COMMERCIAL PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: January 1, 2025 Notification Posted: November 18, 2024

BlueCross BlueShield Minnesota

Contents

NEW DRUG TARGETS

This section reflects new drug targets added to existing policies which are not reflected elsewhere in this document.

Program	*Target*
Attention Deficit [Hyperactivity] Disorder (ADHD/ADD) Agents QL	Onyda XR (clonidine hydrochloride) suspension 0.1 mg/mL

Cholestasis Pruritus PA	Livmarli (maralixibat) oral solution 19 mg/mL
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors and Combinations STQL	Zituvimet (sitagliptin-metformin) tablet Zituvimet XR (sitagliptin-metformin, extended release 24hr) tablet
Insulin Pumps QL	Omnipod 5 G6 Intro Kit
Interleukin-13 (IL-13) Antagonist PAQL	Ebglyss (lebrikizumab-lbkz) subcutaneous solution auto-injection 250 mg/2 mL
Opioids Immediate Release (IR) New To Therapy QL	Oxycodone tablet 10 mg (abuse deterrent tablet)
Otezla (apremilast) PAQL	Otezla (apremilast) tablet 20 mg, starter therapy pack 4 x 10 mg & 51 x 20 mg
Oxybate PAQL	Lumryz starter pack (sodium oxybate pack for extended-release suspension 4.5 & 6 & 7.5 gm)
Primary Biliary Cholangitis PAQL	Livdelzi (seladelpar) capsule 10 mg
Saxenda Wegovy Zepbound Coverage Exception & Formulary Exception CEFE	Zepbound (tirzepatide) injection vial 2.5 mg/0.5 mL Zepbound (tirzepatide) injection vial 5 mg/0.5 mL
Self-Administered Oncology Agents PAQL	Lazcluze (lazertinib) tablet 80 mg, 240 mg Voranigo (vorasidenip) tablet 10 mg, 40 mg dasatinib tablet 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, 140 mg TruQuap Pak (capivasertib) tablet 160 mg, 200 mg
Weight Management PAQL	Zepbound (tirzepatide) injection vial 2.5 mg/0.5 mL Zepbound (tirzepatide) injection vial 5 mg/0.5 mL

NEW POLICIES DEVELOPED

• Program Summary: Alternative Dosage Form

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
66100030005210		Indomethacin Suppos	100 MG	60	Suppositories	30	DAYS				
49300010001820	Carafate	Sucralfate Susp 1 GM/10ML	1 GM/10ML	1200	mLs	30	DAYS				
37500020001820	Carospir	Spironolactone Susp 25 MG/5ML	25 MG/5ML	450	mLs	30	DAYS				
40992002606830	Entresto	sacubitril-valsartan sprinkle cap	15-16 MG	240	Capsules	30	DAYS				
40992002606820	Entresto	sacubitril-valsartan sprinkle cap	6-6 MG	240	Capsules	30	DAYS				
36100020102020	Epaned	Enalapril Maleate Oral Soln 1 MG/ML	1 MG/ML	1200	mLs	30	DAYS				
66100030005205	Indocin	Indomethacin Suppos 50 MG	50 MG	120	Suppositories	30	DAYS				
21300050002075	Jylamvo	methotrexate oral soln	2 MG/ML	180	mLs	28	DAYS				
34000003081820	Katerzia	Amlodipine Benzoate Oral Susp 1 MG/ML (Base Equivalent)	1 MG/ML	300	mLs	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
34000003102020	Norliqva	Amlodipine Besylate Oral Soln	1 MG/ML	30	mLs	30	DAYS				
36100030002020	Qbrelis	Lisinopril Oral Soln 1 MG/ML	1 MG/ML	1200	mLs	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Target Agent(s) will be approved when BOTH of the following are met: 1. ONE of the following: A. The patient is 12 years of age or younger **OR** B. There is support for why the patient is unable to use a solid dosage form (e.g., difficulty swallowing tablets or capsules) **OR** C. The patient has tried and had an inadequate response to the solid dosage form **OR** D. The patient has an intolerance or hypersensitivity to the solid dosage form that is not expected to occur with the brand agent **OR** E. The patient has an FDA labeled contraindication to the solid dosage form that is not expected to occur with the brand agent **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 solid dosage form cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 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:** up to 12 months

• Program Summary: Resmetirom

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
52601060000340	Rezdiffra	resmetirom	100 MG	30	Tablets	30	DAYS				
52601060000320	Rezdiffra	resmetirom	60 MG	30	Tablets	30	DAYS				
52601060000330	Rezdiffra	resmetirom	80 MG	30	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 the following are met: 1. The patient has a diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) or metabolic dysfunction associated steatohepatitis (MASH) (medical records required) **AND** 2. The patient has stage F2 or F3 fibrosis as confirmed by BOTH of the following (prior to therapy with the requested agent): A. A FIB-4 score consistent with stage F2 or F3 fibrosis adjusted for age **AND** B. The patient has ONE of the following: 1. A liver biopsy within the past 2 years **OR** 2. Transient elastography **OR** 3. Enhanced liver fibrosis (ELF) score **OR** 4. Magnetic resonance elastography (MRE) **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 has ONE of the following: A. A BMI less than or equal to 25 kg/m^2 **OR** B. A BMI less than or equal to 23 kg/m^2 if the patient is of South Asian, Southeast Asian, or East Asian descent **OR** C. ONE of the following: 1. The patient has tried and had an inadequate response after 72 weeks of therapy with Wegovy **OR** 2. The patient has tried and had an inadequate response after 72 weeks of therapy with another subcutaneous GLP-1 for the treatment of the requested indication **OR** 3. The patient has an intolerance or hypersensitivity to therapy with Wegovy **OR**

4. The patient has an FDA labeled contraindication to Wegovy **OR**
5. 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**
6. The prescriber has provided documentation that Wegovy 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. ONE of the following:
    A. If the patient's sex is female then the patient's alcohol consumption is less than 20 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits) **OR**
    B. If the patient's sex is male then the patient's alcohol consumption is less than 30 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits) **AND**
6. The patient is being monitored and/or treated for any comorbid conditions (e.g., cardiovascular disease, diabetes, dyslipidemia, hypertension) **AND**
7. BOTH of the following:
    A. The patient is currently on a weight management regimen of a low-calorie diet, increased physical activity, and behavioral modifications **AND**
    B. The patient will continue the weight management regimen in combination with the requested agent **AND**
8. The patient does NOT have ANY of the following:
    A. Decompensated cirrhosis **AND**
    B. Moderate to severe hepatic impairment (Child-Pugh Class B or C) **AND**
    C. Any other liver disease (e.g., Wilson's disease, hepatocellular carcinoma, hepatitis) **AND**
9. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hepatologist, gastroenterologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
10. 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. ONE of the following:
    A. If the patient's sex is female then the patient's alcohol consumption is less than 20 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits) **OR**

	B. If the patient's sex is male then the patient's alcohol consumption is less than 30 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits) **AND** 3. BOTH of the following: A. The patient is currently on a weight management regimen of a low-calorie diet, increased physical activity, and behavioral modifications **AND** B. The patient will continue the weight management regimen in combination with the requested agent **AND** 4. The patient does NOT have ANY of the following: A. Decompensated cirrhosis **AND** B. Moderate to severe hepatic impairment (Child-Pugh Class B or C) **AND** C. Any other liver disease (e.g., Wilson's disease, hepatocellular carcinoma, hepatitis) **AND** 5. The patient has had clinical benefit with the requested agent **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hepatologist, gastroenterologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
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 **Length of Approval:** up to 12 months

• Program Summary: Xolremdi

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
82502046000120	Xolremdi	mavorixafor cap	100 MG	120	Capsules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Initial Evaluation

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

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

Agents Eligible for Continuation of Therapy
None

      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 WHIM (warts, hypogammaglobulinemia, infections and myelokathexis) syndrome AND ALL of the following:
            1. Genetic analysis confirms mutation in the CXC chemokine receptor 4 (CXCR4) gene **AND**
            2. Confirmed absolute neutrophil count (ANC) OR total white blood cell (WBC) count is less than or equal to 400 cells/microliter (prior to therapy with the requested agent AND during no clinical evidence of infection) **AND**
            3. The prescriber has assessed baseline status (prior to therapy with the requested agent) of the patient's symptoms (e.g., absolute neutrophil counts [ANC], absolute lymphocyte counts [ALC], number of infections) **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 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 patient will NOT be using the requested agent in combination with any other CXCR4 antagonists (e.g., plerixafor) for the requested indication **AND**
3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., geneticist, immunologist) 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

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 any other CXCR4 antagonists (e.g., plerixafor) for the requested indication **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., geneticist, immunologist) 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
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:** up to 12 months

POLICIES REVISED

• Program Summary: Anti-Obesity Non-GLP-1 Agents Formulary Exception with Quantity Limit

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

POLICY AGENT SUMMARY COVERAGE EXCEPTION

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
	61200020107510		Diethylpropion HCl Tab ER 24HR 75 MG	75 MG	M; N; O; Y				
	612000501070		phendimetrazine tartrate cap er	105 MG	M; N; O; Y				
	612000701001	Adipex-p	phentermine hcl cap	15 MG; 30 MG; 37.5 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
	612000701003	Adipex-p; Lomaira	phentermine hcl tab	37.5 MG; 8 MG	M; N; O				
	612599025074	Contrave	naltrexone hcl-bupropion hcl tab er	8-90 MG	M; N; O; Y				
	612099023070	Qsymia	phentermine hcl-topiramate cap er	11.25-69 MG; 15-92 MG; 3.75-23 MG; 7.5-46 MG	M; N; O; Y				
	61253560000120	Xenical	Orlistat Cap 120 MG	120 MG	M; N; O; Y				

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
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				
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				
612099023070	Qsymia	phentermine hcl-topiramate cap er	11.25-69 MG; 15-92 MG; 3.75-23 MG; 7.5-46 MG	30	Capsules	30	DAYS				
61253560000120	Xenical	Orlistat Cap 120 MG	120 MG	90	Capsules	30	DAYS				

COVERAGE EXCEPTION 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 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 an adult (18 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 has a weight loss of less than 1 pound 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 pediatric (12 to 17 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 weight-related comorbidity/risk factor/complication (e.g., hypertension, dyslipidemia, type 2 diabetes, or obstructive sleep apnea) **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 has a weight loss of less than 1 pound 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**

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 NOT tried a targeted weight loss agent (e.g., benzphetamine, Contrave, diethylpropion, phendimetrazine, phentermine, Qsymia, Xenical/Orlistat) in the past 12 months **OR**
B. BOTH of the following:
1. The patient has tried a targeted weight loss agent for a previous course of therapy in the past 12 months **AND**
2. The prescriber anticipates success with repeating therapy with any targeted weight loss agent **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:
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 a pediatric patient (12 to less than 18 years of age), the patient has experienced a reduction of at least 5% of baseline BMI (prior to initiation of the requested agent) **OR**

2. For an adult, 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**

3. There is support for 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**

6. The patient will NOT be using the requested agent in combination with another weight loss agent (e.g., Contrave, phentermine, Qsymia, Xenical, Saxenda, Wegovy, Zepbound) 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

Length of Approval:
Contrave: 4 months
All other agents: 3 months

NOTE: if Quantity Limit applies, please refer to Quantity Limit Criteria

Renewal Evaluation

(Patient continuing a current weight loss course of therapy)

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

1. The 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. The requested agent is Qsymia AND ONE of the following: 1. For a pediatric patient (12 to 17 years of age), the patient has achieved and maintained a reduction of greater than or equal to 5% of baseline BMI (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. The requested agent is Xenical or orlistat AND 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** 4. If the patient is pediatric, then 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 weight loss agent (e.g., Contrave, phentermine, Qsymia, Xenical, Saxenda, Wegovy, Zepbound) 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 **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
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**: up to 12 months

• Program Summary: Atypical Antipsychotics

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

POLICY AGENT SUMMARY STEP THERAPY

Final Module	Target Agent GPI	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status	Effective Date	Targeted NDCs When Exclusions Exist
	592500150020		aripiprazole oral solution	1 MG/ML	M; N; O	Y				
	592500150072		aripiprazole orally disintegrating tab	10 MG; 15 MG	M; N; O	Y				
	590700700072		risperidone orally disintegrating tab	0.25 MG; 0.5 MG; 1 MG; 2 MG; 3 MG; 4 MG	M; N; O	N; Y				
	592500150003	Abilify	aripiprazole tab	10 MG; 15 MG; 2 MG; 20 MG; 30 MG; 5 MG	M; N; O	O; Y				
	5925001503	Abilify mycite maintenanc; Abilify mycite starter ki	aripiprazole tab	10 MG; 15 MG; 2 MG; 20 MG; 30 MG; 5 MG	M; N; O	N				
	59400022	Caplyta	lumateperone tosylate cap	10.5 MG; 21 MG; 42 MG	M; N; O	N				
	59152020	Clozaril; Versacloz	clozapine orally disintegrating tab; clozapine susp; clozapine tab	100 MG; 12.5 MG; 150 MG; 200 MG; 25 MG; 50 MG; 50 MG/ML	M; N; O	N; O; Y				

Final Module	Target Agent GPI	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status	Effective Date	Targeted NDCs When Exclusions Exist
	5919990280	Cobenfy; Cobenfy starter pack	xanomeline tartrate-trospium chloride cap; xanomeline-trospium chloride cap pack	100-20 MG; 125-30 MG; 50-20 & 100-20 MG; 50-20 MG	M; N; O	N				
	59070035	Fanapt; Fanapt titration pack	iloperidone tab	1 & 2 & 4 & 6 MG; 1 MG; 10 MG; 12 MG; 2 MG; 4 MG; 6 MG; 8 MG	M; N; O	N				
	5940008510	Geodon	ziprasidone hcl cap	20 MG; 40 MG; 60 MG; 80 MG	M; N; O	O; Y				
	590700500075	Invega	paliperidone tab er	1.5 MG; 3 MG; 6 MG; 9 MG	M; N; O	O; Y				
	59400023	Latuda	lurasidone hcl tab	120 MG; 20 MG; 40 MG; 60 MG; 80 MG	M; N; O	O; Y				
	6299480250	Lybalvi	olanzapine-samidorphan l-malate tab	10-10 MG; 15-10 MG; 20-10 MG; 5-10 MG	M; N; O	N				
	590700700020	Risperdal	risperidone soln	1 MG/ML	M; N; O	O; Y				
	590700700003	Risperdal	risperidone tab	0.25 MG; 0.5 MG; 1 MG; 2 MG; 3 MG; 4 MG	M; N; O	O; Y				
	59155015	Saphris; Secuado	asenapine maleate sl tab; asenapine td patch	10 MG; 2.5 MG; 3.8 MG/24HR; 5MG; 5.7 MG/24HR; 7.6 MG/24HR	M; N; O	N; O; Y				
	591530701003	Seroquel	quetiapine fumarate tab	100 MG; 150 MG; 200 MG; 25 MG; 300 MG; 400 MG; 50 MG	M; N; O	N; O; Y				
	591530701075	Seroquel xr	quetiapine fumarate tab er	150 MG; 200 MG; 300 MG; 400 MG; 50 MG	M; N; O	O; Y				

Final Module	Target Agent GPI	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status	Effective Date	Targeted NDCs When Exclusions Exist
	591570600003	Zyprexa	olanzapine tab	10 MG; 15 MG; 2.5 MG; 20 MG; 5 MG; 7.5 MG	M; N; O	O; Y				
	591570600072	Zyprexa zydis	olanzapine orally disintegrating tab	10 MG; 15 MG; 20 MG; 5 MG	M; N; O	O; Y				

