 3 months o All other agents: 12 months

• Program Summary: Winlevi (clascoterone)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☐ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	90050011	Winlevi	clascoterone cream	1%	M; N; O; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Winlevi (clascoterone) will be approved when BOTH of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. The patient has a diagnosis of acne vulgaris AND ONE of the following: 1. The patient's medication history includes use of at least ONE generic topical antibiotic agent OR at least ONE generic topical retinoid agent as indicated by: A. Evidence of a paid claim(s) **OR** B. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) AND the required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR** 2. The patient has an intolerance or hypersensitivity to generic topical antibiotic OR generic topical retinoid therapy **OR** 3. The patient has an FDA labeled contraindication to ALL generic topical antibiotic AND generic topical retinoid agents **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL generic topical antibiotic AND generic topical retinoid agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age **Length of Approval:** 12 months

• Program Summary: Zeposia (ozanimod)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
624070502001	Zeposia	ozanimod hcl cap	0.92 MG	30	Capsules	30	DAYS			
6240705020B210	Zeposia 7-day starter pac	Ozanimod Cap Pack 4 x 0.23 MG & 3 x 0.46 MG	4 x 0.23MG & 3 x 0.46MG	7	Capsules	180	DAYS			
6240705020B215	Zeposia starter kit	ozanimod cap pack	0.23MG &0.46MG 0.92MG(21)	28	Capsules	180	DAYS			
6240705020B220	Zeposia starter kit	Ozanimod Cap Pack 4 x 0.23 MG & 3 x 0.46 MG & 30 x 0.92 MG	0.23MG & 0.46MG & 0.92MG	37	Capsules	180	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Zeposia PA with MS Step	**Initial Evaluation** **Target Agent(s)** will be approved when ONE of the following is met: 1. The requested agent is eligible for continuation of therapy AND ONE of following: **Agents Eligible for Continuation of Therapy** Zeposia (ozanimod) A. Information has been provided that the patient has been treated with the requested agent within the past 90 days **OR** B. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR** 2. The patient has a diagnosis of multiple sclerosis (MS) AND BOTH of the following: A. ONE of the following: 1. The patient has highly active MS disease activity AND BOTH of the following: A. The patient has greater than or equal to 2 relapses in the previous year **AND** B. ONE of the following: 1. The patient has greater than or equal to 1 gadolinium enhancing lesion on MRI **OR** 2. The patient has significant increase in T2 lesion load compared with a previous MRI **OR** 2. The patient has been treated with at least 3 MS agents from different drug classes (see MS disease modifying agents drug class table) **OR** 3. ONE of the following A. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**

Module	Clinical Criteria for Approval
	3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** B. The patient's medication history incudes use of ONE Preferred generic MS agent* **OR** C. BOTH of the following: 1. The prescriber has stated that the patient has tried a preferred generic MS agent* **AND** 2. The preferred generic MS agent* was discontinued due to lack of effectiveness or an adverse event **OR** D. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE preferred generic MS agent* **OR** E. The patient has an FDA labeled contraindication to ALL preferred generic MS agents* **OR** F. The prescriber has provided documentation that ALL preferred generic MS agents* cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. The patient will NOT be using the requested agent in combination with another MS disease modifying agent (DMA) (Please refer to "Multiple Sclerosis Disease Modifying Agents" contraindicated use table) **OR** 3. The patient has a diagnosis of moderately to severely active ulcerative colitis (UC) AND ALL of the following: A. ONE of the following: 1. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. The patient has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC **OR** 3. The patient has severely active ulcerative colitis **OR** 4. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of UC **OR** 5. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of UC **OR** 6. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of UC OR 7. The prescriber has provided documentation that ALL of the conventional agents (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, steroid suppositories, sulfasalazine) used in the treatment of UC cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. ONE of the following: 1. The patient is currently being treated with the requested agent as indicated by ALL of the following:

Module	Clinical Criteria for Approval
	A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. The patient has tried and had an inadequate response to TWO Step 1a and/or Step 1b immunomodulatory agents (see Immunomodulatory Agent Step table) **OR** 3. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to at least TWO Step 1a and/or Step 1b immunomodulatory agents **OR** 4. The patient has an FDA labeled contraindication to ALL Step 1a AND Step1b immunomodulatory agents **OR** 5. The prescriber has provided documentation that ALL Step 1a AND Step1b immunomodulatory agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** C. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) (Please refer to "Immunomodulatory Agents NOT to be used Concomitantly" table) **AND** D. If the patient has an FDA approved indication, then ONE of the following: 1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** 2. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** E. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** F. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months. NOTE: The starter dose can be approved for the FDA labeled starting dose and the maintenance dose can be approved for the remainder of 12 months **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when BOTH of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. ONE of the following: A. The patient has a diagnosis of multiple sclerosis (MS) AND BOTH of the following: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of following: Agents Eligible for Continuation of Therapy Zeposia (ozanimod) 1. Information has been provided that the patient has been treated with

Module	Clinical Criteria for Approval
	the requested agent within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR** B. The patient has highly active MS disease activity AND BOTH of the following: 1. The patient has greater than or equal to 2 relapses in the previous year **AND** 2. ONE of the following: A. The patient has greater than or equal to 1 gadolinium enhancing lesion on MRI **OR** B. The patient has significant increase in T2 lesion load compared with a previous MRI OR C. The patient has been treated with at least 3 MS agents from different drug classes (see MS disease modifying agents drug class table) **OR** D. ONE of the following: 1. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. The patient's medication history incudes use of ONE Preferred generic MS agent* **OR** 3. BOTH of the following: A. The prescriber has stated that the patient has tried a preferred generic MS agent* **AND** B. The preferred generic MS agent* was discontinued due to lack of effectiveness or an adverse event **OR** 4. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE preferred generic MS agent* **OR** 5. The patient has an FDA labeled contraindication to ALL preferred generic MS agents* **OR** 6. The prescriber has provided documentation that ALL preferred generic MS agents* cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient will not be using the requested agent in combination with another MS disease modifying agent (DMA) (Please refer to "Multiple Sclerosis Disease Modifying Agents" contraindicated use table) **OR** B. The patient has a diagnosis of ulcerative colitis AND ALL of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. The patient will NOT be using the requested agent in combination with another

