COMMERCIAL PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: October 1, 2023 Notification Posted: August 17, 2023

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

• Program Summary: Daybue (trofinetide)

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
74653075002020	Daybue	trofinetide oral soln	200 MG/ML	8	Bottles	30	DAYS				05-18-2023	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy**: Daybue 1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. BOTH of the following: 1. The patient has a diagnosis of classic/typical Rett syndrome (RTT) **AND** 2. The patient has a disease-causing mutation in the MECP2 gene **AND** 2. If the patient has an FDA approved indication, then ONE of the following**:** A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient's weight is 9 kg or greater **AND** 4. The patient has a baseline (prior to therapy with the requested agent) Rett Syndrome Behavior Questionnaire (RSBQ) and Clinical Global Impression-Improvement (CGI-I) **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., geneticist, neurologist, pediatrician) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 3 months

Module	Clinical Criteria for Approval
	NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent (e.g., improvement in RSBQ or CGI-I) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., geneticist, neurologist, pediatrician) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Filspari (sparsentan)

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
56483065000320	Filspari	sparsentan tab	200 MG	30	Tablets	30	DAYS				05-18-2023	
56483065000340	Filspari	sparsentan tab	400 MG	30	Tablets	30	DAYS				05-18-2023	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy **AND** 2. ONE of the following: A. The patient has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g **OR** B. The patient has proteinuria greater than or equal to 1 g/day **AND** 3. The patient's eGFR is greater than or equal to 30 mL/min/1.73 m^2 **AND** 4. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 5. ONE of the following A. The patient has tried and had an inadequate response after at least 3 months of therapy with 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, that is not expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to ALL ACEI or ARB 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 ACEI and 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** 6. 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 **OR** C. The patient has an FDA labeled contraindication to ALL glucocorticoids **OR** D. The prescriber has provided information to 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 glucocorticoids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse

Module	Clinical Criteria for Approval
	reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 7. The patient will NOT use the requested agent in combination with an ACEI, ARB, endothelin receptor antagonist (ERA, e.g., bosentan), or aliskiren **AND** 8. The patient does NOT have any of the following: A. IgAN secondary to another condition B. Chronic kidney disease C. History of organ transplantation, with exception of corneal transplants D. History of heart failure or previous hospitalization for heart failure or unexplained dyspnea, orthopnea, paroxysmal nocturnal dyspnea, ascites, and/or peripheral edema E. Clinically significant cerebrovascular disease or coronary artery disease within 6 months F. Jaundice, hepatitis, or known hepatobiliary disease or elevations of transaminases (ALT/AST) greater than 2 times upper limit of normal at screening G. History of malignancy other than adequately treated basal cell or squamous cell skin cancer or cervical carcinoma within the past 2 years H. Hematocrit value less than 27% (0.27 V/V) or hemoglobin value less than 9 g/dL (90 g/L) I. Potassium greater than 5.5 mEq/L (5.5 mmol/L) **AND** 9. 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** 10. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 9 months NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had improvements or stabilization 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** 3. The patient will NOT use the requested agent in combination with an angiotensin-converting-enzyme inhibitor (ACEI, e.g., benazepril, lisinopril), angiotensin II blocker (ARB, e.g., losartan), endothelin receptor antagonist (ERA, e.g., bosentan), or aliskiren **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR**

Module	Clinical Criteria for Approval
	2. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval:** Initial, 9 months; Renewal, 12 months

• Program Summary: Jesduvroq (daprodustat)

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
TBD	Jesduvroq	Daprodustat 2 mg tablets		30	Tablets	30	DAYS				05-18-2023	
TBD	Jesduvroq	Daprodustat 4 mg tablets		30	Tablets	30	DAYS				05-18-2023	
TBD	Jesduvroq	Daprodustat 6 mg tablets		60	Tablets	30	DAYS				05-18-2023	
TBD	Jesduvroq	Daprodustat 8 mg tablets		90	Tablets	30	DAYS				05-18-2023	
TBD	Jesduvroq	Daprodustat 1 mg tablets		30	Tablets	30	DAYS				05-18-2023	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR**

Module	Clinical Criteria for Approval
	B. The patient has a diagnosis of chronic kidney disease AND ALL of the following: 1. The patient has been on dialysis for at least 4 months **AND** 2. The patient's hemoglobin was measured in the previous 4 weeks **AND** 3. ONE of the following: A. The patient is currently using an erythropoietin receptor agonist (ESA) (e.g., Aranesp, Epogen, Mircera, Procrit, Retacrit) AND the patient's hemoglobin does NOT exceed 12 g/dL (medical records required) **OR** B. The patient is NOT currently using an ESA AND the patient's hemoglobin is less than or equal to 11 g/dL **AND** 4. The patient's ferritin was measured in the previous 4 weeks **AND** 5. The patient's ferritin is greater than 100 mcg/L **AND** 6. ONE of the following: A. The patient's transferrin saturation (TSAT) is greater than 20% **OR** B. The patient's TSTAT is 20% or lower and is due to recent infection **AND** 7. Other causes of anemia (e.g., pernicious anemia, thalassemia major, sickle cell) have been addressed **OR** C. The patient has another FDA approved indication for the requested agent and route of administration **AND** 2. If the patient has an FDA approved indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist) or 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 an ESA (e.g., Aranesp, Epogen, Mircera, Procrit, Retacrit) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months NOTE If Quantity Limit applies, please refer to Quantity Limit criteria **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent (e.g., increase in hemoglobin) **AND** 3. The patient's hemoglobin was measured within the previous 4 weeks **AND** 4. The patient's hemoglobin does NOT exceed 12 g/dL (medical records required) **AND** 5. 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** 6. The patient will NOT be using the requested agent in combination with an ESA (e.g., Aranesp, Epogen, Mircera, Procrit, Retacrit) **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
QL with PA	**Evaluation** **Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested 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

• Program Summary: Skyclarys (omaveloxolone)

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
74135060000120	Skyclarys	omaveloxolone cap	50 MG	90	Capsules	30	DAYS				05-18-2023	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** Skyclarys 1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. The patient has a diagnosis of Friedreich ataxia (FA, FRDA) with genetic analysis confirming mutation in the frataxin (FXN) gene **AND** 2. The prescriber has assessed the patient's baseline (prior to therapy with the requested agent) neurological function (as scored by the modified Friedreich Ataxia Rating Scale [mFARS]) **AND** 3. If the patient has an FDA approved indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**

Module	Clinical Criteria for Approval
	B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, geneticist, neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval**: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had improvements or stabilization with the requested agent (e.g., improvement in mFARS score) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, geneticist, neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval**: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

POLICIES REVISED

• Program Summary: Angiotensin II Receptor Agonists (ARBs), Renin Inhibitors and Combinations

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

Angiotensin II Receptor Antagonists (ARBs), Renin Inhibitors, and Combinations Step Therapy (1-Step)

TARGET AGENT(S)
Atacand® (candesartan) tablet[a]
Atacand HCT® (candesartan/hydrochlorothiazide) tablet[a]
Avapro® (irbesartan)[a]
Avalide® (irbesartan/hydrochlorothiazide) tablet[a]
Azor® (olmesartan/amlodipine) tablet[a]
Benicar® (olmesartan) tablet[a]
Benicar HCT® (olmesartan/hydrochlorothiazide) tablet[a]
Cozaar® (losartan) tablet[a]
Diovan® (valsartan) tablet[a]
Diovan HCT® (valsartan/hydrochlorothiazide) tablet[a]
Edarbi® (azilsartan) tablet
Edarbyclor® (azilsartan/chlorthalidone) tablet
Exforge® (valsartan/amlodipine) tablet[a]
Exforge HCT® (valsartan/amlodipine/hydrochlorothiazide) tablet[a]
Hyzaar® (losartan/hydrochlorothiazide) tablet[a]
Micardis® (telmisartan) tablet[a]
Micardis HCT® (telmisartan/hydrochrolothiazide) tablet[a]
Tribenzor® (olmesartan/amlodipine/hydrochlorothiazide) tablet[a]
Twynsta® (telmisartan/amlodipine) tablet[a]
Tekturna® (aliskiren) tablet[a]
Tekturna HCT® (aliskiren/hydrochlorothiazide) tablet
Valsartan oral suspension^
a – generic available included as a prerequisite agent for step therapy program
^ - Branded generic products available; targeted in the step therapy program

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

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

1. Information has been provided that indicates the patient is currently being treated with the requested agent within the past 90 days
   OR
2. The prescriber states the patient is currently being treated with the requested agent within the past 90 days AND is at risk if therapy is changed
   OR
3. The patient is currently being treated with the requested agent as indicated by ALL of the following:
   A. A statement by the prescriber that the patient is currently taking the requested agent
      AND
   B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
      AND
   C. The prescriber states that a change in therapy is expected to be ineffective or cause harm

   OR
4. The patient's medication history includes use of a generic ACEI, generic ACEI combination, generic ARB, generic ARB combination, or generic renin inhibitor product
   OR

5. The patient has an intolerance or hypersensitivity to a generic ACEI, generic ACEI combination, generic ARB, generic ARB combination, or generic renin inhibitor product
   OR
6. The patient has an FDA labeled contraindication to ALL generic ACEIs, generic ACEI combinations, generic ARBs, generic ARB combinations, or generic renin inhibitor products
   OR
7. BOTH of the following:
   A. The prescriber has stated that the patient has tried a generic ACEI, generic ACEI combination, generic ARB, generic ARB combination, or generic renin inhibitor product
      AND
   B. A generic ACEI, generic ACEI combination, generic ARB, generic ARB combination, or generic renin inhibitor product was discontinued due to lack of effectiveness or an adverse event
   OR
8. The prescriber has provided documentation that ALL generic ACEI, generic ACEI combination, generic ARB, generic ARB combination, or generic renin inhibitor products cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

Length of Approval: 12 months

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

• Program Summary: Antifungals

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
11507040100320	Brexafemme	Ibrexafungerp Citrate Tab	150 MG	4	Tablets	90	DAYS					
1140805000B220	Vivjoa	Oteseconazole Cap Therapy Pack	150 MG	18	Capsules	180	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Brexafemme	**Evaluation** **Brexafemme (ibrexafungerp)** will be approved when BOTH of the following are met 1. ONE of the following: A. BOTH of the following: 1. The patient is an adult or post-menarchal pediatric patient AND ONE of the following: A. The requested agent will be used for the treatment of vulvovaginal candidiasis (VVC) **OR** B. BOTH of the following: 1. The patient is using the requested agent to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) **AND** 2. The patient has experienced greater than or equal to 3 episodes of vulvovaginal candidiasis (VVC) in a 12 months period **AND**

Module	Clinical Criteria for Approval
	2. ONE of the following: A. The patient has tried and had an inadequate response to fluconazole for the current infection **OR** B. The patient has an intolerance or hypersensitivity to fluconazole **OR** C. The patient has an FDA labeled contraindication to fluconazole **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 fluconazole cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has another FDA approved indication for the requested agent and route of administration **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:** 3 months for treatment of vulvovaginal candidiasis, 6 months for recurrent vulvovaginal candidiasis NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Cresemba	**Initial Evaluation** **Cresemba (isavuconazole)** will be approved when BOTH of the following are met: 1. ONE of the following: A. The patient has a diagnosis of invasive aspergillosis **OR** B. The patient has a diagnosis of invasive mucormycosis **OR** C. The patient has another FDA approved indication for the requested agent and route of administration **OR** D. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. 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:** 6 months **Renewal Evaluation** **Cresemba (isavuconazole)** 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 review process **AND**

Module	Clinical Criteria for Approval
	2. ONE of the following: A. BOTH of the following: 1. The patient has a diagnosis of invasive aspergillosis **AND** 2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay) **OR** B. BOTH of the following: 1. The patient has a diagnosis of invasive mucormycosis **AND** 2. The patient has continued indicators of active disease (e.g., continued radiologic findings, direct microscopy findings, histopathology findings, positive cultures, positive serum galactomannan assay) **OR** C. BOTH of the following: 1. The patient has another FDA approved indication or another indication that is supported in compendia for the requested agent and route of administration **AND** 2. The prescriber has submitted information supporting continued use of the requested agent for the requested indication **AND** 3. 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:** 6 months
Noxafil	**Initial Evaluation** **Noxafil (posaconazole)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of oropharyngeal candidiasis AND ONE of the following: 1. The patient has tried and had an inadequate response to itraconazole or fluconazole **OR** 2. The patient has an intolerance or hypersensitivity to itraconazole or fluconazole **OR** 3. The patient has an FDA labeled contraindication to BOTH fluconazole AND itraconazole **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that BOTH fluconazole AND itraconazole cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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. BOTH of the following: 1. The requested agent is prescribed for prophylaxis of invasive Aspergillus or Candida **AND** 2. The patient is severely immunocompromised (e.g., hematopoietic stem cell transplant (HSCT) recipients, a hematologic malignancy with prolonged neutropenia from chemotherapy), or is a high-risk solid organ (lung, heart-lung, heart, pancreas, liver, kidney, small bowel) transplant patient **OR** C. The patient has an infection caused by Scedosporium or Zygomycetes **OR** D. The patient has a diagnosis of invasive Aspergillus AND ONE of the following:

Module	Clinical Criteria for Approval
	1. The patient has tried and had an inadequate response to voriconazole, amphotericin B, or isavuconazole **OR** 2. The patient has an intolerance or hypersensitivity to voriconazole, amphotericin B, or isavuconazole **OR** 3. The patient has an FDA labeled contraindication to voriconazole, amphotericin B, AND isavuconazole **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 voriconazole, amphotericin B, AND isavuconazole cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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 another FDA approved indication for the requested agent and route of administration **OR** F. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA approved indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 1 month for oropharyngeal candidiasis, 6 months for all other indications **Renewal Evaluation** **Noxafil (posaconazole)** 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 review process (NOTE: See initial criteria for a diagnosis of oropharyngeal candidiasis) **AND** 2. ONE of the following: A. BOTH of the following: 1. The requested agent is being prescribed for prophylaxis of invasive Aspergillus or Candida **AND** 2. The patient continues to be severely immunocompromised (e.g., hematopoietic stem cell transplant (HSCT) recipients, a hematologic malignancy with prolonged neutropenia from chemotherapy), or is a high-risk solid organ (lung, heart-lung, heart, pancreas, liver, kidney, small bowel) transplant patient **OR** B. BOTH of the following: 1. The patient has a serious infection caused by Scedosporium or Zygomycetes **AND** 2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) **OR** C. BOTH of the following:

Module	Clinical Criteria for Approval
	1. The patient has a diagnosis of invasive Aspergillus **AND** 2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) **OR** D. BOTH of the following: 1. The patient has another FDA approved indication or another indication that is supported in compendia for the requested agent and route of administration **AND** 2. The prescriber has submitted information supporting continued use of the requested agent for the requested indication **AND** 3. 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:** 6 months
Vfend	**Initial Evaluation** **Vfend (voriconazole)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of invasive Aspergillus **OR** B. BOTH of the following: 1. The requested agent is being prescribed for prophylaxis of invasive Aspergillus or Candida **AND** 2. The patient is severely immunocompromised (e.g., hematopoietic stem cell transplant (HSCT) recipients, a hematologic malignancy with prolonged neutropenia from chemotherapy), or is a high-risk solid organ (lung, heart-lung, heart, pancreas, liver, kidney, small bowel) transplant patient **OR** C. The patient has a diagnosis of esophageal candidiasis, candidemia, or other deep tissue Candida infection AND ONE of the following: 1. The patient has tried and had an inadequate response to fluconazole **OR** 2. The patient has an intolerance or hypersensitivity to fluconazole **OR** 3. The patient has an FDA labeled contraindication to fluconazole **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 fluconazole cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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 serious infection caused by Scedosporium or Fusarium species **OR** E. The patient has a diagnosis of blastomycosis AND ONE of the following: 1. The patient has tried and had an inadequate response to itraconazole **OR** 2. The patient has an intolerance or hypersensitivity to itraconazole **OR** 3. The patient has an FDA labeled contraindication to itraconazole **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

Module	Clinical Criteria for Approval
	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 itraconazole cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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 another FDA approved indication for the requested agent and route of administration **OR** G. 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, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 1 month for esophageal candidiasis, 6 months for all other indications **Renewal Evaluation** **Vfend (voriconazole)** 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 review process **AND** 2. ONE of the following: A. BOTH of the following: 1. The patient has a diagnosis of invasive Aspergillus **AND** 2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) **OR** B. BOTH of the following: 1. The requested agent is being prescribed for prophylaxis of invasive Aspergillus or Candida **AND** 2. The patient is severely immunocompromised (e.g., hematopoietic stem cell transplant (HSCT) recipients, a hematologic malignancy with prolonged neutropenia from chemotherapy), or is a high-risk solid organ (lung, heart-lung, heart, pancreas, liver, kidney, small bowel) transplant patient **OR** C. BOTH of the following: 1. The patient has a diagnosis of esophageal candidiasis, candidemia, or other deep tissue Candida infection **AND** 2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) **OR** D. BOTH of the following: 1. The patient has a serious infection caused by Scedosporium or Fusarium species **AND** 2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) **OR** E. BOTH of the following: 1. The patient has a diagnosis of blastomycosis **AND** 2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) **OR** F. BOTH of the following:

Module	Clinical Criteria for Approval
	1. The patient has another FDA approved indication or another indication that is supported in compendia for the requested agent and route of administration **AND** 2. The prescriber has submitted information supporting continued use of the requested agent for the intended diagnosis **AND** 3. 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:** 1 month for esophageal candidiasis, 6 months for all other indications
Vivjoa	**Evaluation** **Vivjoa (oteseconazole)** will be approved when BOTH of the following are met: 1. ONE of the following: A. BOTH of the following: 1. The patient has a diagnosis of recurrent vulvovaginal candidiasis **AND** 2. The patient has experienced greater than or equal to 3 episodes of vulvovaginal candidiasis (VVC) in a 12 months period **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to fluconazole **OR** B. The patient has an intolerance or hypersensitivity to fluconazole **OR** C. The patient has an FDA labeled contraindication to fluconazole **OR** D. The patient will be using fluconazole as part of the combination dosing regimen (fluconazole with Vivjoa) for the current infection **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 fluconazole cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has another FDA approved indication for the requested agent and route of administration **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:** 4 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Brexafemme, Vivjoa	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: Brexafemme: 3 months for treatment of vulvovaginal candidiasis 6 months for recurrent vulvovaginal candidiasis Vivjoa: 4 months