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
59250015002020		Aripiprazole Oral Solution 1 MG/ML	1 MG/ML	900	mLs	30	DAYS				
59250015007220		Aripiprazole Orally Disintegrating Tab 10 MG	10 MG	60	Tablets	30	DAYS				
59250015007230		Aripiprazole Orally Disintegrating Tab 15 MG	15 MG	60	Tablets	30	DAYS				
59152020007230		Clozapine Orally Disintegrating Tab 100 MG	100 MG	90	Tablets	30	DAYS				
59152020007210		Clozapine Orally Disintegrating Tab 12.5 MG	12.5 MG	90	Tablets	30	DAYS				
59152020007240		Clozapine Orally Disintegrating Tab 150 MG	150 MG	180	Tablets	30	DAYS				
59152020007250		Clozapine Orally Disintegrating Tab 200 MG	200 MG	120	Tablets	30	DAYS				
59152020007220		Clozapine Orally Disintegrating Tab 25 MG	25 MG	270	Tablets	30	DAYS				
59153070100325		Quetiapine Fumarate Tab	150 MG	30	Tablets	30	DAYS				
59070070007210		Risperidone Orally Disintegrating Tab 0.25 MG	0.25 MG	60	Tablets	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
59070070007220		Risperidone Orally Disintegrating Tab 0.5 MG	0.5 MG	60	Tablets	30	DAYS				
59070070007230		Risperidone Orally Disintegrating Tab 1 MG	1 MG	60	Tablets	30	DAYS				
59070070007240		Risperidone Orally Disintegrating Tab 2 MG	2 MG	60	Tablets	30	DAYS				
59070070007250		Risperidone Orally Disintegrating Tab 3 MG	3 MG	60	Tablets	30	DAYS				
59070070007260		Risperidone Orally Disintegrating Tab 4 MG	4 MG	120	Tablets	30	DAYS				
59070070000303		Risperidone Tab 0.25 MG	0.25 MG	60	Tablets	30	DAYS				
59250015000320	Abilify	Aripiprazole Tab 10 MG	10 MG	30	Tablets	30	DAYS				
59250015000330	Abilify	Aripiprazole Tab 15 MG	15 MG	30	Tablets	30	DAYS				
59250015000305	Abilify	Aripiprazole Tab 2 MG	2 MG	30	Tablets	30	DAYS				
59250015000340	Abilify	Aripiprazole Tab 20 MG	20 MG	30	Tablets	30	DAYS				
59250015000350	Abilify	Aripiprazole Tab 30 MG	30 MG	30	Tablets	30	DAYS				
59250015000310	Abilify	Aripiprazole Tab 5 MG	5 MG	30	Tablets	30	DAYS				
5925001503B751	Abilify mycite mainten anc	Aripiprazole Tab	30 MG	30	Tablets	30	DAYS				
5925001503B721	Abilify mycite mainten anc	Aripiprazole Tab	10 MG	30	Tablets	30	DAYS				
5925001503B741	Abilify mycite mainten anc	Aripiprazole Tab	20 MG	30	Tablets	30	DAYS				
5925001503B711	Abilify mycite mainten anc	Aripiprazole Tab	5 MG	30	Tablets	30	DAYS				
5925001503B731	Abilify mycite mainten anc	Aripiprazole Tab	15 MG	30	Tablets	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
5925001503B706	Abilify mycite mainten anc	Aripiprazole Tab	2 MG	30	Tablets	30	DAYS				
5925001503B750	Abilify mycite starter ki	Aripiprazole Tab	30 MG	30	Tablets	30	DAYS				
5925001503B710	Abilify mycite starter ki	Aripiprazole Tab	5 MG	30	Tablets	30	DAYS				
5925001503B705	Abilify mycite starter ki	Aripiprazole Tab	2 MG	30	Tablets	30	DAYS				
5925001503B730	Abilify mycite starter ki	Aripiprazole Tab	15 MG	30	Tablets	30	DAYS				
5925001503B720	Abilify mycite starter ki	Aripiprazole Tab	10 MG	30	Tablets	30	DAYS				
5925001503B740	Abilify mycite starter ki	Aripiprazole Tab	20 MG	30	Tablets	30	DAYS				
59400022400115	Caplyta	Lumateperone Tosylate Cap	21 MG	30	Capsules	30	DAYS				
59400022400110	Caplyta	Lumateperone Tosylate Cap	10.5 MG	30	Capsules	30	DAYS				
59400022400120	Caplyta	Lumateperone Tosylate Cap 42 MG	42 MG	30	Capsules	30	DAYS				
59152020000330	Clozaril	Clozapine Tab 100 MG	100 MG	270	Tablets	30	DAYS				
59152020000340	Clozaril	Clozapine Tab 200 MG	200 MG	120	Tablets	30	DAYS				
59152020000320	Clozaril	Clozapine Tab 25 MG	25 MG	90	Tablets	30	DAYS				
59152020000325	Clozaril	Clozapine Tab 50 MG	50 MG	90	Tablets	30	DAYS				
59199902800135	Cobenfy	xanomeline tartrate-trospium chloride cap	125-30 MG	60	Capsules	30	DAYS				
59199902800130	Cobenfy	xanomeline tartrate-trospium chloride cap	100-20 MG	60	Capsules	30	DAYS				
59199902800120	Cobenfy	xanomeline tartrate-trospium chloride cap	50-20 MG	60	Capsules	30	DAYS				
5919990280B220	Cobenfy starter pack	xanomeline-trospium chloride cap pack	50-20 & 100-20 MG	56	Capsules	180	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
59070035000310	Fanapt	Iloperidone Tab 1 MG	1 MG	60	Tablets	30	DAYS				
59070035000385	Fanapt	Iloperidone Tab 10 MG	10 MG	60	Tablets	30	DAYS				
59070035000390	Fanapt	Iloperidone Tab 12 MG	12 MG	60	Tablets	30	DAYS				
59070035000320	Fanapt	Iloperidone Tab 2 MG	2 MG	60	Tablets	30	DAYS				
59070035000340	Fanapt	Iloperidone Tab 4 MG	4 MG	60	Tablets	30	DAYS				
59070035000360	Fanapt	Iloperidone Tab 6 MG	6 MG	60	Tablets	30	DAYS				
59070035000380	Fanapt	Iloperidone Tab 8 MG	8 MG	60	Tablets	30	DAYS				
59070035006320	Fanapt titration pack	Iloperidone Tab 1 MG & 2 MG & 4 MG & 6 MG Titration Pak	1 & 2 & 4 & 6 MG	1	Pack	180	DAYS				
59400085100120	Geodon	Ziprasidone HCl Cap 20 MG	20 MG	60	Capsules	30	DAYS				
59400085100130	Geodon	Ziprasidone HCl Cap 40 MG	40 MG	60	Capsules	30	DAYS				
59400085100140	Geodon	Ziprasidone HCl Cap 60 MG	60 MG	60	Capsules	30	DAYS				
59400085100150	Geodon	Ziprasidone HCl Cap 80 MG	80 MG	60	Capsules	30	DAYS				
59070050007505	Invega	Paliperidone Tab ER 24HR 1.5 MG	1.5 MG	30	Tablets	30	DAYS				
59070050007510	Invega	Paliperidone Tab ER 24HR 3 MG	3 MG	30	Tablets	30	DAYS				
59070050007520	Invega	Paliperidone Tab ER 24HR 6 MG	6 MG	60	Tablets	30	DAYS				
59070050007530	Invega	Paliperidone Tab ER 24HR 9 MG	9 MG	30	Tablets	30	DAYS				
59400023100350	Latuda	Lurasidone HCl Tab 120 MG	120 MG	30	Tablets	30	DAYS				
59400023100310	Latuda	Lurasidone HCl Tab 20 MG	20 MG	30	Tablets	30	DAYS				
59400023100320	Latuda	Lurasidone HCl Tab 40 MG	40 MG	30	Tablets	30	DAYS				
59400023100330	Latuda	Lurasidone HCl Tab 60 MG	60 MG	30	Tablets	30	DAYS				
59400023100340	Latuda	Lurasidone HCl Tab 80 MG	80 MG	60	Tablets	30	DAYS				
62994802500340	Lybalvi	Olanzapine-Samidorphan L-Malate Tab	20-10 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	Age Limit	Effective Date	Term Date
62994802500320	Lybalvi	Olanzapine-Samidorphan L-Malate Tab	10-10 MG	30	Tablets	30	DAYS				
62994802500330	Lybalvi	Olanzapine-Samidorphan L-Malate Tab	15-10 MG	30	Tablets	30	DAYS				
62994802500310	Lybalvi	Olanzapine-Samidorphan L-Malate Tab	5-10 MG	30	Tablets	30	DAYS				
59250020000310	Rexulti	Brexpiprazole Tab 0.25 MG	0.25 MG	30	Tablets	30	DAYS				
59250020000320	Rexulti	Brexpiprazole Tab 0.5 MG	0.5 MG	30	Tablets	30	DAYS				
59250020000330	Rexulti	Brexpiprazole Tab 1 MG	1 MG	30	Tablets	30	DAYS				
59250020000340	Rexulti	Brexpiprazole Tab 2 MG	2 MG	30	Tablets	30	DAYS				
59250020000350	Rexulti	Brexpiprazole Tab 3 MG	3 MG	30	Tablets	30	DAYS				
59250020000360	Rexulti	Brexpiprazole Tab 4 MG	4 MG	30	Tablets	30	DAYS				
59070070002010	Risperdal	Risperidone Soln 1 MG/ML	1 MG/ML	480	mLs	30	DAYS				
59070070000306	Risperdal	Risperidone Tab 0.5 MG	0.5 MG	60	Tablets	30	DAYS				
59070070000310	Risperdal	Risperidone Tab 1 MG	1 MG	60	Tablets	30	DAYS				
59070070000320	Risperdal	Risperidone Tab 2 MG	2 MG	60	Tablets	30	DAYS				
59070070000330	Risperdal	Risperidone Tab 3 MG	3 MG	60	Tablets	30	DAYS				
59070070000340	Risperdal	Risperidone Tab 4 MG	4 MG	120	Tablets	30	DAYS				
59155015100730	Saphris	Asenapine Maleate SL Tab 10 MG (Base Equiv)	10 MG	60	Tablets	30	DAYS				
59155015100710	Saphris	Asenapine Maleate SL Tab 2.5 MG (Base Equiv)	2.5 MG	60	Tablets	30	DAYS				
59155015100720	Saphris	Asenapine Maleate SL Tab 5 MG (Base Equiv)	5 MG	60	Tablets	30	DAYS				
59155015008520	Secuado	Asenapine TD Patch 24 HR 3.8 MG/24HR	3.8 MG/24HR	30	Patches	30	DAYS				
59155015008530	Secuado	Asenapine TD Patch 24 HR 5.7 MG/24HR	5.7 MG/24HR	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	Age Limit	Effective Date	Term Date
59155015008540	Secuado	Asenapine TD Patch 24 HR 7.6 MG/24HR	7.6 MG/24HR	30	Patches	30	DAYS				
59153070100320	Seroquel	Quetiapine Fumarate Tab 100 MG	100 MG	90	Tablets	30	DAYS				
59153070100330	Seroquel	Quetiapine Fumarate Tab 200 MG	200 MG	90	Tablets	30	DAYS				
59153070100310	Seroquel	Quetiapine Fumarate Tab 25 MG	25 MG	90	Tablets	30	DAYS				
59153070100340	Seroquel	Quetiapine Fumarate Tab 300 MG	300 MG	60	Tablets	30	DAYS				
59153070100350	Seroquel	Quetiapine Fumarate Tab 400 MG	400 MG	60	Tablets	30	DAYS				
59153070100314	Seroquel	Quetiapine Fumarate Tab 50 MG	50 MG	90	Tablets	30	DAYS				
59153070107515	Seroquel xr	Quetiapine Fumarate Tab ER 24HR 150 MG	150 MG	30	Tablets	30	DAYS				
59153070107520	Seroquel xr	Quetiapine Fumarate Tab ER 24HR 200 MG	200 MG	30	Tablets	30	DAYS				
59153070107530	Seroquel xr	Quetiapine Fumarate Tab ER 24HR 300 MG	300 MG	60	Tablets	30	DAYS				
59153070107540	Seroquel xr	Quetiapine Fumarate Tab ER 24HR 400 MG	400 MG	60	Tablets	30	DAYS				
59153070107505	Seroquel xr	Quetiapine Fumarate Tab ER 24HR 50 MG	50 MG	60	Tablets	30	DAYS				
59152020001820	Versaclo z	Clozapine Susp 50 MG/ML	50 MG/ML	540	mLs	30	DAYS				
59400018100120	Vraylar	Cariprazine HCl Cap 1.5 MG (Base Equivalent)	1.5 MG	30	Capsules	30	DAYS				
59400018100130	Vraylar	Cariprazine HCl Cap 3 MG (Base Equivalent)	3 MG	30	Capsules	30	DAYS				
59400018100140	Vraylar	Cariprazine HCl Cap 4.5 MG	4.5 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	Age Limit	Effective Date	Term Date
		(Base Equivalent)									
59400018100150	Vraylar	Cariprazine HCl Cap 6 MG (Base Equivalent)	6 MG	30	Capsules	30	DAYS				
5940001810B220	Vraylar	Cariprazine HCl Cap Therapy Pack 1.5 MG (1) & 3 MG (6)	1.5 & 3 MG	7	Capsules	180	DAYS				
59157060000320	Zyprexa	Olanzapine Tab 10 MG	10 MG	30	Tablets	30	DAYS				
59157060000330	Zyprexa	Olanzapine Tab 15 MG	15 MG	30	Tablets	30	DAYS				
59157060000305	Zyprexa	Olanzapine Tab 2.5 MG	2.5 MG	30	Tablets	30	DAYS				
59157060000340	Zyprexa	Olanzapine Tab 20 MG	20 MG	30	Tablets	30	DAYS				
59157060000310	Zyprexa	Olanzapine Tab 5 MG	5 MG	30	Tablets	30	DAYS				
59157060000315	Zyprexa	Olanzapine Tab 7.5 MG	7.5 MG	30	Tablets	30	DAY				
59157060007220	Zyprexa zydis	Olanzapine Orally Disintegrating Tab 10 MG	10 MG	30	Tablets	30	DAYS				
59157060007230	Zyprexa zydis	Olanzapine Orally Disintegrating Tab 15 MG	15 MG	30	Tablets	30	DAYS				
59157060007240	Zyprexa zydis	Olanzapine Orally Disintegrating Tab 20 MG	20 MG	30	Tablets	30	DAYS				
59157060007210	Zyprexa zydis	Olanzapine Orally Disintegrating Tab 5 MG	5 MG	30	Tablets	30	DAYS				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Applicable Formularies	Target Agent(s)	Prerequisite Agents
FlexRx Open, FocusRx, GenRx Open, HIM, KeyRx	**Abilify** (aripiprazole)*	Any generic atypical antipsychotic Any generic antidepressant (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone) haloperidol or pimozide
FlexRx Open, FocusRx, GenRx Open, HIM, KeyRx	**Abilify Mycite** (aripiprazole) **Seroquel XR** (quetiapine)*	Any generic atypical antipsychotic

		Any generic antidepressant (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone)
FlexRx Open, FocusRx, GenRx Open, HIM, KeyRx	**Zyprexa** (olanzapine)* **Zyprexa Zydis** (olanzapine)*	Any generic atypical antipsychotic Generic fluoxetine
FlexRx Open, FocusRx, GenRx Open, HIM, KeyRx	**Clozapine ODT** **Clozaril** (clozapine)* **Cobenfy** (xanomeline/trospium) **Fanapt** (iloperidone) **Geodon** (ziprasidone)* **Invega** (paliperidone)* **Latuda** (lurasidone)* **Risperdal** (risperidone)* **Risperidone ODT^/risperidone ODT** **Saphris** (asenapine)* **Secuado** (asenapine) **Seroquel** (quetiapine)* **Versacloz** (clozapine)	Any generic atypical antipsychotic
FlexRx Open, GenRx Open, HIM, KeyRx	**Caplyta** (lumateperone) **Lybalvi** (olanzapine/samidorphan)	Any generic atypical antipsychotic

*generic available
^ branded generic product

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

1. The request is for Abilify (aripiprazole) AND ONE of the following:
   A. The patient has a medication history of use in the past 365 days, intolerance, or hypersensitivity to ONE generic antidepressant agent (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone), generic haloperidol, or pimozide **OR**
   B. The patient has an FDA labeled contraindication to ALL generic antidepressant agents (i.e., SSRI, SNRI, bupropion, mirtazapine, and vilazodone), haloperidol, and pimozide **OR**
2. The request is for Abilify Mycite, Rexulti, Seroquel XR, or Vraylar AND ONE of the following:
   A. The patient has a medication history of use in the past 365 days, intolerance, or hypersensitivity to ONE generic antidepressant agent (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**
3. The request is for Zyprexa or Zyprexa Zydis AND ONE of the following:
   A. The patient has a medication history of use in the past 365 days, intolerance, or hypersensitivity to ONE generic fluoxetine **OR**
   B. The patient has an FDA labeled contraindication to ALL generic fluoxetine **OR**
4. The patient has been treated with the requested agent within the past 180 days **OR**
5. 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**
6. The patient has a medication history of use in the past 365 days, intolerance, or hypersensitivity to ONE generic atypical antipsychotic **OR**
7. The patient has an FDA labeled contraindication to ALL generic atypical antipsychotics **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 patient has an intolerance or hypersensitivity to a prerequisite agent **OR** 10. The patient has an FDA labeled contraindication to ALL prerequisite agents **OR** 11. 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:** For dementia-related psychosis: 3 months for initial approval; 6 months for renewals For all other indications: 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 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: Benign Prostatic Hypertrophy (BPH)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
36202040100105		Terazosin HCl Cap 1 MG (Base Equivalent)	1 MG	30	Capsules	30	DAYS				
36202040100120		Terazosin HCl Cap 10 MG (Base Equivalent)	10 MG	60	Capsules	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
36202040100110		Terazosin HCl Cap 2 MG (Base Equivalent)	2 MG	30	Capsules	30	DAYS				
36202040100115		Terazosin HCl Cap 5 MG (Base Equivalent)	5 MG	30	Capsules	30	DAYS				
568510200001	Avodart	dutasteride cap	0.5 MG	30	Capsules	30	DAYS				
36202005100310	Cardura	Doxazosin Mesylate Tab 1 MG	1 MG	30	Tablets	30	DAYS				
36202005100320	Cardura	Doxazosin Mesylate Tab 2 MG	2 MG	30	Tablets	30	DAYS				
36202005100330	Cardura	Doxazosin Mesylate Tab 4 MG	4 MG	30	Tablets	30	DAYS				
36202005100340	Cardura	Doxazosin Mesylate Tab 8 MG	8 MG	60	Tablets	30	DAYS				
568520252075	Cardura xl	doxazosin mesylate tab er	4 MG; 8 MG	30	Tablets	30	DAYS				
40304080000302	Cialis	Tadalafil Tab 2.5 MG	2.5 MG	30	Tablets	30	DAYS				
40304080000305	Cialis	Tadalafil Tab 5 MG	5 MG	30	Tablets	30	DAYS				
56859902300120	Entadfi	Finasteride-Tadalafil Cap	5-5 MG	30	Capsules	30	DAYS				
568520701001	Flomax	tamsulosin hcl cap	0.4 MG	60	Capsules	30	DAYS				
568599022501	Jalyn	dutasteride-tamsulosin hcl cap	0.5-0.4 MG	30	Capsules	30	DAYS				
568510300003	Proscar	finasteride tab	5 MG	30	Tablets	30	DAYS				
568520600001	Rapaflo	silodosin cap	4 MG; 8 MG	30	Capsules	30	DAYS				
568520101075	Uroxatral	alfuzosin hcl tab er	10 MG	30	Tablets	30	DAYS				

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 agent is Cialis (tadalafil) AND the requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested agent is NOT for Cialis (tadalafil), then 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: 1. 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** 2. 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** 3. 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**: 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	Age Limit	Effective Date	Term Date
6627001540F820		adalimumab-ryvk prefilled syringe kit	40 MG/0.4ML	2	Syringes	28	DAYS				
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				
6627001510D520	Amjevita	adalimumab-atto soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS				
6627001510D517	Amjevita	adalimumab-atto soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				
6627001510D537	Amjevita	adalimumab-atto soln auto-injector	80 MG/0.8ML	2	Pens	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6627001510E517	Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001510E510	Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001510E520	Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001510E508	Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.2ML	2	Syringes	28	DAYS				
6627001510E505	Amjevita	adalimumab-atto soln prefilled syringe	10 MG/0.2ML	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	50474071079;			
5250502010F840	Cimzia starter kit	certolizumab pegol prefilled syringe kit	200 MG/ML	1	Kit	180	DAYS	50474071081;			
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	150 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	Age Limit	Effective Date	Term Date
		MG/ML (300 MG Dose)									
9025057500D520	Cosentyx sensoready pen	Secukinumab Subcutaneous Soln Auto-injector 150 MG/ML	150 MG/ML	1	Pen	28	DAYS				
9025057500D550	Cosentyx unoready	secukinumab subcutaneous soln auto-injector	300 MG/2ML	1	Pen	28	DAYS				
6627001505F520	Cyltezo	adalimumab-adbm auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS	00597037597; 00597054522; 82009014822			
6627001505F515	Cyltezo	adalimumab-adbm auto-injector kit	40 MG/0.4ML	2	Pens	28	DAYS	00597049550; 00597057550; 82009014422			
6627001505F820	Cyltezo	adalimumab-adbm prefilled syringe kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001505F810	Cyltezo	adalimumab-adbm prefilled syringe kit	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001505F805	Cyltezo	adalimumab-adbm prefilled syringe kit	10 MG/0.2ML	2	Syringes	28	DAYS				
6627001505F815	Cyltezo	adalimumab-adbm prefilled syringe kit	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001505F515	Cyltezo starter package for CD/UC/HS	adalimumab-adbm auto-injector kit	40 MG/0.4ML	1	Kit	180	DAYS	00597049560; 00597057560;			
6627001505F520	Cyltezo starter package for CD/UC/HS	adalimumab-adbm auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00597037516; 00597054566;			
6627001505F520	Cyltezo starter package for PS/Uveitis	adalimumab-adbm auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00597037523; 00597054544;			
6627001505F515	Cyltezo starter package for PS/Uveitis	adalimumab-adbm auto-injector kit	40 MG/0.4ML	1	Kit	180	DAYS	00597049540; 00597057540;			
66290030002015	Enbrel	Etanercept Subcutaneous Inj 25 mg/0.5ml	25 MG/0.5ML	8	Vials	28	DAYS				
6629003000E525	Enbrel	Etanercept Subcutaneous	25 MG/0.5ML	4	Syringes	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		Soln Prefilled Syringe 25 MG/0.5ML									
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				
5250308000D520	Entyvio	vedolizumab soln pen-injector 108 mg/0.68ml	108 MG/0.68ML	2	Pens	28	DAYS				
6627001520E520	Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001520E510	Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001520D520	Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS				
6627001520D510	Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				
6627001535F520	Hulio	adalimumab-fkjp auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS				
6627001535F820	Hulio	adalimumab-fkjp prefilled syringe kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001535F810	Hulio	adalimumab-fkjp prefilled syringe kit	20 MG/0.4ML	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				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
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				
6627001500F540	Humira pen	adalimumab auto-injector kit	80 MG/0.8ML	2	Pens	28	DAYS	00074012402; 83457012402			
6627001500F530	Humira pen	Adalimumab Pen-injector Kit 40 MG/0.4ML	40 MG/0.4ML	2	Pens	28	DAYS				
6627001500F540	Humira pen-cd/uc/hs start	adalimumab auto-injector kit	80 MG/0.8ML	1	Kit	180	DAYS	00074012403;			
6627001500F520	Humira pen-cd/uc/hs start	adalimumab auto-injector kit; adalimumab pen-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00074433906;			
6627001500F540	Humira pen-pediatric ucs	adalimumab auto-injector kit	80 MG/0.8ML	4	Pens	180	DAYS	00074012404;			
6627001500F520	Humira pen-ps/uv starter	adalimumab auto-injector kit; adalimumab pen-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00074433907;			
6627001500F550	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				
6627001504D520	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS				
6627001504D515	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6627001504D515	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				
6627001504E508	Hyrimoz	adalimumab-adaz soln prefilled syringe	10 MG/0.1 ML	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				
6627001504E513	Hyrimoz	adalimumab-adaz soln prefilled syringe	20 MG/0.2ML	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; 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	1	Kit	28	DAYS				
6627001502F540	Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	65219055438; 65219061289			
6627001502F540	Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	65219055428; 65219061269			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
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				
5250405040E520	Omvoh	mirikizumab-mrkz subcutaneous sol prefill syringe	100 MG/ML	2	Syringes	28	DAYS				
5250405040D520	Omvoh	mirikizumab-mrkz subcutaneous soln auto-injector	100 MG/ML	2	Pens	28	DAYS				
6640001000E520	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 125 MG/ML	125 MG/ML	4	Syringes	28	DAYS				
6640001000E510	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 50 MG/0.4ML	50 MG/0.4ML	4	Syringes	28	DAYS				
6640001000E515	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 87.5 MG/0.7ML	87.5 MG/0.7ML	4	Syringes	28	DAYS				
6640001000D5	Orencia clickject	abatacept subcutaneous soln auto-injector	125 MG/ML	4	Syringes	28	DAYS				
66603072007540	Rinvoq	Upadacitinib Tab ER	45 MG	84	Tablets	365	DAYS				
66603072007530	Rinvoq	Upadacitinib Tab ER	30 MG	30	Tablets	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
66603072007520	Rinvoq	Upadacitinib Tab ER 24HR 15 MG	15 MG	30	Tablets	30	DAYS				
66603072002020	Rinvoq lq	upadacitinib oral soln	1 MG/ML	360	mLs	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				
5250406070E220	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	360 MG/2.4ML	1	Cartridges	56	DAYS				
5250406070E210	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	180 MG/1.2ML	1	Cartridges	56	DAY				
9025057070D5	Skyrizi pen	risankizumab-rzaa soln auto-injector	150 MG/ML	1	Pen	84	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
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				
9025055400E515	Taltz	ixekizumab subcutaneous soln prefilled syringe	40 MG/0.5ML	1	Syringe	28	DAYS				
9025055400E510	Taltz	ixekizumab subcutaneous soln prefilled syringe	20 MG/0.25ML	1	Syringe	28	DAYS				
9025055400E5	Taltz	ixekizumab subcutaneous soln prefilled syringe	20 MG/0.25ML; 40 MG/0.5ML; 80 MG/ML	1	Syringe	28	DAYS				
9025054200D540	Tremfya	guselkumab soln auto-injector	200 MG/2ML	1	Pen	28	DAYS				
9025054200D520	Tremfya	Guselkumab Soln Pen-Injector 100 MG/ML	100 MG/ML	1	Pen	56	DAYS				
9025054200E540	Tremfya	guselkumab soln prefilled syringe	200 MG/2ML	1	Syringe	28	DAYS				
9025054200E520	Tremfya	Guselkumab Soln Prefilled Syringe 100 MG/ML	100 MG/ML	1	Syringe	56	DAYS				
6650007017D520	Tyenne	tocilizumab-aazg subcutaneous soln auto-inj	162 MG/0.9ML	4	Pens	28	DAYS				
6650007017E520	Tyenne	tocilizumab-aazg	162 MG/0.9ML	4	Syringes	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		subcutaneous soln pref syr									
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			
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			
6627001509D520	Yusimry	adalimumab-aqvh soln pen-injector 40 mg/0.8ml	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			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
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