Module	Clinical Criteria for Approval

immunomodulatory agent (see "Immunomodulatory Agents NOT to be used Concomitantly" table)

Length of Approval: 12 months

NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

*** Preferred and Non-preferred MS agents**

Preferred generic agents
dimethyl fumarate
fingolimod
Glatopa (glatiramer)
glatiramer
teriflunomide

Preferred brand agents
Avonex (interferon b-1a)
Betaseron (interferon b-1b)
Kesimpta (ofatumumab)
Mavenclad (cladribine)
Mayzent (siponimod)***
Plegridy (peginterferon b-1a)
Rebif (interferon b-1a)
Vumerity (diroximel fumarate)
Zeposia (ozanimod)

Non-Preferred Agents
Aubagio (teriflunomide)
Bafiertam (monomethyl fumarate)
Copaxone (glatiramer)**
Extavia (interferon b-1b)
Gilenya (fingolimod)**
Glatopa (glatiramer)**
Ponvory (ponesimod)
Tascenso ODT (fingolimod)
Tecfidera (dimethyl fumarate)**
** generic available

*** Mayzent preferred or non-preferred status is determined by the client

Immunomodulatory Agent Step table****

Formulary ID	Step 1a	Step 1b (Directed to ONE TNF inhibitor) NOTE please see Step 1a for preferred TNF inhibitors	Step 2 (Directed to ONE step 1 agent)	Step 3a (Directed to TWO Step 1 agents)	Step 3b (Directed to TWO agents from step 1a and/or Step 1b)	Step 3c (Directed to THREE step 1 agents)
FocusRx	SQ:	Oral:	SQ:	N/A	Zeposia	SQ: Abrilada**,

Module	Clinical Criteria for Approval						
		Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Cyltezo, Humira, Stelara	Rinvoq, Xeljanz, Xeljanz XR	Simponi (Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Cyltezo, or Humira are required Step 1 agents)		(Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Cyltezo, Humira, Rinvoq, Stelara, OR Xeljanz/Xeljanz XR are required step agents)	Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Entyvio, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Omvoh, Yusimry** Oral Velsipity
	FlexRx, GenRx, KeyRx, BasicRx	SQ: Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Hadlima, Humira, Stelara	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Hadlima, or Humira are required Step 1 agents)	N/A	Zeposia (Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Humira, Rinvoq, Stelara, OR Xeljanz/Xeljanz XR are required step agents)	SQ: Abrilada***, Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Cyltezo***, Entyvio, Hulio***, Hyrimoz***, Idacio***, Omvoh, Yusimry*** Oral Velsipity
	** Note Amjevita (one of: 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL), Cyltezo and Humira are required Step 1 agents *** Note Amjevita (one of: 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL), Hadlima, and Humira are required Step 1 agents **** Noted preferred status is effective upon launch						

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Zeposia PA through preferred and Zeposia PA with MS step	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** 3. ALL of the following:

Module	Clinical Criteria for Approval
	A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: 12 months. NOTE: The starter dose can be approved for the FDA labeled starting dose and the maintenance dose can be approved for the remainder of 12 months.

CLASS AGENTS

Class	Class Drug Agents
MS Disease Modifying Agents drug class: CD20 monoclonal antibody	
MS Disease Modifying Agents drug class: CD20 monoclonal antibody	BRIUMVI*ublituximab-xiiy soln for iv infusion
MS Disease Modifying Agents drug classes: CD20 monoclonal antibody	
MS Disease Modifying Agents drug classes: CD20 monoclonal antibody	KESIMPTA*Ofatumumab Soln Auto-Injector
MS Disease Modifying Agents drug classes: CD20 monoclonal antibody	OCREVUS*Ocrelizumab Soln For IV Infusion
MS Disease Modifying Agents drug classes: CD52 monoclonal antibody	
MS Disease Modifying Agents drug classes: CD52 monoclonal antibody	LEMTRADA*Alemtuzumab IV Inj
MS Disease Modifying Agents drug classes: Fumarates	
MS Disease Modifying Agents drug classes: Fumarates	BAFIERTAM*Monomethyl Fumarate Capsule Delayed Release
MS Disease Modifying Agents drug classes: Fumarates	TECFIDERA*Dimethyl Fumarate Capsule Delayed Release
MS Disease Modifying Agents drug classes: Fumarates	VUMERITY*Diroximel Fumarate Capsule Delayed Release
MS Disease Modifying Agents drug classes: Glatiramer	
MS Disease Modifying Agents drug classes: Glatiramer	COPAXONE*Glatiramer Acetate Soln Prefilled Syringe
MS Disease Modifying Agents drug classes: Glatiramer	GLATOPA*Glatiramer Acetate Soln Prefilled Syringe
MS Disease Modifying Agents drug classes: IgG4k monoclonal antibody	
MS Disease Modifying Agents drug classes: IgG4k monoclonal antibody	TYSABRI*Natalizumab for IV Inj Conc
MS Disease Modifying Agents drug classes: Interferons	
MS Disease Modifying Agents drug classes: Interferons	AVONEX*Interferon beta-1a injection
MS Disease Modifying Agents drug classes: Interferons	BETASERON*Interferon beta-1b injection
MS Disease Modifying Agents drug classes: Interferons	EXTAVIA*Interferon beta-1b injection
MS Disease Modifying Agents drug classes: Interferons	PLEGRIDY*Peginterferon beta-1a injection
MS Disease Modifying Agents drug classes: Interferons	REBIF*Interferon beta-1a injection