• Program Summary: Antiretroviral

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
12109050000320		Nevirapine Tab 200 MG	200 MG	60	Tablets	30	DAYS					
12109050007510		Nevirapine Tab ER 24HR 100 MG	100 MG	90	Tablets	30	DAYS					
121080700001		stavudine cap	15 MG; 20 MG; 30 MG; 40 MG	60	Capsules	30	DAYS					
12108085000330		Zidovudine Tab 300 MG	300 MG	60	Tablets	30	DAYS					
121099033003	Atripla	efavirenz-emtricitabine-tenofovir df tab	600-200-300 MG	30	Tablets	30	DAYS					
12109903240320	Biktarvy	Bictegravir-Emtricitabine-Tenofovir AF Tab	30-120-15 MG	30	Tablets	30	DAYS					
12109903240330	Biktarvy	Bictegravir-Emtricitabine-	50-200-25 MG	30	Tablets	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		Tenofovir AF Tab 50-200-25 MG										
12109902470330	Cimduo ; Temixys	Lamivudine-Tenofovir Disoproxil Fumarate Tab 300-300 MG	300-300 MG	30	Tablets	30	DAYS					
121099025003	Combivir	lamivudine-zidovudine tab	150-300 MG	60	Tablets	30	DAYS					
121099034003	Complera	emtricitabine-rilpivirine-tenofovir df tab	200-25-300 MG	30	Tablets	30	DAYS					
12104530200140	Crixivan	Indinavir Sulfate Cap 400 MG	400 MG	180	Capsules	30	DAYS					
121099032703	Delstrigo	doravirine-lamivudine-tenofovir df tab	100-300-300 MG	30	Tablets	30	DAYS					
12109902290310	Descovy	Emtricitabine-Tenofovir Alafenamide Fumarate Tab	120-15 MG	30	Tablets	30	DAYS					
12109902290320	Descovy	Emtricitabine-Tenofovir Alafenamide Fumarate Tab 200-25 MG	200-25 MG	30	Tablets	30	DAYS					
121099022603	Dovato	dolutegravir sodium-lamivudine tab	50-300 MG	30	Tablets	30	DAYS					
121090801003	Edurant	rilpivirine hcl tab	25 MG	30	Tablets	30	DAYS					
121060300001	Emtriva	emtricitabine caps	200 MG	30	Capsules	30	DAYS					
121060300020	Emtriva	emtricitabine soln	10 MG/ML	680	mLs	28	DAYS					
121060600020	Epivir	lamivudine oral soln	10 MG/ML	960	mLs	30	DAYS					
12106060000320	Epivir	Lamivudine Tab 150 MG	150 MG	60	Tablets	30	DAYS					
12106060000330	Epivir	Lamivudine Tab 300 MG	300 MG	30	Tablets	30	DAYS					
121099022003	Epzicom	abacavir sulfate-lamivudine tab	600-300 MG	30	Tablets	30	DAYS					
121099022203	Evotaz	atazanavir sulfate-cobicistat tab	300-150 MG	30	Tablets	30	DAYS					
121025300021	Fuzeon	enfuvirtide for inj	90 MG	60	Vials	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
121099042903	Genvoya	elvitegrav-cobic-emtricitab-tenofov af tab	150-150-200-10 MG	30	Tablets	30	DAYS					
12109035000320	Intelence	Etravirine Tab 100 MG	100 MG	60	Tablets	30	DAYS					
12109035000340	Intelence	Etravirine Tab 200 MG	200 MG	60	Tablets	30	DAYS					
12109035000310	Intelence	Etravirine Tab 25 MG	25 MG	120	Tablets	30	DAYS					
12104580200320	Invirase	Saquinavir Mesylate Tab 500 MG	500 MG	120	Tablets	30	DAYS					
12103060100540	Isentress	Raltegravir Potassium Chew Tab 100 MG (Base Equiv)	100 MG	180	Tablets	30	DAYS					
12103060100510	Isentress	Raltegravir Potassium Chew Tab 25 MG (Base Equiv)	25 MG	180	Tablets	30	DAYS					
12103060103020	Isentress	Raltegravir Potassium Packet For Susp 100 MG (Base Equiv)	100 MG	60	Packets	30	DAYS					
12103060100320	Isentress	Raltegravir Potassium Tab 400 MG (Base Equiv)	400 MG	60	Tablets	30	DAYS					
12103060100330	Isentress hd	Raltegravir Potassium Tab 600 MG (Base Equiv)	600 MG	60	Tablets	30	DAYS					
121099022803	Juluca	dolutegravir sodium-rilpivirine hcl tab	50-25 MG	30	Tablets	30	DAYS					
121099025520	Kaletra	lopinavir-ritonavir soln	400-100 MG/5ML	480	mLs	30	DAYS					
12109902550310	Kaletra	Lopinavir-Ritonavir Tab 100-25 MG	100-25 MG	180	Tablets	30	DAYS					
12109902550320	Kaletra	Lopinavir-Ritonavir Tab 200-50 MG	200-50 MG	120	Tablets	30	DAYS					
121045251018	Lexiva	fosamprenavir calcium susp	50 MG/ML	1800	mLs	30	DAYS					
121045251003	Lexiva	fosamprenavir calcium tab	700 MG	120	Tablets	30	DAYS					
121045600020	Norvir	ritonavir oral	80	480	mLs	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		soln	MG/ML									
121045600030	Norvir	ritonavir powder packet	100 MG	360	Packets	30	DAYS					
121045600003	Norvir	Ritonavir Tab ; ritonavir tab	100 MG	360	Tablets	30	DAYS					
12109903390320	Odefsey	Emtricitabine-Rilpivirine-Tenofovir AF Tab 200-25-25 MG	200-25-25 MG	30	Tablets	30	DAYS					
121090250003	Pifeltro	doravirine tab	100 MG	30	Tablets	30	DAYS					
121099022703	Prezcobix	darunavir-cobicistat tab	800-150 MG	30	Tablets	30	DAYS					
12104520001820	Prezista	Darunavir Oral Susp	100 MG/ML	400	mLs	30	DAYS					
12104520000305	Prezista	Darunavir Tab	75 MG	300	Tablets	30	DAYS					
12104520000310	Prezista	Darunavir Tab	150 MG	180	Tablets	30	DAYS					
12104520000325	Prezista	Darunavir Tab	600 MG	60	Tablets	30	DAYS					
12104520000350	Prezista	Darunavir Tab	800 MG	30	Tablets	30	DAYS					
12108085000110	Retrovir	Zidovudine Cap 100 MG	100 MG	180	Capsules	30	DAYS					
12108085001210	Retrovir	Zidovudine Syrup 10 MG/ML	50 MG/5ML	1920	mLs	30	DAYS					
12104515200130	Reyataz	Atazanavir Sulfate Cap 150 MG (Base Equiv)	150 MG	30	Tablets	30	DAYS					
12104515200140	Reyataz	Atazanavir Sulfate Cap 200 MG (Base Equiv)	200 MG	60	Capsules	30	DAYS					
12104515200150	Reyataz	Atazanavir Sulfate Cap 300 MG (Base Equiv)	300 MG	30	Capsules	30	DAYS					
12104515203020	Reyataz	Atazanavir Sulfate Oral Powder Packet 50 MG (Base Equiv)	50 MG	240	Packets	30	DAYS					
121023304074	Rukobia	fostemsavir tromethamine tab er	600 MG	60	Tablets	30	DAYS					
12102060002020	Selzentry	Maraviroc Oral Soln 20 MG/ML	20 MG/ML	1840	mLs	30	DAYS					
12102060000320	Selzentry	Maraviroc Tab 150 MG	150 MG	60	Tablets	30	DAYS					
12102060000305	Selzentry	Maraviroc Tab 25 MG	25 MG	240	Tablets	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
12102060000330	Selzentry	Maraviroc Tab 300 MG	300 MG	120	Tablets	30	DAYS					
12102060000310	Selzentry	Maraviroc Tab 75 MG	75 MG	60	Tablets	30	DAYS					
12109904300320	Stribild	Elvitegrav-Cobic-Emtricitab-TenofovDF Tab 150-150-200-300 MG	150-150-200-300 MG	30	Tablets	30	DAYS					
1210155520B720	Sunlenca	Lenacapavir Sodium Tab Therapy Pack	300 MG	4	Tablets	365	DAYS				04-01-2023	12-31-9999
1210155520B725	Sunlenca	Lenacapavir Sodium Tab Therapy Pack	300 MG	5	Tablets	365	DAYS				04-01-2023	12-31-9999
12109030000140	Sustiva	Efavirenz Cap 200 MG	200 MG	60	Capsules	30	DAYS					
12109030000110	Sustiva	Efavirenz Cap 50 MG	50 MG	90	Capsules	30	DAYS					
12109030000330	Sustiva	Efavirenz Tab 600 MG	600 MG	30	Tablets	30	DAYS					
12109903330340	Symfi	Efavirenz-Lamivudine-Tenofovir DF Tab 600-300-300 MG	600-300-300 MG	30	Tablets	30	DAYS					
12109903330330	Symfi lo	Efavirenz-Lamivudine-Tenofovir DF Tab 400-300-300 MG	400-300-300 MG	30	Tablets	30	DAYS					
12109904200320	Symtuza	Darunavir-Cobic-Emtricitab-Tenofov AF Tab 800-150-200-10 MG	800-150-200-10 MG	30	Tablets	30	DAYS					
12103015100305	Tivicay	Dolutegravir Sodium Tab 10 MG (Base Equiv)	10 MG	240	Tablets	30	DAYS					
12103015100310	Tivicay	Dolutegravir Sodium Tab 25 MG (Base Equiv)	25 MG	60	Tablets	30	DAYS					
12103015100320	Tivicay	Dolutegravir Sodium Tab 50 MG (Base Equiv)	50 MG	60	Tablets	30	DAYS					
12103015107320	Tivicay pd	Dolutegravir Sodium Tab for Oral Susp 5 MG (Base Equiv)	5 MG	360	Tablets	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
12109903150320	Triumeq	Abacavir-Dolutegravir-Lamivudine Tab 600-50-300 MG	600-50-300 MG	30	Tablets	30	DAYS					
12109903157320	Triumeq pd	Abacavir-Dolutegravir-Lamivudine Tab for Oral Sus	60-5-30 MG	180	Tablets	30	DAYS					
121099032003	Trizivir	abacavir sulfate-lamivudine-zidovudine tab	300-150-300 MG	60	Tablets	30	DAYS					
121099023003	Truvada	emtricitabine-tenofovir disoproxil fumarate tab	100-150 MG; 133-200 MG; 167-250 MG; 200-300 MG	30	Tablets	30	DAYS					
121095300003	Tybost	cobicistat tab	150 MG	30	Tablets	30	DAYS					
12104545200320	Viracept	Nelfinavir Mesylate Tab 250 MG	250 MG	270	Tablets	30	DAYS					
12104545200340	Viracept	Nelfinavir Mesylate Tab 625 MG	625 MG	120	Tablets	30	DAYS					
12109050001820	Viramune	Nevirapine Susp 50 MG/5ML	50 MG/5ML	1200	mLs	30	DAYS					
12109050007520	Viramune xr	Nevirapine Tab ER 24HR 400 MG	400 MG	30	Tablets	30	DAYS					
121085701029	Viread	tenofovir disoproxil fumarate oral powder	40 MG/GM	240	Grams	30	DAYS					
121085701003	Viread	tenofovir disoproxil fumarate tab	150 MG; 200 MG; 250 MG; 300 MG	30	Tablets	30	DAYS					
12105005102020	Ziagen	Abacavir Sulfate Soln 20 MG/ML (Base Equiv)	20 MG/ML	960	mLs	30	DAYS					
121050051003	Ziagen	abacavir sulfate tab	300 MG	60	Tablets	30	DAYS					

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

● Program Summary: Atypical Antipsychotics – Extended Maintenance Agents

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

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

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

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

1. Information has been provided that indicates the patient is currently being treated with the requested agent within the past 180 days
   OR
2. The prescriber states the patient is currently being treated with the requested agent with the past 180 days AND is at risk if therapy is changed
   OR
3. The patient is currently being treated with the requested agent as indicated by ALL of the following:
   A. A statement by the prescriber that the patient is currently taking the requested agent
      AND
   B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
      AND
   C. The prescriber states that a change in therapy is expected to be ineffective or cause harm
   OR
4. The patient's medication history includes prerequisite agent use, intolerance, or hypersensitivity
   OR
5. BOTH of the following:
   A. The prescriber has stated that the patient has tried the prerequisite agent
      AND
   B. The prerequisite agent was discontinued due to lack of effectiveness or an adverse event
   OR
6. The patient has an FDA labeled contraindication to ALL prerequisite agents that is not expected to occur with the requested agent
   OR
7. The prescriber has provided documentation that ALL prerequisite agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

Length of Approval: 12 months

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

• Program Summary: Baclofen

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
75100010001825	Fleqsuvy	Baclofen Susp	25 MG/5ML	480	mLs	30	DAYS					
75100010003010	Lyvispah	Baclofen Granules Packet	5 MG	120	Packets	30	DAYS					
75100010003020	Lyvispah	Baclofen Granules Packet	10 MG	120	Packets	30	DAYS					
75100010003030	Lyvispah	Baclofen	20 MG	120	Packets	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		Granules Packet										
75100010002070	Ozobax	Baclofen Oral Soln 5 MG/5ML	5 MG/5ML	2400	mLs	30	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of spasticity resulting from multiple sclerosis (MS) AND BOTH of the following: 1. The requested agent will be used for at least ONE of the following: A. Flexor spasms and concomitant pain **OR** B. Clonus **OR** C. Muscular rigidity **AND** 2. ONE of the following: A. ONE of the following: 1. BOTH of the following: A. The patient has an intolerance or hypersensitivity to generic baclofen tablets that is not expected to occur with the requested agent **OR** 1. The patient has an FDA labeled contraindication to generic baclofen tablets that is not expected to occur with the requested agent **OR** 2. The prescriber has provided information to support use of the requested agent over generic baclofen tablets **OR** 3. BOTH of the following: A. The prescriber has stated that the patient has tried to generic baclofen tablets **AND** B. Generic baclofen tablets were discontinued due to lack of effectiveness or an adverse event **OR** B. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** C. The prescriber has provided documentation that generic baclofen tablets cannot be used due to a documented

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

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

Module	Clinical Criteria for Approval
	NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent (e.g., decreased spasms) **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **Length of Approval:** Initial - 6 months Renewal - 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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	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					
36202040100110		Terazosin HCl Cap 2 MG (Base Equivalent)	2 MG	30	Capsules	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
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					
56859902300120	Entadfi	Finasteride-Tadalafil Cap	5-5 MG	30	Capsules	30	DAYS					
568520701001	Flomax	Tamsulosin HCl Cap ; 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 Standalone	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) is greater than the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**

