COMMERCIAL PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: July 1, 2024 Notification Posted: May 17, 2024

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

• Program Summary: Anti-Obesity GLP-1 Agents

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

TARGET AGENT(S)

Saxenda® (liraglutide)
Wegovy™ (semaglutide)
Zepbound™ (tirzepatide)

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
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

* - These strengths are not approvable for maintenance dosing

FORMULARY EXCEPTION CRITERIA FOR APPROVAL

Initial Evaluation

Target Agent(s) 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. ALL of the following:
    A. ONE of the following:
        i. The patient's requested use is to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease (medical records required) and the patient is either obese or overweight AND ALL of the following:
            a. The requested agent and strength have an FDA labeled indication for the requested diagnosis and route of administration **AND**
            b. The patient has a history of ONE of the following: (medical records required)
                1. Myocardial infarction **OR**
                2. Stroke **OR**
                3. Peripheral artery disease as defined by intermittent claudication with ankle-brachial index less than 0.85 at rest, or peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease **AND**
            c. The patient has a BMI greater than or equal to 27 kg/m^2 **AND**
            d. The patient does NOT have type 2 diabetes **AND**
            e. The patient's age is 45 years or over **AND**
            f. ONE of the following:

1. The patient does not currently use any tobacco products (e.g., cigarettes, chewing tobacco) **OR**
2. The patient is being managed for tobacco cessation **AND**

g. ALL of the following:
1. The patient is currently being treated in the past 90 days with antihypertensive therapy (e.g., ACE inhibitor, angiotensin receptor blocker, beta blocker) **AND**
2. The patient is currently being treated in the past 90 days with lipid lowering therapy (e.g., any statin, ezetimibe) **AND**
3. The patient will continue antihypertensive therapy (e.g., ACE inhibitor, angiotensin receptor blocker, beta blocker) AND lipid lowering therapy (e.g., any statin, ezetimibe) **AND**

h. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **OR**

ii. The patient is overweight or obese and is using the requested agent for weight management and ALL of the following:
a. Obesity is NOT restricted from coverage under the patient's benefit **AND**
b. The patient new to therapy, new to Prime, or attempting a repeat weight loss course of therapy **AND**
c. ONE of the following:
1. The patient is 17 years of age or over and has ONE of the following:
A. A BMI greater than or equal to 30 kg/m^2 **OR**
B. 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**
C. A BMI greater than or equal to 27 kg/m^2 with at least one weight-related comorbidity/risk factor/complication (e.g., hypertension, type 2 diabetes mellitus, obstructive sleep apnea, cardiovascular disease, dyslipidemia) **OR**
2. The patient is 12 to 16 years of age and has ONE of the following:
A. A BMI greater than or equal to 95th percentile for age and sex **OR**
B. A BMI greater than or equal to 30 kg/m^2 **OR**
C. A BMI greater than or equal to 85th percentile for age and sex AND at least one severe weight-related comorbidity/risk factor/complication **AND**

d. BOTH of the following:
1. 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 from baseline (prior to initiation of pharmacotherapy) **AND**
2. The patient has experienced weight loss of less than 1 pound per week while on a weight loss regimen from baseline (prior to initiation of pharmacotherapy) **AND**

e. If the requested agent is Saxenda, then ONE of the following:
1. The patient is 18 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 16 weeks (4 months) of therapy **OR**
C. The patient has achieved and maintained a weight loss of greater than or equal to 4% from baseline (prior to initiation of pharmacotherapy) **OR**
2. The patient is pediatric (12 to less than 18 years of age) and BOTH of the following:
A. The requested agent is NOT being used to treat type 2 diabetes **AND**
B. ONE of the following:
i. The patient is newly starting therapy **OR**
ii. The patient is currently being treated and has received less than 20 weeks (5 months) of therapy **OR**
iii. The patient has achieved and maintained a reduction in BMI of greater than or equal to 1% from baseline (prior to initiation of pharmacotherapy) **OR**

f. If the requested agent is Wegovy, then ONE of the following:

1. The patient is newly starting therapy **OR**
2. The patient is currently being treated and has received less than 52 weeks (1 year) of therapy **OR**
3. ONE of the following:
    A. 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 pharmacotherapy) **OR**
    B. 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 pharmacotherapy) **OR**

g. If the requested agent is Zepbound, then ONE of the following:
1. The patient is newly starting therapy **OR**
2. The patient is currently being treated and has received less than 52 weeks (1 year) 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 pharmacotherapy) **OR**

iii. The patient has another FDA labeled indication for the requested agent and route of administration **AND**

B. The patient will NOT be using the requested agent in combination with another weight loss agent (e.g., Contrave, phentermine, Qsymia, Xenical) for the requested indication **AND**

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

D. If the patient has an FDA labeled indication, then ONE of the following:
i. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
ii. There is support for using the requested agent for the patient's age for the requested indication **AND**

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

F. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**

3. 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**
4. ONE of the following:
    A. The requested quantity (dose) does NOT exceed the program quantity limit **OR**
    B. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following:
        i. BOTH of the following:
            a. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND**
            b. There is support for therapy with a higher dose for the requested indication **OR**
        ii. BOTH of the following:
            a. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**
            b. 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 quantity limit **OR**
        iii. BOTH of the following:
            a. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND**
            b. There is support for therapy with a higher dose for the requested indication

Length of Approval:

- For Wegovy, Zepbound: 12 months
- For Saxenda: Pediatric patients (age 12 to less than 18): 5 months; Adults: 4 months

Renewal Evaluation

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

1. The 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 [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**
3. ALL of the following:
    A. ONE of the following:
        i. The patient's requested use is to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease (medical records required) and the patient is either obese or overweight AND ALL of the following:
            a. The requested agent and strength have an FDA labeled indication for the requested diagnosis and route of administration **AND**
            b. The patient has a history of ONE of the following: (medical records required)
                1. Myocardial infarction **OR**
                2. Stroke **OR**
                3. Peripheral artery disease as defined by intermittent claudication with ankle-brachial index less than 0.85 at rest, or peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease **AND**
            c. The patient does NOT have type 2 diabetes **AND**
            d. ONE of the following:
                1. The patient does not currently use any tobacco products (e.g., cigarettes, chewing tobacco) **OR**
                2. The patient is being managed for tobacco cessation **AND**
            e. ALL of the following:
                1. The patient is currently being treated in the past 90 days with antihypertensive therapy (e.g., ACE inhibitor, angiotensin receptor blocker, beta blocker) **AND**
                2. The patient is currently being treated in the past 90 days with lipid lowering therapy (e.g., any statin, ezetimibe) **AND**
                3. The patient will continue antihypertensive therapy (e.g., ACE inhibitor, angiotensin receptor blocker, beta blocker) AND lipid lowering therapy (e.g., any statin, ezetimibe) **AND**
            f. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **OR**
        ii. The patient is overweight or obese and is using the requested agent for weight management and ALL of the following:
            a. Obesity is NOT restricted from coverage under the patient's benefit **AND**
            b. The patient is continuing a current weight loss course of therapy **AND**
            c. If the patient is 12 to less than 18 years of age, then the current BMI is greater than 85th percentile for age and sex **AND**
            d. If the requested agent is Saxenda, then 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 has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR**
                    B. 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 pharmacotherapy) **OR**
                    C. 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 pharmacotherapy) **OR**
            e. If the requested agent is Wegovy, then BOTH of the following:
                1. The requested dose is 1.7 mg or 2.4 mg **AND**

2. 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 pharmacotherapy) **OR**
    B. The patient is 12 years of age and over AND has received less than 52 weeks of therapy on the maximum-tolerated dose **OR**
    C. 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 pharmacotherapy) **OR**

f. If the requested agent is Zepbound, then ONE of the following:
    1. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR**
    2. The patient has received less than 52 weeks of therapy on the maximum-tolerated dose **OR**

iii. The patient has another FDA labeled indication for the requested agent and route of administration **AND**

B. The patient will NOT be using the requested agent in combination with another weight loss agent (e.g., Contrave, phentermine, Qsymia, Xenical) for the requested indication **AND**

C. 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**

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

E. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**

4. 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**
5. ONE of the following:
    A. The requested quantity (dose) does NOT exceed the program quantity limit **OR**
    B. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following:
        i. BOTH of the following:
            a. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND**
            b. There is support for therapy with a higher dose for the requested indication **OR**
        ii. BOTH of the following:
            a. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**
            b. 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 quantity limit **OR**
        iii. BOTH of the following:
            a. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND**
            b. There is support for therapy with a higher dose for the requested indication

Length of Approval: 12 months

• Program Summary: Fabhalta (iptacopan)

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
85807535200130	Fabhalta	iptacopan 200 mg capsules	200 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 Paroxysmal Nocturnal Hemoglobinuria (PNH) AND ALL of the following: 1. The diagnosis was confirmed by flow cytometry with at least 2 independent flow cytometry reagents on at least 2 cell lineages (e.g., RBCs and WBCs) demonstrating that the patient's peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI) – linked proteins (lab tests required) **AND** 2. The patient's hemoglobin is less than 10 g/dL (lab tests required) **AND** 3. If the patient has NOT been previously treated with complement inhibitor therapy (e.g., Empaveli [pegcetacoplan], Soliris [eculizumab], or Ultomiris [ravulizumab-cwvz]) BOTH of the following (lab tests required): A. The patient has red blood cell clone size greater than or equal to 10% **AND** B. The patient has a lactate dehydrogenase (LDH) level greater than 1.5 times the upper limit of normal (ULN) **AND** 4. ONE of the following: A. The patient has tried and had an inadequate response to Empaveli (pegcetacoplan), Soliris (eculizumab), or Ultomiris (ravulizumab-cwvz) **OR** B. The patient has an intolerance or hypersensitivity to Empaveli (pegcetacoplan), Soliris (eculizumab), or Ultomiris (ravulizumab-cwvz) **OR** C. The patient has an FDA labeled contraindication to Empaveli (pegcetacoplan), Soliris (eculizumab), AND Ultomiris (ravulizumab-cwvz) **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 Empaveli (pegcetacoplan), Soliris (eculizumab), AND Ultomiris (ravulizumab-cwvz) 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**

Module	Clinical Criteria for Approval
	B. The patient has another FDA labeled indication for the requested agent **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. There is support for 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., hematologist) 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 Empaveli (pegcetacoplan), Soliris (eculizumab), or Ultomiris (ravulizumab-cwvz) for the requested indication **AND** 5. 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 [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had improvements or stabilization with the requested agent (e.g., decreased requirement of RBC transfusions, stabilization/improvement of hemoglobin, reduction of lactate dehydrogenase (LDH), stabilization/improvement of symptoms) (medical records required) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist) 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 Empaveli (pegcetacoplan), Soliris (eculizumab), or Ultomiris (ravulizumab-cwvz) **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 **Length of Approval**: Initial approval up to 6 months Renewal approval up to 12 months

• Program Summary: Weight Management

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
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 Mngmt) Soln Auto-Injector	0.25 MG/0.5ML	8	Pens	180	DAYS			
6125207000D525	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	0.5 MG/0.5ML	8	Pens	180	DAYS			
6125207000D530	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	1 MG/0.5ML	8	Pens	180	DAYS			
6125207000D535	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	1.7 MG/0.75ML	4	Pens	28	DAYS			
6125207000D540	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	2.4 MG/0.75ML	4	Pens	28	DAYS			
6125258000D520	Zepbound	tirzepatide (weight mngmt) soln auto-injector	2.5 MG/0.5ML	4	Pens	180	DAYS			
6125258000D525	Zepbound	tirzepatide (weight mngmt) soln auto-injector	5 MG/0.5ML	4	Pens	28	DAYS			
6125258000D530	Zepbound	tirzepatide (weight mngmt) soln auto-injector	7.5 MG/0.5ML	4	Pens	28	DAYS			
6125258000D535	Zepbound	tirzepatide (weight mngmt) soln auto-injector	10 MG/0.5ML	4	Pens	28	DAYS			
6125258000D540	Zepbound	tirzepatide (weight mngmt) soln auto-injector	12.5 MG/0.5ML	4	Pens	28	DAYS			
6125258000D545	Zepbound	tirzepatide (weight mngmt) soln auto-injector	15 MG/0.5ML	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 Mngmt) Soln Auto-Injector	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
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 **Target Agent(s)** will be approved when ALL the following are met: 1. ONE of the following: A. The patient's requested use is to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease (medical records required) and the patient is either obese or overweight AND ALL of the following: 1. The requested agent and strength have an FDA labeled indication for the requested diagnosis and route of administration **AND** 2. The patient has a history of ONE of the following: (medical records required) A. Myocardial infarction **OR** B. Stroke **OR** C. Peripheral artery disease as defined by intermittent claudication with ankle-brachial index less than 0.85 at rest, or peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease **AND** 3. The patient has a BMI greater than or equal to 27 kg/m^2 **AND** 4. The patient does NOT have type 2 diabetes **AND** 5. The patient's age is 45 years or over **AND** 6. ONE of the following: A. The patient does not currently use any tobacco products (e.g., cigarettes, chewing tobacco) **OR** B. The patient is being managed for tobacco cessation **AND** 7. ALL of the following: A. The patient is currently being treated in the past 90 days with antihypertensive therapy (e.g., ACE inhibitor, angiotensin receptor blocker, beta blocker) **AND** B. The patient is currently being treated in the past 90 days with lipid lowering therapy (e.g., any statin, ezetimibe) **AND** C. The patient will continue antihypertensive therapy (e.g., ACE inhibitor, angiotensin receptor blocker, beta blocker) AND lipid lowering therapy (e.g., any statin, ezetimibe) **AND** 8. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **OR** B. The patient is overweight or obese and is using the requested agent for weight management and ALL of the following: 1. Obesity is NOT restricted from coverage under the patient's benefit **AND** 2. The patient new to therapy, new to Prime, or attempting a repeat weight loss course of therapy **AND** 3. ONE of the following: A. The patient is 17 years of age or over and has ONE of the following: 1. A BMI greater than or equal to 30 kg/m^2 **OR** 2. 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**

Module	Clinical Criteria for Approval
	3. A BMI greater than or equal to 27 kg/m^2 with at least one weight-related comorbidity/risk factor/complication (e.g., hypertension, type 2 diabetes mellitus, obstructive sleep apnea, cardiovascular disease, dyslipidemia) **OR** B. The patient is 12 to 16 years of age and has ONE of the following: 1. A BMI greater than or equal to 95th percentile for age and sex **OR** 2. A BMI greater than or equal to 30 kg/m^2 **OR** 3. A BMI greater than or equal to 85th percentile for age and sex AND at least one severe weight-related comorbidity/risk factor/complication **AND** 4. BOTH of the following: A. 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 from baseline (prior to initiation of pharmacotherapy) **AND** B. The patient has experienced weight loss of less than 1 pound per week while on a weight loss regimen from baseline (prior to initiation of pharmacotherapy) **AND** 5. If the requested agent is Saxenda, then 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 pharmacotherapy) **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 pharmacotherapy) **AND** 6. If the requested agent is Wegovy, then 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 pharmacotherapy) **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 pharmacotherapy) **AND** 7. If the requested agent is Zepbound, then 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. The patient has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR**

Module	Clinical Criteria for Approval
	C. The patient has another FDA labeled indication for the requested agent and route of administration **AND** 2. The patient will NOT be using the requested agent in combination with another weight loss agent (e.g., Contrave, phentermine, Qsymia, Xenical) for the requested indication **AND** 3. The patient is currently on and will continue a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **AND** 4. 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. There is support for using the requested agent for the patient's age for the requested indication **AND** 5. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** • For Wegovy, Zepbound: 12 months • For Saxenda: Pediatric patients (age 12 to less than 18): 5 months; Adults: 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 [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. ONE of the following: A. The patient's requested use is to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease (medical records required) and the patient is either obese or overweight AND ALL of the following: 1. The requested agent and strength have an FDA labeled indication for the requested diagnosis and route of administration **AND** 2. The patient has a history of ONE of the following: (medical records required) A. Myocardial infarction **OR** B. Stroke **OR** C. Peripheral artery disease as defined by intermittent claudication with ankle-brachial index less than 0.85 at rest, or peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease **AND** 3. The patient does NOT have type 2 diabetes **AND** 4. ONE of the following: A. The patient does not currently use any tobacco products (e.g., cigarettes, chewing tobacco) **OR** B. The patient is being managed for tobacco cessation **AND** 5. ALL of the following: A. The patient is currently being treated in the past 90 days with antihypertensive therapy (e.g., ACE inhibitor, angiotensin receptor blocker, beta blocker) **AND** B. The patient is currently being treated in the past 90 days with lipid lowering therapy (e.g., any statin, ezetimibe) **AND** C. The patient will continue antihypertensive therapy (e.g., ACE inhibitor, angiotensin receptor blocker, beta blocker) AND lipid lowering therapy (e.g., any

Module	Clinical Criteria for Approval
	statin, ezetimibe) **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **OR** B. The patient is overweight or obese and is using the requested agent for weight management and ALL of the following: 1. Obesity is NOT restricted from coverage under the patient's benefit **AND** 2. The patient is continuing a current weight loss course of therapy **AND** 3. If the patient is 12 to less than 18 years of age, then the current BMI is greater than 85th percentile for age and sex **AND** 4. If the requested agent is Saxenda, then BOTH of the following: A. The requested agent is NOT being used to treat type 2 diabetes **AND** B. ONE of the following: 1. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR** 2. 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 pharmacotherapy) **OR** 3. 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 pharmacotherapy) **AND** 5. If the requested agent is Wegovy, then BOTH of the following: A. The requested dose is 1.7 mg or 2.4 mg **AND** B. ONE of the following: 1. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR** 2. The patient is 12 years of age and over AND has received less than 52 weeks of therapy on the maximum-tolerated dose **OR** 3. 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 pharmacotherapy) **AND** 6. If the requested agent is Zepbound, then 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 pharmacotherapy) **OR** B. The patient has received less than 52 weeks of therapy on the maximum-tolerated dose **OR** C. The patient has another FDA labeled indication for the requested agent and route of administration **AND** 3. The patient will NOT be using the requested agent in combination with another weight loss agent (e.g., Contrave, phentermine, Qsymia, Xenical) for the requested indication **AND** 4. 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** 5. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist 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
Universal 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. 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. There is support for 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 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. There is support for therapy with a higher dose for the requested indication **Length of Approval**: • Initial Approval: ○ For Wegovy, Zepbound: up to 12 months ○ For Saxenda: Pediatric patients (age 12 to less than 18): up to 5 months; Adults: up to 4 months • Renewal Approval: up to 12 months

• Program Summary: Xphozah (tenapanor)

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
30903260600325	Xphozah	tenapanor hcl tab	20 MG	60	Tablets	30	DAYS			
30903260600330	Xphozah	tenapanor hcl tab	30 MG	60	Tablets	30	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Initial Evaluation

PREREQUISITE GENERIC PHOSPHATE BINDER(S)
calcium carbonate calcium acetate calcium with magnesium sevelamer carbonate sevelamer HCl

PREREQUISITE PREFERRED BRAND PHOSPHATE BINDER(S)
Velphoro

Target Agent(s) 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. 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. ONE of the following:
        - A. The patient has a diagnosis of chronic kidney disease (CKD) AND ALL of the following:
          1. The patient is on dialysis **AND**
          2. The patient has a phosphorus level of at least 5.5 mg/dL **AND**
          3. ONE of the following:
             - A. ALL of the following:
               1. The patient has tried and had an inadequate response to at least ONE generic phosphate binder **AND**
               2. The patient has tried and had an inadequate response to at least ONE preferred phosphate binder **AND**
               3. The patient will be using the requested agent in

Module	Clinical Criteria for Approval
	combination with phosphate binder therapy **OR** B. The patient is intolerant or has a hypersensitivity to at least ONE generic phosphate binder AND at least ONE preferred phosphate binder **OR** C. The patient has an FDA labeled contraindication to ALL generic phosphate binders AND ALL preferred phosphate binders **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 generic phosphate binders and ALL preferred phosphate binders 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 labeled 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. There is support for using the requested agent for the patient's age for the requested indication **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 [NOTE: Patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. ONE of the following: A. The patient is using the requested agent in combination with phosphate binder therapy **OR** B. The patient is intolerant or has a hypersensitivity to phosphate binder therapy **OR** C. The patient has an FDA labeled contraindication to ALL phosphate binders **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. There is support for therapy with a higher dose for the requested indication **Length of Approval**: Initial - up to 6 months; Renewal - up to 12 months

POLICIES REVISED

• Program Summary: Agamree (vamorolone), Emflaza (deflazacort) [*fka Emflaza (deflazacort)]*

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
22100075001820	Agamree	vamorolone oral susp	40 MG/ML	3	Bottles	30	DAYS			
22100017000350	Emflaza	Deflazacort Tab 18 MG	18 MG	30	Tablets	30	DAYS			
22100017000340	Emflaza	Deflazacort Tab 6 MG	6 MG	60	Tablets	30	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. 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. The patient has been treated with the requested agent (starting on samples is not approvable) with 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. ONE of the following: A. The patient has a diagnosis of Duchenne Muscular Dystrophy confirmed by