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td>Adalimumab and Adalimumab Biosimilars</td><td>
<table>
<tr><th>Preferred Biosimilar Agent(s)</th><th>Preferred Brand Agent(s)*</th><th>Non-Preferred Agent(s)</th></tr>
<tr><td></td><td>*<u>Note</u>: Considered preferred brand agent(s) for current utilizers only; considered non-preferred for new starts.</td><td></td></tr>
<tr><td>Adalimumab-aaty

Adalimumab-adaz

Hadlima (adalimumab-bwwd)

Simlandi (adalimumab-ryvk)</td><td>Humira (adalimumab)</td><td>Abrilada (adalimumab-afzb)

Adalimumab-aacf

Adalimumab-adbm

Adalimumab-fkjp

Adalimumab-ryvk

Amjevita (adalimumab-atto)

Cyltezo (adalimumab-adbm)

Hulio (adalimumab-fkjp)

Hyrimoz (adalimumab-adaz)

Idacio (adalimumab-aacf)

Yuflyma (adalimumab-aaty)

Yusimry (adalimumab-aqvh)</td></tr>
</table>
Initial Evaluation

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

1. ONE of the following:
</td></tr>
</table>

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 Adalimumab-ryvk Amjevita Cyltezo, Adalimumab-adbm Hulio, Adalimumab-fkjp Hyrimoz Idacio, Adalimumab-aacf Yuflyma Yusimry

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**
            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:
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 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 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 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 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**

H. 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**

I. 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**

J. 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**

K. The patient has a diagnosis not mentioned previously **AND**

2. If the client has preferred agents, then ONE of the following (reference preferred agents table):
    A. The requested agent is a preferred biosimilar agent **OR**
    B. The requested agent is a preferred brand agent AND ONE of the following:
        1. The patient has tried and had an inadequate response to ONE preferred biosimilar agent after at least a 3-month trial (medical records required) **OR**
        2. The patient has an intolerance or hypersensitivity to ONE of the preferred biosimilar agents that is not expected to occur with the requested agent (medical records required) **OR**

3. The patient has an FDA labeled contraindication to ALL of the preferred biosimilar agents that is not expected to occur with the requested agent (medical records required) **OR**
4. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
    B. A statement by the prescriber that the patient is currently receiving a positive 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 preferred biosimilar 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**

C. The requested agent is a non-preferred agent AND ONE of the following:
1. The patient has tried and had an inadequate response to THREE preferred biosimilar agents after at least a 3-month trial per agent (medical records required) **OR**
2. The patient has an intolerance or hypersensitivity to THREE of the preferred biosimilar agents that is not expected to occur with the requested agent (medical records required) **OR**
3. The patient has an FDA labeled contraindication to ALL of the preferred biosimilar agents that is not expected to occur with the requested agent (medical records required) **OR**
4. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
    B. A statement by the prescriber that the patient is currently receiving a positive 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 preferred biosimilar 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**

D. BOTH of the following (medical records required):
1. ALL of the preferred biosimilar agents are not clinically appropriate for the patient **AND**
2. The prescriber has provided a complete list of previously tried agents **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**

2. 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) or has consulted with a specialist in the area of the patient's diagnosis **AND**
3. 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 (submitted copy of clinical trials, phase III studies, guidelines required) **AND**
4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
5. 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), 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 length of approval. Adalimumab containing products for UC may be approved for 12 weeks.

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. If the client has preferred agents, then ONE of the following (reference preferred agents table):
    A. The requested agent is a preferred biosimilar agent **OR**
    B. The requested agent is a preferred brand agent AND ONE of the following:
        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**
        3. The patient has tried and had an inadequate response to ONE preferred biosimilar agent after at least a 3-month trial (medical records required) **OR**
        4. The patient has an intolerance or hypersensitivity to ONE of the preferred biosimilar agents that is not expected to occur with the requested agent (medical records required) **OR**
        5. The patient has an FDA labeled contraindication to ALL of the preferred biosimilar agents that is not expected to occur with the requested agent (medical records required) **OR**
        6. The prescriber has provided documentation that ALL preferred biosimilar 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**

C. The requested agent is a non-preferred agent AND ONE of the following:
   1. The patient has tried and had an inadequate response to THREE preferred biosimilar agents after at least a 3-month trial per agent (medical records required) **OR**
   2. The patient has an intolerance or hypersensitivity to THREE of the preferred biosimilar agents that is not expected to occur with the requested agent (medical records required) **OR**
   3. The patient has an FDA labeled contraindication to ALL of the preferred biosimilar agents that is not expected to occur with the requested agent (medical records required) **OR**
   4. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
      B. A statement by the prescriber that the patient is currently receiving a positive 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 preferred biosimilar 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**

D. BOTH of the following (medical records required):
   1. ALL of the preferred biosimilar agents are not clinically appropriate for the patient **AND**
   2. The prescriber has provided a complete list of previously tried agents **AND**

4. 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) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
5. ONE of the following (please refer to "Agents NOT to be used Concomitantly" table):
   A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**
   B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
      1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**
      2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, guidelines required) **AND**
6. The patient does NOT have any FDA labeled contraindications to the requested agent

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

Length of Approval: 12 months

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

All other Target Agents

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)	SC: adalimumab product(s)**, Cosentyx, Enbrel	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SC: Cimzia, Simponi, Taltz	N/A	SC: Bimzelx
Nonradiographic Axial Spondyloarthritis (nr-axSpA)	SC: Cimzia, Cosentyx	Oral: Rinvoq	N/A	SC: Taltz	N/A	SC: Bimzelx
Polyarticular Juvenile Idiopathic Arthritis (PJIA)	SC: adalimumab product(s)**, Enbrel	Oral: Rinvoq, Rinvoq LQ, Xeljanz	SC: Tyenne (an adalimumab product** is a required Step 1 agent)	N/A	SC: Actemra (an adalimumab product** AND Tyenne are required Step agents) Orencia	SC: Kevzara
Psoriatic Arthritis (PsA)	SC: adalimumab product(s)**, Cosentyx, Enbrel, Skyrizi, Stelara, Tremfya Oral: Otezla	Oral: Rinvoq, Rinvoq LQ, Xeljanz, Xeljanz XR	N/A	SC: Cimzia, Orencia, Simponi, Taltz	N/A	SC: Bimzelx
Rheumatoid Arthritis (RA)	SC: adalimumab product(s)**, Enbrel	Oral: Rinvoq, Xeljanz, Xeljanz XR	SC: Tyenne (an adalimumab product** is a required Step 1 agent)	Oral: Olumiant SC: Cimzia, Kevzara, Orencia, Simponi	SC: Actemra (an adalimumab product** AND Tyenne are required Step agents)	SC: Kineret
Systemic Juvenile Idiopathic Arthritis (SJIA)	SC: Tyenne	N/A	SC: Actemra	N/A	N/A	N/A
Dermatological Disorder						

Hidradenitis Suppurativa (HS)	SC: adalimumab product(s)**, Cosentyx	N/A	N/A	N/A	N/A	N/A
Psoriasis (PS)	SC: adalimumab product(s)**, Cosentyx, Enbrel, Skyrizi, Stelara, Tremfya Oral: Otezla, Sotyktu	N/A	N/A	SC: Cimzia, Ilumya	N/A	SC: Bimzelx, Siliq, Taltz
Inflammatory Bowel Disease						
Crohn's Disease (CD)	SC: adalimumab product(s)**, Entyvio, Skyrizi, Stelara	Oral: Rinvoq	N/A	SC: Cimzia (an adalimumab product** is a required Step 1 agent) Zymfentra	N/A	N/A
Ulcerative Colitis (UC)	SC: adalimumab product(s)**, Entyvio, Skyrizi, Stelara, Tremfya	Oral: Rinvoq, Xeljanz, Xeljanz XR	SC: Omvoh Simponi (an adalimumab product** is a required Step 1 agent)	SC: Zymfentra Oral: Zeposia	N/A	Oral: Velsipity
Other						
Giant Cell Arteritis (GCA)	SC: Tyenne	N/A	SC: Actemra	N/A	N/A	N/A
Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)	SC: Tyenne	N/A	SC: Actemra	N/A	N/A	N/A
Uveitis	SC: adalimumab	N/A	N/A	N/A	N/A	N/A

	product(s)**					
Indications Without Prerequisite Biologic Immunomodulators Required						
Alopecia Areata (AA) Atopic Dermatitis (AD) Deficiency of IL-1 Receptor Antagonist (DIRA) Enthesitis Related Arthritis (ERA) Juvenile Psoriatic Arthritis (JPsA) Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Polymyalgia Rheumatica (PMR)	N/A	N/A	N/A	N/A	N/A	N/A

****Allowable preferred adalimumab product(s)**
Adalimumab-aaty, Adalimumab-adaz, Hadlima, Humira*, Simlandi **Humira is considered a preferred adalimumab product for current utilizers only. Humira is considered non-preferred for new starts.*

Note: For Xeljanz products (Xeljanz and Xeljanz XR) and Rinvoq products (Rinvoq and Rinvoq LQ), a trial of either or both dosage forms collectively counts as ONE product

Initial 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. 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: Actemra

      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**
               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:
      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 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 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 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**
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 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 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 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 body sites that are difficult to treat with prolonged topical corticosteroid therapy (e.g., hands, feet, face, neck, scalp, genitals/groin, skin folds) **OR**
        C. The patient has an Eczema Area and Severity Index (EASI) score greater than or equal to 16 **OR**
        D. The patient has an Investigator Global Assessment (IGA) score greater than or equal to 3 **AND**
    2. ONE of the following:
        A. The patient has tried and had an inadequate response to at least a medium-potency topical corticosteroid 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 medium-potency topical corticosteroid used in the treatment of AD **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 medium-, high-, and super-potency topical corticosteroids used in the treatment of AD **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 medium-, high-, and super-potency topical corticosteroids used in the treatment of AD **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 (prior to therapy with the requested agent) pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **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., 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 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 (medical records 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 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 (medical records 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 (medical records 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, then 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 BOTH of the following:
      1. The requested dose is 300 mg every 4 weeks **AND**
      2. The patient 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, then 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 or Crohn's disease, then 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 or ulcerative colitis, then 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 an ustekinumab product is requested for the treatment of Crohn's disease or ulcerative colitis, then ONE of the following:
   A. The patient received an ustekinumab IV product for induction therapy **OR**
   B. The patient is new to therapy and will receive an ustekinumab IV product for induction therapy **AND**
8. If Zymfentra is requested for the treatment of Crohn's disease or ulcerative colitis, then ONE of the following:
   A. The patient received an infliximab IV product for induction therapy **OR**
   B. The patient is new to therapy and will receive an infliximab IV product for induction therapy **AND**
9. If Tremfya is requested for the treatment of ulcerative colitis, then ONE of the following:
   A. The patient received Tremfya IV for induction therapy **OR**
   B. The patient is new to therapy and will receive Tremfya IV for induction therapy **AND**
10. 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 an ustekinumab 90 mg product is requested, then 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. If Kevzara is requested for a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA), the patient weighs 63 kg or greater **AND**
7. If the patient has a diagnosis of moderate-to-severe atopic dermatitis (AD), then 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 **AND**
8. 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**
9. 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 (submitted copy of clinical trials, phase III studies, guidelines required) **AND**

10. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
11. 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 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 length of approval. 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 ustekinumab product 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 **OR**
         D. A decrease in the Eczema Area and Severity Index (EASI) score **OR**
         E. A decrease in the Investigator Global Assessment (IGA) score **AND**
      2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR**
   B. The patient has a diagnosis of 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 (submitted copy of clinical trials, phase III studies, guidelines required) **AND**
7. ONE of the following:
   A. The requested agent is eligible for continuation of therapy **OR**

Agents Eligible for Continuation of Therapy
All target agents EXCEPT the following are eligible for continuation of therapy: Actemra

   B. ONE of the following (reference Step table):
      1. The requested indication does NOT require any prerequisite biologic immunomodulator agents **OR**
      2. The requested agent is a Step 1a agent for the requested indication **OR**
      3. If the requested agent is a Step 1b agent for the requested indication, then ONE of the following:
         A. 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**
         B. 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**
         C. The patient has an FDA labeled contraindication to ALL TNF inhibitors for the requested indication **OR**
         D. 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**
         E. 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**

F. The prescriber has provided documentation that ALL Tumor Necrosis Factor (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**

4. If the requested agent is a Step 2 agent for the requested indication, then ONE of the following:
   A. 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**
   B. 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**
   C. The patient has an FDA labeled contraindication to ALL required Step 1 agents for the requested indication **OR**
   D. 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**
   E. 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**
   F. The prescriber has provided documentation that ALL of the 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**
5. If the requested agent is a Step 3a agent for the requested indication, then ONE of the following (medical records required):
   A. 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**
   B. 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**
   C. The patient has an FDA labeled contraindication to ALL required Step 1 agents for the requested indication **OR**
   D. 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**
   E. 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**

F. 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**

6. If the requested agent is a Step 3b agent for the requested indication, then ONE of the following (medical records required):
   A. 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**
   B. 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 agents from Step 1 and/or Step 2 for the requested indication **OR**
   C. The patient has an FDA labeled contraindication to ALL of the Step 1 AND Step 2 agents for the requested indication **OR**
   D. 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**
   E. 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**
   F. 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**
7. If the requested agent is a Step 3c agent for the requested indication, then ONE of the following (medical records required):
   A. 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**
   B. 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 agents from Step 1 agents for the requested indication **OR**
   C. The patient has an FDA labeled contraindication to ALL of the Step 1 agents for the requested indication **OR**
   D. 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**

	E. 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** F. The prescriber has provided documentation that ALL 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** 8. If Cosentyx 300 mg is requested as maintenance dosing, then 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 BOTH of the following: 1. The requested dose is 300 mg every 4 weeks **AND** 2. The patient has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks after at least a 3-month duration of therapy **AND** 9. 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** 10. 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.

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 for the requested indication **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 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. ALL of the following:
            1. The requested quantity (dose) exceeds the FDA maximum labeled dose for the requested indication **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 for the requested indication (medical records required) **AND**
            3. ONE of the following:
                A. BOTH of the following:
                    1. The requested quantity (dose) does NOT exceed the maximum compendia supported dose for the requested indication **AND**
                    2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does NOT exceed the program quantity limit **OR**
                B. BOTH of the following:
                    1. The requested quantity (dose) exceeds the maximum FDA labeled dose AND the maximum compendia supported dose for the requested indication **AND**
                    2. 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 length of approval. 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. **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)

Contraindicated as Concomitant Therapy
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)
Leqselvi (deuruxolitinib)
Litfulo (ritlecitinib)
Nemluvio (nemolizumab-ilto)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Pyzchiva (ustekinumab-ttwe)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Saphnelo (anifrolumab-fnia)
Selarsdi (ustekinumab-aekn)
Siliq (brodalumab)
Simlandi (adalimumab-ryvk)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Spevigo (spesolimab-sbzo) subcutaneous injection
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)