Module	Clinical Criteria for Approval
	2. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval**: 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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
TBD	Abrilada	adalimumab-afzb Injection										
6650007000E5	Actemra	tocilizumab subcutaneous soln prefilled syringe	162 MG/0.9 ML	4	Syringes	28	DAYS					
6650007000D5	Actemra actpen	tocilizumab subcutaneous soln auto-injector	162 MG/0.9 ML	4	Pens	28	DAYS					
6627001510D520	Amjevita	adalimumab-atto soln auto-injector	40 MG/0.8 ML	2	Pens	28	DAYS					
6627001510E505	Amjevita	adalimumab-atto soln prefilled syringe	10 MG/0.2 ML	2	Syringes	28	DAYS					
6627001510E510	Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.4 ML	2	Syringes	28	DAYS					
6627001510E520	Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.8 ML	2	Syringes	28	DAYS					
525050201064	Cimzia	certolizumab pegol for inj kit	200 MG	2	Kits	28	DAYS					
5250502010F840	Cimzia	Certolizumab Pegol Prefilled Syringe Kit	200 MG/ML	2	Kits	28	DAYS					
5250502010F860	Cimzia starter kit	Certolizumab Pegol Prefilled Syringe Kit	200 MG/ML	1	Kit	180	DAYS				04-08-2022	
9025057500E530	Cosentyx	Secukinumab Subcutaneous	150 MG/ML	2	Syringes	28	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		Pref Syr 150 MG/ML (300 MG Dose)										
9025057500E510	Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe	75 MG/0.5 ML	1	Syringe	28	DAYS					
9025057500E520	Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe 150 MG/ML	150 MG/ML	1	Syringe	28	DAYS					
9025057500D530	Cosentyx sensoready pen	Secukinumab Subcutaneous Auto-inj 150 MG/ML (300 MG Dose)	150 MG/ML	2	Pens	28	DAYS					
9025057500D520	Cosentyx sensoready pen	Secukinumab Subcutaneous Soln Auto-injector 150 MG/ML	150 MG/ML	1	Pen	28	DAYS					
6627001505F520	Cyltezo	adalimumab-adbm auto-injector kit	40 MG/0.8 ML	2	Pens	28	DAYS			00597037597		
6627001505F805	Cyltezo	adalimumab-adbm prefilled syringe kit	10 MG/0.2 ML	2	Syringes	28	DAYS					
6627001505F810	Cyltezo	adalimumab-adbm prefilled syringe kit	20 MG/0.4 ML	2	Syringes	28	DAYS					
6627001505F820	Cyltezo	adalimumab-adbm prefilled syringe kit	40 MG/0.8 ML	2	Syringes	28	DAYS					
6627001505F520	Cyltezo starter package for crohns disease/UC/HS	adalimumab-adbm auto-injector kit	40 MG/0.8 ML	1	Kit	180	DAYS			00597037516		
6627001505F520	Cyltezo starter package for psoriasis	adalimumab-adbm auto-injector kit	40 MG/0.8 ML	1	Kit	180	DAYS			00597037523		
662900300021	Enbrel	etanercept for subcutaneous inj	25 MG	8	Vials	28	DAYS					
66290030002015	Enbrel	Etanercept Subcutaneous Inj 25 mg/0.5ml	25 MG/0.5 ML	8	Vials	28	DAYS					
6629003000E525	Enbrel	Etanercept Subcutaneous	25 MG/0.5	4	Syringes	28	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		Soln Prefilled Syringe 25 MG/0.5ML	ML									
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					
6627001520E510	Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.4 ML	2	Syringes	28	DAYS					
6627001520E520	Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.8 ML	2	Syringes	28	DAYS					
6627001520D510	Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.4 ML	2	Pens	28	DAYS					
6627001520D520	Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.8 ML	2	Pens	28	DAYS					
6627001535F520	Hulio	adalimumab-fkjp auto-injector kit	40 MG/0.8 ML	2	Pens	28	DAYS					
6627001535F810	Hulio	adalimumab-fkjp prefilled syringe kit	20 MG/0.4 ML	2	Syringes	28	DAYS					
6627001535F820	Hulio	adalimumab-fkjp prefilled syringe kit	40 MG/0.8 ML	2	Syringes	28	DAYS					
6627001500F804	Humira	Adalimumab Prefilled Syringe Kit 10 MG/0.1ML	10 MG/0.1 ML	2	Syringes	28	DAYS					
6627001500F809	Humira	Adalimumab Prefilled Syringe Kit 20 MG/0.2ML	20 MG/0.2 ML	2	Syringes	28	DAYS					
6627001500F830	Humira	Adalimumab Prefilled Syringe Kit 40 MG/0.4ML	40 MG/0.4 ML	2	Syringes	28	DAYS					
6627001500F820	Humira	Adalimumab Prefilled Syringe Kit 40 MG/0.8ML	40 MG/0.8 ML	2	Syringes	28	DAYS					
6627001500F840	Humira	Adalimumab	80	1	Kit	180	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
	pediatric crohns disease starter	Prefilled Syringe Kit 80 MG/0.8ML	MG/0.8 ML									
6627001500F880	Humira pediatric crohns disease starter	Adalimumab Prefilled Syringe Kit 80 MG/0.8ML & 40 MG/0.4ML	80 MG/0.8 ML & 40MG/0.4ML	1	Kit	180	DAYS					
6627001500F440	Humira pen	adalimumab pen-injector kit	80 MG/0.8 ML	2	Pens	28	DAYS			00074012402		
6627001500F430	Humira pen	Adalimumab Pen-injector Kit 40 MG/0.4ML	40 MG/0.4 ML	2	Pens	28	DAYS					
6627001500F420	Humira pen ; Humira pen-cd/uc/hs starter	Adalimumab Pen-injector Kit ; adalimumab pen-injector kit	40 MG/0.8 ML	1	Kit	180	DAYS			00074433906 ; 50090448700		
6627001500F420	Humira pen ; Humira pen-ps/uv starter	Adalimumab Pen-injector Kit ; adalimumab pen-injector kit	40 MG/0.8 ML	1	Kit	180	DAYS			00074433907 ; 50090448700		
6627001500F440	Humira pen-cd/uc/hs starter	adalimumab pen-injector kit	80 MG/0.8 ML	1	Kit	180	DAYS			00074012403		
6627001500F440	Humira pen-pediatric uc starter	adalimumab pen-injector kit	80 MG/0.8 ML	4	Pens	180	DAYS			00074012404		
6627001500F450	Humira pen-ps/uv starter	Adalimumab Pen-injector Kit 80 MG/0.8ML & 40 MG/0.4ML	80 MG/0.8 ML & 40MG/0.4ML	1	Kit	180	DAYS					
6627001504D515	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.4 ML	2	Pens	28	DAYS					
6627001504D515	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.4 ML	2	Pens	28	DAYS					
6627001504D540	Hyrimoz	adalimumab-adaz soln auto-injector	80 MG/0.8 ML	2	Pens	28	DAYS			61314045420		
6627001504E508	Hyrimoz	adalimumab-adaz soln prefilled syringe	10 MG/0.1 ML	2	Syringes	28	DAYS					
6627001504E513	Hyrimoz	adalimumab-adaz soln prefilled syringe	20 MG/0.2 ML	2	Syringes	28	DAYS					
6627001504E515	Hyrimoz	adalimumab-adaz	40	2	Syringes	28	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		soln prefilled syringe	MG/0.4 ML									
6627001504D540	Hyrimoz crohn's disease and ulcerative colitis	adalimumab-adaz soln auto-injector	80 MG/0.8 ML	1	Starter Kit	180	DAYS			61314045436		
6627001504E560	Hyrimoz pediatric crohn's	adalimumab-adaz soln prefilled syr	80 MG/0.8 ML & 40MG/0.4ML	2	Syringes	180	DAYS					
6627001504E540	Hyrimoz pediatric crohns	adalimumab-adaz soln prefilled syringe	80 MG/0.8 ML	3	Syringes	180	DAYS					
6627001504D560	Hyrimoz plaque psoriasis	adalimumab-adaz soln auto-injector	80 MG/0.8 ML & 40MG/0.4ML	1.6	Starter Kit	180	DAYS					
6627001502F540	Idacio	adalimumab-aacf auto-injector kit	40 MG/0.8 ML	2	Pens	28	DAYS			65219055408		
6627001502F840	Idacio	adalimumab-aacf prefilled syringe kit	40 MG/0.8 ML	2	Syringes	28	DAYS					
6627001502F540	Idacio starter package for crohns disease	adalimumab-aacf auto-injector kit	40 MG/0.8 ML	1	Kit	180	DAYS			65219055438		
6627001502F540	Idacio starter package for plaque psoriasis	adalimumab-aacf auto-injector kit	40 MG/0.8 ML	1	Kit	180	DAYS			65219055428		
6650006000E5	Kevzara	sarilumab subcutaneous soln prefilled syringe	150 MG/1.14 ML; 200 MG/1.14 ML	2	Syringes	28	DAYS					
6650006000D5	Kevzara	sarilumab subcutaneous solution auto-injector	150 MG/1.14 ML; 200 MG/1.14 ML	2	Pens	28	DAYS					
6626001000E5	Kineret	anakinra subcutaneous soln prefilled syringe	100 MG/0.67 ML	28	Syringes	28	DAYS					
90731060100120	Litfulo	ritlecitinib tosylate cap	50 MG	28	Capsules	28	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
666030100003	Olumiant	baricitinib tab	1 MG; 2 MG; 4 MG	30	Tablets	30	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/0.4 ML	4	Syringes	28	DAYS					
6640001000E515	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 87.5 MG/0.7ML	87.5 MG/0.7 ML	4	Syringes	28	DAYS					
6640001000D5	Orencia clickject	abatacept subcutaneous soln auto-injector	125 MG/ML	4	Syringes	28	DAYS					
66603072007530	Rinvoq	Upadacitinib Tab ER	30 MG	30	Tablets	30	DAYS					
66603072007540	Rinvoq	Upadacitinib Tab ER	45 MG	84	Tablets	365	DAYS					
66603072007520	Rinvoq	Upadacitinib Tab ER 24HR 15 MG	15 MG	30	Tablets	30	DAYS					
9025052000E5	Siliq	brodalumab subcutaneous soln prefilled syringe	210 MG/1.5 ML	2	Syringes	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/0.5 ML	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/0.5 ML	1	Syringe	28	DAYS					
9025057070F8	Skyrizi	risankizumab-rzaa	75	1	Box	84	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		sol prefilled syringe	MG/0.83 ML									
9025057070E5	Skyrizi	risankizumab-rzaa soln prefilled syringe	150 MG/ML	1	Injection Device	84	DAYS					
5250406070E210	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	180 MG/1.2 ML	1	Cartridges	56	DAY					
5250406070E220	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	360 MG/2.4 ML	1	Cartridges	56	DAYS					
9025057070D5	Skyrizi pen	risankizumab-rzaa soln auto-injector	150 MG/ML	1	Pen	84	DAYS					
90250524000320	Sotyktu	Deucravacitinib Tab	6 MG	30	Tablets	30	DAYS					
90250585002020	Stelara	Ustekinumab Inj 45 MG/0.5ML	45 MG/0.5 ML	1	Vial	84	DAYS					
9025058500E520	Stelara	Ustekinumab Soln Prefilled Syringe 45 MG/0.5ML	45 MG/0.5 ML	1	Syringe	84	DAYS					
9025058500E540	Stelara	Ustekinumab Soln Prefilled Syringe 90 MG/ML	90 MG/ML	1	Syringe	56	DAYS					
9025055400D5	Taltz	ixekizumab subcutaneous soln auto-injector	80 MG/ML	1	Syringe	28	DAYS					
9025055400E5	Taltz	ixekizumab subcutaneous soln prefilled syringe	80 MG/ML	1	Syringe	28	DAYS					
9025054200D2	Tremfya	guselkumab soln pen-injector	100 MG/ML	1	Pen	56	DAYS					
9025054200E5	Tremfya	guselkumab soln prefilled syringe	100 MG/ML	1	Syringe	56	DAYS					
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					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
66603065107550	Xeljanz xr	Tofacitinib Citrate Tab ER 24HR 22 MG (Base Equivalent)	22 MG	120	Tablets	365	DAYS					
6627001503F530	Yuflyma 1-pen kit ; Yuflyma 2-pen kit	adalimumab-aaty auto-injector kit	40 MG/0.4 ML	2	Pens	28	DAYS					
6627001509D240	Yusimry	adalimumab-aqvh soln pen-injector	40 MG/0.8 ML	2	Pens	28	DAYS					

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

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Option A - FlexRx, GenRx, BasicRx, and KeyRx	**Step Table**

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

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

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Uveitis	SQ: Amjevita, Hadlima, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
Indications Without Prerequisite Biologic Immunomodulators Required						
Alopecia Areata Atopic Dermatitis Deficiency of IL-1 Receptor Antagonist (DIRA) Enthesitis Related Arthritis (ERA) Giant Cell Arteritis (GCA) Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Systemic Juvenile Idiopathic Arthritis (SJIA) Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)	N/A	N/A	N/A	N/A	N/A	N/A

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

**Note: Amjevita, Hadlima, and Humira are required Step 1 agents

***Listed preferred status is effective upon launch

Initial Evaluation

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

1. The request is NOT for use of Olumiant in the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) *NOTE: This indication is not covered under the pharmacy

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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 1. Abrilada 2. Cyltezo 3. Hulio 4. Hyrimoz 5. Idacio 6. Yusimry

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

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

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

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

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

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

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

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

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	treatment of PJIA for at least 3-months **OR** 2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of PJIA **OR** 3. The patient has an FDA labeled contraindication 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 active systemic juvenile idiopathic arthritis (SJIA) AND ONE of the following: 1. The patient has tried and had an inadequate response to at least ONE NSAID (e.g., ibuprofen, celecoxib) used in the treatment of SJIA for at least 1-month **OR** 2. The patient has an intolerance or hypersensitivity to NSAIDs used in the treatment of SJIA **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of SJIA **OR** 4. The patient has tried and had an inadequate response to another conventional agent (i.e., methotrexate, leflunomide, systemic corticosteroids) used in the treatment of SJIA for at least 3-months **OR** 5. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of SJIA **OR** 6. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of SJIA **OR** 7. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of SJIA **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 therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 9. The prescriber has provided documentation that ALL NSAIDs (e.g.,

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	ibuprofen, celecoxib) used in the treatment of SJIA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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. The patient has a diagnosis of moderate to severe hidradenitis suppurativa (HS) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., oral tetracyclines [doxycycline, minocycline, tetracycline]; oral contraceptives [females only]; metformin [females only]; finasteride [females only]; spironolactone [females only]; intralesional corticosteroids [triamcinolone]; clindamycin in combination with rifampin; combination of rifampin, moxifloxacin, and metronidazole; cyclosporine, oral retinoids) used in the treatment of HS for at least 3-months **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of HS **OR** 3. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of HS **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of HS **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL conventional agents (i.e., oral tetracyclines [doxycycline, minocycline, tetracycline]; oral contraceptives [females only]; metformin [females only]; finasteride [females only]; spironolactone [females only]; intralesional corticosteroids [triamcinolone]; clindamycin in combination with rifampin; combination of rifampin, moxifloxacin, and metronidazole; cyclosporine, oral retinoids) used in the treatment of HS cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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** M. 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** N. The patient has a diagnosis of active enthesitis related arthritis (ERA) and ONE of the following: 1. The patient has tried and had an inadequate response to two different NSAIDs used in the treatment of ERA for at least a 4-week total trial **OR** 2. The patient has an intolerance or hypersensitivity to two different

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	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** O. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following: 1. ONE of the following: A. The patient has at least 10% body surface area involvement **OR** B. The patient has involvement of the palms and/or soles of the feet **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to at least a mid- potency topical steroid used in the treatment of AD for a minimum of 4 weeks **AND** a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD for a minimum of 6 weeks **OR** B. The patient has an intolerance or hypersensitivity to at least a mid- potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors used in the treatment of AD cannot be used due to a

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	documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. ONE of the following**:** A. The patient has tried and had an inadequate response to a systemic immunosuppressant, including a biologic, used in the treatment of AD for a minimum of 3 months **OR** B. The patient has an intolerance or hypersensitivity to therapy with systemic immunosuppressants, including a biologic, used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL systemic immunosuppressants, including biologics, used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL systemic immunosuppressants, including biologics, used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The prescriber has documented the patient's baseline pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **AND** 5. BOTH of the following: A. The patient is currently treated with topical emollients and practicing good skin care **AND** B. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent **OR** P. 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** Q. The patient has a diagnosis of polymyalgia rheumatica (PMR) AND ONE of the following: 1. The patient has tried and had an inadequate response to systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR for a minimum of 8 weeks **OR** 2. The patient is currently treated with systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone and cannot tolerate a corticosteroid taper **OR** 3. The patient is currently being treated with the requested agent as

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	indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 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** 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 for at least 3-months (See Step 1a for preferred TNF inhibitors) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to therapy with a TNF inhibitor for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL TNF inhibitors for the requested indication **OR** 4. BOTH of the following: A. The prescriber has provided information indicating why ALL TNF inhibitors are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 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

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

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

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	B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL of the Step 1 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. If Cosentyx 300 mg every 4 weeks is requested as maintenance dosing, ONE of the following: A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis **OR** B. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks for at least 3-months **AND** 4. If Skyrizi is requested for the treatment of Crohn's disease, the patient received Skyrizi IV for induction therapy **AND** 5. If Stelara is requested for the treatment of Crohn's disease or ulcerative colitis, the patient received Stelara IV for induction therapy **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. If Stelara 90 mg is requested, ONE of the following: A. The patient has a diagnosis of psoriasis AND weighs >100kg **OR** B. The patient has a dual diagnosis of psoriasis AND psoriatic arthritis AND the patient is >100kg **OR** C. The patient has a diagnosis of Crohn's disease or ulcerative colitis **AND** 4. 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** 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 has consulted with a specialist in the area of the patient's diagnosis **AND** 6. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, i.e., clinical trials, phase III studies, guidelines required) **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**

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	8. The patient has been tested for latent tuberculosis (TB) when required by the prescribing information for the requested agent AND if positive the patient has begun therapy for latent TB **Length of Approval:** 12 months for all agents EXCEPT adalimumab containing products for ulcerative colitis (UC), Rinvoq for atopic dermatitis (AD), Siliq for plaque psoriasis (PS), Xeljanz and Xeljanz XR for induction therapy for UC, and the agents with indications that require loading doses for new starts. NOTE: For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of the 12 months. Adalimumab containing products for UC may be approved for 12 weeks, Rinvoq for AD may be approved for 6 months, Siliq for PS may be approved for 16 weeks, and Xeljanz and Xeljanz XR for UC may be approved for 16 weeks. **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The request is NOT for use of Olumiant or Actemra in the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) *NOTE: This indication is not covered under the pharmacy benefit **AND** 2. The request is for use in Alopecia Areata and Alopecia Areata is NOT restricted from coverage under the patient's benefit **AND** 3. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (*please note Stelara renewal must be for the same strength as the initial approval) **AND** 4. ONE of the following: A. The patient has a diagnosis of moderate to severe atopic dermatitis AND BOTH of the following: 1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following: A. Affected body surface area **OR** B. Flares **OR** C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **AND** 2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has a diagnosis of polymyalgia rheumatica AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. If the requested agent is Kevzara, the patient does NOT have any of the following: A. Neutropenia (ANC less than 1,000 per mm^3 at the end of the dosing interval) **AND** B. Thrombocytopenia (platelet count is less than 100,000 per mm^3) **AND** C. AST or ALT elevations 3 times the upper limit of normal **OR** C. The patient has a diagnosis other than moderate to severe atopic dermatitis or polymyalgia rheumatica AND the patient has had clinical benefit with the requested agent **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):

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	A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, i.e., clinical trials, phase III studies, guidelines required) **AND** 7. If Cosentyx 300 mg every 4 weeks is requested as maintenance dosing, ONE of the following: A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis **OR** B. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks for at least 3-months **AND** 8. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND** 9. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

Option B - Focus Rx

Step Table

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

Juvenile Idiopathic Arthritis (PJIA)	Cyltezo, Enbrel, Humira		(Amjevita, Cyltezo, or Humira are required Step 1 agents)			Abrilada**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
Psoriatic Arthritis (PsA)	SQ: Amjevita, Cosentyx, Cyltezo, Enbrel, Humira, Skyrizi, Stelara, Tremfya Oral: Otezla	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Orencia, Simponi, Taltz	N/A	SQ: Abrilada**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
Rheumatoid Arthritis	SQ: Amjevita, Enbrel, Cyltezo, Humira	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Actemra (Amjevita, Cyltezo, or Humira are required Step 1 agents)	Oral: Olumiant SQ: Cimzia, Kevzara, Kineret, Orencia, Simponi	N/A	SQ: Abrilada**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
Dermatological Disorder						
Hidradenitis Suppurativa (HS)	SQ: Amjevita, Cyltezo, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
Psoriasis (PS)	SQ: Amjevita, Cosentyx, Cyltezo, Enbrel, Humira, Skyrizi, Stelara, Tremfya Oral: Otezla	N/A	N/A	SQ: Cimzia, Ilumya	N/A	SQ: Abrilada**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Siliq, Taltz, Yusimry** Oral: Sotyktu
Inflammatory Bowel Disease						
Crohn's Disease	SQ: Amjevita, Cyltezo, Humira, Skyrizi, Stelara	Oral: Rinvoq	N/A	SQ: Cimzia (Amjevita, Cyltezo, or Humira are required Step 1 agents)	N/A	SQ: Abrilada**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
Ulcerative Colitis	SQ: Amjevita, Cyltezo,	Oral: Rinvoq, Xeljanz,	SQ: Simponi (Amje	N/A	Zeposia (Amjevita,	SQ: Abrilada**,

	Humira, Stelara	Xeljanz XR	vita, Cyltezo, or Humira are required Step 1 agents)		Cyltezo, Humira, Rinvoq, Stelara, OR Xeljanz / Xeljanz XR are required Step agents)	Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
Other						
Uveitis	SQ: Amjevita, Cyltezo, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
Indications Without Prerequisite Biologic Immunomodulators Required						
Alopecia Areata Atopic Dermatitis Deficiency of IL-1 Receptor Antagonist (DIRA) Enthesitis Related Arthritis (ERA) Giant Cell Arteritis (GCA) Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Systemic Juvenile Idiopathic Arthritis (SJIA) Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)	N/A	N/A	N/A	N/A	N/A	N/A

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

**Note: Amjevita, Cyltezo, and Humira are required Step 1 agents

***Listed preferred status is effective upon launch

Initial Evaluation

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

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

Agents Eligible for Continuation of Therapy
All target agents EXCEPT the following are eligible for continuation of therapy 1. Abrilada 2. Hadlima 3. Hulio 4. Hyrimoz 5. Idacio 6. Yusimry