Module	Clinical Criteria for Approval
	genetic analysis (i.e., dystrophin deletion or duplication mutation) (genetic test required) **OR** B. The patient has another FDA labeled 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. There is support for the use of the requested agent for the patient's age for the requested indication **AND** 3. ONE of the following: A. The prescriber has provided information that the patient has tried and failed a generic prednisone (or prednisolone) **OR** B. The prescriber has provided information that the patient has an intolerance or hypersensitivity to generic prednisone (or prednisolone) that is NOT expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to generic prednisone (or prednisolone) **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 generic prednisone (or prednisolone) 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 prescriber is a specialist in the area of the patient's diagnosis (e.g., pediatric neurologist), 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 requested quantity (dose) does NOT exceed the maximum FDA labeled dose based on the patient's weight **Length of Approval:** 6 months for Agamree, 12 months for Emflaza 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 [NOTE: Patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had improvements or stabilization with the requested agent (e.g., slowed disease progression, improved strength, timed motor function, pulmonary function; reduced need for scoliosis surgery) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., pediatric neurologist), 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 **AND**

Module	Clinical Criteria for Approval
	5. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose based on the patient's weight **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	**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 agent strength does not have a program quantity limit **OR** 3. The request agent is Emflaza and ONE of the following: A. The requested agent is Emflaza SUSPENSION **OR** B. BOTH of the following: 1. The requested quantity (dose) exceeds the program quantity limit **AND** 2. The requested quantity (dose) cannot be achieved with a lower quantity of any combination of the four Emflaza tablet strengths **OR** 4. 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 **Approval Length:** up to 12 months

• Program Summary: Antidepressant 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
58300040100310		Bupropion HCl Tab 100 MG	100 MG	120	Tablets	30	DAYS			
58300040100305		Bupropion HCl Tab 75 MG	75 MG	60	Tablets	30	DAYS			
58160020100120		Citalopram Hydrobromide Cap	30 MG	30	Capsules	30	DAYS			
581600201020		citalopram hydrobromide oral soln	10 MG/5ML	600	mLs	30	DAYS			
581800200075		desvenlafaxine tab er	100 MG; 50 MG	30	Tablets	30	DAYS			
58180025106740		Duloxetine HCl Enteric Coated Pellets Cap 40 MG (Base Eq)	40 MG	90	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
581600341020		escitalopram oxalate soln	5 MG/5ML	600	mLs	30	DAYS			
581600400065		fluoxetine hcl cap delayed release	90 MG	4	Capsules	28	DAYS			
581600400020		fluoxetine hcl solution	20 MG/5ML	600	mLs	30	DAYS			
58160040000310		Fluoxetine HCl Tab 10 MG	10 MG	30	Tablets	30	DAYS			
58160040000320		Fluoxetine HCl Tab 20 MG	20 MG	120	Tablets	30	DAYS			
58160040000360		Fluoxetine HCl Tab 60 MG	60 MG	30	Tablets	30	DAYS			
581600451070		fluvoxamine maleate cap er	100 MG; 150 MG	60	Capsules	30	DAYS			
58160045100330		Fluvoxamine Maleate Tab 100 MG	100 MG	90	Tablets	30	DAYS			
58160045100310		Fluvoxamine Maleate Tab 25 MG	25 MG	30	Tablets	30	DAYS			
58160045100320		Fluvoxamine Maleate Tab 50 MG	50 MG	30	Tablets	30	DAYS			
58160070100130		Sertraline HCl Cap	150 MG	30	Capsules	30	DAYS			
58160070100140		Sertraline HCl Cap	200 MG	30	Capsules	30	DAYS			
58180090057520		Venlafaxine Besylate Tab ER	112.5 MG	30	Tablets	30	DAYS			
581800901003		venlafaxine hcl tab	100 MG; 25 MG; 37.5 MG; 50 MG; 75 MG	90	Tablets	30	DAYS			
58180090107530		Venlafaxine HCl Tab ER 24HR 150 MG (Base Equivalent)	150 MG	30	Tablets	30	DAYS			
58180090107540		Venlafaxine HCl Tab ER 24HR 225 MG (Base Equivalent)	225 MG	30	Tablets	30	DAYS			
58180090107510		Venlafaxine HCl Tab ER 24HR 37.5 MG (Base Equivalent)	37.5 MG	30	Tablets	30	DAYS			
58180090107520		Venlafaxine HCl Tab ER 24HR 75 MG (Base Equivalent)	75 MG	90	Tablets	30	DAYS			
583000402075	Aplenzin	bupropion hbr tab er	174 MG; 348 MG; 522 MG	30	Tablets	30	DAYS			
58999902300420	Auvelity	Dextromethorphan HBr-Bupropion HCl Tab ER	45-105 MG	60	Tablets	30	DAYS			
581600201003	Celexa	citalopram	10 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
		hydrobromide tab	20; 20 MG; 40 MG							
58180025106720	Cymbalta	Duloxetine HCl Enteric Coated Pellets Cap 20 MG (Base Eq)	20 MG	60	Capsules	30	DAYS			
58180025106730	Cymbalta	Duloxetine HCl Enteric Coated Pellets Cap 30 MG (Base Eq)	30 MG	60	Capsules	30	DAYS			
58180025106750	Cymbalta	Duloxetine HCl Enteric Coated Pellets Cap 60 MG (Base Eq)	60; 60 MG	60	Capsules	30	DAYS			
58180090107050	Effexor xr	Venlafaxine HCl Cap ER 24HR 150 MG (Base Equivalent)	150 MG	30	Capsules	30	DAYS			
58180090107020	Effexor xr	Venlafaxine HCl Cap ER 24HR 37.5 MG (Base Equivalent)	37.5 MG	30	Capsules	30	DAYS			
58180090107030	Effexor xr	Venlafaxine HCl Cap ER 24HR 75 MG (Base Equivalent)	75 MG	90	Capsules	30	DAYS			
581800501070	Fetzima	levomilnacipran hcl cap er	120 MG; 20 MG; 40 MG; 80 MG	30	Capsules	30	DAYS			
5818005010B6	Fetzima titration pack	levomilnacipran hcl cap er	20 & 40 MG	1	Kit	28	DAYS			
583000401075	Forfivo xl; Wellbutrin xl	bupropion hcl tab er	150; 150 MG; 300; 300 MG; 450 MG	30	Tablets	30	DAYS			
581600341003	Lexapro	escitalopram oxalate tab	10; 10 MG; 20 MG; 5 MG	30	Tablets	30	DAYS			
581600600018	Paxil	paroxetine hcl oral susp	10 MG/5ML	900	mLs	30	DAYS			
58160060000310	Paxil	Paroxetine HCl Tab 10 MG	10 MG	30	Tablets	30	DAYS			
58160060000320	Paxil	Paroxetine HCl Tab 20 MG	20 MG	30	Tablets	30	DAYS			
58160060000330	Paxil	Paroxetine HCl Tab 30 MG	30 MG	60	Tablets	30	DAYS			
58160060000340	Paxil	Paroxetine HCl Tab 40 MG	40 MG	30	Tablets	30	DAYS			
58160060007520	Paxil cr	Paroxetine HCl Tab ER 24HR 12.5 MG	12.5 MG	30	Tablets	30	DAYS			
58160060007530	Paxil cr	Paroxetine HCl Tab ER 24HR 25 MG	25 MG	60	Tablets	30	DAYS			
58160060007540	Paxil cr	Paroxetine HCl Tab ER 24HR 37.5 MG	37.5 MG	60	Tablets	30	DAYS			
58160060300310	Pexeva	Paroxetine Mesylate	10 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
		Tab 10 MG (Base Equiv)								
58160060300320	Pexeva	Paroxetine Mesylate Tab 20 MG (Base Equiv)	20 MG	30	Tablets	30	DAYS			
58160060300330	Pexeva	Paroxetine Mesylate Tab 30 MG (Base Equiv)	30 MG	60	Tablets	30	DAYS			
58160060300340	Pexeva	Paroxetine Mesylate Tab 40 MG (Base Equiv)	40 MG	30	Tablets	30	DAYS			
581800202075	Pristiq	desvenlafaxine succinate tab er	100 MG; 25 MG; 50 MG	30	Tablets	30	DAYS			
58160040000110	Prozac	Fluoxetine HCl Cap 10 MG	10 MG	30	Capsules	30	DAYS			
58160040000120	Prozac	Fluoxetine HCl Cap 20 MG	20 MG	120	Capsules	30	DAYS			
58160040000140	Prozac	Fluoxetine HCl Cap 40 MG	40 MG	60	Capsules	30	DAYS			
580300500003	Remeron	mirtazapine tab	15 MG; 30 MG; 45 MG; 7.5 MG	30	Tablets	30	DAYS			
580300500072	Remeron soltab	mirtazapine orally disintegrating tab	15 MG; 30 MG; 45 MG	30	Tablets	30	DAYS			
581200931003	Trintellix	vortioxetine hbr tab	10 MG; 20 MG; 5 MG	30	Tablets	30	DAYS			
581200881003	Viibryd	vilazodone hcl tab	10 MG; 20 MG; 40 MG	30	Tablets	30	DAYS			
58120088106410	Viibryd starter pack	Vilazodone HCl Tab Starter Kit 10 (7) & 20 (23) MG	10 & 20 MG	1	Kit	180	DAYS			
583000401074	Wellbutrin sr	Bupropion HCl Tab ER; bupropion hcl tab er	100 MG; 150 MG; 200 MG	60	Tablets	30	DAYS			
581600701013	Zoloft	sertraline hcl oral concentrate for solution	20 MG/ML	300	mLs	30	DAYS			
58160070100320	Zoloft	Sertraline HCl Tab 100 MG	100 MG	60	Tablets	30	DAYS			
58160070100305	Zoloft	Sertraline HCl Tab 25 MG	25 MG	30	Tablets	30	DAYS			
58160070100310	Zoloft	Sertraline HCl Tab 50 MG	50 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
58060090000120	Zurzuvae	zuranolone cap	20 MG	28	Capsules	365	DAYS			
58060090000125	Zurzuvae	zuranolone cap	25 MG	28	Capsules	365	DAYS			
58060090000130	Zurzuvae	zuranolone cap	30 MG	14	Capsules	365	DAYS			

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Brand Agents other than Cymbalta	**TARGET AGENT(S)** **Aplenzin** (bupropion) **Auvelity** (dextromethorphan/bupropion ER) **Celexa** (citalopram)* **Citalopram** (capsules)^ **Desvenlafaxine ER** (tablets)^ **Effexor** (venlafaxine)* **Effexor XR** (venlafaxine extended release)* **Fetzima®** (levomilnacipran extended release) **Fluoxetine 60 mg** (tablets)*^ **Fluoxetine delayed release** (capsules)^ **Forfivo XL** (bupropion extended release) **Lexapro** (escitalopram)* **Paxil** (paroxetine hydrochloride)* **Paxil CR** (paroxetine extended release)* **Pexeva** (paroxetine mesylate) **Pristiq** (desvenlafaxine succinate* **Prozac** (fluoxetine)* **Remeron** (mirtazapine)* **Remeron SolTab** (mirtazapine)* **Sertraline** (capsules)^ **Trintellix** (vortioxetine) **Venlafaxine ER** (tablets)^ **Viibryd** (vilazodone)* **Wellbutrin** (bupropion)* **Wellbutrin SR** (bupropion extended release)* **Wellbutrin XL** (bupropion extended release)* **Zoloft** (sertraline)* * - available as a generic; generic included as a prerequisite in step therapy program ^ – branded generic product(s) available; targeted in the step therapy program **Brand Antidepressant Agent(s)** (except Cymbalta) will be approved when ONE of the following are met: 1. The patient has been treated with the requested agent within the past 180 days **OR** 2. The prescriber states that the patient has been treated with the requested agent within 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 request is for Auvelity AND ONE of the following: A. The patient's medication history includes TWO generic antidepressant agents (i.e., SSRI, SNRI,

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	bupropion, mirtazapine, or vilazodone) use, intolerance, or hypersensitivity **OR** B. BOTH of the following: 1. The prescriber has stated that the patient has tried TWO generic antidepressant agents (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone) **AND** 2. BOTH generic antidepressant agents (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone) were discontinued due to lack of effectiveness or an adverse event **OR** C. The patient has an FDA labeled contraindication to ALL generic antidepressant agents (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone) **OR** D. The prescriber has provided documentation that ALL generic antidepressant agents (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone) 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** 5. The request is for a medication other than Auvelity AND ONE of the following: A. The patient's medication history includes generic antidepressant agent (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone) use, intolerance, or hypersensitivity **OR** B. BOTH of the following: 1. The prescriber has stated that the patient has tried a generic antidepressant agent (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone) **AND** 2. The generic antidepressant agent (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone) was discontinued due to lack of effectiveness or an adverse event **OR** C. The patient has an FDA labeled contraindication to ALL generic antidepressants (i.e., SSRI, SNRI, bupropion, mirtazapine, and vilazodone) **OR** D. The prescriber has provided documentation that ALL generic antidepressant agents (i.e., SSRI, SNRI, bupropion, mirtazapine, and vilazodone) 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.
Cymbalta	**TARGET AGENT(S)** **Cymbalta** (duloxetine)* * - available as a generic; generic included as a prerequisite in step therapy program **Cymbalta** will be approved when ONE of the following are met: 1. The patient has been treated with the requested agent within the past 180 days **OR** 2. The prescriber states the patient has been treated with the requested agent within 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 has a medication history of use that includes use of a generic antidepressant agent (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone) **OR** 5. BOTH of the following: A. The prescriber has stated that the patient has tried a generic antidepressant agent (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone) **AND** B. The generic antidepressant agent (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone) was

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	discontinued due to lack of effectiveness or an adverse event **OR** 6. The patient has a diagnosis of neuropathic pain and ONE of the following: A. The patient has a medication history of use that includes use of ONE prerequisite agent (i.e., amitriptyline, nortriptyline, desipramine, imipramine, or gabapentin) intolerance, or hypersensitivity **OR** B. BOTH of the following: 1. The prescriber has stated that the patient has tried amitriptyline, nortriptyline, desipramine, imipramine, or gabapentin **AND** 2. The prerequisite agent (i.e., amitriptyline, nortriptyline, desipramine, imipramine, or gabapentin) was discontinued due to lack of effectiveness or an adverse event **OR** C. The patient has an FDA labeled contraindication to ALL prerequisite agents (i.e., amitriptyline, nortriptyline, desipramine, imipramine, and gabapentin) **OR** D. The prescriber has provided documentation that ALL prerequisite agents (i.e., amitriptyline, nortriptyline, desipramine, imipramine, and gabapentin) 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** 7. The patient has a diagnosis of fibromyalgia and ONE of the following: A. The patient has a medication history of use that includes use of ONE prerequisite agent (i.e., amitriptyline, nortriptyline, desipramine, imipramine, cyclobenzaprine, gabapentin, or tramadol), intolerance, or hypersensitivity **OR** B. BOTH of the following: 1. The prescriber has stated that the patient has tried amitriptyline, nortriptyline, desipramine, imipramine, cyclobenzaprine, gabapentin, or tramadol **AND** 2. The prerequisite agent (i.e., amitriptyline, nortriptyline, desipramine, imipramine, cyclobenzaprine, gabapentin, or tramadol) was discontinued due to lack of effectiveness or an adverse event **OR** C. The patient has an FDA labeled contraindication to ALL prerequisite agents (i.e., amitriptyline, nortriptyline, desipramine, imipramine, cyclobenzaprine, gabapentin, and tramadol) **OR** D. The prescriber has provided documentation that ALL prerequisite agents (i.e., amitriptyline, nortriptyline, desipramine, imipramine, cyclobenzaprine, gabapentin and tramadol) 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** 8. The patient has a diagnosis of chronic musculoskeletal pain and ONE of the following: A. The patient has a medication history of use that includes use of ONE prerequisite agent (i.e., acetaminophen, oral NSAID, topical NSAID, tramadol, amitriptyline, nortriptyline, desipramine, imipramine, cyclobenzaprine, or gabapentin), intolerance, or hypersensitivity **OR** B. BOTH of the following: 1. The prescriber has stated that the patient has tried ONE prerequisite agent (i.e., acetaminophen, oral NSAID, topical NSAID, tramadol, amitriptyline, nortriptyline, desipramine, imipramine, cyclobenzaprine, or gabapentin) **AND** 2. The prerequisite agent (i.e., acetaminophen, oral NSAID, topical NSAID, tramadol, amitriptyline, nortriptyline, desipramine, imipramine, cyclobenzaprine, or gabapentin) was discontinued due to lack of effectiveness or an adverse event **OR** C. The patient has an FDA labeled contraindication to ALL prerequisite agents (i.e., acetaminophen, oral NSAID, topical NSAID, tramadol, amitriptyline, nortriptyline, desipramine, imipramine, cyclobenzaprine, and gabapentin) **OR** D. The prescriber has provided documentation that ALL prerequisite agents (i.e., acetaminophen, oral NSAID, topical NSAID, tramadol, amitriptyline, nortriptyline, desipramine, imipramine, cyclobenzaprine, and gabapentin) 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**

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	9. If using for a diagnosis other than neuropathic pain, fibromyalgia for Cymbalta only, or musculoskeletal pain ONE of the following: A. The patient has an intolerance or hypersensitivity to a generic antidepressant (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone) **OR** B. The patient has an FDA labeled contraindication to ALL generic antidepressants (i.e., SSRI, SNRI, bupropion, mirtazapine, and vilazodone) **OR** C. If using for a diagnosis other than neuropathic pain, fibromyalgia for Cymbalta only, or musculoskeletal pain: The prescriber has provided documentation that ALL generic antidepressant agents (i.e., SSRI, SNRI, bupropion, mirtazapine, and vilazodone) 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. There is support for 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 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. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• Program Summary: Anti-Obesity Non-GLP-1 Agents *(fka Anti-Obesity Agents)*

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

TARGET AGENT(S)

Adipex-P® (phentermine)[a]
Contrave® (naltrexone/bupropion)
Diethylpropion[a]
Lomaira™ (phentermine)
Phendimetrazine[a]
Phentermine[a]
Qsymia® (phentermine/topiramate)
Xenical® (orlistat)
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, or O	1 capsule
37.5 mg tablet	61200070100310	M, N, or O	1 tablet
Contrave (naltrexone/bupropion)			
8 mg / 90 mg tablet	61259902507420	M, N, O, or Y	4 tablets
Diethylpropion[a]			
75 mg extended-release tablet	61200020107510	M, N, O, or Y	1 tablet
Phendimetrazine[a]			
105 mg extended-release capsule	61200050107010	M, N, O, or Y	1 capsule
Phentermine[a]			
15 mg capsule	61200070100110	M, N, or O	1 capsule
30 mg capsule	61200070100115	M, N, or O	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
Xenical (orlistat)			
120 mg capsule	61253560000120	M, N, O, or Y	3 capsules

a – Generic equivalent available

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 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. There is support for using the requested agent for the patient's age for the requested indication

AND

4. 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

5. ONE of the following:
   A. The requested agent is diethylpropion, phendimetrazine, or phentermine
   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 or Orlistat 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)

AND

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

AND

7. The patient does NOT have any FDA labeled contraindications to 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 Contrave: 4 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. The 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 [Note: patients not previously approved for the requested agent will require initial evaluation review]
AND
3. 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 Qsymia only, ONE of the following:
i. 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
ii. 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

C. 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)

AND
4. 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
5. 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

6. The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication
7. The patient does NOT have any FDA labeled contraindications to 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: 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: Attention Deficit [Hyperactivity] Disorder (ADHD/ADD) 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
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			

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
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 Tab 20 MG	20 MG	90	Tablets	30	DAYS			
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-	30 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
		Dextroamphetamine Cap ER 24HR 30 MG								
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 Disintegrating 18.8 MG	18.8 MG	30	Tablets	30	DAYS			
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			

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
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			
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	5 MG	90	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
		Sulfate Cap ER 24HR 5 MG								
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; 20 MG; 25 MG; 30 MG; 35 MG; 40 MG; 5 MG	30	Capsules	30	DAYS			
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	80 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
		Cap Delayed ER 24HR 80 MG (PM)								
61353020107420	Kapvay	Clonidine HCl Tab ER 12HR 0.1 MG	0.1 MG	120	Tablets	30	DAYS			
614000201002	Metadate cd	methylphenidate hcl cap er	10 MG; 20 MG; 30 MG; 40 MG; 50 MG; 60 MG	30	Capsules	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			
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	45 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
		Tab ER Osmotic Release (OSM)								
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			
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			

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
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	**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. There is support for 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 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. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• Program Summary: Atypical Antipsychotics – Extended Maintenance Agents