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

• Program Summary: Biologic Immunomodulators - FocusRx

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6627001540F820		adalimumab-ryvk prefilled syringe kit	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001507F820	Abrilada	adalimumab-afzb prefilled syringe kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001507F810	Abrilada	adalimumab-afzb prefilled syringe kit	20 MG/0.4ML	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				
6627001510D520	Amjevita	adalimumab-atto soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS				
6627001510D517	Amjevita	adalimumab-atto soln auto-injector	40 MG/0.4ML	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	Age Limit	Effective Date	Term Date
6627001510E510	Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001510E508	Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.2ML	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	50474071079;			
5250502010F840	Cimzia starter kit	certolizumab pegol prefilled syringe kit	200 MG/ML	1	Kit	180	DAYS	50474071081;			
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	150 MG/ML	1	Syringe	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		Syringe 150 MG/ML									
9025057500D530	Cosentyx sensoready pen	Secukinumab Subcutaneous Auto-inj 150 MG/ML (300 MG Dose)	150 MG/ML	2	Pens	28	DAYS				
9025057500D520	Cosentyx sensoready pen	Secukinumab Subcutaneous Soln Auto-injector 150 MG/ML	150 MG/ML	1	Pen	28	DAYS				
9025057500D550	Cosentyx unoready	secukinumab subcutaneous soln auto-injector	300 MG/2ML	1	Pen	28	DAYS				
6627001505F520	Cyltezo	adalimumab-adbm auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS	00597037597; 00597054522; 82009014822			
6627001505F515	Cyltezo	adalimumab-adbm auto-injector kit	40 MG/0.4ML	2	Pens	28	DAYS	00597049550; 00597057550; 82009014422			
6627001505F815	Cyltezo	adalimumab-adbm prefilled syringe kit	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001505F810	Cyltezo	adalimumab-adbm prefilled syringe kit	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001505F805	Cyltezo	adalimumab-adbm prefilled syringe kit	10 MG/0.2ML	2	Syringes	28	DAYS				
6627001505F820	Cyltezo	adalimumab-adbm prefilled syringe kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001505F515	Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.4ML	1	Kit	180	DAYS	00597049560; 00597057560;			
6627001505F515	Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.4ML	1	Kit	180	DAYS	00597049540; 00597057540			
6627001505F520	Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00597037516; 00597054566;			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6627001505F520	Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00597037523; 00597054544;			
66290030002015	Enbrel	Etanercept Subcutaneous Inj 25 mg/0.5ml	25 MG/0.5ML	8	Vials	28	DAYS				
6629003000E5	Enbrel	etanercept subcutaneous soln prefilled syringe	25 MG/0.5ML; 50 MG/ML	4	Syringes	28	DAYS	58406002101; 58406002104;			
6629003000E525	Enbrel	Etanercept Subcutaneous Soln Prefilled Syringe 25 MG/0.5ML	25 MG/0.5ML	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				
5250308000D520	Entyvio	vedolizumab soln pen-injector 108 mg/0.68ml	108 MG/0.68ML	2	Pens	28	DAYS				
6627001520E520	Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001520E510	Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001520D520	Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS				
6627001520D510	Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				
6627001535F520	Hulio	adalimumab-fkjp auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS				
6627001535F820	Hulio	adalimumab-fkjp prefilled syringe kit	40 MG/0.8ML	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	Age Limit	Effective Date	Term Date
6627001535F810	Hulio	adalimumab-fkjp prefilled syringe kit	20 MG/0.4ML	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				
6627001500F530	Humira pen	Adalimumab Pen-injector Kit 40 MG/0.4ML	40 MG/0.4ML	2	Pens	28	DAYS				
6627001500F540	Humira pen-cd/uc/hs start	adalimumab auto-injector kit	80 MG/0.8ML	1	Kit	180	DAYS	00074012403;			
6627001500F520	Humira pen-cd/uc/hs start	adalimumab auto-injector kit; adalimumab pen-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00074433906;			
6627001500F540	Humira pen-pediatric uc s	adalimumab auto-injector kit	80 MG/0.8ML	1	Kit	180	DAYS	00074012404;			
6627001500F520	Humira pen-ps/uv starter	adalimumab auto-injector kit; adalimumab	40 MG/0.8ML	1	Kit	180	DAYS	00074433907;			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		pen-injector kit									
6627001500F550	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				
6627001504E513	Hyrimoz	adalimumab-adaz soln prefilled syringe	20 MG/0.2ML	2	Syringes	28	DAYS				
6627001504E520	Hyrimoz	adalimumab-adaz soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001504E508	Hyrimoz	adalimumab-adaz soln prefilled syringe	10 MG/0.1 ML	2	Syringes	28	DAYS				
6627001504E515	Hyrimoz	adalimumab-adaz soln prefilled syringe	40 MG/0.4ML	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				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6627001504D560	Hyrimoz plaque psoriasis; 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	1	Kit	28	DAYS				
6627001502F540	Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	65219055428; 65219061269			
6627001502F540	Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	65219055438; 65219061289			
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				
5250405040E520	Omvoh	mirikizumab-mrkz subcutaneous sol prefill syringe	100 MG/ML	2	Syringes	28	DAYS				
5250405040D520	Omvoh	mirikizumab-mrkz subcutaneous soln auto-injector	100 MG/ML	2	Pens	28	DAYS				
6640001000E520	Orencia	Abatacept Subcutaneous Soln Prefilled	125 MG/ML	4	Syringes	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		Syringe 125 MG/ML									
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				
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				
66603072002020	Rinvoq lq	upadacitinib oral soln	1 MG/ML	360	mLs	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				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6627004000E520	Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 50 MG/0.5ML	50 MG/0.5ML	1	Syringe	28	DAYS				
9025057070F820	Skyrizi	Risankizumab-rzaa Sol Prefilled Syringe 2 x 75 MG/0.83ML Kit	75 MG/0.83ML	1	Box	84	DAYS				
9025057070E540	Skyrizi	Risankizumab-rzaa Soln Prefilled Syringe	150 MG/ML	1	Syringe	84	DAYS				
5250406070E210	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	180 MG/1.2ML	1	Cartridge	56	DAYS				
9025057070D520	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				
9025055400D520	Taltz	Ixekizumab Subcutaneous Soln Auto-injector 80 MG/ML	80 MG/ML	1	Syringe	28	DAYS				
9025055400E515	Taltz	ixekizumab subcutaneous soln prefilled syringe	40 MG/0.5ML	1	Syringe	28	DAYS				
9025055400E510	Taltz	ixekizumab subcutaneous soln	20 MG/0.25ML	1	Syringe	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		prefilled syringe									
9025055400E510	Taltz	ixekizumab subcutaneous soln prefilled syringe	20 MG/0.25ML	1	Syringe	28	DAYS				
9025055400E520	Taltz	Ixekizumab Subcutaneous Soln Prefilled Syringe 80 MG/ML	80 MG/ML	1	Syringe	28	DAYS				
9025054200D540	Tremfya	guselkumab soln auto-injector	200 MG/2ML	1	Pen	28	DAYS				
9025054200D520	Tremfya	Guselkumab Soln Pen-Injector 100 MG/ML	100 MG/ML	1	Pen	56	DAYS				
9025054200E540	Tremfya	guselkumab soln prefilled syringe	200 MG/2ML	1	Syringe	28	DAYS				
9025054200E520	Tremfya	Guselkumab Soln Prefilled Syringe 100 MG/ML	100 MG/ML	1	Syringe	56	DAYS				
6650007017D520	Tyenne	tocilizumab-aazg subcutaneous soln auto-inj	162 MG/0.9ML	4	Pens	28	DAYS				
6650007017E520	Tyenne	tocilizumab-aazg subcutaneous soln pref syr	162 MG/0.9ML	4	Syringes	28	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				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
66603065107530	Xeljanz xr	Tofacitinib Citrate Tab ER 24HR 11 MG (Base Equivalent)	11 MG	30	Tablets	30	DAYS				
66603065107550	Xeljanz xr	Tofacitinib Citrate Tab ER 24HR 22 MG (Base Equivalent)	22 MG	120	Tablets	365	DAYS				
6627001503F560	Yuflyma 1-pen kit	adalimumab-aaty auto-injector kit	80 MG/0.8ML	2	Pens	28	DAYS	72606002304; 72606004004			
6627001503F530	Yuflyma 1-pen kit	adalimumab-aaty auto-injector kit	40 MG/0.4ML	2	Pens	28	DAYS	72606002209; 72606003009			
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			
6627001509D520	Yusimry	adalimumab-aqvh soln pen-injector 40 mg/0.8ml	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				
66603072007530	Rinvoq	Upadacitinib Tab ER	30 MG	30	Tablets	30	DAYS				
5250406070E220	Skyrizi	Risankizumab-rzaa Subcutaneou	360 MG/2.4ML	1	Cartridge	56	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		s Soln Cartridge									

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Adalimumab and Adalimumab Biosimilars	

Preferred Agent(s)	Non-Preferred Agent(s)
Adalimumab-aaty	**Abrilada** (adalimumab-afzb)
Adalimumab-adaz	**Adalimumab-aacf**
Hadlima (adalimumab-bwwd)	**Adalimumab-adbm**
Humira (adalimumab)	**Adalimumab-fkjp**
Simlandi (adalimumab-ryvk)	**Adalimumab-ryvk**
	Amjevita (adalimumab-atto)
	Cyltezo (adalimumab-adbm)
	Hulio (adalimumab-fkjp)
	Hyrimoz (adalimumab-adaz)
	Idacio (adalimumab-aacf)
	Yuflyma (adalimumab-aaty)
	Yusimry (adalimumab-aqvh)

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 EXCEPT the following are eligible for continuation of therapy: Abrilada

Adalimumab-ryvk Amjevita Cyltezo, Adalimumab-adbm Hulio, Adalimumab-fkjp Hyrimoz Idacio, Adalimumab-aacf Yuflyma Yusimry

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 ONE of the following:
        1. 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**
        2. 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**
        3. 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**
        4. 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**
        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 RA **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., 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 **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: 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 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 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 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 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**

H. 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**

I. 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**

J. 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**

K. The patient has a diagnosis not mentioned previously **AND**

2. If the client has preferred agents, then ONE of the following (reference preferred agents table):
    A. The requested agent is a preferred agent **OR**
    B. The patient has tried and had an inadequate response to THREE preferred agents after at least a 3-month trial per agent (medical records required) **OR**
    C. The patient has an intolerance or hypersensitivity to THREE of the preferred agents that is not expected to occur with the requested agent (medical records required) **OR**
    D. The patient has an FDA labeled contraindication to ALL of the preferred agents that is not expected to occur with the requested agent (medical records required) **OR**
    E. BOTH of the following (medical records required):
        1. ALL of the preferred agents are not clinically appropriate for the patient **AND**
        2. The prescriber has provided a complete list of previously tried agents **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 of the preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm (medical records required) **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**

2. 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) or has consulted with a specialist in the area of the patient's diagnosis **AND**
3. 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 (submitted copy of clinical trials, phase III studies, guidelines required) **AND**
4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
5. 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), 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 length of approval. Adalimumab containing products for UC may be approved for 12 weeks.

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. If the client has preferred agents, then ONE of the following (reference preferred agents table):
   A. The requested agent is a preferred agent **OR**
   B. The patient has tried and had an inadequate response to THREE preferred agents after at least a 3-month trial per agent (medical records required) **OR**
   C. The patient has an intolerance or hypersensitivity to THREE of the preferred agents that is not expected to occur with the requested agent (medical records required) **OR**
   D. The patient has an FDA labeled contraindication to ALL of the preferred agents that is not expected to occur with the requested agent (medical records required) **OR**

E. BOTH of the following (medical records required):
   1. ALL of the preferred agents are not clinically appropriate for the patient **AND**
   2. The prescriber has provided a complete list of previously tried agents **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 of the preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm (medical records required) **AND**

4. 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) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
5. ONE of the following (please refer to "Agents NOT to be used Concomitantly" table):
   A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**
   B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
      1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**
      2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, guidelines required) **AND**
6. The patient does NOT have any FDA labeled contraindications to the requested agent

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

Length of Approval: 12 months

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

All other Target Agents

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)	SC: adalimumab product(s)*	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SC: Cimzia, Simponi, Taltz	N/A	SC: Bimzelx

	*, Cosentyx, Enbrel					
Nonradiographic Axial Spondyloarthritis (nr-axSpA)	SC: Cimzia, Cosentyx	Oral: Rinvoq	N/A	SC: Taltz	N/A	SC: Bimzelx
Polyarticular Juvenile Idiopathic Arthritis (PJIA)	SC: adalimumab product(s)**, Enbrel	Oral: Rinvoq, Rinvoq LQ, Xeljanz	SC: Tyenne (an adalimumab product** is a required Step 1 agent)	N/A	SC: Actemra (an adalimumab product** AND Tyenne are required Step agents) Orencia	SC: Kevzara
Psoriatic Arthritis (PsA)	SC: adalimumab product(s)**, Cosentyx, Enbrel, Skyrizi, Stelara, Tremfya Oral: Otezla	Oral: Rinvoq, Rinvoq LQ, Xeljanz, Xeljanz XR	N/A	SC: Cimzia, Orencia, Simponi, Taltz	N/A	SC: Bimzelx
Rheumatoid Arthritis (RA)	SC: adalimumab product(s)**, Enbrel	Oral: Rinvoq, Xeljanz, Xeljanz XR	SC: Tyenne (an adalimumab product** is a required Step 1 agent)	Oral: Olumiant SC: Cimzia, Kevzara, Orencia, Simponi	SC: Actemra (an adalimumab product** AND Tyenne are required Step agents)	SC: Kineret
Systemic Juvenile Idiopathic Arthritis (SJIA)	SC: Tyenne	N/A	SC: Actemra	N/A	N/A	N/A
Dermatological Disorder						
Hidradenitis Suppurativa (HS)	SC: adalimumab product(s)**, Cosentyx	N/A	N/A	N/A	N/A	N/A

Psoriasis (PS)	SC: adalimumab product(s)**, Cosentyx, Enbrel, Skyrizi, Stelara, Tremfya Oral: Otezla, Sotyktu	N/A	N/A	SC: Cimzia, Ilumya	N/A	SC: Bimzelx, Siliq, Taltz
Inflammatory Bowel Disease						
Crohn's Disease (CD)	SC: adalimumab product(s)**, Entyvio, Skyrizi, Stelara	Oral: Rinvoq	N/A	SC: Cimzia (an adalimumab product** is a required Step 1 agent) Zymfentra	N/A	N/A
Ulcerative Colitis (UC)	SC: adalimumab product(s)**, Entyvio, Skyrizi, Stelara, Tremfya	Oral: Rinvoq, Xeljanz, Xeljanz XR	SC: Omvoh Simponi (an adalimumab product** is a required Step 1 agent)	SC: Zymfentra Oral: Zeposia	N/A	Oral: Velsipity
Other						
Giant Cell Arteritis (GCA)	SC: Tyenne	N/A	SC: Actemra	N/A	N/A	N/A
Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)	SC: Tyenne	N/A	SC: Actemra	N/A	N/A	N/A
Uveitis	SC: adalimumab product(s)**	N/A	N/A	N/A	N/A	N/A
Indications Without Prerequisite Biologic Immunomodulators Required						

Alopecia Areata (AA) Atopic Dermatitis (AD) Deficiency of IL-1 Receptor Antagonist (DIRA) Enthesitis Related Arthritis (ERA) Juvenile Psoriatic Arthritis (JPsA) Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Polymyalgia Rheumatica (PMR)	N/A	N/A	N/A	N/A	N/A	N/A

****Allowable preferred adalimumab product(s)**
Adalimumab-aaty, Adalimumab-adaz, Hadlima, Humira, Simlandi

Note: For Xeljanz products (Xeljanz and Xeljanz XR) and Rinvoq products (Rinvoq and Rinvoq LQ), a trial of either or both dosage forms collectively counts as ONE product

Initial 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. 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: Actemra

      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**
               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:
    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 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 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 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**
   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 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 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 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 body sites that are difficult to treat with prolonged topical corticosteroid therapy (e.g., hands, feet, face, neck, scalp, genitals/groin, skin folds) **OR**
        C. The patient has an Eczema Area and Severity Index (EASI) score greater than or equal to 16 **OR**
        D. The patient has an Investigator Global Assessment (IGA) score greater than or equal to 3 **AND**
    2. ONE of the following:
        A. The patient has tried and had an inadequate response to at least a medium-potency topical corticosteroid 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 medium-potency topical corticosteroid used in the treatment of AD **AND** a topical calcineurin inhibitor used in the treatment of AD **OR**
C. The patient has an FDA labeled contraindication to ALL medium-, high-, and super-potency topical corticosteroids used in the treatment of AD **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 medium-, high-, and super-potency topical corticosteroids **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 (prior to therapy with the requested agent) pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **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., 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 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 (medical records 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 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 (medical records 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 (medical records 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, then 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 BOTH of the following:
        1. The requested dose is 300 mg every 4 weeks **AND**
        2. The patient 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, then 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 or Crohn's disease, then 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 or ulcerative colitis, then 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 an ustekinumab product is requested for the treatment of Crohn's disease or ulcerative colitis, then ONE of the following:
    A. The patient received an ustekinumab IV product for induction therapy **OR**
    B. The patient is new to therapy and will receive an ustekinumab IV product for induction therapy **AND**
8. If Zymfentra is requested for the treatment of Crohn's disease or ulcerative colitis, then ONE of the following:
    A. The patient received an infliximab IV product for induction therapy **OR**
    B. The patient is new to therapy and will receive an infliximab IV product for induction therapy **AND**
9. If Tremfya is requested for the treatment of ulcerative colitis, then ONE of the following:
    A. The patient received Tremfya IV for induction therapy **OR**
    B. The patient is new to therapy and will receive Tremfya IV for induction therapy **AND**
10. 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 an ustekinumab 90 mg product 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. If Kevzara is requested for a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA), the patient weighs 63 kg or greater **AND**
7. If the patient has a diagnosis of moderate-to-severe atopic dermatitis (AD), then BOTH of the following:
    1. The patient is currently treated with topical emollients and practicing good skin care **AND**
    2. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent **AND**
8. 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**
9. 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 (submitted copy of support required, i.e., clinical trials, phase III studies, guidelines required) **AND**

10. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
11. 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 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 length of approval. 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 ustekinumab product 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 **OR**
            D. A decrease in the Eczema Area and Severity Index (EASI) score **OR**
            E. A decrease in the Investigator Global Assessment (IGA) score **AND**
        2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR**
    B. The patient has a diagnosis of 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):
    1. 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**
    2. 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 (submitted copy of support required, i.e., clinical trials, phase III studies, guidelines required) **AND**
7. ONE of the following:
    A. The requested agent is eligible for continuation of therapy **OR**

Agents Eligible for Continuation of Therapy
All target agents EXCEPT the following are eligible for continuation of therapy: Actemra

B. ONE of the following (reference Step table):
    1. The requested indication does NOT require any prerequisite biologic immunomodulator agents **OR**
    2. The requested agent is a Step 1a agent for the requested indication **OR**
    3. If the requested agent is a Step 1b agent for the requested indication, then ONE of the following:
        A. 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**
        B. 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**
        C. The patient has an FDA labeled contraindication to ALL TNF inhibitors for the requested indication **OR**
        D. BOTH of the following:
            1. ALL TNF inhibitors are not clinically appropriate for the patient **AND**
            2. The prescriber has provided a complete list of previously tried agents for the requested indication **OR**
        E. The patient is currently being treated with the requested agent as indicated by ALL of the following:
            1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
            2. A statement by the prescriber that the patient is currently receiving a positive therapeutics 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 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** 4. If the requested agent is a Step 2 agent for the requested indication, then ONE of the following: A. 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** B. 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** C. The patient has an FDA labeled contraindication to ALL required Step 1 agents for the requested indication **OR** D. BOTH of the following: 1. ALL of the required Step 1 agents are not clinically appropriate for the patient **AND** 2. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutics 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 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** 5. If the requested agent is a Step 3a agent for the requested indication, then ONE of the following (medical records required): A. 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** B. 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** C. The patient has an FDA labeled contraindication to ALL of the Step 1 agents for the requested indication **OR** D. BOTH of the following: 1. ALL of the Step 1 agents are not clinically appropriate for the patient **AND** 2. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutics 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 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**

6. If the requested agent is a Step 3b agent for the requested indication, then ONE of the following (medical records required):
   A. 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**
   B. 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**
   C. The patient has an FDA labeled contraindication to ALL of the Step 1 AND Step 2 agents for the requested indication **OR**
   D. BOTH of the following:
      1. ALL of the Step 1 AND Step 2 agents are not clinically appropriate for the patient **AND**
      2. The prescriber has provided a complete list of previously tried agents for the requested indication **OR**
   E. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
      2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND**
      3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
   F. The prescriber has provided documentation that ALL of the 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**
7. If the requested agent is a Step 3c agent for the requested indication, then ONE of the following (medical records required):
   A. 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**
   B. 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**
   C. The patient has an FDA labeled contraindication to ALL of the Step 1 agents for the requested indication **OR**
   D. BOTH of the following:
      1. ALL of the Step 1 agents are not clinically appropriate for the patient **AND**
      2. The prescriber has provided a complete list of previously tried agents for the requested indication **OR**
   E. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      1. A statement by the prescriber that the patient is currently taking the requested agent **AND**

	2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that ALL of the 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** 8. If Cosentyx 300 mg is requested as maintenance dosing, then 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 BOTH of the following: 1. The requested dose is 300 mg every 4 weeks **AND** 2. The patient has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks after at least a 3-month duration of therapy **AND** 9. 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** 10. 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.