        1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**
        2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR**
    B. ALL of the following:
        1. The patient has an FDA labeled indication or an indication supported in compendia for the requested agent and route of administration AND **ONE** of the following:
            A. The patient has a diagnosis of moderately to severely active rheumatoid arthritis (RA) AND BOTH of the following:
                1. ONE of the following:
                    A. The patient has tried and had an inadequate response to maximally tolerated methotrexate (e.g., titrated to 25 mg weekly) for at least 3-months **OR**
                    B. The patient has tried and had an inadequate response to another conventional agent (i.e., hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA for at least 3-months **OR**
                    C. The patient has an intolerance or hypersensitivity to ONE of the following conventional agents (i.e., maximally tolerated methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR**
                    D. The patient has an FDA labeled contraindication to ALL of the

following conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR**

E. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of RA **OR**
F. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
    2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND**
    3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
G. The prescriber has provided documentation that ALL conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

2. If the request is for Simponi, ONE of the following:
    A. The patient will be taking the requested agent in combination with methotrexate **OR**
    B. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to methotrexate **OR**

B. The patient has a diagnosis of active psoriatic arthritis (PsA) AND ONE of the following:
    1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA for at least 3-months **OR**
    2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of PsA **OR**
    3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PsA **OR**
    4. The patient has severe active PsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR**
    5. The patient has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR**
    6. The patient's medication history indicates use of another biologic immunomodulator agent OR Otezla that is FDA labeled or supported in compendia for the treatment of PsA **OR**
    7. The patient is currently being treated with the requested agent as indicated by ALL of the following:
        A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
        B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested

agent **AND**

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

8. The prescriber has provided documentation that ALL conventional agents (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

C. The patient has a diagnosis of moderate to severe plaque psoriasis (PS) AND ONE of the following:

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

D. The patient has a diagnosis of moderately to severely active Crohn's disease (CD) AND ONE of the following:

1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, corticosteroids

[e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD for at least 3-months **OR**

2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of CD **OR**
3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of CD **OR**
4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of CD **OR**
5. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
    B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND**
    C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
6. The prescriber has provided documentation that ALL conventional agents (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

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

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

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

4. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
    B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND**
    C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
5. The prescriber has provided documentation that ALL conventional systemic agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

2. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR**

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

H. The patient has a diagnosis of active ankylosing spondylitis (AS) AND ONE of the following:
1. The patient has tried and had an inadequate response to two different NSAIDs used in the treatment of AS for at least a 4-week total trial **OR**
2. The patient has an intolerance or hypersensitivity to two different

NSAIDs used in the treatment of AS **OR**

3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of AS **OR**
4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of AS **OR**
5. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
    B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND**
    C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of AS cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

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

J. The patient has a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) AND ONE of the following:
1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., methotrexate, leflunomide) used in the treatment of PJIA for at least 3-months **OR**
2. The patient has an intolerance or hypersensitivity to ONE of the

conventional agents used in the treatment of PJIA **OR**

3. The patient has an FDA labeled contraindication 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 active systemic juvenile idiopathic arthritis (SJIA) AND ONE of the following:

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

M. 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**

N. The patient has a diagnosis of active enthesitis related arthritis (ERA) and ONE of the following:
    1. The patient has tried and had an inadequate response to two different NSAIDs used in the treatment of ERA for at least a 4-week total trial **OR**
    2. The patient has an intolerance or hypersensitivity to two different NSAIDs used in the treatment of ERA **OR**
    3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of ERA **OR**
    4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of ERA **OR**

5. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
    B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND**
    C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of ERA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

O. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following:
1. ONE of the following:
    A. The patient has at least 10% body surface area involvement **OR**
    B. The patient has involvement of the palms and/or soles of the feet **AND**
2. ONE of the following:
    A. The patient has tried and had an inadequate response to at least a mid- potency topical steroid used in the treatment of AD for a minimum of 4 weeks **AND** a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD for a minimum of 6 weeks **OR**
    B. The patient has an intolerance or hypersensitivity to at least a mid- potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR**
    C. The patient has an FDA labeled contraindication to ALL mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors used in the treatment of AD **OR**
    D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
        1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
        2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND**
        3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
    E. The prescriber has provided documentation that ALL mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
3. ONE of the following**:**
    A. The patient has tried and had an inadequate response to a systemic immunosuppressant, including a biologic, used in the

treatment of AD for a minimum of 3 months **OR**

B. The patient has an intolerance or hypersensitivity to therapy with systemic immunosuppressants, including a biologic, used in the treatment of AD **OR**

C. The patient has an FDA labeled contraindication to ALL systemic immunosuppressants, including biologics, used in the treatment of AD **OR**

D. The patient is currently being treated with the requested agent as indicated by ALL of the following:

1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND**
3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

E. The prescriber has provided documentation that ALL systemic immunosuppressants, including biologics, used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

4. The prescriber has documented the patient's baseline pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **AND**
5. BOTH of the following:

A. The patient is currently treated with topical emollients and practicing good skin care **AND**

B. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent **OR**

P. 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**

Q. The patient has a diagnosis of polymyalgia rheumatica (PMR) AND ONE of the following:

1. The patient has tried and had an inadequate response to systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR for a minimum of 8 weeks **OR**
2. The patient is currently treated with systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone and cannot tolerate a corticosteroid taper **OR**
3. The patient is currently being treated with the requested agent as indicated by ALL of the following:

A. A statement by the prescriber that the patient is currently taking the requested agent **AND**

B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND**

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

4. The prescriber has provided documentation that ALL systemic corticosteroids used in the treatment of PMR cannot be used due to a

documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

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

agents for the requested indication **OR**

5. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
    B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND**
    C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
6. The prescriber has provided documentation that ALL required Step 1 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

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

F. If the requested agent is a Step 3b agent for the requested indication, then ONE of the following (chart notes required):
1. The patient has tried and had an inadequate response to TWO agents from Step 1 and/or Step 2 for the requested indication for at least 3-months (See Step 3b) **OR**
2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to

TWO agents from Step 1 and/or Step 2 for the requested indication **OR**

3. The patient has an FDA labeled contraindication to ALL of the Step 1 AND Step 2 agents for the requested indication **OR**
4. BOTH of the following:
    A. The prescriber has provided information indicating why ALL of the Step 1 AND Step 2 agents are not clinically appropriate for the patient **AND**
    B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR**
5. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
    B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND**
    C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
6. The prescriber has provided documentation that ALL of the Step 1 AND Step 2 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

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

physical or mental harm **AND**

3. If Cosentyx 300 mg every 4 weeks is requested as maintenance dosing, ONE of the following:
    A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis **OR**
    B. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks for at least 3-months **AND**
4. If Skyrizi is requested for the treatment of Crohn's disease, the patient received Skyrizi IV for induction therapy **AND**
5. If Stelara is requested for the treatment of Crohn's disease or ulcerative colitis, the patient received Stelara IV for induction therapy **AND**

2. If the patient has an FDA approved indication, then ONE of the following:
    A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
    B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**
3. If Stelara 90 mg is requested, ONE of the following:
    A. The patient has a diagnosis of psoriasis AND weighs >100kg **OR**
    B. The patient has a dual diagnosis of psoriasis AND psoriatic arthritis AND the patient is >100kg **OR**
    C. The patient has a diagnosis of Crohn's disease or ulcerative colitis **AND**
4. 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**
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 has consulted with a specialist in the area of the patient's diagnosis **AND**
6. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):
    A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**
    B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
        1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**
        2. The prescriber has provided information in support of combination therapy (submitted copy required, i.e., clinical trials, phase III studies, guidelines required) **AND**
7. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
8. The patient has been tested for latent tuberculosis (TB) when required by the prescribing information for the requested agent AND if positive the patient has begun therapy for latent TB

Length of Approval: 12 months for all agents EXCEPT adalimumab containing products for ulcerative colitis (UC), Rinvoq for atopic dermatitis (AD), Siliq for plaque psoriasis (PS), Xeljanz and Xeljanz XR for induction therapy for UC, and the agents with indications that require loading doses for new starts. NOTE: For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of the 12 months. Adalimumab containing products for UC may be approved for 12 weeks, Rinvoq for AD may be approved for 6 months, Siliq for PS may be approved for 16 weeks, and Xeljanz and Xeljanz XR for UC may be approved for 16 weeks.

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

**NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable.

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

Renewal Evaluation

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

1. The request is NOT for use of Olumiant or Actemra in the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) *NOTE: This indication is not covered under the pharmacy benefit **AND**
2. The request is for use in Alopecia Areata and Alopecia Areata is NOT restricted from coverage under the patient's benefit **AND**
3. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (*please note Stelara renewal must be for the same strength as the initial approval) **AND**
4. ONE of the following:
    A. The patient has a diagnosis of moderate to severe atopic dermatitis AND BOTH of the following:
        1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following:
            A. Affected body surface area **OR**
            B. Flares **OR**
            C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **AND**
        2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR**
    B. The patient has a diagnosis of polymyalgia rheumatica AND BOTH of the following:
        1. The patient has had clinical benefit with the requested agent **AND**
        2. If the requested agent is Kevzara, the patient does NOT have any of the following:
            A. Neutropenia (ANC less than 1,000 per mm^3 at the end of the dosing interval) **AND**
            B. Thrombocytopenia (platelet count is less than 100,000 per mm^3) **AND**
            C. AST or ALT elevations 3 times the upper limit of normal **OR**
    C. The patient has a diagnosis other than moderate to severe atopic dermatitis or polymyalgia rheumatica AND the patient has had clinical benefit with the requested agent **AND**
5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
6. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):
    A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**
    B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
        1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**
        2. The prescriber has provided information in support of combination therapy (submitted copy required, i.e., clinical trials, phase III studies, guidelines required) **AND**
7. If Cosentyx 300 mg every 4 weeks is requested as maintenance dosing, ONE of the following:
    A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis **OR**
    B. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks for at least 3-months **AND**
8. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND**
9. The patient does NOT have any FDA labeled contraindications to the requested agent

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

	Length of Approval: 12 months **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

Module	Clinical Criteria for Approval
	D. 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** 4. If the requested agent is NOT Xeljanz/Xeljanz XR for a diagnosis of ulcerative colitis or polyarticular course juvenile idiopathic arthritis, then ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. If the patient has an FDA approved indication, then BOTH of the following: 1. The requested quantity (dose) is greater than the maximum FDA labeled dose AND the maximum compendia supported 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 (medical records required) **AND** C. If the patient has a compendia supported indication, the requested quantity (dose) is greater than the maximum compendia supported dose for the requested indication **AND** D. The prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy required; e.g., clinical trials, phase III studies, guidelines required) **Length of Approval:** • Initial Approval with PA: 12 months for all agents EXCEPT adalimumab containing products for ulcerative colitis (UC), Rinvoq for atopic dermatitis (AD), Siliq for plaque psoriasis (PS), Xeljanz and Xeljanz XR for induction therapy for UC, and the agents with indications that require loading doses for new starts. NOTE: For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of the 12 months. Adalimumab containing products for UC may be approved for 12 weeks, Rinvoq for AD may be approved for 6 months, Siliq for PS may be approved for 16 weeks, and Xeljanz and Xeljanz XR for UC may be approved for 16 weeks. • Renewal Approval with PA: 12 months • Standalone QL approval: 12 months or through the remainder of an existing authorization, whichever is shorter **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable.

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) Cibinqo (abrocitinib) Cimzia (certolizumab) Cinqair (reslizumab) Cosentyx (secukinumab) Cyltezo (adalimumab-adbm) Dupixent (dupilumab)

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

• Program Summary: Calcitonin Gene-Related Peptide (CGRP)

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
67701060707220	Nurtec	Rimegepant Sulfate Tab Disint 75 MG	75 MG	16	Tablets	30	DAYS					
67701010000310	Qulipta	Atogepant Tab	10 MG	30	Tablets	30	DAYS					
67701010000320	Qulipta	Atogepant Tab	30 MG	30	Tablets	30	DAYS					
67701010000330	Qulipta	Atogepant Tab	60 MG	30	Tablets	30	DAYS					
67701080000340	Ubrelvy	Ubrogepant Tab 100 MG	100 MG	16	Tablets	30	DAYS					
67701080000320	Ubrelvy	Ubrogepant Tab 50 MG	50 MG	16	Tablets	30	DAYS					
67701090202020	Zavzpret	zavegepant hcl nasal spray	10 MG/ACT	8	Units	30						
6770202010D540	Aimovig	Erenumab-aooe Subcutaneous Soln Auto-Injector 140 MG/ML	140 MG/ML	1	Injection Device	28	DAYS					
6770202010D520	Aimovig	Erenumab-aooe Subcutaneous Soln Auto-Injector 70 MG/ML	70 MG/ML	1	Injection Device	28	DAYS					
6770203530D520	Emgality	Galcanezumab-gnlm Subcutaneous Soln Auto-Injector 120 MG/ML	120 MG/ML	1	Injection Device	28	DAYS					
6770203530E515	Emgality	Galcanezumab-gnlm Subcutaneous Soln Prefilled Syr 100 MG/ML	100 MG/ML	9	Syringes	180	DAYS					
6770203530E520	Emgality	Galcanezumab-gnlm Subcutaneous Soln Prefilled Syr 120 MG/ML	120 MG/ML	1	Syringe	28	DAYS					
6770203020D520	Ajovy	Fremanezumab-vfrm Subcutaneous Soln Auto-inj 225 MG/1.5ML	225 MG/1.5ML	3	Injection Devices	84	DAYS					
6770203020E520	Ajovy	Fremanezumab	225	3	Syringes	84	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		-vfrm Subcutaneous Soln Pref Syr 225 MG/1.5ML	MG/1.5ML									

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 being used for migraine prophylaxis AND ALL of the following: 1. ONE of the following: A. The patient has a diagnosis of chronic migraine (defined as greater than or equal to 15 headache days per month) AND ALL of the following: 1. Greater than or equal to 15 headache days per month of migraine-like or tension-like headache for a minimum of 3 months **AND** 2. Greater than or equal to 8 migraine headache days per month for a minimum of 3 months **AND** 3. The patient will NOT be using the requested agent in combination with another prophylactic use CGRP **AND** 4. The requested agent and strength is FDA approved for chronic migraine prophylaxis **OR** B. The patient has a diagnosis of episodic migraine (defined as less than 15 headache days per month) AND ALL of the following: 1. ONE of the following: A. The patient has greater than 4 migraine headache days per month **OR** B. The patient's migraine headaches last greater than 12 hours **OR** C. The patient's migraine attacks cause significant disability or diminished quality of life despite appropriate therapy with acute agents only **OR** D. The patient has contraindications to acute therapies **OR** E. The patient has tried and received inadequate response to acute therapies **OR** F. The patient has serious side effects to acute therapies **OR** G. The patient is at risk of medication overuse headache without preventative therapy **OR** H. 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** I. The prescriber has provided documentation that acute

Module	Clinical Criteria for Approval
	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** 2. The patient will NOT be using the requested agent in combination with another prophylactic use CGRP **AND** 3. The requested agent and strength is FDA approved for episodic migraine prophylaxis **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to at least one migraine prophylaxis class [i.e., anticonvulsants (divalproex, valproate, topiramate), beta blockers (i.e., atenolol, metoprolol, nadolol, propranolol, timolol), antidepressants (i.e., amitriptyline, venlafaxine), candesartan] **OR** B. The patient has an intolerance or hypersensitivity to therapy with at least one migraine prophylaxis class listed above **OR** C. The patient has an FDA labeled contraindication to ALL migraine prophylaxis agents listed above **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 migraine prophylaxis class (i.e., anticonvulsants [i.e., divalproex, valproate, topiramate], beta blockers [i.e., atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [i.e., amitriptyline, venlafaxine], candesartan) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. ONE of the following: A. The requested agent is a preferred agent **OR** B. The requested agent is a non-preferred agent and ALL of the following: 1. The patient has tried and had an inadequate response to ONE preferred agent(s) **OR** 2. The patient has tried has an intolerance or hypersensitivity to ONE preferred agent(s) **OR** 3. The patient has an FDA labeled contraindication to ALL preferred agent(s) **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**

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	5. The prescriber has provided documentation that ALL preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. Medication overuse headache has been ruled out **OR** B. The requested agent is being used for the treatment of episodic cluster headache AND ALL of the following: 1. The patient has a diagnosis of episodic cluster headache as confirmed by ALL of the following: A. The patient has had at least 5 cluster headache attacks **AND** B. The patient has at least two cluster period lasting 7-365 days **AND** C. The patient's cluster periods are separated by a pain-free remission period of greater than or equal to 3 months **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to verapamil, melatonin, corticosteroids, topiramate, OR lithium **OR** B. The patient has an intolerance or hypersensitivity to verapamil, melatonin, corticosteroid, topiramate, OR lithium **OR** C. The patient has an FDA labeled contraindication to verapamil, melatonin, corticosteroid, topiramate, AND lithium **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 verapamil, melatonin, corticosteroids, topiramate, OR lithium cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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. Medication overuse headache has been ruled out **AND** 4. The requested agent and strength is FDA approved for episodic cluster headache treatment **OR** C. The requested agent is being used for acute migraine treatment AND ALL of the following: 1. ONE of the following: A. The patient has tried and had an inadequate response to at least one triptan agent **OR** B. The patient has an intolerance or hypersensitivity to a triptan agent **OR** C. The patient has an FDA labeled contraindication to ALL triptan 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

Module	Clinical Criteria for Approval
	ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL triptan agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient will NOT be using the requested agent in combination with another acute migraine therapy (i.e., triptan, 5HT-1F, ergotamine, acute use CGRP) **AND** 3. Medication overuse headache has been ruled out **AND** 4. The requested agent and strength is FDA approved for acute migraine treatment **OR** D. The patient has another FDA approved indication for the requested agent and route of administration **OR** E. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA labeled indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient does not have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** For migraine prophylaxis: 6 months. For agents that require a loading dose for new starts, approve the loading dose noted with the quantity limits table above AND the maintenance dose for the remainder of 6 months. For cluster headache treatment: 6 months All other indications: 12 months **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been approved for the requested agent previously through the plan's Prior Authorization process **AND** 2. ONE of the following: A. BOTH of the following: 1. ONE of the following: A. The requested agent is being used for migraine prophylaxis AND ALL of the following: 1. The prescriber has provided information indicating improvement in migraine prevention (e.g., reduced migraine headache days, reduced migraine frequency, reduced use of acute abortive migraine medication) with the requested agent **AND** 2. The patient will NOT be using the requested agent in combination with another prophylactic use CGRP **AND** 3. ONE of the following: A. BOTH of the following: 1. The patient has a diagnosis of chronic migraine (defined as greater than or equal to 15 headache days per month) **AND** 2. The requested agent and strength is FDA approved for chronic migraine **OR** B. BOTH of the following:

Module	Clinical Criteria for Approval
	1. The patient has a diagnosis of episodic migraine (defined as less than 15 headache days per month) **AND** 2. The requested agent and strength is FDA approved for episodic migraine **OR** B. The requested agent is being used for episodic cluster headache treatment AND BOTH of the following: 1. The prescriber has provided information indicating improvement in cluster headaches management with the requested agent **AND** 2. The requested agent and strength is FDA approved for episodic cluster headache treatment **OR** C. The requested agent is being used for acute migraine treatment AND ALL of the following: 1. The prescriber has provided information indicating improvement in acute migraine management with the requested agent **AND** 2. The patient will NOT be using the requested agent in combination with another acute migraine therapy (i.e., triptan, 5HT-1F, ergotamine, acute use CGRP) **AND** 3. The requested agent and strength is FDA approved for acute migraine treatment **AND** 2. Medication overuse headache has been ruled out **OR** B. BOTH of the following: 1. ONE of the following: A. The patient has another FDA approved indication for the requested agent and route of administration **OR** B. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient does not have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the limit **OR** 3. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** C. If the requested agent is being used for treatment of acute migraine, the patient has greater than 4 migraine headaches per month AND ONE of the following:

Module	Clinical Criteria for Approval
	1. The patient is currently being treated with a migraine prophylactic medication [i.e., anticonvulsants (i.e., divalproex, valproate, topiramate), beta blockers (i.e., atenolol, metoprolol, nadolol, propranolol, timolol), antidepressants (i.e., amitriptyline, venlafaxine), candesartan, prophylactic use CGRP (e.g., Aimovig, Ajovy, Emgality, Vyepti), onabotulinum toxin A (Botox)] **OR** 2. The patient has an intolerance or hypersensitivity to therapy with migraine prophylactic medication [i.e., anticonvulsants (i.e., divalproex, valproate, topiramate), beta blockers (i.e., atenolol, metoprolol, nadolol, propranolol, timolol), antidepressants (i.e., amitriptyline, venlafaxine), candesartan, prophylactic use CGRP (e.g., Aimovig, Ajovy, Emgality, Vyepti), OR onabotulinum toxin A (Botox)] **OR** 3. The patient has an FDA labeled contraindication to ALL migraine prophylactic medications [i.e., anticonvulsants (i.e., divalproex, valproate, topiramate), beta blockers (i.e., atenolol, metoprolol, nadolol, propranolol, timolol), antidepressants (i.e., amitriptyline, venlafaxine), candesartan, prophylactic use CGRP (e.g., Aimovig, Ajovy, Emgality, Vyepti), AND onabotulinum toxin A (Botox)] **OR** 4. The prescriber has provided information that the patient's migraine is manageable with acute therapy alone **AND** D. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** Initial: For migraine prophylaxis: 6 months. For agents that require a loading dose for new starts, approve the loading dose noted with the quantity limits table above AND the maintenance dose for the remainder of 6 months. For cluster headache treatment: 6 months All other indications: 12 months Renewal: 12 months

• Program Summary: Cystic Fibrosis Transmembrane Conductance Regulator (CFTR)

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
45302030003005	Kalydeco	ivacaftor packet	13.4 MG	60	Packets	30	DAYS					
45302030003010	Kalydeco	Ivacaftor Packet 25 MG	25 MG	60	Packets	30	DAYS					
45302030003020	Kalydeco	Ivacaftor Packet 50 MG	50 MG	60	Packets	30	DAYS					
45302030003030	Kalydeco	Ivacaftor Packet 75 MG	75 MG	60	Packets	30	DAYS					
45302030000320	Kalydeco	Ivacaftor Tab 150	150 MG	60	Tablets	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		MG										
45309902303005	Orkambi	Lumacaftor-Ivacaftor Granules Packet	75-94 MG	60	Packets	30	DAYS					
45309902303010	Orkambi	Lumacaftor-Ivacaftor Granules Packet 100-125 MG	100-125 MG	60	Packets	30	DAYS					
45309902303020	Orkambi	Lumacaftor-Ivacaftor Granules Packet 150-188 MG	150-188 MG	60	Packets	30	DAYS					
45309902300310	Orkambi	Lumacaftor-Ivacaftor Tab 100-125 MG	100-125 MG	120	Tablets	30	DAYS					
45309902300320	Orkambi	Lumacaftor-Ivacaftor Tab 200-125 MG	200-125 MG	120	Tablets	30	DAYS					
4530990280B720	Symdeko	Tezacaftor-Ivacaftor 100-150 MG & Ivacaftor 150 MG Tab TBPK	100-150 & 150 MG	60	Tablets	30	DAYS					
4530990280B710	Symdeko	Tezacaftor-Ivacaftor 50-75 MG & Ivacaftor 75 MG Tab TBPK	50-75 & 75 MG	60	Tablets	30	DAYS					
4530990340B120	Trikafta	elexacaf-tezacaf-ivacaf THPK Gran	80-40-60 & 59.5 MG	56	Packs	28	DAYS					
4530990340B140	Trikafta	elexacaf-tezacaf-ivacaf THPK Gran	100-50-75 & 75 MG	56	Packs	28	DAYS					
4530990340B720	Trikafta	Elexacaf-Tezacaf-Ivacaf TBPK	50-25-37.5 & 75 MG	90	Tablets	30	DAYS					
4530990340B740	Trikafta	Elexacaf-Tezacaf-Ivacaf 100-50-75 MG & Ivacaftor 150 MG TBPK	100-50-75 & 150 MG	90	Tablets	30	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. ALL of the following: 1. The patient has a diagnosis of cystic fibrosis **AND** 2. Information has been provided that indicates the patient has a CFTR gene mutation(s),

Module	Clinical Criteria for Approval
	confirmed by genetic testing, according to the FDA label for the requested agent (medical records required) **AND** 3. If the requested agent is Kalydeco, the patient does NOT have F508del mutation on BOTH alleles of CFTR gene (NOT homozygous) **OR** B. The patient has another FDA approved indication for the requested agent **AND** 2. ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient will NOT be using the requested agent in combination with another CFTR modulator agent for the requested indication **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cystic fibrosis, pulmonologist) 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:** 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. ONE of the following: A. If the patient has a diagnosis of cystic fibrosis, the prescriber has provided information that the patient has had clinical improvement or stabilization with the requested agent from baseline (prior to treatment with the requested agent) [e.g., improvement in FEV1, increase in weight/BMI, improvement in Cystic Fibrosis Questionnaire-Revised (CFQ-R) Respiratory Domain score, improvements in respiratory symptoms related to patients with CF (cough, sputum production, and difficulty breathing), and/or reduced number of pulmonary exacerbations] **OR** B. If the patient has another FDA approved indication for the requested agent, the patient has had clinical benefit with the requested agent **AND** 3. The patient will NOT be using the requested agent in combination with another CFTR modulator agent for the requested indication **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cystic fibrosis, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

Module	Clinical Criteria for Approval
	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) is greater than the program quantity limit **AND** B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: Initial: 6 months, Renewal: 12 months

• Program Summary: Erythropoietins

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
	824010151020	Aranesp albumin free	darbepoetin alfa soln inj	100 MCG/ML; 200 MCG/ML; 25 MCG/ML; 40 MCG/ML; 60 MCG/ML	M; N; O; Y				
	8240101510E5	Aranesp albumin free	darbepoetin alfa soln prefilled syringe	10 MCG/0.4ML; 100 MCG/0.5ML; 150 MCG/0.3ML; 200 MCG/0.4ML; 25 MCG/0.42ML; 300 MCG/0.6ML; 40 MCG/0.4ML; 500 MCG/ML; 60 MCG/0.3ML	M; N; O; Y				
	824010200020	Epogen ; Procrit	epoetin alfa inj	10000 UNIT/ML; 2000 UNIT/ML; 20000 UNIT/ML; 3000 UNIT/ML; 4000 UNIT/ML; 40000 UNIT/ML	M; N; O; Y				
	8240104010E5	Mircera	methoxy peg-epoetin beta soln prefilled syr	100 MCG/0.3ML; 120 MCG/0.3ML; 150 MCG/0.3ML; 200 MCG/0.3ML; 30 MCG/0.3ML; 50 MCG/0.3ML; 75 MCG/0.3ML	M; N; O; Y				
	824010200420	Retacrit	epoetin alfa-epbx inj	10000 UNIT/ML; 2000 UNIT/ML; 20000 UNIT/2ML; 20000 UNIT/ML 3000 UNIT/ML;	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
				4000 UNIT/ML; 40000 UNIT/ML					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Evaluation **Target Agent(s)** will be approved when BOTH of the following are met: 1. The patient's hemoglobin was measured within the previous 4 weeks **AND** 2. ONE of the following: A. The patient will use the requested agent as part of dialysis AND ONE of the following: 1. The patient is initiating an erythropoietin stimulating agent (ESA) AND the patient's hemoglobin level is less than 10 g/dL **OR** 2. The patient is stabilized on an ESA AND the patient's hemoglobin is less than or equal to 11 g/dL **OR** B. ALL of the following: 1. ONE of the following: A. The requested agent is being prescribed to reduce the possibility of allogeneic blood transfusion in a surgery patient AND the patient's hemoglobin level is greater than 10 g/dL but less than or equal to 13 g/dL **OR** B. The requested agent is being prescribed for anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy AND ALL of the following: 1. The requested agent is NOT Mircera **AND** 2. ONE of the following: A. The patient is initiating an erythropoietin stimulating agent (ESA) AND the patient's hemoglobin level is less than 10 g/dL **OR** B. The patient is stabilized on an ESA AND the patient's hemoglobin is less than or equal to 12 g/dL **AND** 3. The patient is concurrently treated with chemotherapy (with or without radiation) **AND** 4. Chemotherapy is being used for palliative intent **AND** 5. The patient's serum ferritin and transferrin saturation have been evaluated within the previous 4 weeks AND BOTH of the following: A. The patient's serum ferritin is NOT greater than 800 ng/mL **AND** B. The patient's transferrin saturation is NOT greater than 50% **OR** C. The requested agent is being prescribed for anemia associated with chronic kidney disease in a patient NOT on dialysis AND ALL of the following: 1. ONE of the following: A. The patient is initiating an erythropoietin stimulating agent (ESA) AND the patient's hemoglobin level is less than 10 g/dL OR B. The patient is stabilized on an ESA AND the patient's hemoglobin is less than or equal to 11 g/dL **AND** 2. The rate of hemoglobin decline is likely to result in a red blood cell (RBC) transfusion **AND** 3. The intent of therapy is to reduce the risk of alloimmunization and/or other RBC transfusion related risks **OR**

Module	Clinical Criteria for Approval
	D. The requested agent is being prescribed for anemia due to myelodysplastic syndrome, or for anemia resulting from zidovudine treatment of HIV infection AND ONE of the following: 1. The patient is initiating an erythropoietin stimulating agent (ESA) AND the patient's hemoglobin level is less than 12 g/dL **OR** 2. The patient is stabilized on an ESA AND the patient's hemoglobin is less than or equal to 12 g/dL **OR** E. The requested agent is being prescribed for another FDA approved indication or another indication that is supported in compendia AND the patient's hemoglobin level is within the FDA labeling or compendia recommended range for the requested indication for patients initiating ESA therapy OR for patients stabilized on therapy for the requested indication **AND** 2. The patient's serum ferritin and transferrin saturation have been evaluated within the previous 4 weeks **AND** 3. ONE of the following: A. The patient's serum ferritin is greater than or equal to 100 ng/mL AND the patient's transferrin saturation is greater than or equal to 20% **OR** B. The patient has started supplemental iron therapy **AND** 4. If the patient has an FDA approved indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 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, NCCN 1 or 2a recommended use **Length of Approval**: 1 month for allogenic blood transfusion in a surgery patient; 6 months for anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy 12 months for anemia associated with chronic kidney disease in patients on/not on dialysis, anemia due to myelodysplastic syndrome, anemia resulting from zidovudine treatment of HIV infection 6 months for all other diagnoses

• Program Summary: Fibrates - *Retired*

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

This program is retired, effective 10/1/2023.

• Program Summary: Growth Hormone

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

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

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

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Adults: Short-Acting Growth Hormone with Preferred Exception	**TARGET AGENT(S)** **Preferred Agent(s)** **Short Acting Agent(s)** **Norditropin FlexPro** (somatropin) **Genotropin, Genotropin MiniQuick (somatropin)** **Nonpreferred Agent(s)** **Short Acting Agent(s)** **Humatrope** (somatropin) **Nutropin AQ NuSpin** (somatropin) **Omnitrope** (somatropin) **Saizen, Saizenprep** (somatropin) **Serostim** (somatropin) **Zomacton** (somatropin) **Zorbtive** (somatropin) **Long Acting Agent(s)** **Skytrofa** (lonapegsomatropin-tcgd) **Sogroya** (somapacitan-beco) **Adults – Initial Evaluation** **Target Short-Acting Growth Hormone Agent(s)** will be approved when ALL of the following are met: 1. The patient is an adult (as defined by the prescriber) **AND**

Module	Clinical Criteria for Approval
	2. The patient has ONE of the following diagnoses: A. The patient has a diagnosis of AIDS wasting/cachexia AND ALL of the following: 1. The patient is currently treated with antiretroviral therapy **AND** 2. The patient will continue antiretroviral therapy in combination with the requested agent **AND** 3. BOTH of the following: A. ONE of the following: 1. The patient has had weight loss that meets ONE of the following: A. 10% unintentional weight loss over 12 months **OR** B. 7.5% unintentional weight loss over 6 months **OR** 2. The patient has a body cell mass (BCM) loss greater than or equal to 5% within 6 months **OR** 3. The patient's sex is male and has BCM less than 35% of total body weight and body mass index (BMI) less than 27 kg/m^2 **OR** 4. The patient's sex is female and has BCM less than 23% of total body weight and BMI less than 27 kg/m^2 **OR** 5. The prescriber has provided information that the patient's BCM less than 35% or less than 23% and BMI less than 27 kg/m^2 are medically appropriate for diagnosing AIDS wasting/cachexia for the patient's sex **OR** 6. The patient's BMI is less than 20 kg/m^2 **AND** B. All other causes of weight loss have been ruled out **OR** B. The patient has a diagnosis of short bowel syndrome (SBS) AND is receiving specialized nutritional support AND ONE of the following: 1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** 2. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **OR** C. The patient has a diagnosis of growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone AND ONE of the following: 1. The patient had a diagnosis of childhood-onset growth hormone deficiency AND has failed at least one growth hormone (GH) stimulation test as an adult **OR** 2. The patient has a low insulin-like growth factor-1 (IGF-1) level AND ONE of the following: A. Organic hypothalamic-pituitary disease **OR** B. Pituitary structural lesion or trauma **OR** C. The patient has panhypopituitarism or multiple (greater than or equal to 3) pituitary hormone deficiency **OR** 3. The patient has an established causal genetic mutation OR hypothalamic-pituitary structural defect other than ectopic posterior pituitary **OR** 4. The patient has failed at least two growth hormone (GH) stimulation tests as an adult **OR** 5. The patient has failed at least one GH stimulation test as an adult AND the patient has an organic pituitary disease **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication **AND** 6. ONE of the following: A. BOTH of the following: 1. The request is for a preferred agent **AND**

Module	Clinical Criteria for Approval
	2. The preferred agent is supported in FDA labeling for the requested indication **OR** B. If the request is for a nonpreferred agent and BOTH of the following: 1. The nonpreferred agent is supported in FDA labeling for the requested indication **AND** 2. ONE of the following: A. The preferred agent is not supported in FDA labeling for the requested indication **OR** B. ONE of the following: 1. The preferred agent is not supported in FDA labeling for the requested indication **OR** 2. ONE of the following: A. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a preferred agent that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** B. The prescriber has provided information to support the efficacy of the requested nonpreferred agent over the preferred agent for the intended diagnosis (medical record required) **OR** C. The patient's medication history includes use of the preferred agent **OR** D. BOTH of the following: 1. The prescriber has stated that the patient has tried the preferred agent **AND** 2. The preferred agent was discontinued due to lack of effectiveness or an adverse event **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that the preferred agent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval:** 4 weeks for SBS 12 weeks for AIDS wasting/cachexia 12 months for other indications **Adults – Renewal Evaluation** **Target Short-Acting Growth Hormone Agent(s)** will be approved when ALL of the following are met: 1. The patient has been approved for therapy with GH previously through the plan's prior authorization process **AND** 2. The patient is an adult (as defined by the prescriber) **AND** 3. ONE of the following:

Module	Clinical Criteria for Approval
	A. BOTH of the following: 1. The request is for a preferred agent **AND** 2. The preferred agent is supported in FDA labeling for the requested indication **OR** B. The request is for a nonpreferred agent and BOTH of the following: 1. The nonpreferred agent is supported in FDA labeling for the requested indication **AND** 2. ONE of the following: A. The preferred agent is not supported in FDA labeling for the requested indication **OR** B. ONE of the following: 1. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a preferred agent that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 2. The prescriber has provided information to support the efficacy of the requested nonpreferred agent over the preferred agent for the intended diagnosis (medical record required) **OR** 3. The patient's medication history includes use of the preferred agent **OR** 4. BOTH of the following: A. The prescriber has stated that the patient has tried the preferred agent **AND** B. The preferred agent was discontinued due to lack of effectiveness or an adverse event **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that the preferred agent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. ONE of the following: A. The patient has a diagnosis of short bowel syndrome (SBS) AND has had clinical benefit with the requested agent **OR** B. The patient has a diagnosis of AIDS wasting/cachexia AND ALL of the following: 1. The patient is currently treated with antiretroviral therapy **AND** 2. The patient will continue antiretroviral therapy in combination with the requested agent **AND** 3. The patient has had clinical benefit with the requested agent (i.e., an increase in weight or weight stabilization) **OR** C. The patient has any other diagnosis AND BOTH of the following: 1. The patient's IGF-I level has been evaluated to confirm the appropriateness of the current dose **AND** 2. The patient has had clinical benefit with the requested agent (i.e., body composition, hip-to-waist ratio, cardiovascular health, bone mineral density, serum cholesterol, physical strength, or quality of life) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**