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

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
5925001500E455	Abilify asimtufii	aripiprazole im er susp prefilled syringe	720 MG/2.4ML	1	Syringe	56	DAYS			
5925001500E465	Abilify asimtufii	aripiprazole im er susp prefilled syringe	960 MG/3.2ML	1	Syringes	56	DAYS			
5925001500E430	Abilify maintena	Aripiprazole IM For ER Susp Prefilled Syringe 300 MG	300 MG	1	Syringe	28	DAYS			
5925001500E440	Abilify maintena	Aripiprazole IM For ER Susp Prefilled Syringe 400 MG	400 MG	1	Syringe	28	DAYS			
5925001500G230	Abilify maintena	Aripiprazole IM For Extended Release Susp 300 MG	300 MG	1	Vial	28	DAYS			
5925001500G240	Abilify maintena	Aripiprazole IM For Extended Release Susp 400 MG	400 MG	1	Vial	28	DAYS			
5925001520E450	Aristada	Aripiprazole Lauroxil IM ER Susp Prefilled Syr 1064 MG/3.9ML	1064 MG/3.9ML	1	Syringe	56	DAYS			
5925001520E420	Aristada	Aripiprazole Lauroxil IM ER Susp Prefilled Syr 441 MG/1.6ML	441 MG/1.6ML	1	Syringe	28	DAYS			
5925001520E430	Aristada	Aripiprazole Lauroxil IM ER Susp Prefilled Syr 662 MG/2.4ML	662 MG/2.4ML	1	Syringe	28	DAYS			
5925001520E440	Aristada	Aripiprazole Lauroxil IM ER Susp Prefilled Syr 882 MG/3.2ML	882 MG/3.2ML	1	Syringe	28	DAYS			
5925001520E435	Aristada initio	Aripiprazole Lauroxil IM ER Susp Prefilled Syr 675 MG/2.4ML	675 MG/2.4ML	1	Kit	180	DAYS			
5907005010E670	Invega hafyera	Paliperidone Palmitate ER Susp Pref Syr	1092 MG/3.5ML	1	Syringe	180	DAYS			
5907005010E675	Invega hafyera	Paliperidone Palmitate ER Susp Pref Syr	1560 MG/5ML	1	Syringe	180	DAYS			
5907005010E632	Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 117 MG/0.75ML	117 MG/0.75ML	1	Kit	28	DAYS			
5907005010E635	Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 156 MG/ML	156 MG/ML	1	Kit	28	DAYS			
5907005010E638	Invega sustenna	Paliperidone	234	1	Kit	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
		Palmitate ER Susp Pref Syr 234 MG/1.5ML	MG/1.5ML							
5907005010E626	Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 39 MG/0.25ML	39 MG/0.25ML	1	Kit	28	DAYS			
5907005010E629	Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 78 MG/0.5ML	78 MG/0.5ML	1	Kit	28	DAYS			
5907005010E643	Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 273 MG/0.875ML	273 MG/0.88ML	1	Syringe	84	DAYS			
5907005010E647	Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 410 MG/1.315ML	410 MG/1.32ML	1	Syringe	84	DAYS			
5907005010E651	Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 546 MG/1.75ML	546 MG/1.75ML	1	Syringe	84	DAYS			
5907005010E655	Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 819 MG/2.625ML	819 MG/2.63ML	1	Syringe	84	DAYS			
5907007000E430	Perseris	Risperidone Subcutaneous For ER Susp Prefilled Syr 120 MG	120 MG	1	Kit	28	DAYS			
5907007000E420	Perseris	Risperidone Subcutaneous For ER Susp Prefilled Syr 90 MG	90 MG	1	Kit	28	DAYS			
5907007010G210	Risperdal consta	Risperidone Microspheres For IM Extended Rel Susp 12.5 MG	12.5 MG	2	Vials	28	DAYS			
5907007010G220	Risperdal consta	Risperidone Microspheres For IM Extended Rel Susp 25 MG	25 MG	2	Vials	28	DAYS			
5907007010G230	Risperdal consta	Risperidone Microspheres For IM Extended Rel Susp 37.5 MG	37.5 MG	2	Vials	28	DAYS			
5907007010G240	Risperdal consta	Risperidone Microspheres For IM Extended Rel Susp 50 MG	50 MG	2	Vials	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
5907007000G220	Rykindo	risperidone for im extended release suspension	25 MG	2	Vials	28	DAYS			
5907007000G230	Rykindo	risperidone for im extended release suspension	37.5 MG	2	Vials	28	DAYS			
5907007000G240	Rykindo	risperidone for im extended release suspension	50 MG	2	Vials	28	DAYS			
5907007000E610	Uzedy	risperidone subcutaneous er susp pref syr	50 MG/0.14ML	1	Syringe	28	DAYS			
5907007000E618	Uzedy	risperidone subcutaneous er susp pref syr	75 MG/0.21ML	1	Syringe	28	DAYS			
5907007000E626	Uzedy	risperidone subcutaneous er susp pref syr	100 MG/0.28ML	1	Syringe	28	DAYS			
5907007000E634	Uzedy	risperidone subcutaneous er susp pref syr	125 MG/0.35ML	1	Syringe	28	DAYS			
5907007000E642	Uzedy	risperidone subcutaneous er susp pref syr	150 MG/0.42ML	1	Syringe	56	DAYS			
5907007000E658	Uzedy	risperidone subcutaneous er susp pref syr	200 MG/0.56ML	1	Syringe	56	DAYS			
5907007000E674	Uzedy	risperidone subcutaneous er susp pref syr	250 MG/0.7ML	1	Syringe	56	DAYS			
59157060101950	Zyprexa relprevv	Olanzapine Pamoate For Extended Rel IM Susp 210 MG (Base Eq)	210 MG	2	Vials	28	DAYS			
59157060101960	Zyprexa relprevv	Olanzapine Pamoate For Extended Rel IM Susp 300 MG (Base Eq)	300 MG	2	Vials	28	DAYS			
59157060101970	Zyprexa relprevv	Olanzapine Pamoate For Extended Rel IM Susp 405 MG (Base Eq)	405 MG	1	Vial	28	DAYS			

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

TARGET AGENT(S)	PREREQUISITE AGENT(S)
Abilify Asimtufii (aripiprazole) **Abilify Maintena** (aripiprazole) **Aristada** (aripiprazole) **Aristada Initio** (aripiprazole)	Any oral brand or generic: Abilify Abilify Mycite aripiprazole ODT aripiprazole 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)* **Rykindo** (risperidone ER) **Uzedy** (risperidone ER)	Any oral brand or generic: Risperdal Risperdal solution risperidone Risperidone ODT, risperidone ODT
Zyprexa Relprevv (olanzapine)	Any oral brand or generic: olanzapine Zyprexa Zyprexa Zydis

* - generic available; generic is a target

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

1. 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 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. There is support for 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** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 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	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			

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
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 inj kit	200 MG	2	Kits	28	DAYS			
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	40 MG/0.8ML	2	Pens	28	DAYS	00597037597;		

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
		auto-injector kit						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			
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			

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
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; 83457012402		
6627001500F430	Humira pen	Adalimumab Pen-injector Kit 40 MG/0.4ML	40 MG/0.4ML	2	Pens	28	DAYS			
6627001500F440	Humira pen-cd/uc/hs start	adalimumab pen-injector kit	80 MG/0.8ML	1	Kit	180	DAYS	00074012403		
6627001500F420	Humira pen-cd/uc/hs start	Adalimumab Pen-injector Kit ; adalimumab pen-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00074433906		
6627001500F440	Humira pen-pediatric uc s	adalimumab pen-injector kit	80 MG/0.8ML	4	Pens	180	DAYS	00074012404		
6627001500F420	Humira pen-ps/uv starter	Adalimumab Pen-injector Kit ; adalimumab pen-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00074433907		
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	10 MG/0.1 ML	2	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	Effective Date	Term Date
		syringe								
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		
6627001504D540	Hyrimoz crohn's disease a; Hyrimoz sensoready pens	adalimumab-adaz soln auto-injector	80 MG/0.8ML	1	Starter Kit	180	DAYS	61314045436; 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 (2 pen)	adalimumab-aacf auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS	65219055408; 65219061299		
6627001502F840	Idacio (2 syringe)	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	65219055438		
6627001502F540	Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	65219055428		
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	100 MG/ML	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	Effective Date	Term Date
		auto-injector								
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			
6627001540F520	Simlandi 1-pen kit; Simlandi 2-pen kit	adalimumab-ryvk auto-injector kit	40 MG/0.4ML	2	Pens	28	DAYS			
6627004000D540	Simponi	Golimumab Subcutaneous Soln Auto-injector 100 MG/ML	100 MG/ML	1	Syringe	28	DAYS			
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	180	1	Cartridge	56	DAY			

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 Cartridge	MG/1.2ML		s					
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			
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			
6627001503F530	Yuflyma 1-pen kit	adalimumab-aaty auto-injector kit	40 MG/0.4ML	2	Pens	28	DAYS	72606002209; 72606003009		
6627001503F560	Yuflyma 1-pen kit	adalimumab-aaty auto-injector kit	80 MG/0.8ML	2	Pens	28	DAYS	72606002304; 72606004004		

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
6627001503F530	Yuflyma 2-pen kit	adalimumab-aaty auto-injector kit	40 MG/0.4ML	2	Pens	28	DAYS	72606002210; 72606003010		
6627001503F820	Yuflyma 2-syringe kit	adalimumab-aaty prefilled syringe kit	20 MG/0.2ML	2	Syringes	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			
5250504020F530	Zymfentra 1-pen	infliximab-dyyb soln auto-injector kit	120 MG/ML	2	Pens	28	DAYS	72606002501		
5250504020F530	Zymfentra 2-pen	infliximab-dyyb soln auto-injector kit	120 MG/ML	2	Pens	28	DAYS	72606002502		
5250504020F830	Zymfentra 2-syringe	infliximab-dyyb soln prefilled syringe kit	120 MG/ML	2	Syringes	28	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Option A - FlexRx, GenRx, BasicRx, and KeyRx	**Step Table**

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: Hadlima, Cosentyx, Enbrel, Humira	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Simponi, Taltz	N/A	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
Nonradiogra	SQ: Cimzia,	Oral: Rinvoq	N/A	SQ: Taltz	N/A	N/A

Module	Clinical Criteria for Approval						
	phic Axial Spondyloarthritis (nr-axSpA)	Cosentyx					
	Polyarticular Juvenile Idiopathic Arthritis (PJIA)	SQ: Enbrel, Hadlima, Humira	Oral: Xeljanz	SQ: Actemra (Hadlima, or Humira is required Step 1 agent)	N/A	SQ: Orencia	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Psoriatic Arthritis (PsA)	SQ: 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**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Rheumatoid Arthritis	SQ: Enbrel, Hadlima, Humira	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Actemra (Hadlima, or Humira is required Step 1 agent)	Oral: Olumiant SQ: Cimzia, Kevzara, Kineret, Orencia, Simponi	N/A	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Dermatological Disorder						
	Hidradenitis Suppurativa (HS)	SQ: Cosentyx, Hadlima, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**

Module	Clinical Criteria for Approval						
	Psoriasis (PS)	SQ: Cosentyx, Enbrel, Hadlima, Humira, Skyrizi, Stelara, Tremfya Oral: Otezla	N/A	Oral: Sotyktu	SQ: Cimzia, Ilumya	N/A	SQ: Abrilada**, Amjevita**, Bimzelx, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Siliq, Simlandi**, Taltz, Yuflyma**, Yusimry**
	Inflammatory Bowel Disease						
	Crohn's Disease	SQ: Hadlima, Humira, Skyrizi, Stelara	Oral: Rinvoq	N/A	SQ: Cimzia (Hadlima, or Humira is a required Step 1 agent)	N/A	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**, Zymfentra
	Ulcerative Colitis	SQ: Hadlima, Humira, Stelara	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Hadlima, or Humira is required Step 1 agent)	N/A	Zeposia (Hadlima, Humira, Rinvoq, Stelara, OR Xeljanz/Xeljanz XR are required Step agents)	SQ: Abrilada**, Amjevita**, Cyltezo**, Entyvio, Hulio**, Hyrimoz**, Idacio**, Omvoh, Simlandi**, Yuflyma**, Yusimry**, Zymfentra Oral Velsipity
	Other						
	Uveitis	SQ: Hadlima, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Amjevita**, Cyltezo**,

Module	Clinical Criteria for Approval						
							Hulio**, Hyrimoz**, Idacio**, Simlandi**, 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) Juvenile Psoriatic Arthritis (JPsA) Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Polymyalgia Rheumatica (PMR) Systemic Juvenile Idiopathic Arthritis (SJIA)	N/A	N/A	N/A	N/A	N/A	N/A

Module	Clinical Criteria for Approval

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: Hadlima and Humira are required Step 1 agents
Note: Branded generic available for Cyltezo, Idacio, 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
Cyltezo, Adalimumab-adbm
Hulio, Adalimumab-fkjp
Hyrimoz, Adalimumab-adaz
Idacio, Adalimumab-aacf
Omvoh
Simlandi
Yuflyma, Adalimumab-aaty
Yusimry
Zymfentra

      1. 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:

Module	Clinical Criteria for Approval
	A. The patient has tried and had an inadequate response to maximally tolerated methotrexate (e.g., titrated to 25 mg weekly) after at least a 3-month duration of therapy **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 after at least a 3-month duration of therapy **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 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 after at least a 3-month duration of therapy **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

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	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 after at least a 3-month duration of therapy **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

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	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 after at least a 3-month duration of therapy **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 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 after at least a 3-month duration of therapy **OR** 2. The patient has severely active ulcerative colitis **OR** 3. The patient has an intolerance or hypersensitivity to ONE of the

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	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 after at least a 2-week duration of therapy **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

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	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 after at least a 3-month duration of therapy **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 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

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	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 after at least a 7-10 day duration of therapy **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 after 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

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	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 after 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 after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent 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

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	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 after at least a 3-month duration of therapy **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 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:

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	1. The patient has tried and had an inadequate response to TWO different NSAIDs used in the treatment of ERA after 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 after at least a 4-week duration of therapy **AND** a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD after at least a 6-week duration of therapy **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

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	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. 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** 4. 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 after at least an 8-week duration of therapy **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 of juvenile psoriatic arthritis (JPsA) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., methotrexate, leflunomide, sulfasalazine)

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	used in the treatment of JPsA after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of JPsA **OR** 3. The patient has an FDA labeled contraindication to methotrexate **OR** 4. The patient has severe active JPsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to JPsA, 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 that is FDA labeled or supported in compendia for the treatment of JPsA **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 agent (i.e., methotrexate, leflunomide, sulfasalazine) used in the treatment of JPsA 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** R. 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 after at least a 3-month duration of therapy (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. ALL TNF inhibitors are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried

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	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 after at least a 3-month duration of therapy (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. 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 after at least a 3-month trial per agent (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. 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 after at least a 3-month trial per agent (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. 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 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** 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 after at least a 3-month trial per agent (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. 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 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 AND the requested dose is 300 mg every 4 weeks **OR** B. The patient has a diagnosis of hidradenitis suppurativa AND ONE of the following: 1. The requested dose is 300 mg every 4 weeks **OR** 2. The requested dose is 300 mg every 2 weeks AND the patient has tried and had an inadequate response to Cosentyx 300 mg every 4 weeks after at least a 3-month duration of therapy **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 after at least a 3-month duration of therapy **AND** 4. If Omvoh is requested for the treatment of ulcerative colitis, ONE of the following: A. the patient has received Omvoh IV for induction therapy **OR** B. The patient is new to therapy and will receive Omvoh IV for induction therapy **AND** 5. If Entyvio is requested for the treatment of ulcerative colitis, ONE of the following: A. The patient has received at least 2 doses of Entyvio IV therapy **OR** B. The patient is new to therapy and will receive 2 doses of Entyvio IV therapy **AND**

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	6. If Skyrizi is requested for the treatment of Crohn's disease, ONE of the following A. The patient received Skyrizi IV for induction therapy **OR** B. The patient is new to therapy and will receive Skyrizi IV for induction therapy **AND** 7. If Stelara is requested for the treatment of Crohn's disease or ulcerative colitis, ONE of the following: A. The patient received Stelara IV for induction therapy **OR** B. The patient is new to therapy and will receive Stelara IV for induction therapy **AND** 8. 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. There is support for using the requested agent for the patient's age for the requested indication **AND** 4. 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** 5. 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** 6. 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** 7. 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. There is support for the use of combination therapy (copy of support required, i.e., clinical trials, phase III studies, guidelines) **AND** 8. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 9. 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 **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **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. **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.

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	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) [Note: patients not previously approved for the requested agent will require initial evaluation review] **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. There is support for the use of combination therapy (copy of support required, i.e., clinical trials, phase III studies, guidelines) **AND** 7. If Cosentyx 300 mg 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 AND the requested dose is 300 mg every 4 weeks **OR** B. The patient has a diagnosis of hidradenitis suppurativa AND ONE of the following: 1. The requested dose is 300 mg every 4 weeks **OR** 2. The requested dose is 300 mg every 2 weeks AND the patient has tried and had an inadequate response to Cosentyx 300 mg every 4 weeks after at least a 3-month duration of therapy **OR**

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td></td><td>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 after at least a 3-month duration of therapy 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.</td></tr>
<tr><td>Option B - Focus Rx</td><td>Step Table

<table>
<tr><th rowspan="2">Disease State</th><th colspan="2">Step 1</th><th rowspan="2">Step 2 (Directed to ONE step 1 agent)</th><th rowspan="2">Step 3a (Directed to TWO step 1 agents)</th><th rowspan="2">Step 3b (Directed to TWO agents from step 1 and/or step 2)</th><th rowspan="2">Step 3c (Directed to THREE step 1 agents)</th></tr>
<tr><th>Step 1a</th><th>Step 1b (Directed to ONE TNF inhibitor) NOTE: Please see Step 1a for preferred TNF inhibitors</th></tr>
<tr><td colspan="7">Rheumatoid Disorders</td></tr>
<tr><td>Ankylosing Spondylitis (AS)</td><td>SQ: Cyltezo, Cosentyx, Enbrel, 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**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**</td></tr>
<tr><td>Nonradiographic Axial Spondyloarthritis (nr-axSpA)</td><td>SQ: Cimzia, Cosentyx</td><td>Oral: Rinvoq</td><td>N/A</td><td>SQ: Taltz</td><td>N/A</td><td>N/A</td></tr>
<tr><td>Polyarticular Juvenile Idiopathic Arthritis (PJIA)</td><td>SQ: Cyltezo, Enbrel, Humira</td><td>Oral: Xeljanz</td><td>SQ: Actemra (Cyltezo, or Humira is required Step 1</td><td>N/A</td><td>SQ: Orencia</td><td>SQ:

Abrilada**, Amjevita**, Hadlima**,</td></tr>
</table>
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</table>

Module	Clinical Criteria for Approval						
				agent)			Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Psoriatic Arthritis (PsA)	SQ: Cyltezo, Cosentyx, Enbrel, Humira, Skyrizi, Stelara, Tremfya Oral: Otezla	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Orencia, Simponi, Taltz	N/A	SQ: Abrilada**, Amjevita*, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Rheumatoid Arthritis	SQ: Cyltezo, Enbrel, Humira	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Actemra (Cyltezo, or Humira is required Step 1 agent)	Oral: Olumiant SQ: Cimzia, Kevzara, Kineret, Orencia, Simponi	N/A	SQ: Abrilada**, Amjevita**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Dermatological Disorder						
	Hidradenitis Suppurativa (HS)	SQ: Cosentyx, Cyltezo, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Amjevita**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Psoriasis (PS)	SQ: Cyltezo, Cosentyx, Enbrel, Humira, Skyrizi, Stelara, Tremfya Oral: Otezla	N/A	Oral: Sotyktu	SQ: Cimzia, Ilumya	N/A	SQ: Abrilada**, Amjevita**, Bimzelx, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Siliq,

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							Simlandi**, Taltz, Yuflyma**, Yusimry**
	Inflammatory Bowel Disease						
	Crohn's Disease	SQ: Cyltezo, Humira, Skyrizi, Stelara	Oral: Rinvoq	N/A	SQ: Cimzia (Cyltezo, or Humira is a required Step 1 agent)	N/A	SQ: Abrilada**, Amjevita**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**, Zymfentra
	Ulcerative Colitis	SQ: Cyltezo, Humira, Stelara	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Cyltezo, or Humira is required Step 1 agent)	N/A	Zeposia (Cyltezo, Humira, Rinvoq, Stelara, OR Xeljanz/Xeljanz XR are required Step agents)	SQ: Abrilada**, Amjevita**, Entyvio, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Omvoh, Simlandi**, Yuflyma**, Yusimry**, Zymfentra Oral Velsipity
	Other						
	Uveitis	SQ: Cyltezo, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Amjevita**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
	Indications Without Prerequisite Biologic Immunomodulators Required						
	Alopecia Areata	N/A	N/A	N/A	N/A	N/A	N/A