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 for the requested indication **AND**
B. There is support for 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 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. ALL of the following:
      1. The requested quantity (dose) exceeds the FDA maximum labeled dose for the requested indication **AND**
      2. The patient has tried and had an inadequate response to at least a 3 month trial of the maximum FDA labeled dose for the requested indication (medical records required) **AND**
      3. ONE of the following:
         A. BOTH of the following:
            1. The requested quantity (dose) does NOT exceed the maximum compendia supported dose for the requested indication **AND**
            2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does NOT exceed the program quantity limit **OR**
         B. BOTH of the following:
            1. The requested quantity (dose) exceeds the maximum FDA labeled dose AND the maximum compendia supported dose for the requested indication **AND**
            2. 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 length of approval. 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. **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)

Contraindicated as Concomitant Therapy
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)
Leqselvi (deuruxolitinib)
Litfulo (ritlecitinib)
Nemluvio (nemolizumab-ilto)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Pyzchiva (ustekinumab-ttwe)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Saphnelo (anifrolumab-fnia)
Selarsdi (ustekinumab-aekn)
Siliq (brodalumab)
Simlandi (adalimumab-ryvk)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Spevigo (spesolimab-sbzo) subcutaneous injection
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)

Contraindicated as Concomitant Therapy
Yusimry (adalimumab-aqvh) Zeposia (ozanimod) Zymfentra (infliximab-dyyb)

● Program Summary: Coverage Exception - Commercial

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

CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

A coverage exception will be granted when BOTH 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) **AND**

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

2. ONE of the following:
   - A. ALL of the following:
     1. The requested agent is in an Affordable Care Act (ACA) Preventative Care category **AND**
     2. The member's benefit includes ACA Preventative Care for the category requested **AND**
     3. ONE of the following:
        - A. The requested agent is a contraception agent AND BOTH of the following:
          1. There is support 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:
               1. The requested agent is the 81 mg strength aspirin **AND**
               2. There is support that the requested aspirin agent is medically necessary **AND**
               3. 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: 1. There is support that the requested bowel prep agent is medically necessary **AND** 2. The requested agent will be used for the preparation of colorectal cancer screening using fecal occult blood testing, sigmoidoscopy, or colonoscopy **AND** 3. 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: 1. There is support that the requested breast cancer primary prevention agent is medically necessary **AND** 2. The requested agent is tamoxifen, raloxifene, or an aromatase inhibitor (anastrozole, exemestane, letrozole) **AND** 3. The patient is 35 years of age or over **AND** 4. 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: 1. There is support that the requested fluoride supplement is medically necessary **AND** 2. 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: 1. There is support that the requested folic acid supplement is medically necessary **AND** 2. The requested folic acid supplement contains 0.4-0.8 mg of folic acid **AND** 3. 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: 1. There is support that the requested PrEP agent is medically necessary **AND** 2. The requested agent is being used for PrEP **AND** 3. The requested PrEP agent is ONE of the following: A. Tenofovir disoproxil fumarate and emtricitabine combination ingredient agent **OR** B. Tenofovir alafenamide and emtricitabine combination ingredient age **OR** C. Cabotegravir **AND** 4. The patient has increased risk for HIV infection **AND** 5. The patient has recently tested negative for HIV **OR** G. The requested agent is an infant eye ointment AND ALL of the following: 1. There is support that the requested infant eye ointment is medically necessary **AND** 2. The patient is 3 months of age or younger **AND** 3. 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:
    1. There is support that the requested iron supplement is medically necessary **AND**
    2. The patient is under 12 months of age **AND**
    3. The patient is at increased risk for iron deficiency anemia **OR**

I. The requested agent is a statin AND ALL of the following:
    1. There is support that the requested statin is medically necessary **AND**
    2. The requested statin is for use in the primary prevention of cardiovascular disease (CVD) **AND**
    3. The patient is 40-75 years of age (inclusive) **AND**
    4. The patient has at least one of the following risk factors:
        A. Dyslipidemia **OR**
        B. Diabetes **OR**
        C. Hypertension **OR**
        D. Smoking **AND**
    5. 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:
    1. The patient is a non-pregnant adult **AND**
    2. There is support that the requested tobacco cessation agent is medically necessary **OR**

K. The requested agent is a vaccine AND BOTH of the following:
    1. There is support that the requested vaccine is medically necessary **AND**
    2. The requested vaccine will be used per the recommendations of the Advisory Committee on Immunization Practices/CDC **OR**

B. ALL of the following:
    1. ONE of the following:
        A. The requested agent is in an ACA Preventative Care category AND did NOT meet the preventative service requirements **OR**
        B. BOTH of the following:
            1. ONE of the following:
                A. The requested agent is NOT in an ACA Preventative Care category **OR**
                B. The member's benefit does NOT include ACA Preventative 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 **AND**

Examples of Agents Excluded from Coverage on the Pharmacy Benefit
Brand for Generic*   Agents with the following reject message: #NDC NOT COVERED, USE XXX#

Bulk Powders* (Defined as those products containing the third-party restriction code of B (BULK CHEMICALS) in the product file in RxClaim)
Clinic Packs* (Y in the Clinic Pack field)
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 RXClaim 1. MODIFIER AAAD31 INSTITUTIONAL/HOSP. PACK 2. MODIFIER BBAD9A INSTITUTIONAL 3. MODIFIER TTAAJQ INSTITUTIONAL 4. MODIFIER TTAA5V INSTITUTIONAL USE ONLY 5. MODIFIER AAAB9A HOSPITAL PACK 6. MODIFIER AAADQQ HUD (HOSPITAL UNIT DOSE) 7. 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

2. 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, 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 patient has an intolerance, hypersensitivity, or FDA labeled contraindication to the preferred insulin agents (e.g., Humulin, Humalog) of the same type (rapid or regular, mix or NPH) that is not expected to occur with the requested agent **OR**
   3. 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**
   4. 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 **OR**

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

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. There is support that the requested PEP agent is medically necessary **AND**
3. The requested PEP agent is ONE of the following (agent AND strength must match):
    A. Emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada) **OR**
    B. Tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread) **OR**
    C. Emtricitabine 200 mg single ingredient agent (Emtriva) **OR**
    D. Raltegravir 400 mg single ingredient agent (Isentress) **OR**
    E. Dolutegravir 50 mg single ingredient agent (Tivicay) **OR**
    F. Darunavir 800 mg single ingredient agent (Prezista) **OR**
    G. Ritonavir 100 mg single ingredient agent (Norvir) **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:
        1. The patient has an FDA labeled indication for the requested agent **OR**
        2. 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**
        3. 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:
        1. 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. There is support 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. There is support 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**

2. The requested agent does NOT have formulary (any formulary tier) alternatives for the diagnosis being treated with the requested agent **OR**
3. 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**

3. 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

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

NOTE: if Quantity Limit applies, please refer to Quantity Limit Criteria

• Program Summary: Coverage Exception - Health Insurance Marketplace (HIM)

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

CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	A coverage exception will be granted when BOTH 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) **AND**

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

2. ONE of the following:
    A. ALL of the following:
        1. The requested agent is in an Affordable Care Act (ACA) Preventative Care category **AND**
        2. The member's benefit includes ACA Preventative Care for the category requested **AND**
        3. ONE of the following:
            A. The requested agent is a contraception agent AND BOTH of the following:
                1. There is support 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:
                        1. The requested agent is the 81 mg strength aspirin **AND**
                        2. There is support that the requested aspirin agent is medically necessary **AND**
                        3. 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:
                        1. There is support that the requested bowel prep agent is medically necessary **AND**
                        2. The requested agent will be used for the preparation of colorectal cancer screening using fecal occult blood testing, sigmoidoscopy, or colonoscopy **AND**
                        3. 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:
                        1. There is support that the requested breast cancer primary prevention agent is medically necessary **AND**
                        2. The requested agent is tamoxifen, raloxifene, or an aromatase inhibitor (anastrozole, exemestane, letrozole) **AND**
                        3. The patient is 35 years of age or over **AND**

4. 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:
   1. There is support that the requested fluoride supplement is medically necessary **AND**
   2. 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:
   1. There is support that the requested folic acid supplement is medically necessary **AND**
   2. The requested folic acid supplement contains 0.4-0.8 mg of folic acid **AND**
   3. 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:
   1. There is support that the requested PrEP agent is medically necessary **AND**
   2. The requested PrEP agent is ONE of the following:
      A. Tenofovir disoproxil fumarate and emtricitabine combination ingredient agent **OR**
      B. Tenofovir alafenamide and emtricitabine combination ingredient agent **OR**
      C. Cabotegravir **AND**
   3. The patient has increased risk for HIV infection **AND**
   4. The patient has recently tested negative for HIV **OR**

G. The requested agent is an infant eye ointment AND ALL of the following:
   1. There is support that the requested infant eye ointment is medically necessary **AND**
   2. The patient is 3 months of age or younger **AND**
   3. 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:
   1. There is support that the requested iron supplement is medically necessary **AND**
   2. The patient is under 12 months of age **AND**
   3. The patient is at increased risk for iron deficiency anemia **OR**

I. The requested agent is a statin AND ALL of the following:
   1. There is support that the requested statin is medically necessary **AND**
   2. The requested statin is for use in the primary prevention of cardiovascular disease (CVD) **AND**
   3. The patient is 40-75 years of age (inclusive) **AND**
   4. The patient has at least one of the following risk factors:
      A. Dyslipidemia **OR**
      B. Diabetes **OR**
      C. Hypertension **OR**

D. Smoking **AND**

5. 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:
   1. The patient is a non-pregnant adult **AND**
   2. There is support that the requested tobacco cessation agent is medically necessary **OR**

K. The requested agent is a vaccine AND BOTH of the following:
   1. There is support that the requested vaccine is medically necessary **AND**
   2. The requested vaccine will be used per the recommendations of the Advisory Committee on Immunization Practices/CDC **OR**

B. ALL of the following:
   1. ONE of the following:
      A. The requested agent is in an ACA Preventative Care category AND did NOT meet the preventative service requirements **OR**
      B. BOTH of the following:
         1. ONE of the following:
            A. The requested agent is NOT in an ACA Preventative Care category **OR**
            B. The member's benefit does NOT include ACA Preventative Care for the category requested **AND**
         2. ONE of the following:
            A. The request is for a drug that is on BCBS MN's "CE Formulary Alternative Supplement List" AND BOTH of the following:
               1. The patient has an FDA labeled indication for the requested agent 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. The patient has tried and failed ALL formulary alternatives for the diagnosis being treated with the requested agent **OR**

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

Excluded from Coverage on the Pharmacy Benefit
Alcohol Swabs
Blood Component (not including Hemophilia Factor)
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 DRUG] 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)	
Dietary and Herbal Supplements	
Digital Therapeutics (Defined as those products containing the third-party restriction code of J [DIGITAL THERAPY] in the product file in RxClaim)	
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) for the treatment of infertility	
Institutional Packs* Those that contain any one of the following modifier codes in the product file in RxClaim 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 to 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)	
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) 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)	
Syringes other than insulin syringes	

Weight Loss Agents*
(GPI: 6120**********, 6125**********) for the treatment of weight loss

*Category specific denial reasons apply

2. 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, 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 patient has an intolerance, hypersensitivity, or FDA labeled contraindication to the preferred insulin agents (e.g., Humulin, Humalog) of the same type (rapid or regular, mix or NPH) that is not expected to occur with the requested agent **OR**
        3. 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**
        4. 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 part of the Brand for Generic strategy (i.e., Agents with the following reject message: #NDC NOT COVERED, USE XXX#) AND BOTH of the following:
        1. There is support that the available formulary (any formulary tier) brand 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. There is support 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**
            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) **OR**

F. The requested agent is Procysbi AND the patient has tried and had an inadequate response to therapy with Cystagon in combination with a GI protectant (e.g., proton pump inhibitor, histamine-2 receptor antagonists) **OR**

G. 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 **OR**

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

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

I. The requested agent is an HIV infection post-exposure prophylaxis (PEP) agent being used for PEP AND ALL of the following:
   1. There is support that the requested PEP agent is medically necessary **AND**
   2. The requested PEP agent is ONE of the following (agent AND strength must match):
      A. Emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada) **OR**
      B. Tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread) **OR**
      C. Emtricitabine 200 mg single ingredient agent (Emtriva) **OR**
      D. Raltegravir 400 mg single ingredient agent (Isentress) **OR**
      E. Dolutegravir 50 mg single ingredient agent (Tivicay) **OR**
      F. Darunavir 800 mg single ingredient agent (Prezista) **OR**
      G. Ritonavir 100 mg single ingredient agent (Norvir) **AND**

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

J. ONE of the following:
1. The requested medication is an antipsychotic prescribed to treat emotional disturbance or mental illness AND the following:
   A. 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**
2. The requested agent is Supprelin or Vantas and is being requested for a diagnosis of Gender Identity Disorder (GID) or gender dysphoria **OR**
3. BOTH of the following:
   A. ONE of the following:
      1. The patient has an FDA labeled indication for the requested agent **OR**
      2. 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**
      3. 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:
      1. 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, then ONE of the following:
            1. The patient has tried and failed one or more available formulary generic equivalents to the requested agent **OR**
            2. There is support 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. There is support 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**

2. The requested agent does NOT have formulary (any formulary tier) alternatives for the diagnosis being treated with the requested agent **OR**
3. 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**

3. 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

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

NOTE: if Quantity Limit applies, please refer to Quantity Limit Criteria

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

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

CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	A coverage exception will be granted when BOTH 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) **AND** **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** 2. ONE of the following: A. ALL of the following: 1. The requested agent is in an Affordable Care Act (ACA) Preventative Care category **AND** 2. The member's benefit includes ACA Preventative Care for the category requested **AND** 3. ONE of the following: A. The requested agent is a contraception agent AND BOTH of the following:

1. There is support 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:
1. The requested agent is the 81 mg strength aspirin **AND**
2. There is support that the requested aspirin agent is medically necessary **AND**
3. 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:
1. There is support that the requested bowel prep agent is medically necessary **AND**
2. The requested agent will be used for the preparation of colorectal cancer screening using fecal occult blood testing, sigmoidoscopy, or colonoscopy **AND**
3. 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:
1. There is support that the requested breast cancer primary prevention agent is medically necessary **AND**
2. The requested agent is tamoxifen, raloxifene, or an aromatase inhibitor (anastrozole, exemestane, letrozole) **AND**
3. The patient is 35 years of age or over **AND**
4. 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:
1. There is support that the requested fluoride supplement is medically necessary **AND**
2. 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:
1. There is support that the requested folic acid supplement is medically necessary **AND**
2. The requested folic acid supplement contains 0.4-0.8 mg of folic acid **AND**

3. 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:
   1. There is support that the requested PrEP agent is medically necessary **AND**
   2. The requested PrEP agent is ONE of the following:
      A. Tenofovir disoproxil fumarate and emtricitabine combination ingredient agent **OR**
      B. Tenofovir alafenamide and emtricitabine combination ingredient agent **OR**
      C. Cabotegravir **AND**
   3. The patient has increased risk for HIV infection **AND**
   4. The patient has recently tested negative for HIV **OR**

G. The requested agent is an infant eye ointment AND ALL of the following:
   1. There is support that the requested infant eye ointment is medically necessary **AND**
   2. The patient is 3 months of age or younger **AND**
   3. 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:
   1. There is support that the requested iron supplement is medically necessary **AND**
   2. The patient is under 12 months of age **AND**
   3. The patient is at increased risk for iron deficiency anemia **OR**

I. The requested agent is a statin AND ALL of the following:
   1. There is support that the requested statin is medically necessary **AND**
   2. The requested statin is for use in the primary prevention of cardiovascular disease (CVD) **AND**
   3. The patient is 40-75 years of age (inclusive) **AND**
   4. The patient has at least one of the following risk factors:
      A. Dyslipidemia **OR**
      B. Diabetes **OR**
      C. Hypertension **OR**
      D. Smoking **AND**
   5. 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:
   1. The patient is a non-pregnant adult **AND**
   2. There is support that the requested tobacco cessation agent is medically necessary **OR**

K. The requested agent is a vaccine AND BOTH of the following:

1. There is support that the requested vaccine is medically necessary **AND**
2. The requested vaccine will be used per the recommendations of the Advisory Committee on Immunization Practices/CDC **OR**

B. ALL of the following:
1. ONE of the following:
A. The requested agent is in an ACA Preventative Care category AND did NOT meet the preventative service requirements **OR**
B. BOTH of the following:
1. ONE of the following:
A. The requested agent is NOT in an ACA Preventative Care category **OR**
B. The member's benefit does NOT include ACA Preventative Care for the category requested **AND**
2. ONE of the following:
A. The request is for a drug that is on BCBS MN's "CE Formulary Alternative Supplement List" AND BOTH of the following:
1. The patient has an FDA labeled indication for the requested agent 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. The patient has tried and failed ALL formulary alternatives for the diagnosis being treated with the requested agent **OR**
B. The request is NOT for a drug/drug class/medical condition which are excluded from coverage under the pharmacy benefit **AND**

Excluded from Coverage on the Pharmacy Benefit
Alcohol Swabs
Blood Component (not including Hemophilia Factor)
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 DRUG] 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)
Dietary and Herbal Supplements
Digital Therapeutics (Defined as those products containing the third-party restriction code of J [DIGITAL THERAPY] in the product file in RxClaim)

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) for the treatment of infertility
Institutional Packs* Those that contain any one of the following modifier codes in the product file in RxClaim 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 to 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)
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) 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)
Syringes other than insulin syringes
Weight Loss Agents* (GPI: 6120**********, 6125**********) for the treatment of weight loss

*Category specific denial reasons apply

2. 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, 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 patient has an intolerance, hypersensitivity, or FDA labeled contraindication to the preferred insulin agents (e.g., Humulin, Humalog) of the same type (rapid or regular, mix or NPH) that is not expected to occur with the requested agent **OR**
   3. 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**
   4. 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 part of the Brand for Generic strategy (i.e., Agents with the following reject message: #NDC NOT COVERED, USE XXX#) AND BOTH of the following:
   1. There is support that the available formulary (any formulary tier) brand 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. There is support 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**
      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) **OR**

F. The requested agent is Procysbi AND the patient has tried and had an inadequate response to therapy with Cystagon in combination with a GI protectant (e.g., proton pump inhibitor, histamine-2 receptor antagonists) **OR**

G. 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 **OR**

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

H. The requested agent is Auvi-Q 0.1 mg AND the patient weighs 7.5 to 15 kg (16.5 to 33 pounds) **OR**
I. The requested agent is an HIV infection post-exposure prophylaxis (PEP) agent being used for PEP AND ALL of the following:
    1. There is support that the requested PEP agent is medically necessary **AND**
    2. The requested PEP agent is ONE of the following (agent AND strength must match):
        A. Emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada) **OR**
        B. Tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread) **OR**
        C. Emtricitabine 200 mg single ingredient agent (Emtriva) **OR**
        D. Raltegravir 400 mg single ingredient agent (Isentress) **OR**
        E. Dolutegravir 50 mg single ingredient agent (Tivicay) **OR**
        F. Darunavir 800 mg single ingredient agent (Prezista) **OR**
        G. Ritonavir 100 mg single ingredient agent (Norvir) **AND**
    3. The patient is at high risk of HIV infection **AND**
    4. The patient is initiating or has initiated PEP within 72 hours of suspected exposure to HIV **OR**
J. ONE of the following:
    1. The requested medication is an antipsychotic prescribed to treat emotional disturbance or mental illness AND the following:
        A. 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**

2. The requested agent is Supprelin or Vantas and is being requested for a diagnosis of Gender Identity Disorder (GID) or gender dysphoria **OR**
3. BOTH of the following:
    A. ONE of the following:
        1. The patient has an FDA labeled indication for the requested agent **OR**
        2. 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**
        3. 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:
        1. 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, then ONE of the following:
                1. The patient has tried and failed one or more available formulary generic equivalents to the requested agent **OR**
                2. There is support 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. There is support 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**
        2. The requested agent does NOT have formulary (any formulary tier) alternatives for the diagnosis being treated with the requested agent **OR**
        3. 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**

	3. 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 **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 NOTE: if Quantity Limit applies, please refer to Quantity Limit Criteria

• Program Summary: Endari (L-glutamine)

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

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Endari	glutamine (sickle cell) powd pack	5 GM	M; N; O; Y	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. The patient has a diagnosis of sickle cell disease **AND** 2. The patient is using the requested agent to reduce the acute complications of sickle cell disease **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 **AND** 4. ONE of the following: A. The patient has tried and had an inadequate response to hydroxyurea **OR** B. The patient has an intolerance or hypersensitivity to hydroxyurea **OR** C. The patient has an FDA labeled contraindication to hydroxyurea **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 hydroxyurea 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. ONE of the following: A. The patient will NOT be using the requested agent in combination with Adakevo (crizanlizumab-tmca) OR Oxbryta (voxelotor) **OR** B. There is support for use of the requested agent in combination with Adakveo (crizanlizumab-tmca) or Oxbryta (voxelotor) **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 7. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **Length of Approval:** 12 months **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved 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 (i.e., reduction in acute complications of sickle cell disease since initiating therapy with the requested agent) **AND** 3. ONE of the following: A. The patient will NOT be using the requested agent in combination with Adakevo (crizanlizumab-tmca) OR Oxbryta (voxelotor) **OR** B. There is support for use of the requested agent in combination with Adakevo (crizanlizumab-tmca) or Oxbryta (voxelotor) **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. The requested quantity (dose) does NOT exceed the maximum FDA labeled 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	Age Limit	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) as 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) **OR** B. The patient has a diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy AND ALL of the following: 1. The patient has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g **AND** 2. The patient's eGFR is greater than or equal to 30 mL/min/1.73 m^2 **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to a maximally tolerated angiotensin-converting-enzyme inhibitor (ACEI, e.g., benazepril, lisinopril) or angiotensin II blocker (ARB, e.g., losartan), or a combination medication containing an ACEI or ARB **OR** B. The patient has an intolerance or hypersensitivity to an ACEI or ARB, or a combination medication containing an ACEI or ARB **OR** C. The patient has an FDA labeled contraindication to ALL ACEI or ARB 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 ACEI and ARB agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. ONE of the following: A. The patient has tried and had an inadequate response after a 6-month course of glucocorticoid therapy (e.g., methylprednisolone, prednisolone, prednisone) **OR** B. The patient has an intolerance or hypersensitivity to a glucocorticoid therapy **OR** C. The patient has an FDA labeled contraindication to ALL glucocorticoid therapies **OR** D. There is support that glucocorticoid therapy is NOT appropriate for the patient **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that ALL glucocorticoid therapies cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 5. The patient will continue on standard of care IgAN therapy (e.g., ACEI, ARB, SGLT2, aliskiren) **OR**