Module	Clinical Criteria for Approval
	6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or has consulted with a specialist in the area of the patient's diagnosis **AND** 7. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication **AND** 8. The patient is being monitored for adverse effects of GH **Length of Approval:** 4 weeks for SBS 12 weeks for AIDS wasting/cachexia 12 months for other indications
Children: Long-Acting Growth Hormone with Preferred Exception	**TARGET AGENT(S)** **Preferred Agent(s)** **Short Acting Agent(s)** **Norditropin FlexPro** (somatropin) **Genotropin, Genotropin MiniQuick (somatropin)** **Nonpreferred Agent(s)** **Short Acting Agent(s)** **Humatrope** (somatropin) **Nutropin AQ NuSpin** (somatropin) **Omnitrope** (somatropin) **Saizen, Saizenprep** (somatropin) **Serostim** (somatropin) **Zomacton** (somatropin) **Zorbtive** (somatropin) **Long Acting Agent(s)** **Skytrofa** (lonapegsomatropin-tcgd) **Sogroya** (somapacitan-beco) **Children – Initial Evaluation** **Target Long-Acting Growth Hormone Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has an FDA approved indication for the requested agent **OR** B. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. ONE of the following: A. The patient has a diagnosis of growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone AND ONE of the following: 1. The patient has extreme short stature (e.g., height less than or equal to -3 SD), normal nutrition, significantly reduced IGF-1 and IGFBP-3 (e.g., less than -2 SD), and delayed bone age **OR** 2. BOTH of the following: A. The patient has ONE of the following: 1. Height more than 2 SD below the mean for age and sex **OR** 2. Height more than 1.5 SD below the midparental height **OR** 3. A decrease in height SD of more than 0.5 over one year in children greater than 2 years of age **OR** 4. Height velocity (HV) more than 2 SD below the mean over one year or more than 1.5 SD sustained over two years **OR**

Module	Clinical Criteria for Approval
	5. Height-for-age curve that has deviated downward across two major height percentile curves (e.g., from above the 25th percentile to below the 10th percentile) **OR** 6. BOTH of the following: A. The patient's age is 2-4 years **AND** B. The patient has a HV less than 5.5 cm/year (less than 2.2 inches/year) **OR** 7. BOTH of the following: A. The patient's age is 4-6 years **AND** B. The patient has a HV less than 5 cm/year (less than 2 inches/year) **OR** 8. The patient's age is 6 years to puberty AND ONE of the following: A. The patient's sex is male and HV is less than 4 cm/year (less than 1.6 inches/year) **OR** B. The patient's sex is female and HV is less than 4.5 cm/year (less than 1.8 inches/year) **AND** B. ONE of the following: 1. The patient has failed at least 2 GH stimulation tests (e.g., peak GH value of less than 10 mcg/L after stimulation, or otherwise considered abnormal as determined by testing lab) **OR** 2. The patient has failed at least 1 GH stimulation test (e.g., peak GH value of less than 10 mcg/L after stimulation, or otherwise considered abnormal as determined by testing lab) AND ONE of the following: A. Pathology of the central nervous system **OR** B. History of irradiation **OR** C. Other pituitary hormone defects (e.g., multiple pituitary hormone deficiency [MPHD]) **OR** D. A genetic defect **OR** 3. The patient has a pituitary abnormality and a known deficit of at least one other pituitary hormone **OR** B. The patient has another FDA approved or compendia supported indication for the requested agent and route of administration **AND** 3. The patient is a child (as defined by the prescriber) **AND** 4. ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 5. BOTH of the following: A. The nonpreferred agent is supported in FDA labeling for the requested indication **AND** B. ONE of the following: 1. BOTH of the following: A. The patient has received a trial of the preferred short-acting GH **AND** B. The patient has failed to achieve a 2 cm/year growth velocity due to lack of adherence to a preferred short-acting GH **OR** 2. The patient has an intolerance, hypersensitivity or FDA labeled contraindication to a preferred short-acting GH that is not expected to occur with the requested nonpreferred agent **OR** 3. BOTH of the following: A. The prescriber has stated that the patient has tried the preferred short-acting GH **AND** B. The preferred short-acting GH was discontinued due to lack of effectiveness

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	or an adverse event **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that the preferred short-acting GH cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or has consulted with a specialist in the area of the patient's diagnosis **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 8. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months **Children – Renewal Evaluation** **Target Long-Acting Growth Hormone Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for therapy with GH through the plan's prior authorization process **AND** 2. The patient is a child (as defined by the prescriber) **AND** 3. BOTH of the following: A. The nonpreferred agent is supported in FDA labeling for the requested indication **AND** B. ONE of the following: 1. The preferred agent is not supported in FDA labeling for the requested indication **OR** 2. ONE of the following: A. BOTH of the following: 1. The patient has received a trial of the preferred short-acting GH **AND** 2. The patient failed to achieve a 2 cm/year growth velocity due to lack of adherence to a preferred short-acting GH **OR** B. The patient has an intolerance, hypersensitivity or FDA labeled contraindication to a preferred short-acting growth hormone that is not expected to occur with the requested nonpreferred agent **OR** 3. BOTH of the following: A. The prescriber has stated that the patient has tried the preferred short-acting GH **AND** B. The preferred short-acting GH was discontinued due to lack of effectiveness or an adverse event **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive

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	therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that the preferred short-acting GH cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. ONE of the following: A. The patient has a diagnosis of growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone AND BOTH of the following: 1. The patient does NOT have closed epiphyses **AND** 2. The patient's height has increased or height velocity has improved since initiation or last GH approval **OR** B. BOTH of the following: 1. The patient has another FDA approved or compendia supported indication for the requested agent and route of administration **AND** 2. The patient has had clinical benefit with the requested agent **AND** 5. The patient is being monitored for adverse effects of GH **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or has consulted with a specialist in the area of the patient's diagnosis **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 8. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months
Children: Short-Acting Growth Hormone with Preferred Exception	**TARGET AGENT(S)** **Preferred Agent(s)** **Short Acting Agent(s)** **Norditropin FlexPro** (somatropin) **Genotropin, Genotropin MiniQuick (somatropin)** **Nonpreferred Agent(s)** **Short Acting Agent(s)** **Humatrope** (somatropin) **Nutropin AQ NuSpin** (somatropin) **Omnitrope** (somatropin) **Saizen, Saizenprep** (somatropin) **Serostim** (somatropin) **Zomacton** (somatropin) **Zorbtive** (somatropin) **Long Acting Agent(s)** **Skytrofa** (lonapegsomatropin-tcgd) **Sogroya** (somapacitan-beco)

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	Children – Initial Evaluation **Target Short-Acting Growth Hormone Agent(s)** will be approved when ALL of the following are met: 1. The patient is a child (as defined by the prescriber) **AND** 2. The patient has ONE of the following diagnoses: A. ALL of the following: 1. The patient is a newborn (less than or equal to 4 months of age) with hypoglycemia **AND** 2. The patient has a serum growth hormone (GH) concentration less than or equal to 5 mcg/L **AND** 3. ONE of the following: A. Congenital pituitary abnormality (e.g., ectopic posterior pituitary and pituitary hypoplasia with abnormal stalk) **OR** B. Deficiency of at least one additional pituitary hormone **OR** B. ALL of the following: 1. The patient is a newborn (less than or equal to 4 months of age) with hypoglycemia **AND** 2. The patient has a growth hormone (GH) concentration less than 20 mcg/L **AND** 3. The patient does not have a known metabolic disorder **AND** 4. The patient has a reduced IGFBP-3 level (e.g., less than -2 SD) **OR** C. The patient has a diagnosis of Turner syndrome **OR** D. The patient has a diagnosis of Noonan syndrome **OR** E. The patient has a diagnosis of Prader-Willi syndrome **OR** F. The patient has a diagnosis of SHOX gene deficiency **OR** G. The patient has a diagnosis of short bowel syndrome (SBS) AND is receiving specialized nutritional support AND ONE of the following: 1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** 2. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **OR** H. The patient has a diagnosis of panhypopituitarism or has deficiencies in at least 3 or more pituitary axes AND serum IGF-I levels below the age- and sex-appropriate reference range when off GH therapy **OR** I. The patient has a diagnosis of chronic renal insufficiency and BOTH of the following: 1. The patient's height velocity (HV) for age is less than -1.88 standard deviations (SD) OR HV for age is less than the third percentile **AND** 2. Other etiologies for growth impairment have been addressed **OR** J. The patient has a diagnosis of small for gestational age (SGA) and ALL of the following: 1. The patient is 2 years of age or older **AND** 2. The patient has a documented birth weight and/or birth length that is 2 or more standard deviations (SD) below the mean for gestational age **AND** 3. At 24 months of age, the patient failed to manifest catch-up growth evidenced by a height that remains 2 or more standard deviations (SD) below the mean for age and sex **OR** K. The patient has a diagnosis of idiopathic short stature (ISS) AND ALL of the following: 1. The patient has a height less than or equal to -2.25 SD below the corresponding mean height for age and sex **AND** 2. The patient has open epiphyses **AND** 3. ONE of the following: A. The patient has a predicted adult height that is below the normal range AND ONE of the following:

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	1. The patient's sex is male and predicted adult height is less than 63 inches **OR** 2. The patient's sex is female and predicted adult height is less than 59 inches **OR** B. The patient is more than 2 SD below their mid-parental target height **AND** 4. BOTH of the following: A. The patient has been evaluated for constitutional delay of growth and puberty (CDGP) **AND** B. The patient does NOT have a diagnosis of CDGP **OR** L. The patient has a diagnosis of growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone AND ONE of the following: 1. The patient has extreme short stature (e.g., height less than -3 SD), normal nutrition, significantly reduced IGF-1 and IGFBP-3 (e.g., less than -2 SD), and delayed bone age **OR** 2. BOTH of the following: A. The patient has ONE of the following: 1. Height more than 2 SD below the mean for age and sex **OR** 2. Height more than 1.5 SD below the midparental height **OR** 3. A decrease in height SD of more than 0.5 over one year in children greater than 2 years of age **OR** 4. Height velocity (HV) more than 2 SD below the mean over one year or more than 1.5 SD sustained over two years **OR** 5. Height-for-age curve that has deviated downward across two major height percentile curves (e.g., from above the 25th percentile to below the 10th percentile) **OR** 6. BOTH of the following: A. The patient's age is 2-4 years **AND** B. The patient has a HV less than 5.5 cm/year (less than 2.2 inches/year) **OR** 7. BOTH of the following: A. The patient's age is 4-6 years **AND** B. The patient has a HV less than 5 cm/year (less than 2 inches/year) **OR** 8. The patient's age is 6 years to puberty AND ONE of the following: A. The patient's sex is male and HV is less than 4 cm/year (less than 1.6 inches/year) **OR** B. The patient's sex is female and HV is less than 4.5 cm/year (less than 1.8 inches/year) **AND** B. ONE of the following: 1. The patient has failed at least 2 GH stimulation tests (e.g., peak GH value of less than 10 mcg/L after stimulation, or otherwise considered abnormal as determined by testing lab) **OR** 2. The patient has failed at least 1 GH stimulation test (e.g., peak GH value of less than 10 mcg/L after stimulation, or otherwise considered abnormal as determined by testing lab) AND ONE of the following: A. Pathology of the central nervous system **OR** B. History of irradiation **OR** C. Other pituitary hormone defects (e.g., multiple pituitary hormone deficiency [MPHD]) **OR** D. A genetic defect **OR** 3. The patient has a pituitary abnormality and a known deficit of at

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	least one other pituitary hormone **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication **AND** 6. ONE of the following: A. BOTH of the following: 1. The request is for a preferred agent **AND** 2. The preferred agent is supported in FDA labeling for the requested indication **OR** B. The request is for a nonpreferred agent and BOTH of the following: 1. The nonpreferred agent is supported in FDA labeling for the requested indication **AND** 2. ONE of the following: A. The preferred agent is not supported in FDA labeling for the requested indication **OR** B. ONE of the following: 1. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a preferred agent that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 2. The prescriber has provided information to support the efficacy of the requested nonpreferred agent over the preferred agent for the intended diagnosis (medical record required) **OR** 3. The patient's medication history includes use of the preferred agent **OR** 4. BOTH of the following: A. The prescriber has stated that the patient has tried the preferred agent **AND** B. The preferred agent was discontinued due to lack of effectiveness or an adverse event **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that the preferred agent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval**: 4 weeks for SBS 12 months for other indications **Children – Renewal Evaluation** **Target Short-Acting Growth Hormone Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for therapy with GH through the plan's prior authorization process **AND**

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	2. The patient is a child (as defined by the prescriber) **AND** 3. ONE of the following: A. BOTH of the following: 1. The request is for a preferred agent **AND** 2. The preferred agent is supported in FDA labeling for the requested indication **OR** B. The request is for a nonpreferred agent and BOTH of the following: 1. The nonpreferred agent is supported in FDA labeling for the requested indication **AND** 2. ONE of the following: A. The preferred agent is not supported in FDA labeling for the requested indication **OR** B. ONE of the following: 1. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to a preferred agent that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 2. The prescriber has provided information to support the efficacy of the requested nonpreferred agent over the preferred agent for the intended diagnosis (medical record required) **OR** 3. The patient's medication history includes use of the preferred agent **OR** 4. BOTH of the following: A. The prescriber has stated that the patient has tried the preferred agent **AND** B. The preferred agent was discontinued due to lack of effectiveness or an adverse event **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that the preferred agent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. ONE of the following: A. The patient has a diagnosis of short bowel syndrome (SBS) AND has had clinical benefit with the requested agent AND ONE of the following: 1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** 2. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **OR** B. The patient has a diagnosis of ISS and BOTH of the following: 1. Growth velocity is greater than 2 cm/year **AND** 2. Bone age is less than 16 years in patients with a sex of male and 15 years in patients with a sex of female AND the patient has open epiphyses **OR** C. The patient has any other diagnosis AND BOTH of the following: 1. The patient does NOT have closed epiphyses **AND** 2. The patient's height has increased or height velocity has improved since initiation or

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	last GH approval **AND** 5. The patient is being monitored for adverse effects of GH **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or has consulted with a specialist in the area of the patient's diagnosis **AND** 8. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication **Length of Approval**: 4 weeks for SBS 12 months for other indications

• Program Summary: Insomnia Agents

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

Insomnia Agents Step Therapy

TARGET AGENT(S)	PREREQUISITE AGENT(S)
Ambien® (zolpidem)[a] **Ambien CR®** (zolpidem)[a] **Belsomra®** (suvorexant) **Dayvigo™** (lemborexant) **Edluar®** (zolpidem) **Intermezzo®, Zolpidem**[a,c] **Lunesta®** (eszopiclone)[a] **Quviviq™** (daridorexant) **Rozerem®** (ramelteon)[b] **Silenor®** (doxepin)[b] **Zolpidem tartrate capsule** **Zolpimist™** (zolpidem)	zolpidem eszopiclone zaleplon

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

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Brand Insomnia Agents will be approved when ONE of the following is met:

1. The patient is currently being treated with the requested agent as indicated by ALL of the following:
   A. A statement by the prescriber that the patient is currently taking the requested agent (starting on samples is not approvable)
   AND
   B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
   AND
   C. The prescriber states that a change in therapy is expected to be ineffective or cause harm

   OR
2. The patient's medication history includes the use of a generic nonbenzodiazepine hypnotic agent

   OR
3. BOTH of the following:
   A. The prescriber has stated that the patient has tried a generic nonbenzodiazepine hypnotic agent
   AND
   B. Generic nonbenzodiazepine hypnotic agent was discontinued due to lack of effectiveness or an adverse event

   OR

4. The patient has an intolerance or hypersensitivity to generic nonbenzodiazepine hypnotic agents
   OR
5. The patient has an FDA labeled contraindication to ALL available generic nonbenzodiazepine hypnotic agents
   OR
6. The prescriber has provided documentation that ALL generic nonbenzodiazepine hypnotic agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm
   OR
7. The requested agent is a non-controlled agent AND the patient requires therapy with the non-controlled agent

Length of Approval: 12 months

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

● Program Summary: Insulin Pumps

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

POLICY AGENT SUMMARY QUANTITY LIMIT

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

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
97201030506420	Omnipod go 20 units/day	*insulin infusion disposable pump kit	20 UNIT/24 HR	30	Systems	30	DAYS			08508400020		
97201030506425	Omnipod go 25 units/day	*insulin infusion disposable pump kit	25 UNIT/24 HR	30	Systems	30	DAYS					
97201030506430	Omnipod go 30 units/day	*insulin infusion disposable pump kit	30 UNIT/24 HR	30	Systems	30	DAYS			08508400030		
97201030506435	Omnipod go 35 units/day	*insulin infusion disposable pump kit	35 UNIT/24 HR	30	Systems	30	DAYS					
97201030506440	Omnipod go 40 units/day	*insulin infusion disposable pump kit	40 UNIT/24 HR	30	Systems	30	DAYS			08508400040		
97201030506400	V-go 20	*insulin infusion disposable pump kit		1	Kit	30	DAYS			08560940003		
97201030506400	V-go 30	*insulin infusion disposable pump kit		1	Kit	30	DAYS			08560940002		
97201030506400	V-go 40	*insulin infusion disposable pump kit		1	Kit	30	DAYS			08560940001		

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

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

• Program Summary: Neurotrophic Keratitis

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
86770020202020	Oxervate	Cenegermin-bkbj Ophth Soln 0.002% (20 MCG/ML)	0.002 %	56	Vials	56	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of neurotrophic keratitis (NK) **AND** 2. The patient has stage 2 (persistent epithelial defect [PED]) or stage 3 (corneal ulcer) NK **AND** 3. ONE of the following: A. The patient has NOT been previously treated with the requested agent in the affected eye(s) AND ALL of the following: 1. The patient's PED and/or corneal ulcer have been present for at least 2 weeks **AND** 2. ONE of the following: A. The patient's NK has been refractory to at least ONE conventional non-surgical treatment (i.e., preservative-free lubricant eye drops or ointment, discontinuation of preserved topical agents that can decrease corneal sensitivity, therapeutic soft contact lenses, topical autologous serum application, botulinum A toxin treatment) **OR** B. The patient has an intolerance or hypersensitivity to at least ONE conventional non-surgical treatment for NK **OR** C. The patient has an FDA labeled contraindication to ALL conventional non-surgical treatments for NK **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

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	ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL conventional non-surgical treatment (i.e., preservative-free lubricant eye drops or ointment, discontinuation of preserved topical agents that can decrease corneal sensitivity, therapeutic soft contact lenses, topical autologous serum application, botulinum A toxin treatment) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The patient has decreased corneal sensitivity within the area of the PED or ulcer and outside the area of defect in at least one corneal quadrant **OR** B. The patient has been previously treated with the requested agent in the affected eye(s) AND BOTH of the following: 1. The patient had complete corneal healing in the previously treated eye(s) **AND** 2. The patient has a recurrence of neurotrophic keratitis (NK) that requires another treatment course **AND** 4. ONE of the following: A. The patient does NOT have ocular surface disease(s) associated with or in conjunction with NK **OR** B. BOTH of the following: 1. The patient has ocular surface disease(s) associated with or in conjunction with NK **AND** 2. The ocular surface disease(s) has been properly treated **AND** 5. The patient will NOT be using the requested agent in combination with a topical ophthalmic NSAID **AND** 6. The patient does NOT have any of the following: A. Active ocular infection or active ocular inflammation not related to NK in the affected eye **OR** B. Severe blepharitis and/or severe Meibomian gland disease in the affected eye **OR** C. History of any ocular surgery in the affected eye within the past 90 days that has not been determined to be the cause of NK **OR** D. Corneal perforation, ulceration involving the posterior third of the corneal stroma, or corneal melting **AND** 7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., optometrist, ophthalmologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 8. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 8 weeks 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. BOTH of the following: A. The patient has bilateral NK **AND** B. The requested quantity (dose) does NOT exceed TWICE the program quantity limit **Length of Approval**: 8 weeks

• Program Summary: Ophthalmic Pilocarpine – *Note program name change from 'Vuity QL'*

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
86501030102017	Vuity	Pilocarpine HCl Ophth Soln	1.25 %	5	mL	30	DAYS				07-01-2022	

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) is greater than the program quantity limit AND BOTH of the following: A. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** B. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval**: 12 months

• Program Summary: Ophthalmic Prostaglandins

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
86330015002020		Bimatoprost Ophth Soln 0.03%	0.03 %	2.5	mLs	30	DAYS		Wastage is significant but cannot be avoided.			
86330015002010	Lumigan	Bimatoprost Ophth Soln 0.01%	0.01 %	2.5	mLs	30	DAYS		Wastage is significant but cannot be avoided.			
863300700020	Travatan z	travoprost ophth soln	0.004 %	2.5	mLs	30	DAYS		Wastage is significant but cannot be avoided.			
863300521020	Vyzulta	latanoprostene bunod ophth soln	0.024 %	2.5	mLs	30	DAYS		Wastage is significant but cannot			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
									be avoided.			
86330050002020	Xalatan	Latanoprost Ophth Soln 0.005%	0.005 %	2.5	mLs	30	DAYS		Wastage is significant but cannot be avoided.			
863300500016	Xelpros	latanoprost ophth emulsion	0.005 %	2.5	mLs	30	DAYS		Wastage is significant but cannot be avoided.			
863300650020	Zioptan	tafluprost preservative free (pf) ophth soln	0.015 MG/ML	30	Containers	30	DAYS		Wastage is significant but cannot be avoided.			