Class	Class Drug Agents
MS Disease Modifying Agents drug classes: Purine antimetabolite	
MS Disease Modifying Agents drug classes: Purine antimetabolite	MAVENCLAD*Cladribine Tab Therapy Pack
MS Disease Modifying Agents drug classes: Pyrimidine synthesis inhibitor	
MS Disease Modifying Agents drug classes: Pyrimidine synthesis inhibitor	AUBAGIO*Teriflunomide Tab
MS Disease Modifying Agents drug classes: Sphingosine 1-phosphate (SIP) receptor modulator	
MS Disease Modifying Agents drug classes: Sphingosine 1-phosphate (SIP) receptor modulator	GILENYA*Fingolimod HCl Cap
MS Disease Modifying Agents drug classes: Sphingosine 1-phosphate (SIP) receptor modulator	MAYZENT*Siponimod Fumarate Tab
MS Disease Modifying Agents drug classes: Sphingosine 1-phosphate (SIP) receptor modulator	PONVORY*Ponesimod Tab
MS Disease Modifying Agents drug classes: Sphingosine 1-phosphate (SIP) receptor modulator	TASCENSO*fingolimod lauryl sulfate tablet disintegrating
MS Disease Modifying Agents drug classes: Sphingosine 1-phosphate (SIP) receptor modulator	ZEPOSIA*Ozanimod capsule

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
MS Disease Modifying Agents Aubagio (teriflunomide) Avonex (interferon b-1a) Bafiertam (monomethyl fumarate) Betaseron (interferon b-1b) Briumvi (ublituximab-xiiy) Copaxone (glatiramer) simethyl fumarate Extavia (interferon b-1b) fingolimod Gilenya (fingolimod) Glatopa (glatiramer) glatiramer Kesimpta (ofatumumab) Mavenclad (cladribine) Mayzent (siponimod) Plegridy (peginterferon b-1a) Ponvory (ponesimod) Rebif (interferon b-1a) Tascenso ODT (fingolimod) Tecfidera (dimethyl fumarate)a Vumerity (diroximel fumarate) Zeposia (ozanimod)

Contraindicated as Concomitant Therapy
Immunomodulatory Agents NOT to be used concomitantly
Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)
Cibinqo (abrocitinib)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Litfulo (ritlecitinib)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Stelara (ustekinumab)

Contraindicated as Concomitant Therapy
Taltz (ixekizumab) Tezspire (tezepelumab-ekko) Tremfya (guselkumab) Truxima (rituximab-abbs) Tysabri (natalizumab) Velsipity (etrasimod) Wezlana (ustekinumab-auub) Xeljanz (tofacitinib) Xeljanz XR (tofacitinib extended release) Xolair (omalizumab) Yuflyma (adalimumab-aaty) Yusimry (adalimumab-aqvh) Zymfentra (infliximab-dyyb)

• Program Summary: Zoryve (roflumilast)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☐ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	902500450037	Zoryve	roflumilast cream	0.3 %	M; N; O; Y				
	903000450039	Zoryve	roflumilast foam	0.3 %	M; N; O; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of plaque psoriasis AND ALL of the following: 1. The patient's affected body surface area (BSA) is less than or equal to 20% **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to a topical corticosteroid **OR** B. The patient has an intolerance or hypersensitivity to therapy with topical corticosteroids **OR** C. The patient has an FDA labeled contraindication to ALL topical corticosteroids **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that topical corticosteroids cannot be used due to a documented medical condition or comorbid condition that is

Module	Clinical Criteria for Approval
	likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to another topical psoriasis agent with a different mechanism of action (e.g., vitamin D analogs, calcineurin inhibitors, tazarotene) **OR** B. The patient has an intolerance or hypersensitivity to another topical psoriasis agent with a different mechanism of action **OR** C. The patient has an FDA labeled contraindication to ALL other topical psoriasis agents with a different mechanism of action **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL other topical psoriasis agents with a different mechanism of action cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has another FDA approved indication for the requested agent and route of administration **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months

• Quantity Limit Program Summary: Quantity Limit Changes for April 1, 2024

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☐ Coverage / Formulary Exception

QUANTITY LIMIT CRITERIA FOR APPROVAL:

Target Agent will be approved when ONE Of the following is met:

1. The requested quantity (dose) does NOT exceed the program quantity limit
   OR
2. Information has been provided that fulfills the criteria listed under the "Allowed exception cases/diagnoses" (if applicable)
   OR
3. The requested quantity (dose) is greater than the program quantity limit AND ONE of the following:
   A. BOTH of the following:
      i. The requested agent does not have a maximum FDA labeled dose for the requested indication
      AND
      ii. Information has been provided to support therapy with a higher dose for the requested indication
   OR
   B. BOTH of the following:
      i. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
      AND
      ii. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
   OR
   C. BOTH of the following:
      i. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
      AND
      ii. Information has been provided to support therapy with a higher dose for the requested indication

Length of approval: up to 12 months

NOTE: All brand and generic products for the target drugs and dosage strengths listed are subject to the quantity limits below.