C. The patient has another FDA labeled indication for the requested agent and route of administration **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, 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 Empaveli (pegcetacoplan), Soliris (eculizumab), Ultomiris (ravulizumab-cwvz), or Piasky (crovalimab-akkz) for the requested indication **AND**
5. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 6 months for PNH, 9 months for IgAN, 12 months for all other indications

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 has a diagnosis of primary immunoglobulin A nephropathy (IgAN) AND BOTH of the following:
      1. The patient has had improvements or stabilization with the requested agent as indicated by ONE of the following:
         A. Decrease from baseline (prior to treatment with the requested agent) of urine protein-to-creatinine (UPCR) ratio **OR**
         B. Decrease from baseline (prior to treatment with the requested agent) in proteinuria **AND**
      2. The patient will continue standard of care IgAN therapy (e.g., ACEI, ARB, SGLT2, aliskiren) **OR**
   B. The patient has a diagnosis Paroxysmal Nocturnal Hemoglobinuria (PNH) AND 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) **OR**
   C. The patient has a diagnosis other than IgAN or PNH AND has had clinical benefit with the requested agent **AND**
3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, 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 Empaveli (pegcetacoplan), Soliris (eculizumab), Ultomiris (ravulizumab-cwvz), or Piasky (crovalimab-akkz) for the requested indication **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

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

Length of Approval: up to 12 months

• Program Summary: Kerendia

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

POLICY AGENT SUMMARY STEP THERAPY

Final Module	Target Agent GPI	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status	Effective Date	Targeted NDCs When Exclusions Exist
	303540300003	Kerendia	finerenone tab	10 MG; 20 MG	M; N; O; Y	N				

POLICY AGENT SUMMARY QUANTITY LIMIT

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

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Target Agent(s) will be approved when ONE of the following are met:

TARGET AGENT(S)	PREREQUISITE AGENT(S)
Kerendia (finerenone)	One from each group below: Group 1 • Product containing an ACE inhibitor • Product containing an ARB Group 2 • Product containing a DPP-4 • Product containing a GLP-1

	• Product containing an insulin • Product containing metformin • Product containing a SGLT2

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. The patient's medication history includes use of a product containing an ACE inhibitor AND ALL agents containing an ARB as indicated by:
            A. Evidence of a paid claim(s) **OR**
            B. The prescriber has stated the patient has tried a product containing an ACE inhibitor or an ARB and it was discontinued due to lack of effectiveness or an adverse event **OR**
        2. The patient has an intolerance or hypersensitivity to a product containing an ACE inhibitor or an ARB **OR**
        3. The patient has an FDA labeled contraindication to ALL products containing an ACE inhibitor or an ARB **OR**
        4. The prescriber has provided documentation that ALL agents containing an ACE inhibitor AND ALL agents containing an ARB cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
    B. ONE of the following:
        1. The patient's medication history includes use of a product containing a DPP-4, GLP-1, insulin, metformin, or SGLT2 as indicated by:
            A. Evidence of a paid claim(s) **OR**
            B. The prescriber has stated the patient has tried a product containing a DPP-4, GLP-1, insulin, metformin, or SGLT2 and it was discontinued due to lack of effectiveness or an adverse event **OR**
        2. The patient has an intolerance or hypersensitivity to a product containing a DPP-4, GLP-1, insulin, metformin, or SGLT2 **OR**
        3. The patient has an FDA labeled contraindication to ALL products containing a DPP-4, GLP-1, insulin, metformin, or SGLT2 **OR**
        4. The prescriber has provided documentation that ALL agents containing a DPP-4, GLP-1, insulin, metformin, or SGLT2 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
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 than 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

POLICY AGENT SUMMARY STEP THERAPY DETAILS

Final Module	Targeted Agent(s) GPI	Targeted Brand Agent(s) Name	Targeted Generic Agent(s) Name	Multi-Source	Targeted NDCs When Exclusions Exist	Prerequisite Grouping Description	Auto-Continuation Grouping Description	Contraindicated Grouping Description
	303540300003	Kerendia	finerenone tab	M; N; O; Y		Any 1 of Group 1 and Any 1 of Group 2	Auto-continues itself at a GPI12 with 180 days lookback	

• 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				
	040000601001		tetracycline hcl cap	250 MG; 500 MG	M; N; O				
	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				
	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				

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
	040000201006	Doryx; Doryx mpc	doxycycline hyclate tab delayed release	100 MG; 120 MG; 150 MG; 200 MG; 50MG; 60MG; 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				
	040000601003	Tetracycline hcl tab	tetracycline hcl tab	250 MG; 500 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
PA	**TARGET AGENTS (all targets are non-preferred)** **Doxycycline Agents:** **Acticlate*** (doxycycline hyclate tablet) **doxycycline monohydrate*** (capsule, tablet) **Doryx**** (doxycycline hyclate delayed-release tablet) **Doryx MPC** (doxycycline hyclate delayed-release tablet) **doxycycline hyclate*** (capsule, delayed-release tablet, tablet) **LymePak*** (doxycycline hyclate tablet) **Oracea*** (doxycycline delayed-release capsule) **Targadox*** (doxycycline hyclate tablet) **Vibramycin*** (doxycycline hyclate capsule, doxycycline monohydrate suspension) **Minocycline Agents:** **minocycline hydrochloride*** (capsule, tablet) **minocycline hydrochloride extended-release tablet*** **Minolira** (minocycline hydrochloride extended-release tablet)

Solodyn** (minocycline hydrochloride extended-release tablet)
Ximino (minocycline hydrochloride extended-release capsule)

Other Agents:

Seysara (sarecycline hydrochloride tablet)

Tetracycline Agents:

tetracycline capsule*
Tetracycline tablet

* - available as a generic; generic not targeted and designated as preferred
** - available as a generic; generic targeted and designated as non-preferred

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:
      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**

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

   B. ALL of the following:
      1. The patient has an FDA labeled indication for the requested agent and route of administration **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 agent is a preferred oral generic doxycycline agent **OR**
         B. The requested agent is a preferred oral generic minocycline agent **OR**
         C. The requested agent is a preferred oral generic tetracycline agent **OR**
         D. The requested agent is a nonpreferred doxycycline agent or Seysara AND ONE of the following:
            1. The patient has tried and had an inadequate response to a preferred oral generic doxycycline agent **OR**

2. The patient has an intolerance or hypersensitivity to a preferred oral generic doxycycline agent **OR**
3. The patient has an FDA labeled contraindication to ALL preferred oral generic doxycycline agents **OR**
4. There is support that ALL preferred oral generic doxycycline agents are not appropriate for the requested indication **OR**
5. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
    B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
    C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
6. The prescriber has provided documentation 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 **OR**

E. The requested agent is a nonpreferred minocycline agent AND BOTH of the following:
1. ONE of the following:
    A. The patient has tried and had an inadequate response to a preferred oral generic doxycycline 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. There is support that ALL preferred oral generic doxycycline agents are not appropriate for the requested indication **OR**
    E. The patient is currently being treated with the requested agent as indicated by ALL of the following:
        1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
        2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
        3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
    F. The prescriber has provided documentation 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. There is support that ALL preferred oral generic minocycline agents are not appropriate for the requested indication **OR**

E. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
    2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
    3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
F. The prescriber has provided documentation that ALL preferred oral generic minocycline 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**

F. The requested agent is a nonpreferred tetracycline agent AND BOTH of the following:
1. ONE of the following:
    A. The patient has tried and had an inadequate response to a preferred oral generic doxycycline 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. There is support that ALL preferred oral generic doxycycline agents are not appropriate for the requested indication **OR**
    E. The patient is currently being treated with the requested agent as indicated by ALL of the following:
        1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
        2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
        3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
    F. The prescriber has provided documentation 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. There is support that ALL preferred oral generic minocycline agents are not appropriate for the requested indication **OR**
    E. The patient is currently being treated with the requested agent as indicated by ALL of the following:
        1. A statement by the prescriber that the patient is currently taking the requested agent **AND**

	2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that ALL preferred oral generic minocycline agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. If the patient'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 tried and had an inadequate response to benzoyl peroxide agent OR a retinoid agent **OR** C. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to a benzoyl peroxide agent OR a retinoid agent **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that 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** 3. 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** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months

• Program Summary: Procysbi (cysteamine bitartrate)

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
	564000301065	Procysbi	cysteamine bitartrate cap delayed release	25 MG; 75 MG	M; N; O; Y				
	564000301030	Procysbi	cysteamine bitartrate delayed release granules packet	300 MG; 75 MG	M; N; O; Y				

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 nephropathic cystinosis **OR** B. The patient has another FDA labeled indication for the requested agent and route of administration **OR** C. The patient has an indication that is supported in compendia for the requested agent and route of administration **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 **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 patient has tried and had an inadequate response to Cystagon (immediate release cysteamine) **OR** B. The patient has an intolerance or hypersensitivity to Cystagon that is not expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to Cystagon that is not expected to occur with the requested agent **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that Cystagon 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., 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 **Compendia Allowed:** AHFS or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months

• Program Summary: Rayos

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
	221000450006	Rayos	prednisone tab delayed release	1 MG; 2 MG; 5 MG	M; N; O; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Target Agent will be approved when ALL of the following are met: 1. The patient has an 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. ONE of the following: A. The patient has tried and had an inadequate response to BOTH a generic oral prednisone AND at least 1 other different generic oral corticosteroid (e.g., dexamethasone, methylprednisolone, prednisolone) **OR** B. The patient has an intolerance or hypersensitivity to BOTH a generic oral prednisone AND at least 1 other different generic oral corticosteroid that is NOT expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to ALL generic oral corticosteroids that is NOT expected to occur with the requested agent **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL generic oral corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months

• Program Summary: Topical Actinic Keratosis, Basal Cell Carcinoma, Genital Warts Agents

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
	903740353040		diclofenac sodium (actinic keratoses) gel	3 %	M; N; O; Y				
	90372030003710		Fluorouracil Cream 1%		M; N; O; Y				
	90773040003720		Imiquimod Cream 5%	5 %	M; N; O; Y				
	90372030003705	Carac	Fluorouracil Cream 0.5%	0.5 %	M; N; O; Y				
	90372030003730	Efudex	Fluorouracil Cream 5%	5 %	M; N; O; Y				
	90374580004220	Klisyri	Tirbanibulin Ointment	1 %	M; N; O; Y				
	90372030003725	Tolak	Fluorouracil Cream 4%	4 %	M; N; O; Y				
	90773040003715	Zyclara; Zyclara pump	Imiquimod Cream 3.75%	3.75 %	M; N; O; Y				

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
	90773040003710	Zyclara pump	Imiquimod Cream 2.5%	2.5 %	M; N; O; Y				

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
Prior Authorization with Quantity Limit							
90374035304020		Diclofenac Sodium (Actinic Keratoses) Gel 3%	3 %	Actinic keratoses: one 100-gram tube per month for up to 90 days			
90372030003710		Fluorouracil Cream 1%		Multiple actinic or solar keratoses: one 30-gram tube per month for up to 6 weeks			
90773040003720		Imiquimod Cream 5%	5 %	Actinic keratoses: three boxes (36 packets) for up to 16 weeks External genital and perianal warts (EGW) (condyloma acuminata): 12 packets per month for up to 16 weeks Superficial basal cell carcinoma: three boxes (36 packets) for up to 6 weeks			
90372030003705	Carac	Fluorouracil Cream 0.5%	0.5 %	Multiple actinic or solar keratoses: one 30-gram tube per month for up to 4 weeks			
90372030003730	Efudex	Fluorouracil Cream 5%	5 %	Multiple actinic or solar keratoses: one 40-gram tube per month for up to 4 weeks Superficial basal cell carcinomas: two 40-gram tubes per month for up to 12 weeks			
90374580004220	Klisyri	Tirbanibulin Ointment	1 %	Actinic keratoses (face or scalp): 5 packets for up to 90 days			
90372030003725	Tolak	Fluorouracil Cream 4%	4 %	Actinic keratoses: one 40-gram tube per month for up to 4 weeks			
90773040003715	Zyclara; Zyclara pump	Imiquimod Cream 3.75%	3.75 %	Actinic keratoses: two boxes (56 packets) for up to 6 weeks two 7.5 gm pump bottles for up to 6 weeks External genital or perianal warts (EGW) (condyloma acuminata): two boxes (56 packets) for up to 8 weeks two 7.5 gm pump bottles for up to 8 weeks			
90773040003710	Zyclara pump	Imiquimod Cream 2.5%	2.5 %	Actinic keratoses: two 7.5 gm pump bottles for up to 6 weeks			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Prior Authorization with Quantity Limit	**Evaluation**

Effective 5/1/24 for:
Those who were approved after 5/1/24
Those who have started a new plan year since last authorization

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

1. 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. ONE of the following:
   A. BOTH of the following:
      1. The patient has a diagnosis of actinic (solar) keratoses of the face and/or scalp: **AND**
      2. The requested agent is diclofenac 3% gel, Carac (fluorouracil) 0.5% cream, Efudex (fluorouracil) 5% cream, Fluoroplex, Tolak, imiquimod 5%, Zyclara (imiquimod) 3.75% cream, Zyclara 2.5% cream, OR Klisyri **OR**
   B. BOTH of the following:
      1. The patient has a diagnosis of actinic (solar) keratoses of the trunk and/or extremities: **AND**
      2. The requested agent is diclofenac 3% gel, Efudex (fluorouracil) 5% cream, OR Fluoroplex **OR**
   C. BOTH of the following:
      1. The patient has a diagnosis of superficial basal cell carcinoma **AND**
      2. The requested agent is imiquimod 5% OR Efudex (fluorouracil) 5% cream **OR**
   D. BOTH of the following:
      1. The patient has a diagnosis of external genital and/or perianal warts (EGW) / condyloma acuminata **AND**
      2. The requested agent is imiquimod 5% OR Zyclara (imiquimod) 3.75% cream **AND**
3. ONE of the following:
   A. For a diagnosis of actinic keratoses or superficial basal cell carcinoma, ONE of the following:
      1. The patient has tried and had an inadequate response to generic imiquimod 5% cream or fluorouracil solution **OR**
      2. The patient has an intolerance or hypersensitivity to therapy with generic imiquimod 5% cream or fluorouracil solution **OR**
      3. The patient has an FDA labeled contraindication to generic imiquimod 5% cream AND fluorouracil solution **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 generic imiquimod 5% cream AND fluorouracil solution 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. For a diagnosis of external genital warts, ONE of the following:
      1. The patient has tried and had an inadequate response to generic imiquimod 5% cream **OR**
      2. The patient has an intolerance of hypersensitivity to therapy with generic imiquimod 5% cream **OR**

3. The patient has an FDA labeled contraindication to generic imiquimod 5% cream **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 generic imiquimod 5% cream 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: Up to duration in the program quantity limit for the requested indication; or durations above program quantity limit with appropriate supportive information for up to 12 months

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

Effective until 4/30/25 for:
Those with an original PA date 5/1/24-4/30/25 seeking reauthorization AND that have not started a new plan year.

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

1. 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. ONE of the following:
    A. BOTH of the following:
        1. The patient has a diagnosis of actinic (solar) keratoses **AND**
        2. The requested agent is diclofenac 3% gel, Carac (fluorouracil) 0.5% cream, Efudex (fluorouracil) 5% cream, Fluoroplex, Tolak, imiquimod 5%, Zyclara (imiquimod) 3.75% cream, OR Zyclara 2.5% cream **OR**
    B. BOTH of the following:
        1. The patient has a diagnosis of actinic (solar) keratoses of the face and/or scalp: **AND**
        2. The requested agent is diclofenac 3% gel, Carac (fluorouracil) 0.5% cream, Efudex (fluorouracil) 5% cream, Fluoroplex, Tolak, imiquimod 5%, Zyclara (imiquimod) 3.75% cream, Zyclara 2.5% cream, OR Klisyri **OR**
    C. BOTH of the following:
        1. The patient has a diagnosis of actinic (solar) keratoses of the trunk and/or extremities: **AND**
        2. The requested agent is diclofenac 3% gel, Efudex (fluorouracil) 5% cream, OR Fluoroplex **OR**
    D. BOTH of the following:
        1. The patient has a diagnosis of superficial basal cell carcinoma **AND**
        2. The requested agent is imiquimod 5% OR Efudex (fluorouracil) 5% cream **OR**

E. BOTH of the following:
1. The patient has a diagnosis of external genital and/or perianal warts (EGW) / condyloma acuminata **AND**
2. The requested agent is imiquimod 5% OR Zyclara (imiquimod) 3.75% cream **AND**

3. ONE of the following:
A. For a diagnosis of actinic keratoses or superficial basal cell carcinoma, ONE of the following:
1. The patient has tried and had an inadequate response to generic imiquimod 5% cream or fluorouracil solution **OR**
2. The patient has an intolerance or hypersensitivity to therapy with generic imiquimod 5% cream or fluorouracil solution **OR**
3. The patient has an FDA labeled contraindication to generic imiquimod 5% cream AND fluorouracil solution **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 generic imiquimod 5% cream AND fluorouracil solution 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. For a diagnosis of external genital warts, ONE of the following:
1. The patient has tried and had an inadequate response to generic imiquimod 5% cream **OR**
2. The patient has an intolerance of hypersensitivity to therapy with generic imiquimod 5% cream **OR**
3. The patient has an FDA labeled contraindication to generic imiquimod 5% cream **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 generic imiquimod 5% cream 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: Up to duration in the program quantity limit for the requested indication; or durations above program quantity limit with appropriate supportive information for up to 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) and/or duration does NOT exceed the program quantity limit for the requested indication **OR** 2. There is support for therapy with the requested quantity (dose) and/or duration of therapy for the requested indication **Length of Approval:** up to duration in the program quantity limit for the requested indication; or durations above program quantity limit with appropriate supportive information for up to 12 months

● Program Summary: Topical Antifungals, itraconazole, terbinafine

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
11000080100310		Terbinafine HCl Tab 250 MG	250 MG	30	Tablets	30	DAYS				
90150030002020	Ciclodan	Ciclopirox Solution 8%	8 %	6.6	mLs	30	DAYS				
90154037002020	Jublia	Efinaconazole Soln 10%	10 %	4	mLs	30	DAYS				
90156080002010	Kerydin	Tavaborole Soln 5%	5 %	4	mLs	30	DAYS				
11407035002020	Sporanox	Itraconazole Oral Soln 10 MG/ML	10 MG/ML	1200	mLs	30	DAYS				
11407035000120	Sporanox; Sporanox pulsepak	Itraconazole Cap 100 MG	100 MG	120	Capsules	30	DAYS				
11407035000113	Tolsura	Itraconazole Cap 65 MG	65 MG	120	Capsules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
ciclopirox, efinaconazole, tavaborole	**Jublia (efinaconazole), Kerydin (tavaborole), or ciclopirox** will be approved when ALL of the following are met: 1. The patient has a diagnosis of onychomycosis (tinea unguium) **AND** 2. The patient has ONE of the following: diabetes mellitus, peripheral vascular insufficiency, immune deficiency due to medical condition or treatment (e.g., cancer chemotherapy, HIV/AIDS, anti-rejection therapy post organ transplant), pain limiting normal activity, secondary bacterial infection in the surrounding skin or systemic dermatosis with impaired skin integrity **AND** 3. Treatment of the patient's onychomycosis is medically necessary and not entirely for cosmetic reasons **AND** 4. The fungal nail infection is confirmed by laboratory testing (KOH preparation, fungal culture, periodic acid-Schiff [PAS] staining, or polymerase chain reaction [PCR] testing) **AND** 5. ONE of the following: A. The patient has tried and had an inadequate response to ONE oral antifungal agent (itraconazole, terbinafine) **OR** B. The patient has an intolerance or hypersensitivity to ONE oral antifungal agent **OR** C. The patient has an FDA labeled contraindication to ALL oral antifungal agents **OR**