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) is greater than the program quantity limit AND BOTH of the following: A. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** B. Information has been provided to support therapy with a higher dose for the requested indication **Length of approval**: 12 months

● Program Summary: Oral Pulmonary Arterial Hypertension (PAH)

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
401430800003	Adcirca; Alyq	tadalafil tab	20 MG	60	Tablets	30	DAYS					
4013405000	Adempas	riociguat tab	0.5 MG; 1 MG; 1.5 MG; 2 MG; 2.5 MG	90	Tablets	30	DAYS					
4016000700	Letairis	ambrisentan tab	10 MG;	30	Tablets	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
			5 MG									
40143060101825	Liqrev	sildenafil citrate oral susp	10 MG/ML	2	Bottles	30	DAYS					
4016005000	Opsumit	macitentan tab	10 MG	30	Tablets	30	DAYS					
4017008005C110	Orenitram titr kit Month 1	Treprostinil tab er Mo 1 titr kit	0.125 & 0.25 MG	1	Kit	180	DAYS					
4017008005C120	Orenitram titr kit Month 2	Treprostinil tab er Mo 2 titr kit	0.125 & 0.25 MG	1	Kit	180	DAYS					
4017008005C130	Orenitram titr kit Month 3	Treprostinil tab er Mo 3 titr kit	0.125 & 0.25 &1 MG	1	Kit	180	DAYS					
401430601019	Revatio	sildenafil citrate for suspension	10 MG/ML	224	Bottles	30	DAYS					
401430601003	Revatio	sildenafil citrate tab	20 MG	90	Tablets	30	DAYS					
40143080001820	Tadliq	Tadalafil Oral Susp	20 MG/5ML	300	mLs	30	DAYS				09-23-2022	
401600150003	Tracleer	bosentan tab	125 MG; 62.5 MG	60	Tablets	30	DAYS					
401600150073	Tracleer	bosentan tab for oral susp	32 MG	120	Tablets	30	DAYS					
40170080002020	Tyvaso	treprostinil inhalation solution	0.6 MG/ML	7	Packages	28	DAYS			66302020603		
40170080002920	Tyvaso dpi maintenance ki	Treprostinil Inh Powder	16 MCG	112	Cartridges	28	DAYS				06-17-2022	
40170080002930	Tyvaso dpi maintenance ki	Treprostinil Inh Powder	32 MCG	112	Cartridges	28	DAYS				06-17-2022	
40170080002940	Tyvaso dpi maintenance ki	Treprostinil Inh Powder	48 MCG	112	Cartridges	28	DAYS				06-17-2022	
40170080002950	Tyvaso dpi maintenance ki	Treprostinil Inh Powder	64 MCG	112	Cartridges	28	DAYS				06-17-2022	
40170080002960	Tyvaso dpi maintenance ki	Treprostinil Inh Powder	112 x 32MCG & 112 x48MCG	224	Cartridges	28	DAYS				06-17-2022	
40170080002980	Tyvaso dpi titration kit	Treprostinil Inh Powd	16 & 32 & 48 MCG	252	Cartridges	180	DAYS				06-17-2022	
40170080002970	Tyvaso dpi titration kit	Treprostinil Inh Powder	112 x 16MCG & 84 x 32MCG	196	Cartridges	180	DAYS				06-17-2022	
40170080002020	Tyvaso refill	treprostinil	0.6	1	Kit	28	DAYS			66302020		

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		inhalation solution	MG/ML							602		
40170080002020	Tyvaso starter	treprostinil inhalation solution	0.6 MG/ML	1	Kit	180	DAYS			66302020601		
40170080002020	Tyvaso starter	treprostinil inhalation solution	0.6 MG/ML	1	Kit	180	DAYS			66302020604		
401200700003	Uptravi	selexipag tab	1000 MCG; 1200 MCG; 1400 MCG; 1600 MCG; 200 MCG; 400 MCG; 600 MCG; 800 MCG	60	Tablets	30	DAYS					
40120070000310	Uptravi	selexipag tab	200 MCG	140	Tablets	180	DAYS			66215060214		
40120070000310	Uptravi	selexipag tab	200 MCG	60	Tablets	30	DAYS			66215060206		
4012007000B7	Uptravi titration pack	selexipag tab therapy pack	200 & 800 MCG	1	Pack	180	DAYS					
401700600020	Ventavis	iloprost inhalation solution	10 MCG/ML; 20 MCG/ML	270	Ampules	30						

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. BOTH of the following: 1. The requested agent is eligible for continuation of therapy AND ONE of the following: **Target Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy A. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** B. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **AND** 2. The patient has an FDA approved indication for the requested agent **OR** B. The patient has a diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH), WHO Group 4 and ALL of the following: 1. The requested agent is Adempas **AND**

Module	Clinical Criteria for Approval
	2. The patient's diagnosis has been confirmed by a ventilation-perfusion scan and a confirmatory selective pulmonary angiography **AND** 3. The patient has a mean pulmonary artery pressure of greater than 20 mmHg **AND** 4. The patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg **AND** 5. The patient has a pulmonary vascular resistance greater than or equal to 3 Wood units **AND** 6. ONE of the following: A. The patient is NOT a candidate for surgery **OR** B. The patient has had a pulmonary endarterectomy AND has persistent or recurrent disease **AND** 7. The patient will NOT be using the requested agent in combination with a PDE5 inhibitor (e.g., tadalafil [Adcirca or Cialis] or sildenafil [Revatio or Viagra]) **OR** C. The patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 and ALL of the following: 1. The patient's diagnosis has been confirmed by right heart catheterization (medical records required) **AND** 2. The patient's mean pulmonary arterial pressure is greater than 20 mmHg **AND** 3. The patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg **AND** 4. The patient has a pulmonary vascular resistance greater than or equal to 3 Wood units **AND** 5. The patient's World Health Organization (WHO) functional class is II or greater **AND** 6. If the requested agent is Adcirca, Adempas, Revatio, sildenafil, or tadalafil, the patient will NOT be using the requested agent in combination with a PDE5 inhibitor (e.g., tadalafil [Adcirca or Cialis] or sildenafil [Revatio or Viagra]) **AND** 7. ONE of the following: A. The requested agent will be utilized as monotherapy **OR** B. The requested agent will be utilized as dual therapy that consists of an endothelin receptor antagonist (ERA) plus phosphodiesterase 5 inhibitor (PDE5i) as initial therapy **OR** C. The requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy) [except combo requests for endothelin receptor antagonist (ERA) plus phosphodiesterase 5 inhibitor (PDE5i) for dual therapy], and BOTH of following: 1. The patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy **AND** 2. The requested agent is in a different therapeutic class **OR** D. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy) and ALL of the following: 1. The patient is WHO functional class III or IV **AND** 2. ONE of the following: A. A prostanoid has been started as one of the agents in the triple therapy **OR** B. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ALL prostanoids **AND** 3. The patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy **AND** 4. All three agents in the triple therapy are from a different therapeutic class **OR** D. The patient has a diagnosis of pulmonary hypertension associated with interstitial lung disease

Module	Clinical Criteria for Approval

(PH-ILD, WHO group 3) AND ALL of the following:

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

E. The patient has another FDA approved indication for the requested agent **AND**

2. If the patient has an FDA approved indication, then ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
   B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**
3. If the request is for ONE of the following brand agents with an available generic equivalent (listed below), then ONE of the following:

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

   A. The patient's medication history includes the required generic equivalent as indicated by:
      1. Evidence of a paid claim(s) **OR**
      2. The prescriber has stated that the patient has tried the generic equivalent AND the generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**
   B. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**
   C. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR**
   D. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent **OR**
   E. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
      2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
      3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
   F. The prescriber has provided documentation that the generic equivalent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

Module	Clinical Criteria for Approval

4. If the request is for Tadliq, then one of the following:
    A. The patient has tried and had an inadequate response to generic tadalafil tablets **OR**
    B. The patient has an in intolerance or hypersensitivity to generic tadalafil tablets that is not expected to occur with the requested agent **OR**
    C. The patient had an FDA labeled contraindication to generic tadalafil tablets that is not expected to occur with the requested agent **AND**
5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
6. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 12 months

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

Renewal Evaluation

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

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND**
2. The patient has had clinical benefit with the requested agent (e.g., stabilization, decreased disease progression) (medical records required) **AND**
3. If the requested agent is Tyvaso for a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD, WHO group 3), then the patient will continue standard of care therapy for ILD (e.g., Ofev) **AND**
4. If the request is for ONE of the following brand agents with an available generic equivalent (listed below), then ONE of the following:

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

    A. The patient's medication history includes the required generic equivalent as indicated by:
        1. Evidence of a paid claim(s) **OR**
        2. The prescriber has stated that the patient has tried the generic equivalent AND the generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**
    B. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**
    C. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR**
    D. The prescriber has provided information to support 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**

Module	Clinical Criteria for Approval
	F. The prescriber has provided documentation that the generic equivalent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 5. If the request is for Tadliq, then one of the following: A. The patient has tried and had an inadequate response to generic tadalafil tablets **OR** B. The patient has an in intolerance or hypersensitivity to generic tadalafil tablets that is not expected to occur with the requested agent **OR** C. The patient had an FDA labeled contraindication to generic tadalafil tablets that is not expected to occur with the requested agent **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Oxybate

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
62450060203020	Lumryz	sodium oxybate pack for oral er susp	4.5 GM	30	Packets	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
62450060203025	Lumryz	sodium oxybate pack for oral er susp	6 GM	30	Packets	30	DAYS					
62450060203030	Lumryz	sodium oxybate pack for oral er susp	7.5 GM	30	Packets	30	DAYS					
62450060203035	Lumryz	sodium oxybate pack for oral er susp	9 GM	30	Packets	30	DAYS					
62450060202020	Xyrem	Sodium Oxybate Oral Solution 500 MG/ML	500 MG/ML	540	mLs	30	DAYS					
6245990420	Xywav	calcium, mag, potassium, & sod oxybates oral soln	500 MG/ML	540	mLs	30	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Target Agent(s) will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of narcolepsy with cataplexy OR narcolepsy with excessive daytime sleepiness AND ONE of the following: 1. The patient has tried and had an inadequate response to modafinil OR armodafinil **OR** 2. The patient has an intolerance or hypersensitivity to modafinil OR armodafinil **OR** 3. The patient has an FDA labeled contraindication to BOTH modafinil AND armodafinil **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that BOTH modafinil AND armodafinil cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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 idiopathic hypersomnia AND ALL of the following: 1. The requested agent is Xywav **AND** 2. The patient has completed a sleep study **AND** 3. All other causes of hypersomnia have been ruled out **AND** 4. ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient has tried and had an inadequate response to modafinil OR armodafinil **OR** B. The patient has an intolerance or hypersensitivity to modafinil OR armodafinil **OR** C. The patient has an FDA labeled contraindication to modafinil AND armodafinil **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that BOTH modafinil AND armodafinil cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has another FDA approved indication for the requested agent and route of administration **AND** 2. If the patient has an FDA approved indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. If the request is for brand Xyrem, then ONE of the following: A. The patient has an intolerance or hypersensitivity to authorized generic Sodium Oxybate that is not expected to occur with the requested agent **OR** B. The patient has an FDA labeled contraindication to authorized generic Sodium Oxybate that is not expected to occur with the requested agent **OR** C. The prescriber has provided information to support the use of the requested agent over authorized generic Sodium Oxybate **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that generic Sodium Oxybate cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The patient will NOT be using the requested agent in combination with another oxybate agent, Sunosi, OR Wakix for the requested indication **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., sleep specialist, neurologist, psychiatrist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months

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

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Proton Pump Inhibitors (PPIs)

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

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

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

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

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

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

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL
Target Agent(s) will be approved when ONE of the following is met:
1. The patient's medication history includes use of a prescription strength prerequisite agent

OR

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

Length of Approval: 12 months

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

● Program Summary: Self-Administered Oncology Agents

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

QUANTITY LIMIT TARGET AGENTS - RECOMMENDED LIMITS±

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
Afinitor (everolimus)[a]			
2.5 mg tablet	21532530000310	M, N, O, or Y	1 tablet
5 mg tablet	21532530000320	M, N, O, or Y	1 tablet
7.5 mg tablet	21532530000325	M, N, O, or Y	1 tablet
10 mg tablet	21532530000330	M, N, O, or Y	1 tablet
Afinitor DISPERZ (everolimus)[a]			
2 mg tablet for oral suspension	21532530007310	M, N, O, or Y	2 tablets^
3 mg tablet for oral suspension	21532530007320	M, N, O, or Y	3 tablets^
5 mg tablet for oral suspension	21532530007340	M, N, O, or Y	2 tablets^
Alecensa (alectinib)			
150 mg capsule	21530507100120	M, N, O, or Y	8 capsules
Alunbrig (brigatinib)			
30 mg tablet	21530510000330	M, N, O, or Y	4 tablets
90 mg tablet	21530510000350	M, N, O, or Y	1 tablet
180 mg tablet	21530510000365	M, N, O, or Y	1 tablet
Starter PAK	2153051000B720	M, N, O, or Y	1 pak/180 days
Ayvakit (avapritinib)			

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
25 mg tablet	21490009000310	M, N, O, or Y	1 tablet
50 mg tablet	21490009000315	M, N, O, or Y	1 tablet
100 mg tablet	21490009000320	M, N, O, or Y	1 tablet
200 mg tablet	21490009000330	M, N, O, or Y	1 tablet
300 mg tablet	21490009000340	M, N, O, or Y	1 tablet
Balversa (erdafitinib)			
3 mg tablet	21532225000320	M, N, O, or Y	3 tablets
4 mg tablet	21532225000325	M, N, O, or Y	2 tablets
5 mg tablet	21532225000330	M, N, O, or Y	1 tablet
BESREMi (ropeginterferon alfa-2b-njft)			
500 mcg/mL prefilled syringe	2170007750E520	M, N, O, or Y	2 syringes/28 days
Bosulif (bosutinib)			
100 mg tablet	21531812000320	M, N, O, or Y	3 tablets
400 mg tablet	21531812000327	M, N, O, or Y	1 tablet
500 mg tablet	21531812000340	M, N, O, or Y	1 tablet
Braftovi (encorafenib)			
75 mg capsule	21532040000130	M, N, O, or Y	6 capsules
Brukinsa (zanubrutinib)			
80 mg capsule	21532195000120	M, N, O, or Y	4 capsules
Cabometyx (cabozantinib)			
20 mg tablet	21533010100320	M, N, O, or Y	1 tablet
40 mg tablet	21533010100330	M, N, O, or Y	1 tablet
60 mg tablet	21533010100340	M, N, O, or Y	1 tablet
Calquence (acalabrutinib)			
100 mg capsule	21532103000120	M, N, O, or Y	2 capsules
100 mg tablet	21532103500320	M, N, O, or Y	2 tablets
Caprelsa (vandetanib)			
100 mg tablet	21533085000320	M, N, O, or Y	2 tablets
300 mg tablet	21533085000340	M, N, O, or Y	1 tablet
Cometriq (cabozantinib)			
60 mg daily dose carton	21533010106460	M, N, O, or Y	1 carton/28 days
100 mg daily dose carton	21533010106470	M, N, O, or Y	1 carton/28 days
140 mg daily dose carton	21533010106480	M, N, O, or Y	1 carton/28 days
Copiktra (duvelisib)			
15 mg capsule	21538030000120	M, N, O, or Y	56 capsules/28 days
25 mg capsule	21538030000130	M, N, O, or Y	56 capsules/28 days
Cotellic (cobimetinib)			
20 mg tablet	21533530200320	M, N, O, or Y	63 tablets/28 days
Daurismo (glasdegib)			
25 mg tablet	21370030300320	M, N, O, or Y	2 tablets
100 mg tablet	21370030300335	M, N, O, or Y	1 tablet
Erivedge (vismodegib)			
150 mg capsule	21370070000120	M, N, O, or Y	1 capsule
Erleada (apalutamide)			
60 mg tablet	21402410000320	M, N, O, or Y	4 tablets
240 mg tablet	21402410000360	M, N, O, or Y	1 tablet
Exkivity (mobocertinib)			
40 mg capsule	21360050600120	M, N, O, or Y	4 capsules
Farydak (panobinostat)			
10 mg capsule	21531550100120	M, N, O, or Y	6 capsules/21 days