Program: Antidepressants

TARGET DRUGS	DOSAGE/STRENGTH	QUANTITY LIMIT (Units/Day or As Noted)
Selective Serotonin Reuptake Inhibitors (SSRIs)		
Celexa (citalopram)	10 mg tablet	1 tablet
Celexa (citalopram)	20 mg tablet	1 tablet
Celexa (citalopram)	40 mg tablet	1 tablet
Citalopram	30 mg capsule	1 capsule
Celexa (citalopram)	10 mg/5 mL oral solution	20 mL
Lexapro (escitalopram)	5 mg tablet	1 tablet
Lexapro (escitalopram)	10 mg tablet	1 tablet
Lexapro (escitalopram)	20 mg tablet	1 tablet
escitalopram	5 mg/5 mL oral solution	20 mL
fluvoxamine ER	100 mg extended-release capsule	2 capsules
fluvoxamine ER	150 mg extended-release capsule	2 capsules
fluvoxamine	25 mg tablet	1 tablet
fluvoxamine	50 mg tablet	1 tablet
fluvoxamine	100 mg tablet	3 tablets

TARGET DRUGS	DOSAGE/STRENGTH	QUANTITY LIMIT (Units/Day or As Noted)
Paxil (paroxetine)	10 mg tablet	1 tablet
Paxil (paroxetine)	20 mg tablet	1 tablet
Paxil (paroxetine)	30 mg tablet	2 tablets
Paxil (paroxetine)	40 mg tablet	1 tablet
Paxil (paroxetine)	10 mg/5 mL suspension	30 mL
Paxil CR (paroxetine ER)	12.5 mg controlled-release tablet	1 tablet
Paxil CR (paroxetine ER)	25 mg controlled-release tablet	2 tablets
Paxil CR (paroxetine ER)	37.5 mg controlled-release tablet	2 tablets
Pexeva (paroxetine)	10 mg tablet	1 tablet
Pexeva (paroxetine)	20 mg tablet	1 tablet
Pexeva (paroxetine)	30 mg tablet	2 tablets
Pexeva (paroxetine)	40 mg tablet	1 tablet
Prozac (fluoxetine)	10 mg capsule	1 capsule
Prozac (fluoxetine)	20 mg capsule	4 capsules
Prozac (fluoxetine)	40 mg capsule	2 capsules
Prozac (fluoxetine)	10 mg tablet	1 tablet
Prozac (fluoxetine)	20 mg tablet	4 tablets
Prozac (fluoxetine)	60 mg tablet	1 tablet
Prozac (fluoxetine)	20 mg/5 mL oral solution	20 mL
Fluoxetine	90 mg delayed-release capsule	4 capsules/28 days
Sertraline	150 mg capsule	1 capsule
Sertraline	200 mg capsule	1 capsule
Zoloft (sertraline)	25 mg tablet	1 tablet
Zoloft (sertraline)	50 mg tablet	1 tablet
Zoloft (sertraline)	100 mg tablet	2 tablets
Zoloft (sertraline)	20 mg/mL oral concentrate	10 mL
Serotonin Norepinephrine Reuptake Inhibitors (SNRIs)		
Cymbalta (duloxetine)	20 mg delayed-release capsule	2 capsules
Cymbalta (duloxetine)	30 mg delayed-release capsule	2 capsules
Cymbalta (duloxetine)	60 mg delayed-release capsule	2 capsules
desvenlafaxine	50 mg extended-release tablet	1 tablet
desvenlafaxine	100 mg extended-release tablet	1 tablet
Desvenlafaxine fumarate	50 mg extended-release tablet	1 tablet
Desvenlafaxine fumarate	100 mg extended-release tablet	1 tablet
Drizalma Sprinkle	20 mg delayed release sprinkle capsule	2 capsules
Drizalma Sprinkle	30 mg delayed release sprinkle capsule	2 capsules
Drizalma Sprinkle	40 mg delayed release sprinkle capsule	2 capsules
Drizalma Sprinkle	60 mg delayed release sprinkle capsule	2 capsules
Effexor (venlafaxine)	25 mg tablet	3 tablets
Effexor (venlafaxine)	37.5 mg tablet	3 tablets
Effexor (venlafaxine)	50 mg tablet	3 tablets
Effexor (venlafaxine)	75 mg tablet	3 tablets
Effexor (venlafaxine)	100 mg tablet	3 tablets
Effexor XR (venlafaxine ER)	37.5 mg extended-release capsule	1 capsule