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	Atopic Dermatitis Deficiency of IL-1 Receptor Antagonist (DIRA) Enthesitis Related Arthritis (ERA) Giant Cell Arteritis (GCA) Juvenile Psoriatic Arthritis (JPsA) Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Polymyalgia Rheumatica (PMR) 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: Cyltezo and Humira are required Step 1 agents

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Note: Branded generic available for Cyltezo, Idacio, 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
Hadlima
Hulio, Adalimumab-fkjp
Hyrimoz, Adalimumab-adaz
Idacio, Adalimumab-aacf
Omvoh
Simlandi
Yuflyma, Adalimumab-aaty
Yusimry
Zymfentra

     1. 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) after at least a 3-month duration of therapy **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 after at least a 3-month duration of therapy **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**

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	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 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 after at least a 3-month duration of therapy **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:

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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 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 after at least a 3-month duration of therapy **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

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	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 after at least a 3-month duration of therapy **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 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 after at least a 3-month duration of therapy **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

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	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 after at least a 2-week duration of therapy **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

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	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 after at least a 3-month duration of therapy **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 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 after at least a 7-10 day duration of therapy **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**

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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 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 after 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 after at least a 4-week total trial **OR** 2. The patient has an intolerance or hypersensitivity to TWO different

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	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 after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent 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

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	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 after at least a 3-month duration of therapy **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 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 after 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

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	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 after at least a 4-week duration of therapy **AND** a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD after at least a 6-week duration of therapy **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**

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	3. 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** 4. 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 after at least an 8-week duration of therapy **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 of juvenile psoriatic arthritis (JPsA) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., methotrexate, leflunomide, sulfasalazine) used in the treatment of JPsA after at least a 3-month duration of therapy **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of JPsA **OR** 3. The patient has an FDA labeled contraindication to methotrexate **OR** 4. The patient has severe active JPsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to JPsA, 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.,

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	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 that is FDA labeled or supported in compendia for the treatment of JPsA **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 used in the treatment of JPsA 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** R. 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 after at least a 3-month duration of therapy (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. 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

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	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 after at least a 3-month duration of therapy (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. 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 after at least a 3-month trial per agent (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. 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

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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 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 after at least a 3-month trial per agent (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. 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 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 after at least a 3-month trial per agent (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**

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	4. BOTH of the following: A. 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 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 AND the requested dose is 300 mg every 4 weeks **OR** B. The patient has a diagnosis of hidradenitis suppurativa AND ONE of the following: 1. The requested dose is 300 mg every 4 weeks **OR** 2. The requested dose is 300 mg every 2 weeks AND the patient has tried and had an inadequate response to Cosentyx 300 mg every 4 weeks after at least a 3-month duration of therapy **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 after at least a 3-month duration of therapy **AND** 4. If Omvoh is requested for the treatment of ulcerative colitis ONE of the following: A. The patient has received Omvoh IV for induction therapy **OR** B. The patient is new to therapy and will receive Omvoh IV for induction therapy **AND** 5. If Entyvio is requested for the treatment of ulcerative colitis, ONE of the following: A. The patient has received at least 2 doses of Entyvio IV therapy **OR** B. The patient is new to therapy and will receive at least 2 doses of Entyvio IV therapy **AND** 6. If Skyrizi is requested for the treatment of Crohn's disease, ONE of the following: A. The patient received Skyrizi IV for induction therapy **OR** B. The patient is new to therapy and will receive Skyrizi IV for induction therapy **AND** 7. If Stelara is requested for the treatment of Crohn's disease or ulcerative colitis, ONE of the following: A. The patient received Stelara IV for induction therapy **OR** B. The patient is new to therapy and will receive Stelara IV for induction therapy **AND** 8. 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

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	requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 4. 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** 5. 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** 6. 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** 7. 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. There is support for the use of combination therapy (copy of support required, i.e., clinical trials, phase III studies, guidelines) **AND** 8. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 9. 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 **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **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. **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) [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**

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	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. There is support for the use of combination therapy (copy of support required, i.e., clinical trials, phase III studies, guidelines) **AND** 7. If Cosentyx 300 mg 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 AND the requested dose is 300 mg every 4 weeks **OR** B. The patient has a diagnosis of hidradenitis suppurativa AND ONE of the following: 1. The requested dose is 300 mg every 4 weeks **OR** 2. The requested dose is 300 mg every 2 weeks AND the patient has tried and had an inadequate response to Cosentyx 300 mg every 4 weeks after at least a 3-month duration of therapy **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 after at least a 3-month duration of therapy **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.

Module	Clinical Criteria for Approval
	NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
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. There is support for 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. There is support 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. There is support for 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 a 3 month duration of therapy at the maximum FDA labeled dose (medical records required) **AND** 3. ONE of the following: A. BOTH of the following:

Module	Clinical Criteria for Approval
	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. There is support for 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. There is support for 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. There is support for 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: up to 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 up to 12 weeks, Rinvoq for AD may be approved for up to 6 months, Siliq for PS may be approved for up to 16 weeks, and Xeljanz and Xeljanz XR for UC may be approved for up to 16 weeks.

Module	Clinical Criteria for Approval
	Renewal Approval with PA: up to 12 months **Standalone QL approval:** up to 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) Olumiant (baricitinib) Omvoh (mirikizumab-mrkz) Opzelura (ruxolitinib) Orencia (abatacept) Otezla (apremilast) Remicade (infliximab) Renflexis (infliximab-abda) Riabni (rituximab-arrx) Rinvoq (upadacitinib) Rituxan (rituximab)

Contraindicated as Concomitant Therapy
Rituxan Hycela (rituximab/hyaluronidase human) Ruxience (rituximab-pvvr) Siliq (brodalumab) Simlandi (adalimumab-ryvk) Simponi (golimumab) Simponi ARIA (golimumab) Skyrizi (risankizumab-rzaa) Sotyktu (deucravacitinib) Spevigo (spesolimab-sbzo) Stelara (ustekinumab) Taltz (ixekizumab) Tezspire (tezepelumab-ekko) Tofidence (tocilizumab-bavi) Tremfya (guselkumab) Truxima (rituximab-abbs) Tyenne (tocilizumab-aazg) 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: Combination Nonsteroidal Anti-Inflammatory Drugs (NSAID)

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
349987021003	Consensi	amlodipine besylate-celecoxib tab	10-200 MG; 2.5-200 MG; 5-200 MG	30	Tablets	30	DAYS			
661099023203	Duexis	ibuprofen-famotidine tab	800-26.6 MG	90	Tablets	30	DAYS			
661099024406	Vimovo	naproxen-esomeprazole magnesium tab dr	375-20 MG; 500-20 MG	60	Tablets	30	DAYS			
851599020406	Yosprala	aspirin-omeprazole tab delayed release	325-40 MG; 81-40 MG	30	Tablets	30	DAYS			

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. ONE of the following: A. For Consensi, BOTH of the following: 1. The patient has a diagnosis of hypertension **AND** 2. The patient has a diagnosis of osteoarthritis **OR** B. BOTH of the following: 1. ONE of the following: A. For Duexis or ibuprofen/famotidine requests, the patient has a diagnosis of at least ONE of the following: 1. Rheumatoid arthritis **OR** 2. Osteoarthritis **OR** B. For Vimovo or naproxen/esomeprazole requests, the patient has a diagnosis of at least ONE of the following: 1. Osteoarthritis in adults **OR** 2. Rheumatoid arthritis in adults **OR** 3. Ankylosing spondylitis in adults **OR** 4. Juvenile idiopathic arthritis (JIA) in adolescents weighing greater than or equal to 38 kg **AND** 2. The patient has at least ONE of the following risk factors for developing NSAID-induced gastrointestinal (GI) ulcers: A. Age greater than or equal to 65 years B. Prior history of peptic, gastric, or duodenal ulcer C. History of NSAID-related ulcer D. History of clinically significant GI bleeding E. Untreated or active *H. pylori* gastritis F. Concurrent use of oral corticosteroids G. Concurrent use of anticoagulants H. Concurrent use of antiplatelets **OR** C. For Yosprala or aspirin/omeprazole requests, BOTH of the following: 1. The patient has an indication of use of at least ONE of the following: A. Reducing the combined risk of death and nonfatal stroke in patients who have had ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli **OR** B. Reducing the combined risk of death and nonfatal myocardial infarction (MI) in patients with previous MI or unstable angina pectoris **OR** C. Reducing the combined risk of MI and sudden death in patients with chronic stable angina pectoris **OR** D. Use in patients who have undergone revascularization procedures (coronary artery bypass graft [CABG] or percutaneous transluminal coronary angioplasty [PTCA]) when there is a pre-existing condition for which aspirin is already indicated **AND** 2. The patient has at least ONE of the following risk factors for developing NSAID-induced gastrointestinal (GI) ulcers: A. Age greater than or equal to 55 years B. Prior history of peptic, gastric, or duodenal ulcer C. History of NSAID–related ulcer D. History of clinically significant GI bleeding E. Untreated or active *H. pylori* gastritis F. Concurrent use of oral corticosteroids

Module	Clinical Criteria for Approval
	G. Concurrent use of anticoagulants H. Concurrent use of antiplatelets **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. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. ONE of the following: A. Information has been provided that use of the individual ingredients within the target combination agent, as separate dosage forms, is not clinically appropriate for the patient **OR** B. 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's medication history includes the individual ingredients within the target combination agent, as separate dosage forms, as indicated by: 1. Evidence of a paid claim(s) **OR** 2. The prescriber has stated that the patient has tried the individual ingredients within the target combination agent, as separate dosage forms AND the required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR** D. The prescriber has provided documentation that the individual ingredients within the target combination agent, as separate dosage forms, 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**

Module	Clinical Criteria for Approval
	C. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• 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** BOTH of the following 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** BOTH 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 alafenamide and emtricitabine combination ingredient agent
OR
3. Cabotegravir
OR
b. The prescriber has provided information stating that a tenofovir disoproxil fumarate and emtricitabine combination ingredient agent, tenofovir alafenamide and emtricitabine combination ingredient agent or cabotegravir 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*

Examples of Agents Excluded from Coverage on the Pharmacy Benefit
(Y in the Clinic Pack field)
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
Hypertrichosis
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

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. The requested agent is an HIV infection post-exposure prophylaxis (PEP) agent being used for PEP **AND** ALL of the following:
    1. ONE of the following:
        A. The patient has a Fully Insured plan
        OR
        B. The patient has a Self Insured plan AND the patient's plan covers HIV PEP at $0 member cost-share
    AND
    2. The prescriber has provided information stating that the requested PEP agent is medically necessary compared to other available PEP agents
    AND
    3. ONE of the following:
        A. The requested PEP agent is ONE of the following (agent AND strength must match):
            i. Emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada)
            OR
            ii. Tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread)
            OR
            iii. Emtricitabine 200 mg single ingredient agent (Emtriva)
            OR
            iv. Raltegravir 400 mg single ingredient agent (Isentress)
            OR
            v. Dolutegravir 50 mg single ingredient agent (Tivicay)
            OR
            vi. Darunavir 800 mg single ingredient agent (Prezista)
            OR
            vii. Ritonavir 100 mg single ingredient agent (Norvir)
        OR
        B. The prescriber has provided information stating that emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada), tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread), emtricitabine 200 mg single ingredient agent (Emtriva), raltegravir 400 mg single ingredient agent (Isentress), dolutegravir 50 mg single ingredient agent (Tivicay), darunavir 800 mg single ingredient agent (Prezista), or ritonavir 100 mg single ingredient agent (Norvir) is contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient
    AND
    4. The patient is at high risk of HIV infection
    AND
    5. The patient is initiating or has initiated PEP within 72 hours of suspected exposure to HIV
OR
i. 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: 9 months
- Infant eye ointment: 3 months
- All other indications: 12 months
- Apply $0 copay if ACA criteria met

HIV PEP Length of Approval:

- 12 months
- Apply $0 copay if HIV PEP criteria met

Coverage Exception Length of Approval: 12 months

• Program Summary: Coverage Exception with Quantity Limit - NetResults (KeyRx and FocusRx)

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

Objective

These criteria apply to any request for agents that are included on the covered agents list and can be used to treat a medical condition/disease state that is not otherwise excluded from coverage under the 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 (Injectable drugs included on Tier 40 of FID 33102 that reject "NOT ON DRUG LIST, CHECK MEDICAL BENEFIT. CALL NUMBER ON THE BACK OF YOUR CARD FOR MORE INFORMATION" [Excluding drugs on the following list: BCBSMN Tier 40 Reviewable Drugs List KeyRx/FocusRx])

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** BOTH of 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** BOTH 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 being used for PrEP **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. 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 alafenamide and emtricitabine combination ingredient agent
         OR
         3. Cabotegravir

OR

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

AND

iii. The patient is at high risk of HIV infection

AND

iv. 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) **OR**
      b. Fluvastatin 20-80 mg per day (40 mg capsule) **OR**
      c. Fluvastatin ER 80 mg per day (80 mg tablet) **OR**
      d. Lovastatin 20-40 mg per day (40 mg tablet) **OR**
      e. Lovastatin ER 20-40 mg per day (40 mg tablet) **OR**
      f. Pitavastatin 1-4 mg per day (4 mg tablet) **OR**
      g. Pravastatin 10-80 mg per day (80 mg tablet) **OR**
      h. Rosuvastatin 5-10 mg per day (10 mg tablet) **OR**
      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

      OR

b. Diabetes
OR
c. Hypertension
OR
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** BOTH 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** BOTH 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

Excluded from Coverage on the Pharmacy Benefit
AHFS (devices and pharmaceutical aids, not including needles, syringes, lancets, CGM/sensor/transmitter/receiver) (Defined as those products containing the AHFS code 940000000 (DEVICES) and/ or 960000000 (PHARMACEUTICAL AIDS) in the product file in RxClaim)
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)
Cosmetic Alteration* (Defined as those products containing the third-party restriction code of C (COSMETIC ALTERATION DRUGS) in the product file in RxClaim)
Diagnostic Agents (not including glucose test strips)

(Defined as those products containing the third-party restriction code of 5 (DIAGNOSTIC AGENT) in the product file in RxClaim)
Drugs That Are Not Covered Exclusion (not including glucose test strips, insulin, AuviQ 0.1 mg, ACA required drugs, lancets, syringes, CGM/sensor/transmitter/receiver) [See MN NDC Lock Out List NetResults]
General Anesthetics (Defined as those products containing the third-party restriction code of 6 (GENERAL ANESTHETIC) 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)
Injectable drugs not on covered drug list, not including the drugs on the following list: BCBSMN Tier 40 Reviewable Drugs List KeyRx/FocusRx (Defined as those products included on Tier 40 of FID 33102 with any reject message other than "NOT ON DRUG LIST, CHECK MEDICAL BENEFIT. CALL NUMBER ON THE BACK OF YOUR CARD FOR MORE INFORMATION".)
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
Investigative, experimental, or not medically necessary
Medical Devices and Supplies (not including spacers, lancets, needles, syringes, continuous glucose monitor/sensor/transmitter/receiver) (Defined by GPI 97**********)
Medical devices approved through a different FDA-approval process than drugs (Defined by one of the following: 1) Drug Application File Marketing Category 15 – Premarket Application 2) Drug Application File Marketing Category 16 – Premarket Notification)
Non-FDA Approved Agents* (Refer all tiers on Formulary ID 220 or reject messaging of 'Non-FDA Approved Drug')
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)
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)
RX drugs with OTC Equivalents (Excluded categories listed below) (Defined by an RX NDC (Rx-OTC indicator R or S) with an OTC NDC (RX-OTC indicator O or P) within the same GPI 14 in the product file in RxClaim. Rx drugs with OTC alternatives where the Rx drug category will be excluded: 1. Omega-3 Fatty Acids (GPI 395000********) 2. Non-Sedating Antihistamines (GPI 415500********) 3. Topical Antivirals (GPI 903500********))
Self-Administered Contraceptives* (2510**********, 2540**********, 2596**********, 2597**********, 2599**********, 260000301003**) (ONLY when not covered in BET AND is being requested exclusively for the use of pregnancy prevention)
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)
Surgical Supplies/Medical Devices/Ostomy (not including spacers, lancets, needles, syringes, continuous

glucose monitor/sensor/transmitter/receiver) (Defined as indicated by the third-party restriction code 3 (SURGICAL SUPPLY/MEDICAL DEVICE/OSTOMY) in the product file in RxClaim)
Universal Product Code (UPC), Health Related Item Code (HRI) (not including glucose test strips) (UPCs will be defined as those products designated as product type 1 in the product file in RxClaim. HRIs will be defined as those products designated as product type 2 in the product file in RxClaim.)
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)

*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 of the same type (long-acting) that is not expected to occur with the requested agent

OR

e. The requested agent is Supprelin or Vantas and is being requested for a diagnosis of Gender Identity Disorder (GID) or gender dysphoria

OR

f. The requested agent is a Self-Administered Contraceptive Agent (e.g., 2510**********, 2540**********, 2596**********, 2597**********, 2599**********, 260000301003**) 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. The requested agent is an HIV infection post-exposure prophylaxis (PEP) agent being used for PEP **AND** ALL of the following:
    1. ONE of the following:
        A. The patient has a Fully Insured plan
        OR
        B. The patient has a Self Insured plan AND the patient's plan covers HIV PEP at $0 member cost-share

    AND

    2. The prescriber has provided information stating that the requested PEP agent is medically necessary compared to other available PEP agents

    AND

    3. ONE of the following:
        A. The requested PEP agent is ONE of the following (agent AND strength must match):
            i. Emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada)
            OR
            ii. Tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread)
            OR

iii. Emtricitabine 200 mg single ingredient agent (Emtriva)
OR
iv. Raltegravir 400 mg single ingredient agent (Isentress)
OR
v. Dolutegravir 50 mg single ingredient agent (Tivicay)
OR
vi. Darunavir 800 mg single ingredient agent (Prezista)
OR
vii. Ritonavir 100 mg single ingredient agent (Norvir)

OR

B. The prescriber has provided information stating that emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada), tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread), emtricitabine 200 mg single ingredient agent (Emtriva), raltegravir 400 mg single ingredient agent (Isentress), dolutegravir 50 mg single ingredient agent (Tivicay), darunavir 800 mg single ingredient agent (Prezista), or ritonavir 100 mg single ingredient agent (Norvir) is contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

AND

4. The patient is at high risk of HIV infection
AND
5. The patient is initiating or has initiated PEP within 72 hours of suspected exposure to HIV

OR

i. BOTH of the following:
1. If the requested agent is part of a drug class listed below then ONE of the following:

Prescription drugs with OTC alternatives (partial category lockout)
• Artificial Tears/Dry Eye Therapy (GPI 8672**********, 8673**********) • Topical Acne (GPI 9005**********) • Topical Antifungals; Combination products (GPI 901599********) • Ophthalmic Antiallergic Agents (GPI 868020********) • Prenatal vitamins (GPI 7851**********) • Ulcer drugs/H2 Antagonists/Proton Pump Inhibitors (GPI 4920**********, 4927**********) • Nasal steroids (GPI 4220**********)

A. The patient has tried and failed the OTC alternative for the requested diagnosis
OR
B. The prescriber has provided information stating that OTC equivalents are contraindicated, are likely to be less effective, or will cause an adverse reaction or other harm for the patient

AND

2. ONE of the following:
A. The requested medication is an antipsychotic prescribed to treat emotional disturbance or mental illness AND the following:
i. The prescriber has indicated at least three formulary drugs (or as many as available, if fewer than three) have been considered and they have determined that the medication prescribed will best treat the patient's condition

OR

B. BOTH of the following:
i. ONE of the following:

a. The patient has an FDA labeled indication for the requested agent

OR

b. 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

c. The patient has a diagnosis of Gender Identity Disorder (GID) or gender dysphoria and clinical guidelines support therapy with the requested agent

AND

ii. ONE of the following:

a. The requested agent has formulary alternatives (any formulary tier) for the diagnosis being treated by the requested agent AND BOTH of the following:

1. If the requested agent is a brand product with an available formulary generic equivalent AND 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 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

2. ONE of the following:

A. 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

B. 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

b. The requested agent does NOT have formulary (any formulary tier) alternatives for the diagnosis being treated with the requested agent

OR

c. 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: 9 months
- Infant eye ointment: 3 months
- All other indications: 12 months
- Apply $0 copay if ACA criteria met

HIV PEP Length of Approval:

- 12 months
- Apply $0 copay if HIV PEP criteria is met

Coverage Exception Length of Approval: 12 months

• Program Summary: Formulary Exception with Quantity Limit

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

APPLICATION

These criteria apply only to FDA approved legend drugs which are covered under the member's current benefit plan. Medications which are investigational or otherwise not a covered benefit should be forwarded for review under the appropriate process.

This criteria only applies to FlexRx Closed and GenRx Closed products which are non-formulary.