	D. The oral antifungal agents are not clinically appropriate **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that ALL oral antifungal 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** 6. If the requested agent is ciclopirox 8% topical solution, treatment will include removal of the unattached, infected nail(s) by a health care professional **AND** 7. If the requested agent is a brand agent, ONE of the following: A. The patient's medication history includes use of ONE generic antifungal onychomycosis agent (itraconazole, terbinafine, ciclopirox) **OR** B. The patient has an intolerance or hypersensitivity to ONE generic antifungal onychomycosis agent **OR** C. The patient has an FDA labeled contraindication to ALL generic antifungal onychomycosis agents **OR** D. BOTH of the following: 1. The prescriber has stated that the patient has tried a generic antifungal onychomycosis agent **AND** 2. A generic antifungal onychomycosis agent was discontinued due to lack of effectiveness or an adverse event **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that ALL generic antifungal onychomycosis 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** 8. 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.
itraconazole, terbinafine	**Sporanox (itraconazole), Tolsura (itraconazole), or terbinafine** will be approved when BOTH of the following are met: 1. ONE of the following: A. The patient has a diagnosis of onychomycosis (tinea unguium) AND ALL of the following: 1. The requested agent is Sporanox (itraconazole) capsules or terbinafine **AND** 2. The patient has not received treatment for onychomycosis with the requested agent within the past 12 months **AND**

3. The patient has ONE of the following: diabetes mellitus, peripheral vascular insufficiency, immune deficiency due to medical condition or treatment (e.g., cancer, chemotherapy, HIV/AIDS, anti-rejection therapy post organ transplant), pain limiting normal activity, secondary bacterial infection in the surrounding skin, or systemic dermatosis with impaired skin integrity **AND**
4. Treatment of the patient's onychomycosis (tinea unguium) is medically necessary and not entirely for cosmetic reasons **AND**
5. Fungal nail infection is confirmed by laboratory testing (KOH preparation, fungal culture, periodic acid-Schiff [PAS] staining, or polymerase chain reaction [PCR] testing) **AND**
6. 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**
Sporanox capsules	itraconazole capsules

A. 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**
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 ALL generic equivalents 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 diagnosis for the requested agent and route of administration **OR**
C. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND**

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

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

Length of Approval for onychomycosis*: Toenail infection - 3 months; fingernail infection: terbinafine - 6 weeks, Sporanox (itraconazole) capsules - 5 weeks

*Target agents are limited to one approval within a 12 month period

	Length of Approval for other diagnoses (NOT onychomycosis): Sporanox (itraconazole) solution for oropharyngeal or esophageal candidiasis - 6 weeks; all other requests - 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:** up to 12 months

• Program Summary: Topical Corticosteroids

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

POLICY AGENT SUMMARY STEP THERAPY

Final Module	Target Agent GPI	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status	Effective Date	Targeted NDCs When Exclusions Exist
	9055000510		alclometasone dipropionate cream; alclometasone dipropionate oint	0.05 %	M; N; O	Y				
	905500100037		amcinonide cream	0.1 %	M; N; O	N				
	905500100041		amcinonide lotion	0.1 %	M; N; O	N				
	905500100042		amcinonide oint	0.1 %	M; N; O	N				
	905500200537		betamethasone dipropionate augmented cream	0.05 %	M; N; O	Y				

Final Module	Target Agent GPI	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status	Effective Date	Targeted NDCs When Exclusions Exist
	905500200540		betamethasone dipropionate augmented gel	0.05 %	M; N; O	N				
	905500200541		betamethasone dipropionate augmented lotion	0.05 %	M; N; O	Y				
	905500200037		betamethasone dipropionate cream	0.05 %	M; N; O	Y				
	905500200041		betamethasone dipropionate lotion	0.05 %	M; N; O	Y				
	905500200042		betamethasone dipropionate oint	0.05 %	M; N; O	Y				
	90550020103710		Betamethasone Valerate Cream 0.1% (Base Equivalent)	0.1 %	M; N; O	Y				
	90550020104105		Betamethasone Valerate Lotion 0.1% (Base Equivalent)	0.1 %	M; N; O	Y				
	90550020104205		Betamethasone Valerate Oint 0.1% (Base Equivalent)	0.1 %	M; N; O	Y				
	90550025103705		Clobetasol Propionate Cream 0.05%	0.05 %	M; N; O	Y				
	905500251040		clobetasol propionate gel	0.05 %	M; N; O	Y				
	905500251042		clobetasol propionate oint	0.05 %	M; N; O	Y				
	905500251020		clobetasol propionate soln	0.05 %	M; N; O	Y				
	905500350041		desonide lotion	0.05 %	M; N; O	Y				
	905500350042		desonide oint	0.05 %	M; N; O	Y				
	905500501037		diflorasone diacetate cream	0.05 %	M; N; O	M				
	905500501042		diflorasone diacetate oint	0.05 %	M; N; O	Y				
	90550055103705		Fluocinolone Acetonide Cream 0.01%	0.01 %	M; N; O	N; Y				
	90550060003705		Fluocinonide Cream 0.05%	0.05 %	M; N; O	Y				

Final Module	Target Agent GPI	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status	Effective Date	Targeted NDCs When Exclusions Exist
	9055006010		fluocinonide emulsified base cream	0.05 %	M; N; O	Y				
	905500600040		fluocinonide gel	0.05 %	M; N; O	N; Y				
	905500600042		fluocinonide oint	0.05 %	M; N; O	Y				
	905500600020		fluocinonide soln	0.05 %	M; N; O	Y				
	90550065003710		Flurandrenolide Cream 0.05%	0.05 %	M; N; O	N				
	905500650041		flurandrenolide lotion	0.05 %	M; N; O	N; Y				
	905500681037		fluticasone propionate cream	0.05 %	M; N; O	Y				
	905500681041		fluticasone propionate lotion	0.05 %	M; N; O	N; Y				
	905500681042		fluticasone propionate oint	0.005 %	M; N; O	Y				
	905500731037		halobetasol propionate cream	0.05 %	M; N; O	Y				
	905500731042		halobetasol propionate oint	0.05 %	M; N; O	Y				
	905500752037		hydrocortisone valerate cream	0.2 %	M; N; O	Y				
	905500752042		hydrocortisone valerate oint	0.2 %	M; N; O	Y				
	905500821037		mometasone furoate cream	0.1 %	M; N; O	Y				
	905500821042		mometasone furoate oint	0.1 %	M; N; O	Y				
	905500821020		mometasone furoate solution	0.1 %	M; N; O	Y				
	9055008300		prednicarbate oint	0.1 %	M; N; O	N				
	90550085103705		Triamcinolone Acetonide Cream 0.025%	0.025 %	M; N; O	Y				
	90550085103710		Triamcinolone Acetonide Cream 0.1%	0.1 %	M; N; O	Y				
	90550085104105		Triamcinolone Acetonide Lotion 0.025%	0.025 %	M; N; O	Y				
	90550085104110		Triamcinolone Acetonide Lotion 0.1%	0.1 %	M; N; O	Y				

Final Module	Target Agent GPI	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status	Effective Date	Targeted NDCs When Exclusions Exist
	90550085104205		Triamcinolone Acetonide Oint 0.025%	0.025 %	M; N; O	Y				
	90550085104210		Triamcinolone Acetonide Oint 0.1%	0.1 %	M; N; O	Y				
	90550085104215		Triamcinolone Acetonide Oint 0.5%	0.5 %	M; N; O	Y				
	9055007500	Ala-Scalp, Texacort, Hydrocortisone	hydrocorticosone 1%;2%;2.5%	0.5 %; 1 %; 2 %; 2.5 %	M; N; O	M; N; O; Y				
	905500501537	Apexicon e	diflorasone diacetate emollient base cream	0.05 %	M; N; O	N				
	90550073104105	Bryhali	Halobetasol Propionate Lotion 0.01%	0.01 %	M; N; O	N				
	905500551045	Capex	fluocinolone acetonide shampoo	0.01 %	M; N; O	N				
	905500251537	Clobetasol propionate; Clobetasol propionate emo	clobetasol propionate emollient base cream	0.05 %	M; N; O	Y				
	905500251009	Clobex	clobetasol propionate spray	0.05 %	M; N; O	O; Y				
	905500251045	Clobex; Clodan	clobetasol propionate shampoo	0.05 %	M; N; O	O; Y				
	905500251041	Clobex; Impeklo	clobetasol propionate lotion	0.05 %; 0.15 MG/ACT	M; N; O	N; O; Y				
	9055003010	Cloderm	clocortolone pivalate cream	0.1 %	M; N; O	O; Y				
	90550065003705	Cordran	Flurandrenolide Cream 0.025%	0.025 %	M; N; O	N				
	90550065004210	Cordran	Flurandrenolide Oint 0.05%	0.05 %	M; N; O	N				
	905500650046	Cordran	flurandrenolide tape	4 MCG/SQCM	M; N; O	N				
	905500551017	Derma-smoothe/fs body;	fluocinolone acetonide oil	0.01 %	M; N; O	O; Y				

Final Module	Target Agent GPI	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status	Effective Date	Targeted NDCs When Exclusions Exist
		Derma-smoothe/fs scalp								
	905500350037	Desowen; Tridesilon	desonide cream	0.05 %	M; N; O	O; Y				
	905500350040	Desrx	desonide gel	0.05 %	M; N; O	N; Y				
	905500200542	Diprolene	betamethasone dipropionate augmented oint	0.05 %	M; N; O	O; Y				
	9055007000	Halog	halcinonide cream; halcinonide oint; halcinonide soln	0.1 %	M; N; O	N; O; Y				
	90550025103703	Impoyz	Clobetasol Propionate Cream 0.025%	0.025 %	M; N; O	N				
	905500851034	Kenalog	triamcinolone acetonide aerosol soln	0.147 MG/GM	M; N; O	O; Y				
	905500731039	Lexette	halobetasol propionate foam	0.05 %	M; N; O	O; Y				
	9055007530	Locoid	hydrocortisone butyrate cream; hydrocortisone butyrate lotion; hydrocortisone butyrate oint; hydrocortisone butyrate soln	0.1 %	M; N; O	N; O; Y				
	9055007532	Locoid lipocream	hydrocortisone butyrate hydrophilic lipo base cream	0.1 %	M; N; O	M; N; Y				
	905500201039	Luxiq	betamethasone valerate aerosol foam	0.12 %	M; N; O	O; Y				
	905500251039	Olux	clobetasol propionate foam	0.05 %	M; N; O	O; Y				
	905500252039	Olux-e; Tovet	clobetasol propionate emulsion foam	0.05 %	M; N; O	O; Y				
	9055007527	Pandel	hydrocortisone probutate cream	0.1 %	M; N; O	N				
	905500200016	Sernivo	betamethasone dipropionate spray emulsion	0.05 %	M; N; O	N				
	90550055103710	Synalar	Fluocinolone Acetonide Cream 0.025%	0.025 %	M; N; O	O; Y				

Final Module	Target Agent GPI	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status	Effective Date	Targeted NDCs When Exclusions Exist
	905500551042	Synalar	fluocinolone acetonide oint	0.025 %	M; N; O	O; Y				
	905500551020	Synalar	fluocinolone acetonide soln	0.01; 0.01 %	M; N; O	O; Y				
	90550040003705	Topicort	Desoximetasone Cream 0.05%	0.05 %	M; N; O	O; Y				
	90550040003710	Topicort	Desoximetasone Cream 0.25%	0.25 %	M; N; O	O; Y				
	905500400040	Topicort	desoximetasone gel	0.05 %	M; N; O	O; Y				
	90550040004203	Topicort	Desoximetasone Oint 0.05%	0.05 %	M; N; O	O; Y				
	90550040004205	Topicort	Desoximetasone Oint 0.25%	0.25 %	M; N; O	O; Y				
	905500400009	Topicort	desoximetasone spray	0.25 %	M; N; O	O; Y				
	90550085104207	Trianex; Tritocin	Triamcinolone Acetonide Oint 0.05%	0.05 %	M; N; O	Y				
	90550085103720	Triderm	Triamcinolone Acetonide Cream 0.5%	0.5 %	M; N; O	Y				
	90550073104110	Ultravate	Halobetasol Propionate Lotion 0.05%	0.05 %	M; N; O	N				
	90550060003710	Vanos	Fluocinonide Cream 0.1%	0.1 %	M; N; O	O; Y				
	905500350039	Verdeso	desonide foam	0.05 %	M; N; O	N				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
ST	

TARGET AGENT(S)	PREREQUISITE AGENT(S)
Super High Potency (Group 1)	
Betamethasone dipropionate augmented gel **Clobex** 0.05%* (clobetasol propionate) lotion, shampoo, spray **Cordran** 4 mcg/cm^2 (flurandrenolide) tape **Diprolene** 0.05% (betamethasone dipropionate augmented) ointment* **Impeklo** 0.05% (clobetasol propionate) lotion **Lexette, Halobetasol** 0.05% foam **Olux** 0.05% (clobetasol propionate) foam* **Olux-E** 0.05% (clobetasol propionate) emulsion foam*	Any TWO generic topical corticosteroids within the same potency group

Ultravate 0.05% (halobetasol propionate) lotion **Vanos** 0.1% (fluocinonide) cream*	
<u>High Potency (Group 2)</u>	
Amcinonide 0.1% ointment* **ApexiCon E** 0.05% (diflorasone diacetate) emollient cream **Bryhali** 0.01% (halobetasol propionate) lotion **Halog** 0.1% (halcinonide) cream*, ointment, solution **Fluocinonide** 0.05% gel* **Impoyz** 0.025% (clobetasol propionate) cream **Topicort** 0.05% (desoximetasone) gel* **Topicort** 0.25% (desoximetasone) cream*, ointment*, spray*	Any TWO generic topical corticosteroids within the same potency group
<u>Mid-high potency (Group 3)</u>	
Amcinonide 0.1% cream, lotion **Diflorasone diacetate** 0.05% cream **Luxiq** 0.12% (betamethasone valerate) foam* **Topicort** 0.05% (desoximetasone) cream*, ointment*	Any TWO generic topical corticosteroids within the same potency group
<u>Medium potency (Group 4)</u>	
Cloderm 0.1% (clocortolone pivalate) cream* **Cordran** 0.05% (flurandrenolide) ointment* **Kenalog** 0.147 mg/gm (triamcinolone acetonide) spray* **Sernivo** 0.05% (betamethasone dipropionate) spray **Synalar** 0.025% (fluocinolone acetonide) ointment*	Any TWO generic topical corticosteroids within the same potency group
<u>Lower-mid potency (Group 5)</u>	
Cordran 0.025% (flurandrenolide) cream **Cordran** 0.05% (flurandrenolide) cream*, lotion* **Fluticasone propionate** 0.05% lotion* **Desonide** 0.05% gel* **Locoid, Hydrocortisone butyrate** 0.1% lotion*, solution **Locoid Lipocream, Hydrocortisone butyrate hydrophilic** 0.1% cream* **Pandel** 0.1% (hydrocortisone probutate) cream **Prednicarbate** 0.1% ointment **Synalar** 0.025% (fluocinolone acetonide) cream*	Any TWO generic topical corticosteroids within the same potency group
<u>Low potency (Group 6)</u>	
Capex 0.01% (fluocinolone acetonide) shampoo **Derma-Smoothe/FS** 0.01% (fluocinolone acetonide) body oil*, scalp oil* **DesOwen, Tridesilon** 0.05% (desonide) cream* **Synalar** 0.01% (fluocinolone acetonide) solution* **Verdeso** 0.05% (desonide) foam	Any TWO generic topical corticosteroids within the same potency group
<u>Least potent (Group 7)</u>	
Ala-Scalp, Hydrocortisone 2% lotion **Texacort, Hydrocortisone** 2.5% lotion*, solution	Any TWO generic topical corticosteroids within the same potency group

* – available as a generic; included as a prerequisite in the step therapy program

	Target Agent(s) will be approved when ONE of the following is met: 1. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. The patient's medication history includes use of TWO generic topical corticosteroids within the same potency group as indicated by: A. Evidence of a paid claim(s) **OR** B. The prescriber has stated the patient has tried TWO generic topical corticosteroids within the same potency group AND the TWO generic topical corticosteroids were discontinued due to lack of effectiveness or an adverse event **OR** 3. The patient has an intolerance or hypersensitivity to TWO generic topical corticosteroids within the same potency group **OR** 4. The patient has an FDA labeled contraindication to ALL generic topical corticosteroids within the same potency group **OR** 5. The prescriber has provided documentation that ALL generic topical corticosteroids within the same potency group cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
ST	

TARGET AGENT(S)	PREREQUISITE AGENT(S)
Super High Potency (Group 1)	
Betamethasone dipropionate augmented gel **Clobex** 0.05%* (clobetasol propionate) lotion, shampoo, spray **Cordran** 4 mcg/cm^2 (flurandrenolide) tape **Diprolene** 0.05% (betamethasone dipropionate augmented) ointment* **Impeklo** 0.05% (clobetasol propionate) lotion **Lexette, Halobetasol** 0.05% foam **Olux** 0.05% (clobetasol propionate) foam* **Olux-E** 0.05% (clobetasol propionate) emulsion foam* **Ultravate** 0.05% (halobetasol propionate) lotion **Vanos** 0.1% (fluocinonide) cream*	Any TWO generic topical corticosteroids within the same potency group
High Potency (Group 2)	
Amcinonide 0.1% ointment* **ApexiCon E** 0.05% (diflorasone diacetate) emollient cream **Bryhali** 0.01% (halobetasol propionate) lotion **Halog** 0.1% (halcinonide) cream*, ointment, solution **Fluocinonide** 0.05% gel* **Impoyz** 0.025% (clobetasol propionate) cream **Topicort** 0.05% (desoximetasone) gel*	Any TWO generic topical corticosteroids within the same potency group

Topicort 0.25% (desoximetasone) cream*, ointment*, spray*	
Mid-high potency (Group 3)	
Amcinonide 0.1% cream, lotion **Diflorasone diacetate** 0.05% cream **Luxiq** 0.12% (betamethasone valerate) foam* **Topicort** 0.05% (desoximetasone) cream*, ointment*	Any TWO generic topical corticosteroids within the same potency group
Medium potency (Group 4)	
Cloderm 0.1% (clocortolone pivalate) cream* **Cordran** 0.05% (flurandrenolide) ointment* **Kenalog** 0.147 mg/gm (triamcinolone acetonide) spray* **Sernivo** 0.05% (betamethasone dipropionate) spray **Synalar** 0.025% (fluocinolone acetonide) ointment*	Any TWO generic topical corticosteroids within the same potency group
Lower-mid potency (Group 5)	
Cordran 0.025% (flurandrenolide) cream **Cordran** 0.05% (flurandrenolide) cream*, lotion* **Fluticasone propionate** 0.05% lotion* **Desonide** 0.05% gel* **Locoid, Hydrocortisone butyrate** 0.1% lotion*, solution **Locoid Lipocream, Hydrocortisone butyrate hydrophilic** 0.1% cream* **Pandel** 0.1% (hydrocortisone probutate) cream **Prednicarbate** 0.1% ointment **Synalar** 0.025% (fluocinolone acetonide) cream*	Any TWO generic topical corticosteroids within the same potency group
Low potency (Group 6)	
Capex 0.01% (fluocinolone acetonide) shampoo **Derma-Smoothe/FS** 0.01% (fluocinolone acetonide) body oil*, scalp oil* **DesOwen, Tridesilon** 0.05% (desonide) cream* **Synalar** 0.01% (fluocinolone acetonide) solution* **Verdeso** 0.05% (desonide) foam	Any TWO generic topical corticosteroids within the same potency group
Least potent (Group 7)	
Ala-Scalp, Hydrocortisone 2% lotion **Texacort, Hydrocortisone** 2.5% lotion*, solution	Any TWO generic topical corticosteroids within the same potency group

* – available as a generic; included as a prerequisite in the step therapy program

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

1. The patient is currently being treated with the requested agent as indicated by ALL of the following:
   A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
   B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
   C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
2. The patient's medication history includes use of TWO generic topical corticosteroids within the same potency group as indicated by:
   A. Evidence of a paid claim(s) **OR**

	B. The prescriber has stated the patient has tried TWO generic topical corticosteroids within the same potency group AND the TWO generic topical corticosteroids were discontinued due to lack of effectiveness or an adverse event **OR** 3. The patient has an intolerance or hypersensitivity to TWO generic topical corticosteroids within the same potency group **OR** 4. The patient has an FDA labeled contraindication to ALL generic topical corticosteroids within the same potency group **OR** 5. The prescriber has provided documentation that ALL generic topical corticosteroids within the same potency group cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