TARGET DRUGS	DOSAGE/STRENGTH	QUANTITY LIMIT (Units/Day or As Noted)
Effexor XR (venlafaxine ER)	75 mg extended-release capsule	3 capsules
Effexor XR (venlafaxine ER)	150 mg extended-release capsule	1 capsule
Fetzima (levomilnacipran)	20 mg extended-release capsule	1 capsule
Fetzima (levomilnacipran)	40 mg extended-release capsule	1 capsule
Fetzima (levomilnacipran)	80 mg extended-release capsule	1 capsule
Fetzima (levomilnacipran)	120 mg extended-release capsule	1 capsule
Fetzima (levomilnacipran)	Titration pack (2 x 20 mg, 26 x 40 mg)	1 kit (28 capsules)/28 days
duloxetine delayed release	40 mg delayed release capsule	3 capsules
venlafaxine ER	37.5 mg extended-release tablet	1 tablet
venlafaxine ER	75 mg extended-release tablet	3 tablets
venlafaxine ER	112.5 mg extended-release tablet	1 tablet
venlafaxine ER	150 mg extended-release tablet	1 tablet
venlafaxine ER	225 mg extended-release tablet	1 tablet
Pristiq (desvenlafaxine)	25 mg extended-release tablet	1 tablet
Pristiq (desvenlafaxine)	50 mg extended-release tablet	1 tablet
Pristiq (desvenlafaxine)	100 mg extended-release tablet	1 tablet
Other Antidepressants		
Aplenzin (bupropion)	174 mg extended-release tablet	1 tablet
Aplenzin (bupropion)	348 mg extended-release tablet	1 tablet
Aplenzin (bupropion)	522 mg extended-release tablet	1 tablet
Auvelity (dextromethorphan/bupropion)	45-105 mg extended-release tablet	2 tablets
Forfivo XL (bupropion XL)	450 mg extended-release tablet	1 tablet
Maprotiline	25 mg tablet	3 tablets
Maprotiline	50 mg tablet	3 tablets
Maprotiline	75 mg tablet	3 tablets
Remeron (mirtazapine)	7.5 mg tablet	1 tablet
Remeron (mirtazapine)	15 mg tablet	1 tablet
Remeron (mirtazapine)	30 mg tablet	1 tablet
Remeron (mirtazapine)	45 mg tablet	1 tablet
Remeron SolTab (mirtazapine)	15 mg orally-disintegrating tablet	1 tablet
Remeron SolTab (mirtazapine)	30 mg orally-disintegrating tablet	1 tablet
Remeron SolTab (mirtazapine)	45 mg orally-disintegrating tablet	1 tablet
Trintellix (vortioxetine)	5 mg tablet	1 tablet
Trintellix (vortioxetine)	10 mg tablet	1 tablet
Trintellix (vortioxetine)	20 mg tablet	1 tablet
Viibryd (vilazodone)	10 mg tablet	1 tablet
Viibryd (vilazodone)	20 mg tablet	1 tablet
Viibryd (vilazodone)	40 mg tablet	1 tablet
Viibryd (vilazodone)	Starter Kit (7 x 10mg, 23 x 20mg)	1 tablet (1 kit/180 days)
Wellbutrin (bupropion)	75 mg tablet	2 tablets
Wellbutrin (bupropion)	100 mg tablet	4 tablets
Wellbutrin SR (bupropion SR)	100 mg sustained-release tablet	2 tablets
Wellbutrin SR (bupropion SR)	150 mg sustained-release tablet	2 tablets
Wellbutrin SR (bupropion SR)	200 mg sustained-release tablet	2 tablets
Wellbutrin XL (bupropion ER)	150 mg extended-release tablet	1 tablet

TARGET DRUGS	DOSAGE/STRENGTH	QUANTITY LIMIT (Units/Day or As Noted)
Wellbutrin XL (bupropion ER)	300 mg extended-release tablet	1 tablet
Zurzuvae (zuranolone)	20 mg capsules	28 capsules/365 days
Zurzuvae (zuranolone)	25 mg capsules	28 capsules/365 days
Zurzuvae (zuranolone)	30 mg capsules	14 capsules/365 days

Program: Proton Pump Inhibitors (PPI's)

TARGET DRUGS	DOSAGE/STRENGTH	QUANTITY LIMIT (Units/Day or As Noted)
Aciphex (rabeprazole)	20 mg delayed-release tablets	1 tablet
Aciphex Sprinkle (rabeprazole)	5 mg capsule sprinkle	1 capsule
Aciphex Sprinkle (rabeprazole)	10 mg capsule sprinkle	1 capsule
Esomeprazole strontium	49.3 mg capsule	1 capsule
Dexilant (dexlansoprazole)	30 mg dealyed-release capsules	1 capsule
Dexilant (dexlansoprazole)	60 mg delayed-release capsules	1 capsule
Konvomep	40mg/20ml suspension	20 ml
Nexium (esomeprazole)	20 mg delayed-release capsules	1 capsule
Nexium (esomeprazole)	40 mg delayed-release capsules	1 capsule
Nexium (esomeprazole)	10 mg delayed-release oral suspension	1 packet
Nexium (esomeprazole)	20 mg delayed-release oral suspension	1 packet
Nexium (esomeprazole)	40 mg delayed-release oral suspension	1 packet
Nexium (esomeprazole)	2.5 mg susp pack	1 packet
Nexium (esomeprazole)	5 mg susp pack	1 packet
Prevacid (lansoprazole)	15 mg delayed-release capsules	1 capsule
Prevacid (lansoprazole)	30 mg delayed-release capsules	1 capsule
Prevacid (lansoprazole)	15 mg oral suspension (packets)	1 packet
Prevacid (lansoprazole)	30 mg oral suspension (packets)	1 packet
Prevacid (lansoprazole)	15 mg delayed-release orally disintegrating tablet	1 tablet
Prevacid (lansoprazole)	30 mg delayed-release orally disintegrating tablet	1 tablet
omeprazole	10 mg delayed-release capsules	1 capsule
omeprazole	20 mg delayed-release capsules	1 capsule
omeprazole	40 mg delayed-release capsules	1 capsule
Prilosec (omeprazole)	2.5 mg oral suspension (packets)	2 packets
Prilosec (omeprazole)	10 mg oral suspension (packets)	1 packet
Protonix (pantoprazole)	40 mg delayed-release oral suspension (packets)	1 packet
Protonix (pantoprazole)	20 mg delayed-release tablets	1 tablet
Protonix (pantoprazole)	40 mg delayed-release tablets	1 tablet
Voquezna (vonoprazan)	10 mg tablets	1 tablet
Voquezna (vonoprazan)	20 mg tablets	1 tablet
Zegerid (omeprazole/sodium bicarbonate)	20 mg immediate-release capsules	1 capsule
Zegerid (omeprazole/sodium bicarbonate)	40 mg immediate-release capsules	1 capsule
Zegerid (omeprazole/sodium bicarbonate)	20 mg powder for oral suspension (packets)	1 packet