FORMULARY EXCEPTION CRITERIA FOR APPROVAL

A formulary exception will be granted when the following are met:

1. 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** BOTH of 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 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** BOTH 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 being used for PrEP **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 alafenamide and emtricitabine combination ingredient agent
OR
3. Cabotegravir

OR

b. The prescriber has provided information stating that a tenofovir disoproxil fumarate and emtricitabine combination ingredient agent, tenofovir alafenamide and emtricitabine

combination ingredient agent, or cabotegravir 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) **OR**
      b. Fluvastatin 20-80 mg per day (40 mg capsule) **OR**
      c. Fluvastatin ER 80 mg per day (80 mg tablet) **OR**
      d. Lovastatin 20-40 mg per day (40 mg tablet) **OR**
      e. Lovastatin ER 20-40 mg per day (40 mg tablet) **OR**
      f. Pitavastatin 1-4 mg per day (4 mg tablet) **OR**
      g. Pravastatin 10-80 mg per day (80 mg tablet) **OR**
      h. Rosuvastatin 5-10 mg per day (10 mg tablet) **OR**
      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 **OR**
      b. Diabetes **OR**
      c. Hypertension **OR**
      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** BOTH 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** BOTH 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 requested agent is not excluded from coverage under the pharmacy benefit

   AND

   ii. ONE of the following:
      a. The requested agent is Supprelin or Vantas and is being requested for a diagnosis of Gender Identity Disorder (GID) or gender dysphoria AND the following:
         1. The patient's current benefit plan covers agents for use in the management for GID or gender dysphoria

      OR

      b. The requested medication is an antipsychotic prescribed to treat emotional disturbance or mental illness AND the following:
         1. The prescriber has indicated at least three formulary drugs (or as many as available, if fewer than three) have been considered and he/she has determined that the medication prescribed will best treat the patient's condition

      OR

      c. The requested agent is Omnipod DASH or Omnipod 5
      OR
      d. The requested agent is an HIV infection post-exposure prophylaxis (PEP) agent being used for PEP **AND** ALL of the following:
         1. ONE of the following:
            A. The patient has a Fully Insured plan
            OR
            B. The patient has a Self Insured plan AND the patient's plan covers HIV PEP at $0 member cost-share

AND

2. The prescriber has provided information stating that the requested PEP agent is medically necessary compared to other available PEP agents
   AND
3. ONE of the following:
   A. The requested PEP agent is ONE of the following (agent AND strength must match):
      i. Emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada)
      OR
      ii. Tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread)
      OR
      iii. Emtricitabine 200 mg single ingredient agent (Emtriva)
      OR
      iv. Raltegravir 400 mg single ingredient agent (Isentress)
      OR
      v. Dolutegravir 50 mg single ingredient agent (Tivicay)
      OR
      vi. Darunavir 800 mg single ingredient agent (Prezista)
      OR
      vii. Ritonavir 100 mg single ingredient agent (Norvir)
      OR
   B. The prescriber has provided information stating that emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada), tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread), emtricitabine 200 mg single ingredient agent (Emtriva), raltegravir 400 mg single ingredient agent (Isentress), dolutegravir 50 mg single ingredient agent (Tivicay), darunavir 800 mg single ingredient agent (Prezista), or ritonavir 100 mg single ingredient agent (Norvir) is contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient
   AND
4. The patient is at high risk of HIV infection
   AND
5. The patient is initiating or has initiated PEP within 72 hours of suspected exposure to HIV

OR

e. BOTH of the following:
   1. The patient has an FDA labeled indication or 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
      AND
   2. ONE of the following:
      A. The requested agent has formulary alternatives that can be prescribed in a dose to fit the patient's needs AND ONE of the following:
         i. The patient has tried and failed at least three (or as many as available, if fewer than three) formulary alternatives, if available, for the diagnosis being treated with the requested agent
         OR
         ii. 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

B. The requested agent does NOT have formulary (any formulary tier) alternatives for the diagnosis being treated with the requested agent

OR

C. 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

2. 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: 9 months
- Infant eye ointment: 3 months
- All other indications: 12 months
- Apply $0 copay if ACA criteria met

HIV PEP Length of Approval:

- 12 months
- Apply $0 copay if ACA criteria met

Formulary Exception Length of Approval: 12 months

• Program Summary: Gabapentin ER (extended-release) [Horizant, Gralise]

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
62540030000325	Gralise	gabapentin (once-daily) tab	450 MG	30	Tablets	30	DAYS			
62540030000345	Gralise	gabapentin (once-daily) tab	750 MG	30	Tablets	30	DAYS			
62540030000360	Gralise	gabapentin (once-daily) tab	900 MG	60	Tablets	30	DAYS			
62540030000320	Gralise	Gabapentin (Once-Daily) Tab 300 MG	300 MG	30	Tablets	30	DAYS			
62540030000330	Gralise	Gabapentin (Once-Daily) Tab 600 MG	600 MG	90	Tablets	30	DAYS			
6256003020	Horizant	gabapentin enacarbil tab er	300 MG; 600 MG	60	Tablets	30	DAYS			

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	TARGET AGENT(S) **Gralise*** (gabapentin) **Horizant** (gabapentin enacarbil) * - generic available; included as a 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 generic immediate release gabapentin agent use, intolerance, or hypersensitivity **OR** 3. BOTH of the following: A. The prescriber has stated that the patient has tried generic immediate release gabapentin **AND** B. Generic gabapentin was discontinued due to lack of effectiveness or an adverse event **OR** 4. The patient has an FDA labeled contraindication to ALL generic immediate release gabapentin agents **OR** 5. The prescriber has provided documentation that ALL generic immediate release gabapentin 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 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 patient requires increased quantities of Gralise to accommodate a titration schedule. The increased quantity will be approved for 1 month only **OR** 3. 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. There is support for 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 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. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• Program Summary: Galafold (migalastat)

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
30903650100120	Galafold	Migalastat HCl Cap 123 MG (Base Equivalent)	123 MG	14	Capsules	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** Galafold 1. 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**

Module	Clinical Criteria for Approval
	B. BOTH of the following: 1. The patient has a diagnosis of Fabry disease AND BOTH of the following: A. The diagnosis was confirmed by mutation in the galactosidase alpha (*GLA*) gene **AND** B. The patient has a confirmed amenable *GLA* variant based on in vitro assay data (a complete list of amenable variants is available in the Galafold prescribing information, or a specific variant can be verified as amenable at http://www.galafoldamenabilitytable.com/hcp **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. There is support for using the requested agent for the patient's age for the requested indication **AND** 2. The prescriber has assessed current status of ALL of the following: renal function (e.g., proteinuria, glomerular filtration rate [GFR]), cardiac function (e.g., left ventricular hypertrophy, conduction defects, mitral and/or aortic valve abnormalities), ophthalmological signs (e.g., corneal verticillate, subcapsular cataracts, conjunctival and/or retinal vasculopathy), peripheral nerve symptoms (e.g., neuropathic pain, heat and/or cold intolerance, impaired sweat function), and gastrointestinal involvement (e.g., nausea, vomiting, abdominal pain, diarrhea, constipation) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist, nephrologist) 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 enzyme replacement therapy (ERT) (e.g., Elfabrio, Fabrazyme) for the requested indication **AND** 5. 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 [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had improvements or stabilization with the requested agent as indicated by ONE of the following: A. Renal function (e.g., proteinuria, glomerular filtration rate [GFR]) **OR** B. Cardiac function (e.g., left ventricular hypertrophy, conduction defects, mitral and/or aortic valve abnormalities) **OR** C. Ophthalmological signs (e.g., corneal verticillate, subcapsular cataracts, conjunctival and/or retinal vasculopathy) **OR** D. Peripheral nerve symptoms (e.g., neuropathic pain, heat and/or cold intolerance, impaired sweat function) **OR** E. Gastrointestinal symptoms (e.g., nausea, vomiting, abdominal pain, diarrhea, constipation) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist, nephrologist) 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 enzyme replacement therapy (ERT) (e.g., Elfabrio, Fabrazyme) for the requested indication **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent

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 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 - up to 6 months; Renewal - up to 12 months

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

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	180	DAYS			
2717308000D215	Mounjaro	Tirzepatide Soln Pen-injector	5 MG/0.5ML	4	Pens	28	DAYS			
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-	12.5	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
		injector	MG/0.5ML							
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			
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 MCG/0.2ML	10 & 20 MCG/0.2ML	The patient has a diagnosis of type 2 diabetes mellitus			
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-	2.5 MG/0.5ML	The patient has a diagnosis of type 2			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		injector		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			
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			
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)

Module	Clinical Criteria for Approval
	Target Agent(s) will be approved when ALL of the following are met: 1. The patient has a diagnosis of type 2 diabetes **AND** 2. The patient's diagnosis has been confirmed by lab tests (e.g., A1C greater than or equal to 6.5%) (lab test results required) **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**: Ozempic, Rybelsus, Trulicity, Mounjaro, Bydureon 1. 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** 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:

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** 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 **AND** 4. The patient will NOT be using the requested agent in combination with a DPP-4 agent containing agent for the requested indication **AND** 5. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **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. There is support for therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months

• Program Summary: Glucose Test Strips and Meters

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
94100030006100	Accu-chek aviva plus; Accu-chek guide; Accu-chek smartview strip; Accutrend glucose; Advance intuition test st; Advance micro-draw test s; Advocate redi-code; Advocate redi-code+ test; Advocate test strips; Agamatrix amp no code tes; Agamatrix jazz test strip; Agamatrix keynote test st; Agamatrix presto test str; Assure 3 test strips; Assure 4 test strips; Assure ii; Assure ii check strip; Assure ii test strips; Assure platinum test stri; Assure prism multi test s; Assure pro test strips; Bioscanner glucose test s; Biotel care blood glucose; Careone blood glucose tes; Caresens n blood glucose; Clever chek auto-code voi; Clever choice auto-code p; Clever choice micro test; Contour blood glucose tes; Contour next blood glucos; Cool blood glucose test s; Cvs advanced glucose mete; Cvs glucose meter test st; D-care blood glucose; Diathrive blood glucose t; Diatrue plus blood glucos; Duo-care test strips; Easy plus ii blood glucos; Easy step test strips; Easy talk blood glucose t; Easy touch glucose test s; Easy trak blood glucose t; Easy trak ii blood glucos; Easygluco; Easymax 15 test strips; Easymax test strips; Easypro blood glucose tes; Easypro plus; Element compact test stri; Element test strips; Embrace blood glucose tes; Embrace pro blood glucose; Embrace talk blood glucos; Eq blood glucose test str; Evolution	Glucose Blood Test Strip		204	Strips	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
	autocode; Fifty50 glucose test stri; Fora blood glucose test s; Fora d15g blood glucose t; Fora d20 blood glucose te; Fora d40/g31 blood glucos; Fora g20 blood glucose te; Fora g30/premium v10 bloo; Fora gd20 test strips; Fora gd50 blood glucose t; Fora gtel blood glucose t; Fora tn'g/tn'g voice bloo; Fora v10 blood glucose te; Fora v12 blood glucose te; Fora v30a blood glucose t; Foracare gd40; Foracare premium v10 test; Foracare test n go test s; Fortiscare blood glucose; Freestyle insulinx blood; Freestyle lite test strip; Freestyle precision neo b; Freestyle test strips; Ge100 blood glucose test; Genultimate test strips; Ght test strips; Gluco perfect 3 test stri; Glucocard 01 sensor plus; Glucocard expression bloo; Glucocard shine test stri; Glucocard vital test stri; Glucocard x-sensor; Glucocom test strips; Gluconavii blood glucose; Glucose meter test strips; Gnp easy touch glucose te; Gojji blood glucose test; Goodsense premium blood g; Hw embrace talk blood glu; Iglucose blood glucose te; In touch blood glucose te; Infinity blood glucose te; Infinity voice; Kroger blood glucose test; Kroger healthpro glucose; Kroger premium blood gluc; Liberty next generation b; Liberty test strips; Meijer blood glucose test; Meijer essential blood gl; Meijer truetest blood glu; Meijer truetrack blood gl; Microdot test strips; Microdot xtra test strips; Mm easy touch glucose tes; Myglucohealth blood gluco; Neutek 2tek									

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
	test strips; Nova max glucose test str; On call express blood glu; One drop blood glucose te; Onetouch ultra; Onetouch verio test strip; Optiumez test strips; Pharmacist choice no codi; Pocketchem ez blood gluco; Precision xtra blood gluc; Premium blood glucose tes; Pro voice v8/v9 blood glu; Prodigy no coding blood g; Pts panels glucose test; Quicktek test strips; Quintet blood glucose tes; Refuah plus blood glucose; Relion confirm/micro test; Relion premier blood gluc; Relion prime blood glucos; Relion ultima blood gluco; Rexall blood glucose test; Rightest gs100 blood gluc; Rightest gs300 blood gluc; Rightest gs550 blood gluc; Smart sense premium blood; Smart sense value blood g; Smartest blood glucose te; Solus v2 audible test; Supreme test strips; Tgt blood glucose test st; True focus self monitorin; True metrix blood glucose; True metrix self monitori; Truetest strips; Truetrack blood glucose t; Truetrack test; Unistrip1 generic; Verasens blood glucose te; Vivaguard ino blood gluco									
94100030006020	Pogo automatic test cartr	Glucose Blood Test Automatic Cartridge		200	Strips	30	DAYS			
97202011006200	Relion all-in-one compact	*Blood Glucose Meter Disposable Device with Test Strips***		4	Systems	30	DAYS			

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Traditional QL	Quantities above the program quantity limit for the **Target Agent(s)** will be approved when ONE of the following is met: 1. There is support indicating the need for additional blood glucose testing **Length of Approval:** up to 12 months

● 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
85105030202007	Hemlibra	emicizumab-kxwh subcutaneous soln	12 MG/0.4ML	Determined by patient weight and dosing interval* *See Hemlibra weight based approvable quantities chart for guidance			
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** 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

Module	Clinical Criteria for Approval
	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** 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

Module	Clinical Criteria for Approval

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	12 mg/0.4 mL vials	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 every week	1.6 mL (4 vials)/28 days	4 mL (4 vials)/28 days	0	0	0	0
less than or equal to 5 kg	3 mg/kg every 2 weeks	0	2 mL (2 vials)/28 days	0	0	0	0
less than or equal to 5	6 mg/kg every 4 weeks	0	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	0	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	0	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	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	0	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	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	0	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	0	4 mL (4 vials)/28 days	0	0	0	0
greater than 15 and less	3 mg/kg every 2 weeks	0	0	0.8 mL (2 vials)/28	0	0	0

Module	Clinical Criteria for Approval							
	than or equal to 20 kg				days			
	greater than 15 and less than or equal to 20 kg	6 mg/kg every 4 weeks	0	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	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	0	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	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	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	0	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	0	1.2 mL (3 vials)/28 days	0	0	0
	greater than 30 and less than or equal to 35 kg	1.5 mg/kg once every week	0	0	1.6 mL (4 vials)/28 days	0	0	0
	greater than 30 and less than or equal to 35 kg	3mg/kg every 2 weeks	0	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	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	0	1.6 mL (4 vials)/28 days	0	0	0
	greater than 35 and less than or equal	3 mg/kg every 2 weeks	0	0	1.6 mL (4 vials)/28 days	0	0	0

Module	Clinical Criteria for Approval							
	to 40 kg							
	greater than 35 and less than or equal to 40 kg	6 mg/kg every 4 weeks	0	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	0	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	0	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	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	0	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	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	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	0	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	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	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	0	4 mL (4 vials)/28 days	1.6 mL (4 vials)/28 days	0	0	0
	greater than 55 and less than or equal to 60 kg	3 mg/kg every 2 weeks	0	0	2.4 mL (6 vials)/28 days	0	0	0

Module	Clinical Criteria for Approval							
	greater than 55 and less than or equal to 60 kg	6 mg/kg every 4 weeks	0	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	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	0	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	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	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	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	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	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	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	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	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	0	3.2 mL (8 vials)/28 days	0	0	0
	greater than	6 mg/kg every	0	0	0.4 mL (1	2.8 mL (4	0	0

Module	Clinical Criteria for Approval							
	75 and less than or equal to 80 kg	4 weeks			vial)/28 days	vials)/28 days		
	greater than 80 and less than or equal to 85 kg	1.5 mg/kg once every week	0	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	0	1.4 mL (2 vials)/28 days	2 mL (2 vials)/28 days	0
	greater than 80 and less than or equal to 85 kg	6 mg/kg every 4 weeks	0	0	0.4 mL (1 vial)/28 days		3 mL (3 vials)/28 days	0
	greater than 85 and less than or equal to 90 kg	1.5 mg/kg once every week	0	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	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	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	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	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	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	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	0	4 mL (2 vials)/28 days
	greater than 95 and less	6 mg/kg every 4 weeks	0	0	0	0	0	4 mL (2 vials)/28

Module	Clinical Criteria for Approval							
	than or equal to 100 kg							days
	greater than 100 and less than or equal to105 kg	1.5 mg/kg once every week	0	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	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	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	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	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	0.4 mL (1 vial)/28 days	0	0	4 mL (2 vials/28 days)
	greater than 110 and less than or equal to 115 kg	1.5 mg/kg once every week	0	0	4.8 mL (12 vials)/28 days	0	0	0
	greater than 110 and less than or equal to 115 kg	3 mg/kg every 2 weeks	0	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	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	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	0.8 mL (2 vials)/28 days	0	0	4 mL (2 vials)/28 days
	greater than 115 and less than or equal	6 mg/kg every 4 weeks	0	0	0.8 mL (2 vials)/28 days	0	0	4 mL (2 vials)/28 days

Module	Clinical Criteria for Approval							
	to 120 kg							
	greater than 120 and less than or equal to 125 kg	1.5 mg/kg once every week	0	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	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	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	0	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	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	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	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	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	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	0	5.6 mL (8 vials)/28 days	0	0
	greater than 135 and less than or equal to 140 kg	3 mg/kg every 2 weeks	0	0	1.6 mL (4 vials)/28 days	0	0	4 mL (2 vials)/28 days
	greater than 135 and less than or equal to 140 kg	6 mg/kg every 4 weeks	0	0	0	5.6 mL (8 vials)/28 days	0	0

Module	Clinical Criteria for Approval							
	greater than 140 and less than or equal to 145 kg	1.5 mg/kg once every week	0	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	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	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	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	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	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	0	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	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	0	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	0	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	0	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	0.4 mL (1 vial)/28 days	0	0	6 mL (3 vials)/28 days
	greater than	1.5 mg/kg	0	0	0	2.8 mL (4	4 mL (4	0

Module	Clinical Criteria for Approval							
	160 and less than or equal to 165 kg	once every week				vials)/28 days	vials)/28 days	
	greater than 160 and less than or equal to 165 kg	3 mg/kg every 2 weeks	0	0	2.4 mL (6 vials)/28 days	4.2 mL (6 vials)/28 days	0	0
	greater than 160 and less than or equal to 165 kg	6 mg/kg every 4 weeks	0	1 mL (1 vial)/28 days	0	1.4 mL (2 vials)/28 days	5 mL (5 vials)/28 days	0
	greater than 165 and less than or equal to 170 kg	1.5 mg/kg once every week	0	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	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	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	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	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	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	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	0	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	0	1 mL (1 vial)/28 days	0	0	7 mL (7 vials)/28 days	0
	greater than 180 and less	1.5 mg/kg once every	0	4 mL (4 vials)/28	0	2.8mL (4 vials)/28	4 mL (4 vials)/28	0

Module	Clinical Criteria for Approval							
	than or equal to 185 kg	week		days		days	days	
	greater than 180 and less than or equal to 185 kg	3 mg/kg every 2 weeks	0	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	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	0	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	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	0	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 than or equal to 195 kg	1.5 mg/kg once every week	0	0	0	0	0	8 mL (4 vials)/28 days
	greater than 190 and less than or equal to 195 kg	3 mg/kg every 2 weeks	0	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	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	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	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	0	8 mL (4 vials)/28 days
	greater than 200 kg	Approve quantity requested if appropriate for patient weight and dosing interval						