• Program Summary: Topical Doxepin

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
90220015103710	Prudoxin; Zonalon	Doxepin HCl Cream 5%	5 %	45	Grams	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 moderate pruritus associated with atopic dermatitis AND ONE of the following: 1. The patient has tried and had an inadequate response to BOTH a topical corticosteroid AND a topical calcineurin inhibitor **OR** 2. The patient has an intolerance or hypersensitivity to a topical corticosteroid AND a topical calcineurin inhibitor **OR** 3. The patient has an FDA labeled contraindication to ALL topical corticosteroids AND topical calcineurin inhibitors **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 topical corticosteroids AND topical calcineurin inhibitors cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to

achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

B. The patient has a diagnosis of moderate pruritus associated with lichen simplex chronicus AND ONE of the following:
    1. The patient has tried and had an inadequate response to ONE topical corticosteroid **OR**
    2. The patient has an intolerance or hypersensitivity to ONE topical corticosteroid **OR**
    3. The patient has an FDA labeled contraindication to ALL topical corticosteroids **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 topical corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

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

D. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND**

2. If the patient has an FDA 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 (listed below), then ONE of the following:

Brand	Generic
Prudoxin cream Zonalon cream	doxepin hydrochloride cream 5%

    A. The patient has an intolerance or hypersensitivity to the generic that is not expected to occur with the brand agent **OR**
    B. The patient has an FDA labeled contraindication to the generic that is not expected to occur with the brand agent **OR**
    C. There is support for the use of the requested brand agent over the generic **AND**
4. The patient will NOT be using the requested agent in combination with another topical doxepin agent for the requested indication **AND**
5. The patient has NOT already received 8 days of therapy with a topical doxepin agent for the current course of therapy **AND**
6. The patient does NOT have any FDA labeled contraindications to the requested agent

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

Length of Approval: pruritus associated with atopic dermatitis or lichen simplex chronicus - 1 month; or all other requests - 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. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **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: 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	Age Limit	Effective Date	Term Date
61200010100305		Benzphetamine HCl Tab 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				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
61259902507420	Contrave	Naltrexone HCl-Bupropion HCl Tab ER 12HR 8-90 MG	8-90 MG	120	Tablets	30	DAYS				
61200070100305	Lomaira	Phentermine HCl Tab 8 MG	8 MG	90	Tablets	30	DAYS				
61209902307040	Qsymia	Phentermine HCl-Topiramate Cap ER 24HR 11.25-69 MG	11.25-69 MG	30	Capsules	30	DAYS				
61209902307050	Qsymia	Phentermine HCl-Topiramate Cap ER 24HR 15-92 MG	15-92 MG	30	Capsules	30	DAYS				
61209902307020	Qsymia	Phentermine HCl-Topiramate Cap ER 24HR 3.75-23 MG	3.75-23 MG	30	Capsules	30	DAYS				
61209902307030	Qsymia	Phentermine HCl-Topiramate Cap ER 24HR 7.5-46 MG	7.5-46 MG	30	Capsules	30	DAYS				
61253560000120	Xenical	Orlistat Cap 120 MG	120 MG	90	Capsules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**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 an adult (18 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 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 pediatric (12 to 17 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 weight-related comorbidity/risk factor/complication (e.g., hypertension, dyslipidemia, type 2 diabetes, or obstructive sleep apnea) **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 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**
   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 (e.g., benzphetamine, Contrave, diethylpropion, phendimetrazine, phentermine, Qsymia, Xenical/Orlistat) in the past 12 months **OR**
   B. BOTH of the following:
      1. The patient has tried a targeted weight loss agent for a previous course of therapy in the past 12 months **AND**
      2. The prescriber anticipates success with repeating therapy with any targeted weight loss agent **AND**
4. ONE of the following:
   A. The requested agent is benzphetamine, 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 a pediatric patient, the patient has experienced a reduction of at least 5% of baseline BMI (prior to initiation of the requested agent) **OR**
            2. For an adult, 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**
         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. There is support for 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 weight loss agent (e.g., Contrave, phentermine, Qsymia, Xenical, Saxenda, Wegovy, Zepbound) 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.

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. The requested agent is Qsymia AND ONE of the following:
      1. For a pediatric patient (12 to 17 years of age), the patient has achieved and maintained a reduction of greater than or equal to 5% of baseline BMI (prior to initiation of the requested agent) **OR**
      2. For an adult (18 years of age and over), the patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of the requested agent) **OR**
      3. BOTH of the following:
         A. ONE of the following:
            1. For a pediatric patient, the patient has achieved and maintained less than a 5% reduction of baseline BMI (prior to initiation of the requested agent) **OR**
            2. For an adult, the patient has achieved and maintained a weight loss less than 5% from baseline (prior to initiation of requested agent) **AND**
         B. BOTH of the following:
            1. 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**
            2. The patient has received less than 12 weeks of therapy on the 15mg/92mg strength **OR**
   C. The requested agent is Xenical (or Orlistat) AND 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 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 pediatric, then 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 weight loss agent (e.g., Contrave, phentermine, Qsymia, Xenical, Saxenda, Wegovy, Zepbound) 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
	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: 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	Age Limit	Effective Date	Term Date
Saxenda	Liraglutide (Weight Mngmt) Soln Pen-Inj 18 MG/3ML (6 MG/ML)	18 MG/3ML	15	mLs	30	DAYS					
Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	1 MG/0.5ML	8	Pens	180	DAYS					
Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	0.25 MG/0.5ML	8	Pens	180	DAYS					
Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	2.4 MG/0.75ML	4	Pens	28	DAYS					
Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	1.7 MG/0.75ML	4	Pens	28	DAYS					
Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	0.5 MG/0.5ML	8	Pens	180	DAYS					
Zepbound	tirzepatide (weight mngmt) soln	5 MG/0.5ML	4	Vials	28	DAYS					
Zepbound	tirzepatide (weight mngmt) soln	2.5 MG/0.5ML	4	Vials	180	DAYS					
Zepbound	tirzepatide (weight mngmt) soln auto-injector	12.5 MG/0.5ML	4	Pens	28	DAYS					
Zepbound	tirzepatide (weight mngmt) soln auto-injector	15 MG/0.5ML	4	Pens	28	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
Zepbound	tirzepatide (weight mngmt) soln auto-injector	5 MG/0.5ML	4	Pens	28	DAYS					
Zepbound	tirzepatide (weight mngmt) soln auto-injector	2.5 MG/0.5ML	4	Pens	180	DAYS					
Zepbound	tirzepatide (weight mngmt) soln auto-injector	10 MG/0.5ML	4	Pens	28	DAYS					
Zepbound	tirzepatide (weight mngmt) soln auto-injector	7.5 MG/0.5ML	4	Pens	28	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Initial Evaluation** **Target Agent(s)** will be approved when ALL the following are met: 1. ONE of the following: A. The patient has a diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) or metabolic dysfunction associated steatohepatitis (MASH) (medical records required) AND ALL of the following: 1. The patient has stage F2 or F3 fibrosis as confirmed by BOTH of the following (prior to therapy with the requested agent): A. A FIB-4 score consistent with stage F2 or F3 fibrosis adjusted for age **AND** B. The patient has ONE of the following: 1. A liver biopsy **OR** 2. Vibration-controlled transient elastography (VCTE, e.g., Fibroscan) **OR** 3. Enhanced liver fibrosis (ELF) score **OR** 4. Magnetic resonance elastography (MRE) **AND** 2. The requested agent is Wegovy **AND** 3. The patient is an adult (18 years of age or over) **AND** 4. The patient has ONE of the following: A. A BMI greater than 25 kg/m^2 **OR** B. A BMI greater than 23 kg/m^2 if the patient is of South Asian, Southeast Asian, or East Asian descent **AND** 5. ONE of the following: A. If the patient's sex is female then the patient's alcohol consumption is less than 20 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits) **OR**

B. If the patient's sex is male then the patient's alcohol consumption is less than 30 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits) **AND**

6. The patient does NOT have ANY of the following:
   A. Decompensated cirrhosis **AND**
   B. Moderate to severe hepatic impairment (Child-Pugh Class B or C) **AND**
   C. Any other liver disease (e.g., Wilson's disease, hepatocellular carcinoma, hepatitis) **AND**
7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hepatologist, gastroenterologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **OR**

B. The 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 is FDA labeled for the requested indication and route of administration **AND**
2. The patient has a history of ONE of the following:
   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 will use optimized pharmacotherapy for established cardiovascular disease in combination with the requested agent **OR**

C. 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 new to therapy, not previously approved by Prime, or attempting a repeat weight loss course of therapy **AND**
3. ONE of the following:
   A. The patient is an adult (18 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**
      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 pediatric (12 to 17 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 weight-related comorbidity/risk factor/complication **AND**
4. 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 **AND**
5. ONE of the following:
   A. The patient has NOT tried a targeted weight loss agent (e.g., Saxenda, Wegovy, Zepbound) in the past 12 months **OR**
   B. BOTH of the following:
      1. The patient has tried a targeted weight loss agent for a previous course of therapy in the past 12 months **AND**

2. The prescriber anticipates success with repeating therapy with any targeted weight loss agent **AND**

6. If the requested agent is Saxenda, then ONE of the following:
   A. The patient is an adult (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 17 years of age) AND BOTH of the following:
      1. The patient does NOT have 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**
7. 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. The patient is an adult (18 years of age or over) AND has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR**
   D. The patient is pediatric (12 to 17 years of age) AND has achieved and maintained a reduction in BMI of at least 5% from baseline (prior to initiation of pharmacotherapy) **AND**
8. 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**

D. 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. BOTH of the following:
   A. The patient is currently on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **AND**
   B. The patient will continue the weight loss regimen in combination with the requested agent **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 (e.g., Saxenda, Wegovy, Zepbound, Mounjaro, Ozempic, Trulicity) **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 (12 to 17 years of age): 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 has a diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) or metabolic dysfunction associated steatohepatitis (MASH) (medical records required) AND ALL of the following:
        1. The requested agent is Wegovy **AND**
        2. ONE of the following:
            A. If the patient's sex is female then the patient's alcohol consumption is less than 20 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits) **OR**
            B. If the patient's sex is male then the patient's alcohol consumption is less than 30 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits) **AND**
        3. The patient does NOT have ANY of the following:
            A. Decompensated cirrhosis **AND**
            B. Moderate to severe hepatic impairment (Child-Pugh Class B or C) **AND**
            C. Any other liver disease (e.g., Wilson's disease, hepatocellular carcinoma, hepatitis) **AND**
        4. 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., hepatologist, gastroenterologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **OR**
    B. The 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 AND ALL of the following:
        1. The requested agent is FDA labeled for the requested indication and route of administration **AND**
        2. The patient will use optimized pharmacotherapy for established cardiovascular disease in combination with the requested agent **AND**
        3. The patient has had clinical benefit with the requested agent **OR**
    C. 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 pediatric (12 to 17 years of age), then the current BMI is greater than 85th percentile for age and sex **AND**
        4. 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 the initiation of requested agent) **OR**
            B. If the requested agent is Saxenda, then ONE of the following:

	1. The patient is pediatric (12 to 17 years of age) AND BOTH of the following: A. The patient does NOT have type 2 diabetes **AND** B. 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** 2. The patient is an adult (18 years of age or over) AND has achieved and maintained a weight loss greater than or equal to 4% from baseline (prior to initiation of pharmacotherapy) **OR** C. 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 received less than 52 weeks of therapy on the maximum-tolerated dose **OR** B. The patient is pediatric (12 to 17 years of age) AND has achieved and maintained a reduction in BMI of at least 5% from baseline (prior to initiation of pharmacotherapy) **OR** D. If the requested agent is Zepbound, the patient has received less than 52 weeks of therapy on the maximum-tolerated dose **OR** D. The patient has another FDA labeled indication for the requested agent and route of administration AND has had clinical benefit with the requested agent **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. BOTH of the following: A. The patient is currently on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **AND** B. The patient will continue the weight loss regimen in combination with the requested agent **AND** 5. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist (e.g., Saxenda, Wegovy, Zepbound, Mounjaro, Ozempic, Trulicity) **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL	**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: Zeposia (ozanimod)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

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

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Zeposia PA with MS Step	**Immunomodulatory Agent Step Table**

Formulary ID	Step 1a	Step 1b (Directed to ONE TNF inhibitor) NOTE: Please see Step 1a for preferred TNF inhibitors	Step 2 (Directed to ONE Step 1 agent)	Step 3a (Directed to TWO Step 1 agents)	Step 3b (Directed to TWO agents from Step 1 and/or Step 2)	Step 3c (Directed to THREE Step 1 agents)
FlexRx, GenRx, KeyRx, BasicRx	SC: adalimumab product(s)**, Entyvio, Skyrizi, Stelara, Tremfya	Oral: Rinvoq, Xeljanz*, Xeljanz XR*	SC: Omvoh Simponi (an adalimumab product** is a	SC: Zymfentra Oral: Zeposia	N/A	Oral: Velsipity

			required Step 1 agent)			
FocusRx	SC: adalimumab product(s)***, Entyvio, Skyrizi, Stelara, Tremfya	Oral: Rinvoq, Xeljanz*, Xeljanz XR*	SC: Omvoh Simponi (an adalimumab product*** is a required Step 1 agent)	SC: Zymfentra Oral: Zeposia	N/A	Oral: Velsipity

* A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product
** Allowable preferred adalimumab product(s): Adalimumab-aaty, Adalimumab-adaz, Hadlima, Simlandi
*** Allowable preferred adalimumab product(s): Adalimumab-aaty, Adalimumab-adaz, Hadlima, Humira, Simlandi

Initial Evaluation

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

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

Agents Eligible for Continuation of Therapy
Zeposia (ozanimod)

   A. The patient has been treated with the requested agent within the past 90 days **OR**
   B. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR**
2. BOTH of the following:
   A. The patient has a diagnosis of multiple sclerosis (MS) **AND**
   B. The patient will NOT be using the requested agent in combination with another MS disease modifying agent (DMA) (Please refer to "Multiple Sclerosis Disease Modifying Agents" contraindicated use table) **OR**
3. The patient has a diagnosis of moderately to severely active ulcerative colitis (UC) AND ALL of the following:
   A. ONE of the following:
      1. The patient is currently being treated with the requested agent as indicated by ALL of the following:
         A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
         B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
         C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
      2. The patient has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC **OR**
      3. The patient has severely active ulcerative colitis **OR**
      4. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of UC **OR**
      5. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of UC **OR**
      6. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of UC **OR**

7. The prescriber has provided documentation that ALL of the conventional agents (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, steroid suppositories, sulfasalazine) used in the treatment of UC cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

B. ONE of the following:
   1. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      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**
   2. The patient has tried and had an inadequate response to TWO Step 1 immunomodulatory agents (see Immunomodulatory Agent Step table) **OR**
   3. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to at least TWO Step 1a and/or Step 1b immunomodulatory agents **OR**
   4. The patient has an FDA labeled contraindication to ALL Step 1 immunomodulatory agents **OR**
   5. The prescriber has provided documentation that ALL Step 1a AND Step1b immunomodulatory agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

C. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) (Please refer to "Immunomodulatory Agents NOT to be used Concomitantly" table) **AND**

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

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

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

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

Length of Approval: 12 months. NOTE: The starter dose can be approved for the FDA labeled starting dose and the maintenance dose can be approved for the remainder of 12 months

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

Renewal Evaluation

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

	1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. ONE of the following: A. BOTH of the following: 1. The patient has a diagnosis of multiple sclerosis (MS) **AND** 2. The patient will not be using the requested agent in combination with another MS disease modifying agent (DMA) (Please refer to "Multiple Sclerosis Disease Modifying Agents" contraindicated use table) **OR** B. The patient has a diagnosis of ulcerative colitis AND ALL of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (see "Immunomodulatory Agents NOT to be used Concomitantly" table) **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Zeposia PA through preferred and Zeposia PA with MS step	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** 3. ALL of the following: 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. NOTE: The starter dose can be approved for the FDA labeled starting dose and the maintenance dose can be approved for the remainder of 12 months.

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
MS Disease Modifying Agents
Aubagio (teriflunomide)
Avonex (interferon b-1a)
Bafiertam (monomethyl fumarate)
Betaseron (interferon b-1b)
Briumvi (ublituximab-xiiy)
Copaxone (glatiramer)

Contraindicated as Concomitant Therapy
dimethyl fumarate Extavia (interferon b-1b) fingolimod Gilenya (fingolimod) Glatopa (glatiramer) glatiramer Kesimpta (ofatumumab) Mavenclad (cladribine) Mayzent (siponimod) Plegridy (peginterferon b-1a) Ponvory (ponesimod) Rebif (interferon b-1a) Tascenso ODT (fingolimod) Tecfidera (dimethyl fumarate) Vumerity (diroximel fumarate) Zeposia (ozanimod) **Immunomodulatory Agents NOT to be used concomitantly** Abrilada (adalimumab-afzb) Actemra (tocilizumab) Adalimumab Adbry (tralokinumab-ldrm) Amjevita (adalimumab-atto) Arcalyst (rilonacept) Avsola (infliximab-axxq) Benlysta (belimumab) Bimzelx (bimekizumab-bkzx) Cibinqo (abrocitinib) Cimzia (certolizumab) Cinqair (reslizumab) Cosentyx (secukinumab) Cyltezo (adalimumab-adbm) Dupixent (dupilumab) Enbrel (etanercept) Entyvio (vedolizumab) Fasenra (benralizumab) Hadlima (adalimumab-bwwd) Hulio (adalimumab-fkjp) Humira (adalimumab) Hyrimoz (adalimumab-adaz) Idacio (adalimumab-aacf) Ilaris (canakinumab) Ilumya (tildrakizumab-asmn) Inflectra (infliximab-dyyb) Infliximab Kevzara (sarilumab) Kineret (anakinra) Leqselvi (deuruxolitinib) Litfulo (ritlecitinib) Nemluvio (nemolizumab-ilto)

Contraindicated as Concomitant Therapy
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Pyzchiva (ustekinumab-ttwe)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Saphnelo (anifrolumab-fnia)
Selarsdi (ustekinumab-aekn)
Siliq (brodalumab)
Simlandi (adalimumab-ryvk)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Spevigo (spesolimab-sbzo) subcutaneous injection
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: Zilbrysq (zilucoplan)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
16.6 MG/0.416ML	28	Syringes	28	DAYS							
23 MG/0.574ML	28	Syringes	28	DAYS							
32.4 MG/0.81ML	28	Syringes	28	DAYS							

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of generalized Myasthenia Gravis (gMG) AND ALL of the following: 1. The patient has a positive serological test for anti-AChR antibodies (medical records required) **AND** 2. The patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification class of II-IVb **AND** 3. The patient has a MG-Activities of Daily Living total score of greater than or equal to 6 **AND** 4. ONE of the following: A. The patient's current medications have been assessed and any medications known to exacerbate myasthenia gravis (e.g., beta blockers, procainamide, quinidine, magnesium, anti-programmed death receptor-1 monoclonal antibodies, hydroxychloroquine, aminoglycosides) have been discontinued **OR** B. Discontinuation of the offending agent is NOT clinically appropriate **AND** 5. ONE of the following: A. The patient has tried and had an inadequate response to at least ONE conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **OR** B. The patient has an intolerance or hypersensitivity to ONE conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **OR** C. The patient has an FDA labeled contraindication to ALL conventional agents used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that conventional agents used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) cannot be used due to a documented medical condition or comorbid condition that is likely

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

F. The patient required chronic intravenous immunoglobulin (IVIG) **OR**

G. The patient required chronic plasmapheresis/plasma exchange **AND**

6. If the client has preferred agent(s), then ONE of the following:

A. The patient has tried and had an inadequate response to Ultomiris (ravulizumab-cwvz), Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod), or Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) **OR**

B. The patient has an intolerance or hypersensitivity to Ultomiris (ravulizumab-cwvz), Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod), or Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) **OR**

C. The patient has an FDA labeled contraindication to ALL of the following:

1. Ultomiris (ravulizumab-cwvz) **AND**
2. Rystiggo (rozanolixizumab-noli) **AND**
3. Vyvgart (efgartigimod) **AND**
4. Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) **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 Ultomiris (ravulizumab-cwvz), Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod), AND Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) 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**

3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
4. The patient will NOT be using the requested agent in combination with Rystiggo (rozanolixizumab-noli), Soliris (eculizumab), Ultomiris (ravulizumab-cwvz), Vyvgart (efgartigimod), or Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) for the requested indication **AND**
5. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 3 months

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

Renewal Evaluation

	Target Agent(s) will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [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 prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient will NOT be using the requested agent in combination with Rystiggo (rozanolixizumab-noli), Soliris (eculizumab), Ultomiris (ravulizumab-cwvz), Vyvgart (efgartigimod), or Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) for the requested indication **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
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:** up to 12 months