TARGET DRUGS	DOSAGE/STRENGTH	QUANTITY LIMIT (Units/Day or As Noted)
Zegerid (omeprazole/sodium bicarbonate)	40 mg powder for oral suspension (packets)	1 packet

Program: Statin

TARGET DRUGS	DOSAGE/STRENGTH	QUANTITY LIMIT (Units/Day or As Noted)
Altoprev (lovastatin extended release)	20 mg tablets	1 tablet
Altoprev (lovastatin extended release)	40 mg tablets	1 tablet
Altoprev (lovastatin extended release)	60 mg tablets	1 tablet
Atorvaliq (atorvastatin)	20mg/5ml suspension	20ml
Crestor (rosuvastatin)	5 mg tablets	1½ tablets
Crestor (rosuvastatin)	10 mg tablets	1½ tablets
Crestor (rosuvastatin)	20 mg tablets	1½ tablets
Crestor (rosuvastatin)	40 mg tablets	1 tablet
Ezallor Sprinkle (rosuvastatin)	5 mg capsules	1 capsule
Ezallor Sprinkle (rosuvastatin)	10 mg capsules	2 capsules
Ezallor Sprinkle (rosuvastatin)	20 mg capsules	3 capsules
Ezallor Sprinkle (rosuvastatin)	40 mg capsules	4 capsules
ezetimibe/atorvastatin	10-10mg	1 tablet
ezetimibe/atorvastatin	10-20mg	1 tablet
ezetimibe/atorvastatin	10-40mg	1 tablet
ezetimibe/atorvastatin	10-80mg	1 tablet
Flolipid (simvastatin oral suspension)	20 mg/5 mL suspension	5 mLs
Flolipid (simvastatin oral suspension)	40 mg/5 mL suspension	10 mLs
fluvastatin	20 mg capsules	2 capsules
fluvastatin	40 mg capsules	2 capsules
Lescol XL (fluvastatin extended release)	80 mg tablets	1 tablet
Lipitor (atorvastatin)	10 mg tablets	1½ tablets
Lipitor (atorvastatin)	20 mg tablets	1½ tablets
Lipitor (atorvastatin)	40 mg tablets	1½ tablets
Lipitor (atorvastatin)	80 mg tablets	1 tablet
Livalo (pitavastatin)	1 mg tablets	1½ tablets
Livalo (pitavastatin)	2 mg tablets	1½ tablets
Livalo (pitavastatin)	4 mg tablets	1 tablet
lovastatin	10 mg tablets	2 tablets
lovastatin	20 mg tablets	2 tablets
lovastatin	40 mg tablets	2 tablets
pravastatin	10 mg tablets	1½ tablets
Pravachol (pravastatin)	20 mg tablets	1½ tablets
Pravachol (pravastatin)	40 mg tablets	1½ tablets
pravastatin	80 mg tablets	1 tablet
Roszet (exetimibe/rosuvastatin)	5 mg/10 mg tablet	1 tablet
Roszet (exetimibe/rosuvastatin)	10 mg/10 mg tablet	1 tablet
Roszet (exetimibe/rosuvastatin)	20 mg/10 mg tablet	1 tablet

TARGET DRUGS	DOSAGE/STRENGTH	QUANTITY LIMIT (Units/Day or As Noted)
Roszet (exetimibe/rosuvastatin)	40 mg/10 mg tablet	1 tablet
Vytorin (ezetimibe/simvastatin)	10 mg/ 10 mg tablets	1 tablet
Vytorin (ezetimibe/simvastatin)	10 mg/ 20 mg tablets	1 tablet
Vytorin (ezetimibe/simvastatin)	10 mg/ 40 mg tablets	1 tablet
Vytorin (ezetimibe/simvastatin)	10 mg/ 80 mg tablets	1 tablet
simvastatin	5 mg tablets	1½ tablets
Zocor (simvastatin)	10 mg tablets	1½ tablets
Zocor (simvastatin)	20 mg tablets	2 tablets
Zocor (simvastatin)	40 mg tablets	1½ tablets
Zocor (simvastatin)	80 mg tablets	1 tablet
Zypitamag (pitavastatin)	1 mg	1½ tablets
Zypitamag (pitavastatin)	2 mg	1½ tablets
Zypitamag (pitavastatin)	4 mg	1 tablet