Module	Clinical Criteria for Approval
	The 12 mg and 30 mg vials are the same concentration (30 mg/mL) and may be combined for dosing 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 12 mg vials and 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: Insomnia 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
60204070		zaleplon cap	10 MG; 5 MG	30	Capsules	30	DAYS			
602040801001		zolpidem tartrate cap	7.5 MG	30	Capsules	30	DAYS			
602040801003	Ambien	zolpidem tartrate tab	10 MG; 5 MG	30	Tablets	30	DAYS			
60204080	Ambien; Ambien cr; Edluar; Zolpimist	zolpidem tartrate cap; zolpidem tartrate oral spray; zolpidem tartrate sl tab; zolpidem tartrate tab; zolpidem tartrate tab er	1.75 MG; 10 MG; 12.5 MG; 3.5 MG; 5 MG; 5 MG/ACT; 6.25 MG; 7.5 MG	30	Tablets	30	DAYS			
602040801004	Ambien cr	zolpidem tartrate tab er	12.5 MG; 6.25 MG	30	Tablets	30	DAYS			
605000	Belsomra; Dayvigo; Quviviq	daridorexant hcl tab; lemborexant tab; suvorexant tab	10 MG; 15 MG; 20 MG; 25 MG; 5 MG; 50 MG	30	Tablets	30	DAYS			
602040801007	Edluar	zolpidem tartrate sl tab	1.75 MG; 10 MG; 3.5 MG; 5 MG	30	Tablets	30	DAYS			
60204035	Lunesta	eszopiclone tab	1 MG; 2 MG; 3 MG	30	Tablets	30	DAYS			
60250060	Rozerem	ramelteon tab	8; 8 MG	30	Tablets	30	DAYS			
604000	Silenor	doxepin hcl (sleep) tab	3 MG; 6 MG	30	Tablets	30	DAYS			
60204080102020	Zolpimist	Zolpidem Tartrate Oral Spray 5 MG/ACT	5 MG/ACT	1	Canister	30	DAYS			

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

TARGET AGENT(S)	PREREQUISITE AGENT(S)
Ambien (zolpidem)*	zolpidem
Ambien CR (zolpidem)*	eszopiclone
Belsomra (suvorexant)	zaleplon
Dayvigo (lemborexant)	
Edluar (zolpidem)	
Lunesta (eszopiclone)*	
Quviviq (daridorexant)	
Rozerem (ramelteon)^	
Silenor (doxepin)^	
Zolpidem sublingual tablet+	
Zolpidem tartrate capsule+	
ZolpiMist (zolpidem)	

* – generic available that is a prerequisite agent for step therapy program
^ – generic available
+ – branded generic product(s) available; targeted in the step therapy program

Brand Insomnia 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 (starting on samples is not approvable) **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 the use of a prerequisite agent **OR**
3. BOTH of the following:
    A. The prescriber has stated that the patient has tried a prerequisite agent **AND**
    B. Prerequisite agent was discontinued due to lack of effectiveness or an adverse event **OR**
4. The patient has an intolerance or hypersensitivity to prerequisite agents **OR**
5. The patient has an FDA labeled contraindication to ALL prerequisite agents **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 **OR**
7. The requested agent is a non-controlled agent AND the patient requires therapy with the non-controlled 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. 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. There is support for 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 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. There is support for 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 5 g7 pods (gen 5); Omnipod classic pods (gen 3); Omnipod dash pods (gen 4)	*Insulin Infusion Disposable Pump Supplies***		30	Pods	30	DAYS			
97201030506400	Omnipod 5 g7 intro kit (gen 5)	*insulin infusion disposable pump kit***		1	Kit	720	DAYS	08508300050		
97201030506400	Omnipod classic pdm start	*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		

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 dash pdm kit (gen 4)	*insulin infusion disposable pump kit***		1	Kit	720	DAYS	08508200000		
97201030506410	Omnipod go 1 units/day	*insulin infusion disposable pump kit	10 UNIT/24HR	30	Systems	30	DAYS			
97201030506415	Omnipod go 15 units/day	*insulin infusion disposable pump kit	15 UNIT/24HR	30	Systems	30	DAYS			
97201030506420	Omnipod go 20 units/day	*insulin infusion disposable pump kit	20 UNIT/24HR	30	Systems	30	DAYS	08508400020		
97201030506425	Omnipod go 25 units/day	*insulin infusion disposable pump kit	25 UNIT/24HR	30	Systems	30	DAYS			
97201030506430	Omnipod go 30 units/day	*insulin infusion disposable pump kit	30 UNIT/24HR	30	Systems	30	DAYS	08508400030		
97201030506435	Omnipod go 35 units/day	*insulin infusion disposable pump kit	35 UNIT/24HR	30	Systems	30	DAYS			
97201030506440	Omnipod go 40 units/day	*insulin infusion disposable pump kit	40 UNIT/24HR	30	Systems	30	DAYS	08508400040		
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: Jynarque (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	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. There is support for 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 [Note: patients not previously approved for the requested agent will require initial evaluation review] **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 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 12 months

• Program Summary: Low Molecular Weight Heparins (LMWH) and Arixtra

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
83101020102012		Enoxaparin Sodium Inj 30 MG/0.3ML		30	Syringes	90	DAYS			
83101020102014		Enoxaparin Sodium Inj 60 MG/0.6ML		30	Syringes	90	DAYS			
83101020102015		Enoxaparin Sodium Inj 80 MG/0.8ML		30	Syringes	90	DAYS			
83103030102045	Arixtra	Fondaparinux Sodium Subcutaneous Inj 10 MG/0.8ML	10 MG/0.8ML	30	Syringes	90	DAYS			
83103030102020	Arixtra	Fondaparinux Sodium Subcutaneous Inj 2.5 MG/0.5ML	2.5 MG/0.5ML	30	Syringes	90	DAYS			
83103030102035	Arixtra	Fondaparinux Sodium Subcutaneous Inj 5 MG/0.4ML	5 MG/0.4ML	30	Syringes	90	DAYS			
83103030102040	Arixtra	Fondaparinux Sodium Subcutaneous Inj 7.5 MG/0.6ML	7.5 MG/0.6ML	30	Syringes	90	DAYS			
83101010102017	Fragmin	dalteparin sodium inj 2500 unit/ml	10000 UNIT/4ML	30	Vials	90	DAYS			
83101010102080	Fragmin	Dalteparin Sodium Inj 95000 Unit/3.8ML	95000 UNIT/3.8ML	10	Vials	90	DAYS			
8310101010E505	Fragmin	Dalteparin Sodium Soln Prefilled Syr	2500 UNIT/0.2ML	30	Syringes	90	DAYS			
8310101010E515	Fragmin	Dalteparin Sodium Soln Prefilled Syr	5000 UNIT/0.2ML	30	Syringes	90	DAYS			
8310101010E520	Fragmin	Dalteparin Sodium Soln Prefilled Syr	7500 UNIT/0.3ML	30	Syringes	90	DAYS			
8310101010E530	Fragmin	Dalteparin Sodium Soln Prefilled Syr	10000 UNIT/ML	30	Syringes	90	DAYS			
8310101010E535	Fragmin	Dalteparin Sodium Soln Prefilled Syr	12500 UNIT/0.5ML	30	Syringes	90	DAYS			
8310101010E540	Fragmin	Dalteparin Sodium Soln Prefilled Syr	15000 UNIT/0.6ML	30	Syringes	90	DAYS			
8310101010E550	Fragmin	Dalteparin Sodium Soln Prefilled Syr	18000 UNT/0.72ML	30	Syringes	90	DAYS			
83101020102050	Lovenox	Enoxaparin Sodium Inj 300 MG/3ML	300 MG/3ML	10	Vials	90	DAYS			
8310102010E520	Lovenox	Enoxaparin Sodium Inj Soln Pref Syr	30 MG/0.3ML	30	Syringes	90	DAYS			
8310102010E525	Lovenox	Enoxaparin Sodium Inj Soln Pref Syr	40 MG/0.4ML	30	Syringes	90	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
8310102010E530	Lovenox	Enoxaparin Sodium Inj Soln Pref Syr	60 MG/0.6ML	30	Syringes	90	DAYS			
8310102010E535	Lovenox	Enoxaparin Sodium Inj Soln Pref Syr	80 MG/0.8ML	30	Syringes	90	DAYS			
8310102010E540	Lovenox	Enoxaparin Sodium Inj Soln Pref Syr	100 MG/ML	30	Syringes	90	DAYS			
8310102010E560	Lovenox	Enoxaparin Sodium Inj Soln Pref Syr	120 MG/0.8ML	30	Syringes	90	DAYS			
8310102010E565	Lovenox	Enoxaparin Sodium Inj Soln Pref Syr	150 MG/ML	30	Syringes	90	DAYS			

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 patient requires extended treatment for primary or secondary prophylaxis of thromboembolism during pregnancy and/or puerperium **OR** 3. The patient requires extended prophylaxis and/or treatment of symptomatic VTE (DVT and/or PE) **AND** the patient has cancer **OR** 4. 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. There is support for 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 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. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• Program Summary: Lyrica (pregabalin) Savella (milnacipran)

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
72600057000125	Lyrica	Pregabalin Cap 100 MG	100 MG	90	Capsules	30	DAYS			
72600057000135	Lyrica	Pregabalin Cap 150 MG	150 MG	90	Capsules	30	DAYS			
72600057000145	Lyrica	Pregabalin Cap 200 MG	200 MG	90	Capsules	30	DAYS			
72600057000150	Lyrica	Pregabalin Cap 225 MG	225; 225 MG	60	Capsules	30	DAYS			
72600057000110	Lyrica	Pregabalin Cap 25 MG	25 MG	90	Capsules	30	DAYS			
72600057000160	Lyrica	Pregabalin Cap 300 MG	300; 300 MG	60	Capsules	30	DAYS			
72600057000115	Lyrica	Pregabalin Cap 50 MG	50 MG	90	Capsules	30	DAYS			
72600057000120	Lyrica	Pregabalin Cap 75 MG	75; 75 MG	90	Capsules	30	DAYS			
72600057002020	Lyrica	Pregabalin Soln 20 MG/ML	20 MG/ML	900	mLs	30	DAYS			
62540060007530	Lyrica cr	Pregabalin Tab ER 24HR 165 MG	165 MG	30	Tablets	30	DAYS			
62540060007540	Lyrica cr	Pregabalin Tab ER 24HR 330 MG	330 MG	60	Tablets	30	DAYS			
62540060007520	Lyrica cr	Pregabalin Tab ER 24HR 82.5 MG	82.5 MG	30	Tablets	30	DAYS			
62504050100350	Savella	Milnacipran HCl Tab 100 MG	100 MG	60	Tablets	30	DAYS			
62504050100320	Savella	Milnacipran HCl Tab 12.5 MG	12.5 MG	60	Tablets	30	DAYS			
62504050100330	Savella	Milnacipran HCl Tab 25 MG	25 MG	60	Tablets	30	DAYS			
62504050100340	Savella	Milnacipran HCl Tab 50 MG	50 MG	60	Tablets	30	DAYS			
62504050106320	Savella titration pack	Milnacipran HCl Tab 12.5 MG (5) & 25 MG (8) & 50 MG (42) Pak	12.5 & 25 & 50 MG	1	Pack	180	DAYS			

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Lyrica	**TARGET AGENT(S)** **LYRICA** (pregabalin)* * – available as a generic; included as a prerequisite in the step therapy program **LYRICA** 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 has a diagnosis of a seizure disorder **OR** 3. The patient has medication history of use with another anticonvulsant within the past 90 days **OR** 4. The patient has medication history of use with generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin or tramadol **OR** 5. BOTH of the following: A. The prescriber has stated that the patient has tried generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, or tramadol **AND** B. The prerequisite agent (i.e., generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, or tramadol) was discontinued due to lack of effectiveness or an adverse event **OR** 6. The patient has an intolerance or hypersensitivity to a prerequisite agent (i.e., generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, or tramadol) **OR** 7. The patient has an FDA labeled contraindication to ALL prerequisite agents (i.e., generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, AND tramadol) **OR** 8. The prescriber has provided documentation that ALL prerequisite agents (i.e., generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, AND tramadol) 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.
Lyrica CR	**TARGET AGENT(S)** **LYRICA CR** (pregabalin ER)* * – available as a generic; included as a 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. BOTH of the following: A. ONE of the following: 1. BOTH of the following: A. The prescriber has stated that the patient has tried generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, venlafaxine, or gabapentin **AND** B. The prerequisite agent (i.e., generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, venlafaxine, or gabapentin) was discontinued due to lack of

Module	Clinical Criteria for Approval
	effectiveness or an adverse event **OR** 2. The patient has an intolerance or hypersensitivity to a prerequisite agent (i.e., generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, venlafaxine, or gabapentin) **OR** 3. The patient has an FDA labeled contraindication to ALL prerequisite agents (i.e., generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, venlafaxine, AND gabapentin) **OR** 4. The prescriber has provided documentation that ALL prerequisite agents (i.e., generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, venlafaxine, AND gabapentin) 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. BOTH of the following: A. The prescriber has stated that the patient has tried generic pregabalin immediate release **AND** B. Generic pregabalin immediate release was discontinued due to lack of effectiveness or an adverse event **OR** 2. The patient has an intolerance or hypersensitivity to generic pregabalin immediate release **OR** 3. The patient has an FDA labeled contraindication to generic pregabalin immediate release **OR** 4. The prescriber has provided documentation that generic pregabalin immediate release 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.
Savella	**TARGET AGENT(S)** **Savella®** (milnacipran) **Savella** 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 generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, or tramadol **OR** 3. BOTH of the following: A. The prescriber has stated that the patient has tried generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, or tramadol **AND** B. The prerequisite agent (i.e., generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, or tramadol) was discontinued due to lack of effectiveness or an adverse event **OR** 4. The patient has an intolerance or hypersensitivity to a prerequisite agent (i.e., generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, or tramadol) **OR** 5. The patient has an FDA labeled contraindication to ALL prerequisite agents (i.e., generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, AND

Module	Clinical Criteria for Approval
	tramadol) **OR** 6. The prescriber has provided documentation that ALL prerequisite agents (i.e., generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, AND tramadol) 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. There is support for 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 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. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• Program Summary: Oral Tetracycline Derivatives

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
	040000401003		minocycline hcl tab	100 MG; 50 MG; 75 MG	M; N; O				
	040000601003		tetracycline hcl tab	250 MG; 500 MG	M; N; O; Y				
	040000201003	Acticlate; Lymepak; Targadox	doxycycline hyclate tab	100 MG; 150 MG; 20 MG; 50 MG; 75 MG	M; N; O				
	040000200003	Avidoxy	doxycycline monohydrate tab	100 MG; 150 MG; 50 MG; 75 MG	M; N; O				

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
	040000401075	Coremino; Minolira; Solodyn	minocycline hcl tab er	105 MG; 115 MG; 135 MG; 45 MG; 55 MG; 65 MG; 80 MG; 90 MG	M; N; O; Y				
	040000201006	Doryx; Doryx mpc	doxycycline hyclate tab delayed release	100 MG; 120 MG; 150 MG; 200 MG; 50 MG; 60 MG; 75 MG; 80 MG	M; N; O; Y				
	040000401001	Minocin	minocycline hcl cap	100 MG; 50 MG; 75 MG	M; N; O				
	040000200001	Mondoxyne nl	doxycycline monohydrate cap	100 MG; 150 MG; 50 MG; 75 MG	M; N; O				
	900600250065	Oracea	doxycycline (rosacea) cap delayed release	40 MG	M; N; O				
	040000571003	Seysara	sarecycline hcl tab	100 MG; 150 MG; 60 MG	M; N; O; Y				
	040000201001	Vibramycin	doxycycline hyclate cap	100 MG; 50 MG	M; N; O				
	040000200019	Vibramycin	doxycycline monohydrate for susp	25 MG/5ML	M; N; O				
	040000401070	Ximino	minocycline hcl cap er	135 MG; 45 MG; 90 MG	M; N; O				

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. The patient has an 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. If the patient's diagnosis is acne, ONE of the following: A. The patient will be using a benzoyl peroxide agent OR a retinoid agent in combination with the requested agent **OR** B. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to a benzoyl peroxide agent OR a retinoid agent **OR** C. The patient's medication history includes use of a benzoyl peroxide agent OR a retinoid agent in the past 999 days **OR** D. BOTH of the following: 1. The prescriber has stated that the patient has tried a benzoyl peroxide agent OR a retinoid agent **AND** 2. The benzoyl peroxide agent or retinoid 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

Module	Clinical Criteria for Approval
	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 benzoyl peroxide agents AND ALL 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** 4. If the patient's diagnosis is acne or rosacea, the patient will NOT be using the requested agent in combination with another tetracycline derivative for the treatment of acne or rosacea **AND** 5. ONE of the following: A. The requested agent is a preferred oral generic doxycycline agent **OR** B. The requested agent is a preferred oral generic minocycline agent **OR** C. BOTH of the following: 1. ONE of the following: A. The patient has tried and had an inadequate response to a preferred oral generic doxycyline agent **OR** B. The patient has an intolerance or hypersensitivity to a preferred oral generic doxycycline agent **OR** C. The patient has an FDA labeled contraindication to ALL preferred oral generic doxycycline agents **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 preferred oral generic doxycycline 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. ONE of the following: A. The patient has tried and had an inadequate response to a preferred oral generic minocycline agent **OR** B. The patient has an intolerance or hypersensitivity to a preferred oral generic minocycline agent **OR** C. The patient has an FDA labeled contraindication to ALL preferred oral generic minocycline agents **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 preferred oral generic minocycline agents cannot be used due to a documented medical condition or

Module	Clinical Criteria for Approval
	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: Pulmonary Arterial Hypertension

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
401430800003	Adcirca; Alyq	tadalafil tab	20 MG	60	Tablets	30	DAYS			
4013405000	Adempas	riociguat tab	0.5 MG; 1 MG; 1.5 MG; 2 MG; 2.5 MG	90	Tablets	30	DAYS			
4016000700	Letairis	ambrisentan tab	10 MG; 5 MG	30	Tablets	30	DAYS			
40143060101825	Liqrev	sildenafil citrate oral susp	10 MG/ML	2	Bottles	30	DAYS			
4016005000	Opsumit	macitentan tab	10 MG	30	Tablets	30	DAYS			
40995502500310	Opsynvi	macitentan-tadalafil tab	10-20 MG	30	Tablets	30	DAYS			
40995502500320	Opsynvi	macitentan-tadalafil tab	10-40 MG	30	Tablets	30	DAYS			
4017008005C110	Orenitram titr kit Month 1	Treprostinil tab er Mo 1 titr kit	0.125 & 0.25 MG	1	Kit	180	DAYS			
4017008005C120	Orenitram titr kit Month 2	Treprostinil tab er Mo 2 titr kit	0.125 & 0.25 MG	1	Kit	180	DAYS			
4017008005C130	Orenitram titr kit Month 3	Treprostinil tab er Mo 3 titr kit	0.125 & 0.25 &1 MG	1	Kit	180	DAYS			
401430601019	Revatio	sildenafil citrate for suspension	10 MG/ML	224	Bottles	30	DAYS			
401430601003	Revatio	sildenafil citrate tab	20 MG	90	Tablets	30	DAYS			
40143080001820	Tadliq	Tadalafil Oral Susp	20 MG/5ML	300	mLs	30	DAYS			
401600150003	Tracleer	bosentan tab	125 MG; 62.5 MG	60	Tablets	30	DAYS			
401600150073	Tracleer	bosentan tab for oral susp	32 MG	120	Tablets	30	DAYS			
40170080002020	Tyvaso	treprostinil inhalation solution	0.6 MG/ML	7	Packages	28	DAYS			
40170080002920	Tyvaso dpi	Treprostinil Inh	16 MCG	112	Cartridge	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
	institutional; Tyvaso dpi maintenance ki	Powder			s					
40170080002930	Tyvaso dpi institutional; Tyvaso dpi maintenance ki	Treprostinil Inh Powder	32 MCG	112	Cartridges	28	DAYS			
40170080002940	Tyvaso dpi institutional; Tyvaso dpi maintenance ki	Treprostinil Inh Powder	48 MCG	112	Cartridges	28	DAYS			
40170080002950	Tyvaso dpi institutional; Tyvaso dpi maintenance ki	Treprostinil Inh Powder	64 MCG	112	Cartridges	28	DAYS			
40170080002960	Tyvaso dpi maintenance ki	Treprostinil Inh Powder	112 x 32MCG & 112 x48MCG	224	Cartridges	28	DAYS			
40170080002980	Tyvaso dpi titration kit	Treprostinil Inh Powd	16 & 32 & 48 MCG	252	Cartridges	180	DAYS			
40170080002970	Tyvaso dpi titration kit	Treprostinil Inh Powder	112 x 16MCG & 84 x 32MCG	196	Cartridges	180	DAYS			
40170080002020	Tyvaso refill	treprostinil inhalation solution	0.6 MG/ML	1	Kit	28	DAYS			
40170080002020	Tyvaso starter	treprostinil inhalation solution	0.6 MG/ML	1	Kit	180	DAYS			
40170080002020	Tyvaso starter	treprostinil inhalation solution	0.6 MG/ML	1	Kit	180	DAYS			
401200700003	Uptravi	selexipag tab	1000 MCG; 1200 MCG; 1400 MCG; 1600 MCG; 200 MCG; 400 MCG; 600 MCG; 800 MCG	60	Tablets	30	DAYS			
40120070000310	Uptravi	selexipag tab	200 MCG	140	Tablets	180	DAYS			
40120070000310	Uptravi	selexipag tab	200 MCG	60	Tablets	30	DAYS			
4012007000B7	Uptravi titration pack	selexipag tab therapy pack	200 & 800 MCG	1	Pack	180	DAYS			
401700600020	Ventavis	iloprost inhalation solution	10 MCG/ML; 20 MCG/ML	270	Ampules	30	DAYS			
40110070206420	Winrevair	sotatercept-csrk for	45 MG	1	Kit	21	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 kit								
40110070206425	Winrevair	sotatercept-csrk for subcutaneous soln kit	60 MG	1	Kit	21	DAYS			
40110070206430	Winrevair	sotatercept-csrk for subcutaneous soln kit	2 x 45 MG	1	Kit	21	DAYS			
40110070206435	Winrevair	sotatercept-csrk for subcutaneous soln kit	2 X 60 MG	1	Kit	21	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. BOTH of the following: 1. The requested agent is eligible for continuation of therapy AND ONE of the following: **Target Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy A. 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 **AND** 2. The patient has an FDA labeled indication for the requested agent and route of administration **OR** B. The patient has a diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH), WHO Group 4 and ALL of the following: 1. The requested agent is Adempas **AND** 2. The patient's diagnosis has been confirmed by a ventilation-perfusion scan and a confirmatory selective pulmonary angiography **AND** 3. The patient has a mean pulmonary artery pressure of greater than 20 mmHg **AND** 4. The patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg **AND** 5. The patient has a pulmonary vascular resistance greater than or equal to 3 Wood units **AND** 6. ONE of the following: A. The patient is NOT a candidate for surgery **OR** B. The patient has had a pulmonary endarterectomy AND has persistent or recurrent disease **AND** 7. The patient will NOT be using the requested agent in combination with a PDE5 inhibitor (e.g., tadalafil [Adcirca or Cialis] or sildenafil [Revatio or Viagra]) **OR**

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	C. The patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 and ALL of the following: 1. The patient's diagnosis has been confirmed by right heart catheterization (medical records required) **AND** 2. The patient's mean pulmonary arterial pressure is greater than 20 mmHg **AND** 3. The patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg **AND** 4. The patient has a pulmonary vascular resistance greater than or equal to 3 Wood units **AND** 5. The patient's World Health Organization (WHO) functional class is II or greater **AND** 6. If the requested agent is sotatercept, then BOTH of the following: A. The patient has been stable on background PAH therapy for at least 90 days (Please note: Background therapy refers to combination therapy consisting of drugs from two or more of the following drug classes: ERA, PDE5i, soluble guanylate cyclase stimulator, and/or prostacyclin analogue or receptor agonist) **AND** B. The patient is not pregnant or planning to become pregnant while on therapy with the requested agent **AND** 7. If the requested agent is Adcirca, Adempas, Revatio, sildenafil, or tadalafil, the patient will NOT be using the requested agent in combination with a PDE5 inhibitor (e.g., tadalafil [Adcirca or Cialis] or sildenafil [Revatio or Viagra]) **AND** 8. If the requested agent is NOT sotatercept, then ONE of the following: A. The requested agent will be utilized as monotherapy **OR** B. The requested agent will be utilized as dual therapy that consists of an endothelin receptor antagonist (ERA) plus phosphodiesterase 5 inhibitor (PDE5i) as initial therapy **OR** C. The requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy) [except combo requests for endothelin receptor antagonist (ERA) plus phosphodiesterase 5 inhibitor (PDE5i) for dual therapy], and BOTH of following: 1. The patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy **AND** 2. The requested agent is in a different therapeutic class **OR** D. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy) and ALL of the following: 1. The patient is WHO functional class III or IV **AND** 2. ONE of the following: A. A prostanoid has been started as one of the agents in the triple therapy **OR** B. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ALL prostanoids **AND** 3. The patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy **AND** 4. All three agents in the triple therapy are from a different therapeutic class **OR** E. The requested agent will be utilized as part of triple therapy in a treatment naive patient **AND** both of the following: 1. The patient is WHO functional class IV **AND** 2. The 3 agents being utilized consist of: endothelin receptor antagonist (ERA) plus PDE5i plus prostanoid **OR** D. The patient has a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD, WHO group 3) AND ALL of the following:

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1. The requested agent is Tyvaso **AND**
2. The patient's diagnosis has been confirmed by right heart catheterization (medical records required) **AND**
3. The patient's mean pulmonary arterial pressure is greater than 20 mmHg **AND**
4. The patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg **AND**
5. The patient has a pulmonary vascular resistance greater than or equal to 3 Wood units **AND**
6. The patient has an FVC less than 70% of predicted **AND**
7. The patient has extensive parenchymal changes on computed tomography (CT) **AND**
8. BOTH of the following:
    A. The patient is currently treated with standard of care therapy for ILD (e.g., Ofev) **AND**
    B. The patient will continue standard of care therapy for ILD (e.g., Ofev) **OR**

E. The patient has another FDA approved indication for the requested agent **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. There is support for using the requested agent for the patient's age for the requested indication **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:

Brand	Generic Equivalent
Revatio (tablet, oral suspension)	sildenafil (tablet, oral suspension)
Adcirca	tadalafil
Tracleer 6.25 mg and 125 mg tablets	bosentan 6.25 mg and 125 mg tablets
Letaris	ambrisentan

    A. The patient's medication history includes the required generic equivalent as indicated by:
        1. Evidence of a paid claim(s) **OR**
        2. The prescriber has stated that the patient has tried the generic equivalent AND the generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**
    B. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**
    C. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR**
    D. There is support for the use of the requested brand agent over the generic equivalent **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 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. If the request is for Tadliq, then one of the following:
    A. The patient's medication history includes generic tadalafil tablets as indicated by:
        1. Evidence of a paid claim(s) **OR**

Module	Clinical Criteria for Approval
	2. The prescriber has stated that the patient has tried generic tadalafil tablets AND generic tadalafil tablets were discontinued due to lack of effectiveness or an adverse event **OR** B. The patient has an intolerance or hypersensitivity to generic tadalafil tablets that is not expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to generic tadalafil tablets that is not expected to occur with the requested agent **OR** D. The prescriber has provided information to support the use of the requested agent over generic tadalafil tablets **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 tadalafil 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** 5. If the request is for Liqrev, then one of the following: A. The patient's medication history includes generic sildenafil oral suspension as indicated by: 1. Evidence of a paid claim(s) **OR** 2. The prescriber has stated that the patient has tried generic sildenafil oral suspension AND generic sildenafil oral suspension was discontinued due to lack of effectiveness or an adverse event **OR** B. The patient has an intolerance or hypersensitivity to generic sildenafil oral suspension that is not expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to generic sildenafil oral suspension that is not expected to occur with the requested agent **OR** D. The prescriber has provided information to support the use of the requested agent over generic sildenafil oral suspension **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 sildenafil oral suspension 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. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, pulmonologist) 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.

Module	Clinical Criteria for Approval

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 [NOTE: Patients not previously approved for the requested agent will require initial evaluation review] **AND**
2. The patient has had clinical benefit with the requested agent (e.g., stabilization, decreased disease progression) (medical records required) **AND**
3. If the requested agent is Tyvaso for a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD, WHO group 3), then the patient will continue standard of care therapy for ILD (e.g., Ofev) **AND**
4. If the requested agent is sotatercept for a diagnosis of pulmonary arterial hypertension (PAH), the patient will continue to use background PAH therapy (Please note: Background therapy refers to combination therapy consisting of drugs from two or more of the following drug classes: ERA, PDE5i, soluble guanylate cyclase stimulator, and/or prostacyclin analogue or receptor agonist) **AND**
5. If the request is for ONE of the following brand agents with an available generic equivalent (listed below), then ONE of the following:

Brand	Generic Equivalent
Revatio (tablet, oral suspension)	sildenafil (tablet, oral suspension)
Adcirca	tadalafil
Tracleer 6.25 mg and 125 mg tablets	bosentan 6.25 mg and 125 mg tablets
Letaris	ambrisentan

   A. The patient's medication history includes the required generic equivalent as indicated by:
      1. Evidence of a paid claim(s) **OR**
      2. The prescriber has stated that the patient has tried the generic equivalent AND the generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**
   B. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**
   C. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR**
   D. There is support for the use of the requested brand agent over the generic equivalent **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 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**
6. If the request is for Tadliq, then one of the following:
   A. The patient's medication history includes generic tadalafil tablets as indicated by:
      1. Evidence of a paid claim(s) **OR**
      2. The prescriber has stated that the patient has tried generic tadalafil tablets AND generic tadalafil tablets were discontinued due to lack of effectiveness or an adverse event **OR**
   B. The patient has an intolerance or hypersensitivity to generic tadalafil tablets that is not expected to occur with the requested agent **OR**

Module	Clinical Criteria for Approval
	C. The patient has an FDA labeled contraindication to generic tadalafil tablets that is not expected to occur with the requested agent **OR** D. The prescriber has provided information to support the use of the requested agent over generic tadalafil tablets **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 tadalafil 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** 7. If the request is for Liqrev, then one of the following: A. The patient's medication history includes generic sildenafil oral suspension as indicated by: 1. Evidence of a paid claim(s) **OR** 2. The prescriber has stated that the patient has tried generic sildenafil oral suspension AND generic sildenafil oral suspension was discontinued due to lack of effectiveness or an adverse event **OR** B. The patient has an intolerance or hypersensitivity to generic sildenafil oral suspension that is not expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to generic sildenafil oral suspension that is not expected to occur with the requested agent **OR** D. The prescriber has provided information to support the use of the requested agent over generic sildenafil oral suspension **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 sildenafil oral suspension 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** 8. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, pulmonologist) 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 NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	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. There is support for therapy with a higher dose for the requested indication **Length of Approval**: 12 months

• Program Summary: Radicava (edaravone)

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
74509030001820	Radicava ors; Radicava ors starter kit	Edaravone Oral Susp	105 MG/5ML	50	mLs	28	DAYS			
74509030001820	Radicava ors starter kit	edaravone oral susp	105 MG/5ML	70	mLs	180	DAYS	70510232101; 70510232102		

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. 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 has a diagnosis of amyotrophic lateral sclerosis (ALS) **AND** 2. The patient has had the diagnosis of ALS for a duration of 2 years or less **AND** 3. The patient has a baseline percent forced vital capacity (FVC%) or slow vital capacity (SVC) of 80% or greater **AND** 4. The patient is able to perform most activities of daily living, defined as scores of 2 points or better on each individual item of the ALS Functional Rating Scale – Revised [ALSFRS-R]

Module	Clinical Criteria for Approval
	AND 5. ONE of the following: A. BOTH of the following: 1. The patient is currently being treated with riluzole **AND** 2. The patient will continue riluzole in combination with the requested agent **OR** B. The patient has tried and had an inadequate response to riluzole **OR** C. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to riluzole **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 riluzole 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 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** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months **NOTE:** For patients initiating therapy, approval will include 28 bags per 28 days (initial dose) for the first month and 20 bags per 28 days for the remainder of the 6 months. For patients initiating therapy with oral suspension, approval will include 70 mL starter kit per 180 days (initial dose) and 50 mL per 28 days for the remainder of the 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 [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient is NOT dependent on invasive ventilation or tracheostomy **AND** 4. 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** 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 **Length of Approval:** Initial: up to 6 months; Renewal: up to 12 months

● Program Summary: Selective Serotonin Inverse Agonist (SSIA)

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
59400028200120	Nuplazid	Pimavanserin Tartrate Cap 34 MG (Base Equivalent)	34 MG	30	Capsules	30	DAYS			
59400028200310	Nuplazid	Pimavanserin Tartrate Tab 10 MG (Base Equivalent)	10 MG	30	Tablets	30	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**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 hallucinations or delusions associated with Parkinson's disease psychosis AND ONE of the following: 1. The patient has tried and had an inadequate response to clozapine or quetiapine **OR** 2. The patient has an intolerance or hypersensitivity to clozapine or quetiapine **OR** 3. The patient has an FDA labeled contraindication to BOTH clozapine and quetiapine **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 clozapine and quetiapine 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

Module	Clinical Criteria for Approval
	harm **OR** B. The patient has another FDA labeled indication for the requested agent **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within the FDA labeling for the requested indication for the requested agent **OR** B. There is support for 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, psychiatrist or other mental health professional) or the prescriber has consulted with a specialist in the area of the patient's diagnosis for the requested indication **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. There is support of therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

● 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	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		8	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	Effective Date	Term Date
		Pack 20 MG (40 MG Once Weekly)								
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			
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			

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
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			
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			
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			

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
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			
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			

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
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			
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			

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
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			
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			
21532350200330	Ogsiveo	nirogacestat hydrobromide tab	100 MG	56	Tablets	28	DAYS			
21532350200340	Ogsiveo	nirogacestat	150 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	Effective Date	Term Date
		hydrobromide tab								
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			
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	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
		2.5 MG								
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			
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			

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
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 MG	100 MG	120	Capsules	30	DAYS			
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	90	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			

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
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			
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			

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
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; 150 MG	60	Tablets	30	DAYS			
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			

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
21532530007310	Afinitor disperz	Everolimus Tab for Oral Susp 2 MG	2 MG	Calculation is based on 4.5 mg/m2 with a standard BSA of 2.0 and rounding up to nearest full dose			
214500800001	Pomalyst	pomalidomide cap	1 MG; 2 MG; 3 MG; 4 MG	The quantity limits for Pomalyst are based on dosing for multiple myeloma, which is given daily for 21 days of a 28 day cycle			
99394050000140	Revlimid	Lenalidomide Cap 15 MG	15 MG	The quantity limits for Revlimid 15 mg & 25 mg capsules are based on dosing for multiple			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
				myeloma, which is 25 mg daily for 21 days of a 28 day cycle			
99394050000150	Revlimid	Lenalidomide Cap 25 MG	25 MG	The quantity limits for Revlimid 15 mg & 25 mg capsules are based on dosing for multiple myeloma, which is 25 mg daily for 21 days of a 28 day cycle			
2153305000	Stivarga	regorafenib tab	40 MG	based 160 mg daily for 21 days of a 28 day cycle			

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. The patient has been 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 labeled indication for the requested agent **OR** B. The patient has an indication that is supported by compendia [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 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. There is support for 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 for the requested agent **OR** B. The requested indication requires genetic/specific diagnostic testing per FDA labeling or compendia 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 for the 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 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 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

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	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 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 **Compendia Allowed:** 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 **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 [Note: patients not previously approved for the requested agent will require initial evaluation review] **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** 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

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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. There is support for 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: 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. ONE of the following: A. The requested agent is eligible for continuation of therapy AND BOTH of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. ONE of the following: A. 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

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	(starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **AND** 2. The prescriber has assessed current status of the following: spleen volume, hemoglobin level, liver volume, platelet count, growth, bone pain or crisis **OR** B. ALL of the following: 1. The patient has a diagnosis of Gaucher disease type 1 (GD1) **AND** 2. 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** 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. There is support for using the requested agent for the patient's age for the requested indication **AND** 4. 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** 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): 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 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** 2. 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** 3. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following: **Brand** / **Generic Equivalent** Zavesca / miglustat 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

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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**

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 the 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, Opfolda, 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.

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 [Note: patients not previously approved for the requested agent will require initial evaluation review] **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:

Brand	Generic Equivalent
Zavesca	miglustat

   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

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	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** 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, Opfolda, 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.
Opfolda	**Initial Evaluation** **Opfolda** 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**: Opfolda 1. 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 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: A. Genetic analysis confirms biallelic mutation (two pathogenic variants) in the *GAA* gene **OR** B. 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 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**

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	B. There is support for using the requested agent for the patient's age for the requested indication **AND** 2. 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** 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. **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 [Note: patients not previously approved for the requested agent will require initial evaluation review] **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. There is support of therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• Program Summary: Thrombopoietin Receptor Agonists and Tavalisse

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
82405030050310	Alvaiz	eltrombopag choline tab	9 MG	30	Tablets	30	DAYS			
82405030050320	Alvaiz	eltrombopag choline tab	18 MG	30	Tablets	30	DAYS			
82405030050330	Alvaiz	eltrombopag choline tab	36 MG	60	Tablets	30	DAYS			
82405030050340	Alvaiz	eltrombopag choline tab	54 MG	60	Tablets	30	DAYS			
82405010200320	Doptelet	Avatrombopag Maleate Tab 20 MG (Base Equiv)	20 MG	60	Tablets	30	DAYS			
82405045000320	Mulpleta	Lusutrombopag Tab 3 MG	3 MG	7	Tablets	7	DAYS			
82405030103030	Promacta	Eltrombopag Olamine Powder Pack for Susp 12.5 MG (Base Eq)	12.5 MG	30	Packets	30	DAYS			
82405030103020	Promacta	Eltrombopag Olamine Powder Pack for Susp 25 MG (Base Equiv)	25 MG	30	Packets	30	DAYS			
82405030100310	Promacta	Eltrombopag Olamine Tab 12.5 MG (Base Equiv)	12.5 MG	30	Tablets	30	DAYS			
82405030100320	Promacta	Eltrombopag Olamine Tab 25 MG (Base Equiv)	25 MG	30	Tablets	30	DAYS			
82405030100330	Promacta	Eltrombopag Olamine Tab 50 MG (Base Equiv)	50 MG	60	Tablets	30	DAYS			
82405030100340	Promacta	Eltrombopag Olamine Tab 75 MG (Base Equiv)	75 MG	60	Tablets	30	DAYS			
857560401003	Tavalisse	fostamatinib disodium tab	100 MG; 150 MG	60	Tablets	30	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when the ALL of the following are met: 1. ONE of the following: A. The requested agent is Doptelet AND ONE of the following: 1. The patient has a diagnosis of chronic (defined as lasting for at least 12 months) immune (idiopathic) thrombocytopenia (ITP) AND BOTH of the following:

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	A. ONE of the following: 1. The patient has a platelet count less than or equal to 30 X 10^9/L **OR** 2. The patient has a platelet count greater than 30 X 10^9/L but less than 50 X 10^9/L AND has symptomatic bleeding and/or an increased risk for bleeding **AND** B. ONE of the following: 1. The patient has tried and had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR** 2. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR** 3. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR** 4. The patient has tried and had an inadequate response to another thrombopoietin receptor agonist (e.g., Nplate, Promacta) or Tavalisse **OR** 5. The patient has tried and had an inadequate response to immunoglobulins (IVIg or Anti-D) **OR** 6. The patient has had an inadequate response to a splenectomy **OR** 7. The patient has tried and had an inadequate response to rituximab **OR** 8. 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** 9. The prescriber has provided documentation that 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** 2. The patient has a diagnosis of thrombocytopenia and has chronic liver disease AND ALL of the following: A. The patient has a platelet count less than 50 X 10^9/L **AND** B. The patient is scheduled to undergo a procedure with an associated risk of bleeding (e.g., gastrointestinal endoscopy, liver biopsy, bronchoscopy, dental procedure) **AND** C. The patient would require a platelet transfusion unless platelet counts are clinically increased from baseline (prior to therapy with the requested agent) **OR** 3. The patient has another FDA approved indication for the requested agent **OR** 4. The patient has another indication supported in compendia for the requested agent **OR** B. The requested agent is Mulpleta (lusutrombopag) AND ONE of the following: 1. BOTH of the following: A. The patient has a platelet count less than 50 X 10^9/L **AND** B. The patient has a diagnosis of thrombocytopenia and has chronic liver disease AND BOTH of the following: 1. The patient is scheduled to undergo a procedure with an associated risk of bleeding (e.g., gastrointestinal endoscopy, liver biopsy, bronchoscopy, dental procedure) **AND** 2. The patient would require a platelet transfusion unless platelet counts

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	are clinically increased from baseline (prior to therapy with the requested agent) **OR** 2. The patient has another FDA approved indication for the requested agent **OR** 3. The patient has another indication supported in compendia for the requested agent **OR** C. The requested agent is Nplate (romiplostim) AND ONE of the following: 1. The patient has a diagnosis of hematopoietic syndrome of acute radiation syndrome (HS-ARS) **OR** 2. The patient has a diagnosis of immune (idiopathic) thrombocytopenia (ITP) AND ALL of the following: A. ONE of the following: 1. The patient is between the ages of 1 and 17 years old AND the diagnosis has lasted for at least 6 months **OR** 2. The patient is 18 years old or over **AND** B. ONE of the following: 1. The patient has a platelet count less than or equal to 30 X 10^9/L **OR** 2. The patient has a platelet count greater than 30 X 10^9/L but less than 50 x 10^9/L AND has symptomatic bleeding and/or an increased risk for bleeding **AND** C. ONE of the following: 1. The patient has tried and had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR** 2. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR** 3. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR** 4. The patient has tried and had an inadequate response to immunoglobulins (IVIg or anti-D) **OR** 5. The patient has had an inadequate response to a splenectomy **OR** 6. The patient has tried and had an inadequate response to rituximab **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 therapeutic 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 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** 3. The patient has another FDA approved indication for the requested agent **OR** 4. The patient has another indication supported in compendia for the requested agent **OR** D. The requested agent is Promacta (eltrombopag) or Alvaiz AND ONE of the following: 1. The patient has a diagnosis of hepatitis C associated thrombocytopenia AND ONE of the following: A. The intent of therapy with the requested agent is to increase platelet counts sufficiently to initiate pegylated interferon therapy AND the patient's platelet count is less than 75 x 10^9/L **OR** B. The patient is on concurrent therapy with a pegylated interferon and ribavirin