Program: Topical Corticosteroid

TARGET DRUGS	DOSAGE/STRENGTH	QUANTITY LIMIT (Units/Day or as Noted)
Aclovate (alclometasone dipropionate)	0.05% cream (15 gm, 45 gm, 60 gm)	120 grams/30 days
Aclovate (alclometasone dipropionate)	0.05% ointment (15 gm, 45 gm, 60 gm)	120 grams/30 days
Ala Scalp (hydrocortisone)	2% lotion (29.6 mL, 59.2 mL)	118.4 mL/30 days
ApexiCon E (diflorasone diacetate)	0.05% emollient cream (30 mg, 60 gm)	120 grams/30 days
Aristocort HP (triamcinolone acetonide)	0.5% ointment (15 gm)	120 grams/30 days
Bryhali (halobetasol propionate)	0.01% lotion (60 gm, 100 gm)	200 grams/30 days
Capex (fluocinolone acetonide)	0.01% shampoo (120 mL)	840 mL/28 days
Clobex (clobetasol propionate)	0.05% spray (59 mL, 125 mL)	236 mL/28 days
Clobex (clobetasol propionate)	0.05% lotion (59 mL, 118 mL)	177 mL/28 days
Clobex (clobetasol propionate)	0.05% shampoo (118 mL)	236 mL/28 days
Cloderm (clocortolone pivalate)	0.1% cream (45 gm, 75 gm, 90 gm)	120 grams/30 days
Cordran (flurandrenolide)	4 mcg/cm2 (80 in x 3 in)	1 box/30 days
Cordran (flurandrenolide)	0.025% cream (120 gm)	120 grams/30 days
Cordran (flurandrenolide)	0.05% cream (60 gm, 120 gm)	120 grams/30 days
Cordran (flurandrenolide)	0.05% lotion (120 mL)	120 mL/30 days
Cordran (flurandrenolide)	0.05% ointment (60 gm)	120 grams/30 days
Cutivate (fluticasone propionate)	0.05% lotion (60 mL, 120 mL)	120 mL/30 days
Cutivate (fluticasone propionate)	0.05% cream (15 gm, 30 gm, 60 gm)	120 grams/30 days
Cutivate (fluticasone propionate)	0.005% ointment (15 gm, 30 gm, 60 gm)	120 grams/30 days
Cyclocort (amcinonide)	0.1% cream (15 gm, 30 gm, 60 gm)	120 grams/30 days
Cyclocort (amcinonide)	0.1% lotion (60 mLs)	120 mL/30 days
Cyclocort (amcinonide)	0.1% ointment (60 gm)	120 grams/30 days
Derma-Smoothe (fluocinolone acetonide)	0.01% oil (body) (118.28 mL)	118.28 mL/30 days
Derma-Smoothe (fluocinolone acetonide)	0.01% oil (scalp) (118.28 mL)	118.28 mL/30 days
Dermatop (prednicarbate)	0.1% cream (60 gm)	120 grams/30 days
Dermatop (prednicarbate)	0.1% ointment (15 gm, 60 gm)	120 grams/30 days
Desonate (desonide)	0.05% gel (60 gm)	120 grams/30 days

TARGET DRUGS	DOSAGE/STRENGTH	QUANTITY LIMIT (Units/Day or as Noted)
DesOwen (desonide)	0.05% lotion (59 mL, 118 mL)	118 mL/30 days
DesOwen, Tridesilon (desonide)	0.05% cream (15 gm, 60 gm)	120 grams/30 days
DesOwen, Tridesilon (desonide)	0.05% ointment (15 gm, 60 gm)	120 grams/30 days
Betamethasone dipropionate augmented	0.05% gel (15 gm, 50 gm)	200 grams/28 days
betamethasone dipropionate augmented	0.05% lotion (30 mL, 60 mL)	210 mL/30 days
betamethasone dipropionate augmented	0.05% ointment (15 gm, 45 gm, 50 gm)	200 grams/28 days
Diprolene AF (betamethasone dipropionate)	0.05% cream (15 gm, 50 gm)	200 grams/28 days
Diprosone (betamethasone dipropionate)	0.05% cream (15 gm, 45 gm)	135 grams/30 days
Diprosone (betamethasone dipropionate)	0.05% lotion (60 mL)	120 mL/30 days
betamethasone dipropionate	0.05% ointment (15 gm, 45 gm)	135 grams/30 days
mometasone furoate	0.1% cream (15 gm, 45 gm)	135 grams/30 days
Elocon (mometasone furoate)	0.1% ointment (15 gm, 45 gm)	135 grams/30 days
Elocon (mometasone furoate)	0.1% lotion/solution (30 mL, 60 mL)	120 mL/30 days
Florone (diflorasone diacetate)	0.05% ointment (15 gm, 30 gm, 45 gm, 60 gm)	120 grams/30 days
Halog (halcinonide)	0.1% cream (30 gm, 60 gm, 216 gm)	120 grams/ 30 days
Halog (halcinonide)	0.1% ointment (60 gm)	120 grams/ 30 days
Halog (halcinonide)	0.1% solution (120 mL)	120 mL/ 30 days
Hytone (hydrocortisone)	2.5% cream (20 gm, 28 gm, 28.35 gm, 30 gm, 453.6 gm, 454 gm)	454 grams/30 days
Hytone (hydrocortisone)	1% cream (28.35 gm, 28.4 gm, 30 gm, 85.2 gm, 453.6 gm, 454 gm)	454 grams/30 days
Hytone (hydrocortisone)	2.5% lotion (59 mL, 118 mL)	118 mL/30 days
Hytone (hydrocortisone)	1% ointment (25 gm, 28.35 gm, 28.4 gm, 110 gm, 430 gm, 453.6 gm)	453.6 grams/30 days
Hytone (hydrocortisone)	2.5% ointment (20 gm, 28.35 gm, 453.6 gm, 454 gm)	454 grams/30 days
Impeklo (clobetasol propionate)	0.05% lotion (68 gm)	204 grams/28 days
Impoyz (clobetasol propionate)	0.025% cream (100 gm)	200 grams/30 days
Kenalog (triamcinolone acetonide)	0.147 mg/gm aerosol spray (63 gm, 100 gm)	126 grams/30 days
Kenalog (triamcinolone acetonide)	0.025% lotion (60 mL)	120 mL/30 days
Kenalog (triamcinolone acetonide)	0.1% lotion (60 mL)	120 mL/30 days
Kenalog (triamcinolone acetonide)	0.025% ointment (15 gm, 80 gm, 454 gm)	454 grams/30 days
Kenalog, Aristocort (triamcinolone acetonide)	0.025% cream (15 gm, 80 gm, 454 gm)	454 grams/30 days
Kenalog, Aristocort (triamcinolone acetonide)	0.1% cream (15 gm, 28.4 gm, 30 gm, 80 gm, 85.2 gm, 453.6 gm, 454 gm)	454 grams/30 days
Kenalog, Aristocort (triamcinolone acetonide)	0.5% cream (15 gm, 454 gm)	454 grams/30 days
Kenalog, Aristocort (triamcinolone acetonide)	0.1% ointment (15 gm, 30 gm, 80 gm, 453.6 gm, 454 gm)	454 grams/30 days
Lexette (halobetasol propionate)	0.05% foam (50 gm, 100 gm)	200 grams/28 days
Lidex (fluocinonide)	0.05% solution (20 mL, 60 mL)	120 mL/30 days
Lidex (fluocinonide)	0.05% cream (15 gm, 30 gm, 60 gm, 120 gm)	120 grams/30 days
Lidex (fluocinonide)	0.05% gel (15 gm, 30 gm, 60 gm)	120 grams/30 days
Lidex (fluocinonide)	0.05% ointment (15 gm, 30 gm, 60 gm)	120 grams/30 days