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	AND is at risk for discontinuing hepatitis C therapy due to thrombocytopenia **OR** 2. The patient has a diagnosis of severe aplastic anemia AND ALL of the following: A. The patient has at least 2 of the following blood criteria: 1. Neutrophils less than 0.5 X 10^9/L 2. Platelets less than 30 X 10^9/L 3. Reticulocyte count less than 60 X 10^9/L **AND** B. The patient has 1 of the following marrow criteria: 1. Severe hypocellularity: less than 25% **OR** 2. Moderate hypocellularity, 25-50% with hematopoietic cells representing less than 30% of residual cells **AND** C. ONE of the following: 1. BOTH of the following: A. The patient will use the requested agent as first-line treatment **AND** B. The patient will use the requested agent in combination with standard immunosuppressive therapy (i.e., antithymocyte globulin [ATG] AND cyclosporine) **OR** 2. ONE of the following: A. The patient has tried and had an inadequate response to BOTH antithymocyte globulin (ATG) AND cyclosporine therapy **OR** B. The patient has an intolerance or hypersensitivity to BOTH ATG AND cyclosporine **OR** C. The patient has an FDA labeled contraindication to BOTH ATG AND cyclosporine **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 antithymocyte globulin (ATG) AND cyclosporine therapy 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** 3. The patient has a diagnosis of persistent or chronic (defined as lasting for at least 3 months) immune (idiopathic) thrombocytopenia (ITP) AND BOTH of the following: A. ONE of the following: 1. The patient has a platelet count less than or equal to 30 x 10^9/L **OR** 2. The patient has a platelet count greater than 30 x 10^9/L but less than 50 x 10^9/L AND has symptomatic bleeding and/or an increased risk for bleeding **AND** B. ONE of the following: 1. The patient has tried and had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR** 2. The patient has an intolerance or hypersensitivity to ONE

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	corticosteroid used for the treatment of ITP **OR** 3. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR** 4. The patient has tried and had an inadequate response to immunoglobulins (IVIg or anti-D) **OR** 5. The patient has had an inadequate response to a splenectomy **OR** 6. The patient has tried and had an inadequate response to rituximab **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 therapeutic 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 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** 4. The patient has another FDA approved indication for the requested agent **OR** 5. The patient has another indication supported in compendia for the requested agent **OR** E. The requested agent is Tavalisse (fostamatinib disodium hexahydrate) AND ONE of the following: 1. The patient has a diagnosis of chronic (defined as lasting for at least 12 months) immune (idiopathic) thrombocytopenia (ITP) AND BOTH of the following: A. ONE of the following: 1. The patient has a platelet count less than or equal to 30 X 10^9/L **OR** 2. The patient has a platelet count greater than 30 X 10^9/L but less than 50 x 10^9/L AND has symptomatic bleeding and/or an increased risk for bleeding **AND** B. ONE of the following: 1. The patient has tried and had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR** 2. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR** 3. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR** 4. The patient has tried and had an inadequate response to a thrombopoietin receptor agonist (e.g., Doptelet, Nplate, Promacta) **OR** 5. The patient has tried and had an inadequate response to immunoglobulins (IVIg or Anti-D) **OR** 6. The patient has had an inadequate response to a splenectomy **OR** 7. The patient has tried and had an inadequate response to rituximab **OR** 8. 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

Module	Clinical Criteria for Approval
	be ineffective or cause harm **OR** 9. The prescriber has provided documentation that 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** 2. The patient has another FDA approved indication for the requested agent **OR** 3. The patient has another indication supported in compendia for the requested agent **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. ONE of the following: A. The patient will NOT use the requested agent in combination with another agent included in this program **OR** B. The patient will use the requested agent in combination with another agent included in this program AND BOTH of the following: 1. The requested agent is Nplate **AND** 2. The patient has a diagnosis of hematopoietic syndrome of acute radiation syndrome (HS-ARS) **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 NCCN 1 or 2a recommended use **Lengths of Approval:** **Doptelet:** thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure - 1 month; all other indications - 6 months **Mulpleta:** thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure - 1 month; all other indications - 6 months **Nplate:** HS-ARS - 1 time; ITP - 4 months; all other indications - 6 months **Promacta:** ITP - 2 months; thrombocytopenia in hep C - 3 months; first-line therapy in severe aplastic anemia - 6 months; all other severe aplastic anemia - 4 months; all other indications - 6 months **Alvaiz:** ITP - 2 months; thrombocytopenia in hep C - 3 months; all other severe aplastic anemia - 4 months; all other indications - 6 months **Tavalisse:** all indications - 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. Note: Doptelet and Mulpleta for thrombocytopenia with chronic liver disease AND Nplate for hematopoietic syndrome of acute radiation syndrome (HS-ARS) should always be reviewed under initial criteria **AND** 2. ONE of the following: A. The patient has a diagnosis of immune (idiopathic) thrombocytopenia (ITP) AND ONE of the following: 1. The patient's platelet count is greater than or equal to 50 x 10^9/L **OR** 2. The patient's platelet count has increased sufficiently to avoid clinically significant bleeding **OR** B. The patient has the diagnosis of hepatitis C associated thrombocytopenia AND BOTH of the

Module	Clinical Criteria for Approval
	following: 1. ONE of the following: A. The patient will be initiating hepatitis C therapy with pegylated interferon and ribavirin **OR** B. The patient will be maintaining hepatitis C therapy with pegylated interferon and ribavirin **AND** 2. ONE of the following: A. The patient's platelet count is greater than or equal to 90 x 10^9/L **OR** B. The patient's platelet count has increased sufficiently to initiate or maintain pegylated interferon based therapy for the treatment of hepatitis C **OR** C. The patient has another indication for the requested agent AND has shown clinical improvement (i.e., decreased symptom severity and/or frequency) **AND** 3. The patient will NOT use the requested agent in combination with another agent included in this program **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Lengths of Approval:** thrombocytopenia in hepatitis C - 6 months; all other indications - 12 months NOTE if Quantity Limit Applies, please see 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) 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 limit **OR** 3. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) is greater than 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 **Initial Lengths of Approval:** **Doptelet:** thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure - 1 month; all other indications - up to 6 months **Mulpleta:** thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure - 1 month; all other indications - up to 6 months **Nplate:** HS-ARS - 1 time; ITP - up to 4 months; all other indications - up to 6 months **Promacta:** ITP - up to 2 months; thrombocytopenia in hep C - up to 3 months; first-line therapy in severe aplastic anemia - up to 6 months; all other severe aplastic anemia - up to 4 months; all other indications - up to 6 months **Alvaiz:** ITP - 2 months; thrombocytopenia in hep C - 3 months; all other severe aplastic anemia - 4 months; all other indications - 6 months **Tavalisse:** all indications - up to 6 months

Module	Clinical Criteria for Approval
	Renewal Lengths of Approval: thrombocytopenia in hepatitis C - up to 6 months; all other indications - up to 12 months

• Program Summary: Triptans

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
67406010100330		Almotriptan Malate Tab 12.5 MG	12.5 MG	12	Tablets	30	DAYS			
67406010100320		Almotriptan Malate Tab 6.25 MG	6.25 MG	12	Tablets	30	DAYS			
67406060107220		Rizatriptan Benzoate Oral Disintegrating Tab 5 MG (Base Eq)	5 MG	18	Tablets	30	DAYS			
67406060100310		Rizatriptan Benzoate Tab 5 MG (Base Equivalent)	5 MG	18	Tablets	30	DAYS			
67406070102010		Sumatriptan Succinate Inj 6 MG/0.5ML	6 MG/0.5 ML	10	Vials	30	DAYS			
67406080007220		Zolmitriptan Orally Disintegrating Tab 2.5 MG	2.5 MG	12	Tablets	30	DAYS			
67406080007230		Zolmitriptan Orally Disintegrating Tab 5 MG	5 MG	12	Tablets	30	DAYS			
67406050100310	Amerge	Naratriptan HCl Tab 1 MG (Base Equiv)	1 MG	18	Tablets	30	DAYS			
67406050100320	Amerge	Naratriptan HCl Tab 2.5 MG (Base Equiv)	2.5 MG	18	Tablets	30	DAYS			
67406030100320	Frova	Frovatriptan Succinate Tab 2.5 MG (Base Equivalent)	2.5 MG	18	Tablets	30	DAYS			
67406070002040	Imitrex	Sumatriptan Nasal Spray 20 MG/ACT	20 MG/ACT	12	Inhalers	30	DAYS			
67406070002010	Imitrex	Sumatriptan	5	12	Inhalers	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
		Nasal Spray 5 MG/ACT	MG/ACT							
67406070100320	Imitrex	Sumatriptan Succinate Tab 100 MG	100 MG	18	Tablets	30	DAYS			
67406070100305	Imitrex	Sumatriptan Succinate Tab 25 MG	25 MG	18	Tablets	30	DAYS			
67406070100310	Imitrex	Sumatriptan Succinate Tab 50 MG	50 MG	18	Tablets	30	DAYS			
6740607010E210	Imitrex statdose refill	Sumatriptan Succinate Solution Cartridge 4 MG/0.5ML	4 MG/0.5 ML	12	Doses	30	DAYS			
6740607010E220	Imitrex statdose refill	Sumatriptan Succinate Solution Cartridge 6 MG/0.5ML	6 MG/0.5 ML	12	Doses	30	DAYS			
6740607010D510	Imitrex statdose system	Sumatriptan Succinate Solution Auto-injector 4 MG/0.5ML	4 MG/0.5 ML	12	Doses	30	DAYS			
6740607010D520	Imitrex statdose system	Sumatriptan Succinate Solution Auto-injector 6 MG/0.5ML	6 MG/0.5 ML	12	Doses	30	DAYS			
67406060100320	Maxalt	Rizatriptan Benzoate Tab 10 MG (Base Equivalent)	10 MG	18	Tablets	30	DAYS			
67406060107230	Maxalt-mlt	Rizatriptan Benzoate Oral Disintegrating Tab 10 MG (Base Eq)	10 MG	18	Tablets	30	DAYS			
6740607010G420	Onzetra xsail	Sumatriptan Succinate Exhaler Powder 11 MG/NOSEPIECE	11 MG/NOSEPC	2	Kits	30	DAYS			
67406025100320	Relpax	Eletriptan Hydrobromide Tab 20 MG (Base Equivalent)	20 MG	12	Tablets	30	DAYS			
67406025100340	Relpax	Eletriptan	40 MG	12	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
		Hydrobromide Tab 40 MG (Base Equivalent)								
67406070002020	Tosymra	Sumatriptan Nasal Spray 10 MG/ACT	10 MG/ACT	18	Doses	30	DAYS			
67992002600320	Treximet	Sumatriptan-Naproxen Sodium Tab 85-500 MG	85-500 MG	18	Tablets	30	DAYS			
6740607010D505	Zembrace symtouch	Sumatriptan Succinate Solution Auto-injector 3 MG/0.5ML	3 MG/0.5 ML	24	Pens	30	DAYS			
67406080002010	Zomig	Zolmitriptan Nasal Spray 2.5 MG/Spray Unit	2.5 MG	2	Boxes	30	DAYS			
67406080002020	Zomig	Zolmitriptan Nasal Spray 5 MG/Spray Unit	5 MG	2	Boxes	30	DAYS			
67406080000320	Zomig	Zolmitriptan Tab 2.5 MG	2.5 MG	12	Tablets	30	DAYS			
67406080000330	Zomig	Zolmitriptan Tab 5 MG	5 MG	12	Tablets	30	DAYS			

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

TARGET AGENT(S)	PREREQUISITE AGENT(S)
almotriptan+	
Amerge (naratriptan)*	
Frova (frovatriptan)^	
IMITREX (sumatriptan)*	
Maxalt, Maxalt MLT (rizatriptan)*	eletriptan
ONZETRA Xsail (sumatriptan)	naratriptan
RELPAX (eletriptan)*	rizatriptan
Sumatriptan	sumatriptan
Tosymra (sumatriptan)	zolmitriptan tablets
Treximet (sumatriptan/naproxen sodium)^	zolmitriptan ODT tablets
Zembrace SYMTOUCH (sumatriptan)	
Zolmitriptan	
Zomig (zolmitriptan) nasal spray^	
Zomig (zolmitriptan) tablets*	

+ - available only as a generic, included as a target in step and quantity limit program
* - available as a generic, included as a target in quantity limit program
^ - available as a generic, included as a target in step and quantity limit program

Module	Clinical Criteria for Approval
	Target Agent(s) will be approved when ONE of the following is met: 1. The patient's medication history includes prerequisite agent use, intolerance, or hypersensitivity **OR** 2. 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** 3. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 4. The prescriber states the patient is currently being treated with the requested agent within the past 90 days AND is at risk if therapy is changed **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 patient has an FDA labeled contraindication to ALL prerequisite agents **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 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. ALL of the following: A. The patient has a diagnosis of migraine headache **AND** B. ONE of the following: 1. The patient is currently using migraine prophylactic medication (i.e., anticonvulsants [i.e., divalproex, valproate, topiramate], beta blockers [i.e., atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [i.e., amitriptyline, venlafaxine], candesartan, prophylactic use CGRP [i.e., Aimovig, AJOVY, Emgality, Nurtec, QULIPTA, Vyepti], onabotulinum toxin A (Botox]) **OR** 2. The patient has an intolerance or hypersensitivity to an anticonvulsant, a beta blocker, an antidepressant, candesartan, prophylactic use CGRP, or onabotulinum toxin A listed above **OR** 3. The patient has an FDA labeled contraindication to ALL anticonvulsants, beta blockers, antidepressants, candesartan, prophylactic use CGRP, or onabotulinum toxin A listed above **AND** C. Medication overuse headache has been ruled out **AND** D. The patient will NOT be using the requested agent in combination with another acute migraine therapy (e.g., triptan, 5HT-1F [REYVOW], ergotamine, acute use CGRP [e.g., Nurtec, UBRELVY, Zavzpret]) **AND** E. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **OR** 2. BOTH of the following: A. The patient has a diagnosis of cluster headache **AND**

Module	Clinical Criteria for Approval
	B. The requested agent is an injection or nasal spray **Length of Approval:** up to 12 months [For a diagnosis of migraine, the quantity requested up to the FDA labeled maximum dose allowed per 24 hours will be approved.]

• 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-	3.75-23	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
		Topiramate Cap ER 24HR 3.75-23 MG	MG							
61209902307030	Qsymia	Phentermine HCl-Topiramate Cap ER 24HR 7.5-46 MG	7.5-46 MG	30	Capsules	30	DAYS			
61253560000120	Xenical	Orlistat Cap 120 MG	120 MG	90	Capsules	30	DAYS			

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 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**

Module	Clinical Criteria for Approval
	B. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. 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** 4. ONE of the following: A. The requested agent is diethylpropion, phendimetrazine or phentermine **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 (or 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) **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. 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.

Module	Clinical Criteria for Approval
	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 [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. 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 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** C. For Xenical (or 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) **AND** 3. 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** 4. 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** 5. The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **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**

Module	Clinical Criteria for Approval
	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. There is support for therapy with a higher dose for the requested indication **Length of Approval**: • Initial Approval: o Contrave: up to 4 months o For all other agents: up to 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): up to 12 months o Qsymia. less than 5% weight loss from baseline (adults); less than 5% reduction in BMI from baseline (pediatrics): up to 3 months o All other agents: up to 12 months

• Program Summary: Xolair (omalizumab)

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
	446030600021	Xolair	omalizumab for inj	150 MG	M; N; O; Y				
	4460306000D5	Xolair	omalizumab subcutaneous soln auto-injector	150 MG/ML; 300 MG/2ML; 75 MG/0.5ML	M; N; O; Y				
	4460306000E5	Xolair	omalizumab subcutaneous soln prefilled syringe	150 MG/ML; 300 MG/2ML; 75 MG/0.5ML	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 requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy**

Module	Clinical Criteria for Approval
	No Target Agents are eligible for continuation of therapy 1. 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. ONE of the following: A. The patient has a diagnosis of moderate to severe persistent asthma AND ALL of the following: 1. ONE of the following: A. The patient is 6 to less than 12 years of age AND BOTH of the following: 1. The pretreatment IgE level is 30 IU/mL to 1300 IU/mL **AND** 2. The patient's weight is 20 kg to 150 kg **OR** B. The patient is 12 years of age or over AND BOTH of the following: 1. The pretreatment IgE level is 30 IU/mL to 700 IU/mL **AND** 2. The patient's weight is 30 kg to 150 kg **AND** 2. Allergic asthma has been confirmed by a positive skin test or in vitro reactivity test to a perennial aeroallergen **AND** 3. 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** B. The patient has a diagnosis of chronic spontaneous urticaria (CSU) (otherwise known as chronic idiopathic urticaria [CIU]) AND ALL of the following: 1. The patient has had over 6 weeks of hives and itching **AND** 2. If the patient is currently being treated with medications known to cause or worsen urticaria, then ONE of the following: A. The prescriber has reduced the dose or discontinued any medications known to cause or worsen urticaria (e.g., NSAIDs) **OR** B. A reduced dose or discontinuation of any medications known to cause or worsen urticaria is not appropriate **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to the FDA labeled maximum dose of a second-generation H-1 antihistamine (e.g., cetirizine, levocetirizine, fexofenadine, loratadine, desloratadine) **AND** ONE of the following: 1. The patient has tried and had an inadequate response to a dose titrated up to 4 times the FDA

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	labeled maximum dose of a second-generation H-1 antihistamine **OR** 2. The patient cannot be treated with a dose titrated up to 4 times the FDA labeled maximum dose of a second-generation H-1 antihistamine **OR** B. The patient has an intolerance or hypersensitivity to second-generation H-1 antihistamine therapy **OR** C. The patient has an FDA labeled contraindication to ALL second-generation H-1 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 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 second-generation H-1 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 **OR** C. 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. 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. 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** D. The patient has another FDA labeled indication for the requested agent AND the requested dose is within FDA labeled dosing for the requested indication **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. There is support for using the requested agent for the patient's age for the requested indication **OR**

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	C. The patient has another indication that is supported in compendia for the requested agent **AND** 2. If the patient has a diagnosis of moderate to severe persistent 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 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 **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 inhaled 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 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 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 long-acting beta-2 agonists (LABA) AND long-acting muscarinic antagonists (LAMA) 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 continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **AND**

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	D. The requested dose is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 375 mg every 2 weeks **AND** 3. If the patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP), ALL 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** C. The requested dose is within FDA labeled dosing for the requested indication AND does NOT exceed 600 mg every 2 weeks **AND** 4. If the patient has a diagnosis of chronic spontaneous urticaria (CSU) (otherwise known as chronic idiopathic urticaria [CIU]), the requested dose is within FDA labeled dosing AND does NOT exceed 300 mg every 4 weeks **AND** 5. If the patient has another FDA labeled indication for the requested agent, the requested dose is within FDA labeled dosing for the requested indication **AND** 6. If the patient has another indication that is supported in compendia for the requested agent, the requested dose is supported in compendia for the requested indication **AND** 7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, otolaryngologist, pulmonologist) or the prescriber 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. There is support for the use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) **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:** 6 months for asthma, chronic idiopathic urticaria, and nasal polyps 12 months for all other indications **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 [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. ONE of the following: A. The patient has a diagnosis of moderate to severe persistent asthma AND ALL 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. Increase in percent predicted Forced Expiratory Volume (FEV_1) **OR** B. Decrease in the dose of inhaled corticosteroid required to control the patient's asthma **OR** C. Decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma **OR** D. Decrease in the number of hospitalizations, need for mechanical ventilation, or

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	visits to the emergency room or urgent care due to exacerbations of asthma **AND** 2. The patient is currently treated and is compliant with standard therapy [i.e., inhaled corticosteroids (ICS), ICS/long-acting beta-2 agonist (ICS/LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), theophylline] **AND** 3. The requested dose is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 375 mg every 2 weeks **OR** B. The patient has a diagnosis of chronic spontaneous urticaria (CSU) (otherwise known as chronic idiopathic urticaria [CIU]) AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The requested dose is within FDA labeled dosing for the requested indication AND does NOT exceed 300 mg every 4 weeks **OR** C. The patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND ALL 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 **AND** 3. The requested dose is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 600 mg every 2 weeks **OR** D. The patient has another FDA labeled indication for the requested agent AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The requested dose is within FDA labeled dosing for the requested indication **OR** E. The patient has another indication that is supported in compendia for the requested agent AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The requested dose is supported in compendia for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, otolaryngologist, 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. There is support for the use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) **AND** 5. 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

CONTRAINDICATION AGENTS

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

Contraindicated as Concomitant Therapy
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)

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