TARGET DRUGS	DOSAGE/STRENGTH	QUANTITY LIMIT (Units/Day or as Noted)
Lidex-E (fluocinonide)	0.05% emulsified cream (15 gm, 30 gm, 60 gm)	120 grams/30 days
Hydrocortisone butyrate	0.1% solution (20 mL, 60 mL)	120 mL/30 days
Hydrocortisone butyrate	0.1% cream (15 gm, 45 gm)	135 grams/30 days
Locoid (hydrocortisone butyrate)	0.1% lotion (59 mL, 118 mL)	118 mL/30 days
Locoid (hydrocortisone butyrate)	0.1% ointment (15 gm, 45 gm)	135 grams/30 days
Locoid Lipocream (hydrocortisone butyrate)	0.1% hydrophilic lipo cream (45 gm, 60 gm)	120 grams/30 days
Luxiq (betamethasone valerate)	0.12% foam (50 gm, 100 gm)	150 grams/30 days
Olux (clobetasol propionate)	0.05% foam (50 gm, 100 gm)	200 grams/28 days
Olux-E (clobetasol propionate)	0.05% emulsion foam (50 gm, 100 gm)	200 grams/28 days
Pandel (hydrocortisone probutate)	0.1% cream (80 gm)	160 grams/30 days
Diflorasone diacetate	0.05% cream (15 gm, 30 gm, 60 gm)	120 grams/30 days
Sernivo (betamethasone dipropionate)	0.05% spray (120 mL)	120 mL/30 days
Synalar (fluocinolone acetonide)	0.01% solution (60 mL, 90 mL)	120 mL/30 days
Synalar (fluocinolone acetonide)	0.025% cream (15 gm, 60 gm, 120 gm)	120 grams/30 days
Synalar (fluocinolone acetonide)	0.025% ointment (15 gm, 60 gm, 120 gm)	120 grams/30 days
Synalar (fluocinolone acetonide)	0.01% cream (15 gm, 60 gm)	120 grams/30 days
Temovate (clobetasol propionate)	0.05% solution (25 mL, 50 mL)	200 mL/28 days
Temovate (clobetasol propionate)	0.05% cream (15 gm, 30 gm, 45 gm, 60 gm)	210 grams/28 days
Temovate (clobetasol propionate)	0.05% ointment (15 gm, 30 gm, 45 gm, 60 gm)	210 grams/28 days
Temovate (clobetasol propionate)	0.05% gel (15 gm, 30 gm, 60 gm)	210 grams/28 days
Temovate E (clobetasol propionate)	0.05% emollient cream (15 gm, 30 gm, 45 gm, 60 gm)	210 grams/28 days
Texacort (hydrocortisone)	2.5 % solution (30 mL)	120 mL/30 days
Topicort (desoximetasone)	0.05% cream (15 gm, 60 gm, 100 gm)	120 grams/30 days
Topicort (desoximetasone)	0.25% cream (15 gm, 60 gm, 100 gm)	120 grams/30 days
Topicort (desoximetasone)	0.05% gel (15 gm, 60 gm)	120 grams/30 days
Topicort (desoximetasone)	0.05% ointment (60 gm, 100 gm)	120 grams/30 days
Topicort (desoximetasone)	0.25% ointment (15 gm, 60 gm, 100 gm)	120 grams/30 days
Topicort (desoximetasone)	0.25% spray (100 mL)	100 mL/30 days
triamcinolone acetonide	0.05% ointment (110 gm, 430 gm)	430 grams/30 days
halobetasol propionate	0.05% cream (15 gm, 50 gm)	200 grams/28 days
Ultravate (halobetasol propionate)	0.05% lotion (60 mL, 120 mL)	240 mL/30 days
halobetasol propionate	0.05% ointment (15 gm, 50 gm)	200 grams/28 days
Valisone (betamethasone valerate)	0.1% cream (15 gm, 45 gm)	135 grams/30 days
Valisone (betamethasone valerate)	0.1% lotion (60 mL)	120 mL/30 days
betamethasone valerate	0.1% ointment (15 gm, 45 gm)	135 grams/30 days
Vanos (fluocinonide)	0.1% cream (30 gm, 60 gm, 120 gm)	240 grams/30 days
Verdeso (desonide)	0.05% foam (100 gm)	100 grams/30 days
Westcort (hydrocortisone valerate)	0.2% ointment (15 gm, 45 gm, 60 gm)	120 grams/30 days
Westcort (hydrocortisone valerate)	0.2% cream (15 gm, 45 gm, 60 gm)	120 grams/30 days