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
15 mg capsule	21531550100130	M, N, O, or Y	6 capsules/21 days
20 mg capsule	21531550100140	M, N, O, or Y	6 capsules/21 days
Fotivda (tivozanib)			
0.89 mg (890 mcg) capsule	21533076250120	M, N, O, or Y	21 capsules/28 days
1.34 mg (1340 mcg) capsule	21533076250130	M, N, O, or Y	21 capsules/28 days
Gavreto (pralsetinib)			
100 mg capsule	21535750000120	M, N, O, or Y	4 capsules
Gilotrif (afatinib)			
20 mg tablet	21360006100320	M, N, O, or Y	1 tablet
30 mg tablet	21360006100330	M, N, O, or Y	1 tablet
40 mg tablet	21360006100340	M, N, O, or Y	1 tablet
Gleevec (imatinib)[a]			
100 mg tablet	21531835100320	M, N, O, or Y	3 tablets
400 mg tablet	21531835100340	M, N, O, or Y	2 tablets
Hycamtin (topotecan)			
0.25 mg capsule	21550080100120	M, N, O, or Y	No Quantity Limit
1 mg capsule	21550080100140	M, N, O, or Y	No Quantity Limit
Ibrance (palbociclib)			
75 mg capsule	21531060000120	M, N, O, or Y	21 capsules/28 days
100 mg capsule	21531060000130	M, N, O, or Y	21 capsules/28 days
125 mg capsule	21531060000140	M, N, O, or Y	21 capsules/28 days
75 mg tablet	21531060000320	M, N, O, or Y	21 tablets/28 days
100 mg tablet	21531060000330	M, N, O, or Y	21 tablets/28 days
125 mg tablet	21531060000340	M, N, O, or Y	21 tablets/28 days
Iclusig (ponatinib)			
10 mg tablet	21531875100315	M, N, O, or Y	1 tablet
15 mg tablet	21531875100320	M, N, O, or Y	1 tablet
30 mg tablet	21531875100330	M, N, O, or Y	1 tablet
45 mg tablet	21531875100340	M, N, O, or Y	1 tablet
Idhifa (enasidenib)			
50 mg tablet	21535030200320	M, N, O, or Y	1 tablet
100 mg tablet	21535030200340	M, N, O, or Y	1 tablet
Imbruvica (ibrutinib)			
70 mg capsule	21532133000110	M, N, O, or Y	1 capsule
140 mg capsule	21532133000120	M, N, O, or Y	3 capsules
140 mg tablet	21532133000320	M, N, O, or Y	1 tablet
280 mg tablet	21532133000330	M, N, O, or Y	1 tablet
420 mg tablet	21532133000340	M, N, O, or Y	1 tablet
560 mg tablet	21532133000350	M, N, O, or Y	1 tablet
70 mg/mL oral suspension	21532133001820	M, N, O, or Y	216 mL/30 days
Inlyta (axitinib)			
1 mg tablet	21335013000320	M, N, O, or Y	6 tablets
5 mg tablet	21335013000340	M, N, O, or Y	4 tablets
Inqovi (decitabine/cedazuridine)			
35 mg/100 mg tablet	21990002250320	M, N, O, or Y	5 tablets/28 days
Inrebic (fedratinib)			
100 mg capsule	21537520200120	M, N, O, or Y	4 capsules
Iressa (gefitinib) [a]			
250 mg tablet	21360030000320	M, N, O, or Y	1 tablet
Jakafi (ruxolitinib)			

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
5 mg tablet	21537560200310	M, N, O, or Y	2 tablets
10 mg tablet	21537560200320	M, N, O, or Y	2 tablets
15 mg tablet	21537560200325	M, N, O, or Y	2 tablets
20 mg tablet	21537560200330	M, N, O, or Y	2 tablets
25 mg tablet	21537560200335	M, N, O, or Y	2 tablets
Jaypirca (elecastrant)			
50 mg tablet	21532165000320	M, N, O, or Y	1 tablet
100 mg tablet	21532165000330	M, N, O, or Y	2 tablets
Kisqali (ribociclib)			
200 mg daily dose pack (200 mg tablets)	2153107050B720	M, N, O, or Y	21 tablets/28 days
400 mg daily dose pack (200 mg tablets)	2153107050B740	M, N, O, or Y	42 tablets/28 days
600 mg daily dose pack (200 mg tablets)	2153107050B760	M, N, O, or Y	63 tablets/28 days
Kisqali Femara Pack (ribociclib and letrozole co-packaged)			
200 mg daily dose co-pack (200 mg ribociclib tablets and 2.5 mg letrozole tablets)	2199000260B730	M, N, O, or Y	49 tablets/28 days¥
400 mg daily dose co-pack (200 mg ribociclib tablets and 2.5 mg letrozole tablets)	2199000260B740	M, N, O, or Y	70 tablets/28 days¥
600 mg daily dose co-pack (200 mg ribociclib tablets and 2.5 mg letrozole tablets)	2199000260B760	M, N, O, or Y	91 tablets/28 days¥
Koselugo (selumetinib)			
10 mg capsule	21533565500110	M, N, O, or Y	8 capsules
25 mg capsule	21533565500125	M, N, O, or Y	4 capsules
Krazati (adagrasib)			
200 mg tablet	21532410000320	M, N, O, or Y	6 tablets
Lenvima (lenvatinib)			
4 mg capsule therapy pack	2133505420B210	M, N, O, or Y	30 capsules/30 days
8 mg (2 x 4 mg capsules daily) therapy pack	2133505420B215	M, N, O, or Y	60 capsules/30 days
10 mg capsule therapy pack	2133505420B220	M, N, O, or Y	30 capsules/30 days
12 mg (3 x 4 mg capsules daily) therapy pack	2133505420B223	M, N, O, or Y	90 capsules/30 days
14 mg (10 mg and 4 mg capsule daily) therapy pack	2133505420B240	M, N, O, or Y	60 capsules/30 days
18 mg (10 mg and 2 x 4 mg capsules daily) therapy pack	2133505420B244	M, N, O, or Y	90 capsules/30 days
20 mg (2 x 10mg capsules daily) therapy pack	2133505420B230	M, N, O, or Y	60 capsules/30 days
24 mg (2 x 10mg and 1 x 4 mg capsules daily) therapy pack	2133505420B250	M, N, O, or Y	90 capsules/30 days
Lonsurf (trifluridine/tipiracil)			
15 mg/6.14 mg tablet	21990002750320	M, N, O, or Y	60 tablets/28 days
20 mg/8.19 mg tablet	21990002750330	M, N, O, or Y	80 tablets/28 days
Lorbrena (lorlatinib)			
25 mg tablet	21530556000320	M, N, O, or Y	3 tablets
100 mg tablet	21530556000330	M, N, O, or Y	1 tablet

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
Lumakras (sotorasib)			
120 mg tablet	21532480000320	M, N, O, or Y	8 tablets
320 mg tablet	21532480000340	M, N, O, or Y	3 tablets
Lynparza (olaparib)			
100 mg tablet	21535560000330	M, N, O, or Y	4 tablets
150 mg tablet	21535560000340	M, N, O, or Y	4 tablets
Lysodren (mitotane)			
500 mg tablet	21402250000320	M, N, O, or Y	No Quantity Limit
Lytgobi (futibatinib)			
4 mg tablet (12 mg Daily Dose)	2153222800B720	M, N, O, or Y	84 tablets/28 days
4 mg tablet (16 mg Daily Dose)	2153222800B725	M, N, O, or Y	112 tablets/28 days
4 mg tablet (20 mg Daily Dose)	2153222800B730	M, N, O, or Y	140 tablets/28 days
Matulane (procarbazine)			
50mg capsule	21700050100105	M, N, O, or Y	No Quantity Limit
Mekinist (trametinib)			
0.05 mg/ml oral solution	21533570102120	M, N, O, or Y	1170 ml/28 days
0.5 mg tablet	21533570100310	M, N, O, or Y	3 tablets
2 mg tablet	21533570100330	M, N, O, or Y	1 tablet
Mektovi (binimetinib)			
15 mg tablet	21533520000320	M, N, O, or Y	6 tablets
Nerlynx (neratinib)			
40 mg tablet	21533035100320	M, N, O, or Y	6 tablets
Nexavar (sorafenib)[a]			
200 mg tablet	21533060400320	M, N, O, or Y	4 tablets
Ninlaro (ixazomib)			
2.3 mg capsule	21536045100120	M, N, O, or Y	3 capsules/28 days
3 mg capsule	21536045100130	M, N, O, or Y	3 capsules/28 days
4 mg capsule	21536045100140	M, N, O, or Y	3 capsules/28 days
Nubeqa (darolutamide)			
300 mg tablet	21402425000320	M, N, O, or Y	4 tablets
Odomzo (sonidegib)			
200 mg capsule	21370060200120	M, N, O, or Y	1 capsule
Onureg (azacitidine)			
200 mg tablet	21300003000320	M, N, O, or Y	14 tablets/28 days
300 mg tablet	21300003000330	M, N, O, or Y	14 tablets/28 days
Orgovyx (relugolix)			
120 mg tablet	21405570000320	M, N, O, or Y	1 tablet
Orserdu (elecastrant)			
86 mg tablet	21403720100320	M, N, O, or Y	3 tablets
345 mg tablet	21403720100340	M, N, O, or Y	1 tablet
Pemazyre (pemigatinib)			
4.5 mg tablet	21532260000320	M, N, O, or Y	14 tablets/21 days
9 mg tablet	21532260000330	M, N, O, or Y	14 tablets/21 days
13.5 mg tablet	21532260000340	M, N, O, or Y	14 tablets/21 days
Piqray (alpelisib)			
200 mg daily dose pack (200 mg tablets)	2153801000B720	M, N, O, or Y	1 pack (28 tablets)/28 days

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
250 mg daily dose pack (200 mg tablets and 50 mg tablets)	2153801000B725	M, N, O, or Y	1 pack (56 tablets)/28 days
300 mg daily dose pack (150 mg tablets)	2153801000B730	M, N, O, or Y	1 pack (56 tablets)/28 days
Pomalyst (pomalidomide)			
1 mg capsule	21450080000110	M, N, O, or Y	21 capsules/28 days
2 mg capsule	21450080000115	M, N, O, or Y	21 capsules/28 days
3 mg capsule	21450080000120	M, N, O, or Y	21 capsules/28 days
4 mg capsule	21450080000125	M, N, O, or Y	21 capsules/28 days
Qinlock (ripretinib)			
50 mg tablet	21533053000320	M, N, O, or Y	3 tablets
Retevmo (selpercatinib)			
40 mg capsule	21535779000120	M, N, O, or Y	6 capsules
80 mg capsule	21535779000140	M, N, O, or Y	4 capsules
Revlimid (lenalidomide)[a]			
2.5 mg capsule	99394050000110	M, N, O, or Y	1 capsule
5 mg capsule	99394050000120	M, N, O, or Y	1 capsule
10 mg capsule	99394050000130	M, N, O, or Y	1 capsule
15 mg capsule	99394050000140	M, N, O, or Y	21 capsules/28 days
20 mg capsule	99394050000145	M, N, O, or Y	21 capsules/28 days
25 mg capsule	99394050000150	M, N, O, or Y	21 capsules/28 days
Rezlidhia (olutasidenib)			
150 mg capsule	21534960000120	M, N, O, or Y	2 capsules
Rozlytrek (entrectinib)			
100 mg capsule	21533820000120	M, N, O, or Y	1 capsule
200 mg capsule	21533820000130	M, N, O, or Y	3 capsules
Rubraca (rucaparib)			
200 mg tablet	21535570200320	M, N, O, or Y	4 tablets
250 mg tablet	21535570200325	M, N, O, or Y	4 tablets
300 mg tablet	21535570200330	M, N, O, or Y	4 tablets
Rydapt (midostaurin)			
25 mg capsule	21533030000130	M, N, O, or Y	8 capsules
Scemblix (asciminib)			
20 mg tablet	21531806100320	M, N, O, or Y	2 tablets
40 mg tablet	21531806100340	M, N, O, or Y	10 tablets
Sprycel (dasatinib)			
20 mg tablet	21531820000320	M, N, O, or Y	3 tablets
50 mg tablet	21531820000340	M, N, O, or Y	1 tablet
70 mg tablet	21531820000350	M, N, O, or Y	1 tablet
80 mg tablet	21531820000354	M, N, O, or Y	1 tablet
100 mg tablet	21531820000360	M, N, O, or Y	1 tablet
140 mg tablet	21531820000380	M, N, O, or Y	1 tablet
Stivarga (regorafenib)			
40 mg tablet	21533050000320	M, N, O, or Y	84 tablets/28 days
Sutent (sunitinib)[a]			
12.5 mg capsule	21533070300120	M, N, O, or Y	3 capsules
25 mg capsule	21533070300130	M, N, O, or Y	1 capsule
37.5 mg capsule	21533070300135	M, N, O, or Y	1 capsule
50 mg capsule	21533070300140	M, N, O, or Y	1 capsule
Tabrecta (capmatinib)			

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
150 mg tablet	21533716200320	M, N, O, or Y	4 tablets
200 mg tablet	21533716200330	M, N, O, or Y	4 tablets
Tafinlar (dabrafenib)			
10 mg tablets for oral suspension	21532025107320	M, N, O, or Y	840 tablets/28 days
50 mg capsule	21532025100120	M, N, O, or Y	4 capsules
75 mg capsule	21532025100130	M, N, O, or Y	4 capsules
Tagrisso (osimertinib)			
40 mg tablet	21360068200320	M, N, O, or Y	1 tablet
80 mg tablet	21360068200330	M, N, O, or Y	1 tablet
Talzenna (talazoparib)			
0.1 mg capsule	21535580400105	M, N, O, or Y	1 capsule
0.25 mg capsule	21535580400110	M, N, O, or Y	3 capsules
0.35 mg capsule	21535580400112	M, N, O, or Y	1 capsule
0.5 mg capsule	21535580400114	M, N, O, or Y	1 capsule
0.75 mg capsule	21535580400118	M, N, O, or Y	1 capsule
1 mg capsule	21535580400120	M, N, O, or Y	1 capsule
Tarceva (erlotinib)[a]			
25 mg tablet	21360025100320	M, N, O, or Y	2 tablets
100 mg tablet	21360025100330	M, N, O, or Y	1 tablet
150 mg tablet	21360025100360	M, N, O, or Y	1 tablet
Targretin (bexarotene)[a]			
75 mg capsule	21708220000120	M, N, O, or Y	No Quantity Limit
1% gel (60 gm tube)	90376220004020	M, N, O, or Y	No Quantity Limit
Tasigna (nilotinib)			
50 mg capsule	21531860200110	M, N, O, or Y	4 capsules
150 mg capsule	21531860200115	M, N, O, or Y	4 capsules
200 mg capsule	21531860200125	M, N, O, or Y	4 capsules
Tazverik (tazemetostat)			
200 mg tablet	21533675200320	M, N, O, or Y	8 tablets
Temodar (temozolomide)[a]			
5 mg capsule	21104070000110	M, N, O, or Y	No Quantity Limit
20 mg capsule	21104070000120	M, N, O, or Y	No Quantity Limit
100 mg capsule	21104070000140	M, N, O, or Y	No Quantity Limit
140 mg capsule	21104070000143	M, N, O, or Y	No Quantity Limit
180 mg capsule	21104070000147	M, N, O, or Y	No Quantity Limit
250 mg capsule	21104070000150	M, N, O, or Y	No Quantity Limit
Tepmetko (tepotinib)			
225 mg tablet	21533773100320	M, N, O, or Y	2 tablets
Thalomid (thalidomide)			
50 mg capsule	99392070000120	M, N, O, or Y	1 capsule
100 mg capsule	99392070000130	M, N, O, or Y	1 capsule
150 mg capsule	99392070000135	M, N, O, or Y	2 capsules
200 mg capsule	99392070000140	M, N, O, or Y	2 capsules
Tibsovo (ivosidenib)			
250 mg tablet	21534940000320	M, N, O, or Y	2 tablets
Tretinoin			
10 mg capsule	21708080000110	M, N, O, or Y	No Quantity Limit
Truseltiq (infigratinib)			
50 mg daily dose (2x25 mg	2153223540B220	M, N, O, or Y	42 capsules (1 pack)/28

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
capsules)			days
75 mg daily dose (3x25 mg capsules)	2153223540B225	M, N, O, or Y	63 capsules (1 pack)/28 days
100 mg daily dose (100 mg capsules)	2153223540B230	M, N, O, or Y	21 capsules (1 pack)/28 days
125 mg daily dose (100 mg capsules and 25 mg capsules)	2153223540B235	M, N, O, or Y	42 capsules (1 pack)/28 days
Tukysa (tucatinib)			
50 mg tablet	21170080000320	M, N, O, or Y	10 tablets
150 mg tablet	21170080000340	M, N, O, or Y	4 tablets
Turalio (pexidartinib)			
125 mg capsule	21533045010110	M, N, O, or Y	4 capsules
200 mg capsule	21533045010120	M, N, O, or Y	4 capsules
Tykerb (lapatinib)[a]			
250 mg tablet	21533026100320	M, N, O, or Y	6 tablets
Venclexta (venetoclax)			
10 mg tablet	21470080000320	M, N, O, or Y	2 tablets
50 mg tablet	21470080000340	M, N, O, or Y	1 tablet
100 mg tablet	21470080000360	M, N, O, or Y	6 tablets
Starter pack	2147008000B720	M, N, O, or Y	1 pack (42 tablets)/180 days
Verzenio (abemaciclib)			
50 mg tablet	21531010000305	M, N, O, or Y	2 tablets
100 mg tablet	21531010000310	M, N, O, or Y	2 tablets
150 mg tablet	21531010000315	M, N, O, or Y	2 tablets
200 mg tablet	21531010000320	M, N, O, or Y	2 tablets
Vitrakvi (larotrectinib)			
25 mg capsule	21533835200120	M, N, O, or Y	6 capsules
100 mg capsule	21533835200150	M, N, O, or Y	2 capsules
20 mg/mL oral solution	21533835202020	M, N, O, or Y	10 mL
Vizimpro (dacomitinib)			
15 mg tablet	21360019000320	M, N, O, or Y	1 tablet
30 mg tablet	21360019000330	M, N, O, or Y	1 tablet
45 mg tablet	21360019000340	M, N, O, or Y	1 tablet
Vonjo (pacritinib)			
100 mg capsule	21537550100120	M, N, O, or Y	4 capsules
Votrient (pazopanib)			
200 mg tablet	21533042100320	M, N, O, or Y	4 tablets
Welireg (belzutifan)			
40 mg tablet	21421020000320	M, N, O, or Y	3 tablets
Xalkori (crizotinib)			
200 mg capsule	21530517000120	M, N, O, or Y	4 capsules
250 mg capsule	21530517000125	M, N, O, or Y	4 capsules
Xeloda (capecitabine)[a]			
150 mg tablet	21300005000320	M, N, O, or Y	No Quantity Limit
500 mg tablet	21300005000350	M, N, O, or Y	No Quantity Limit
Xospata (gilteritinib)			
40 mg tablet	21533020200320	M, N, O, or Y	3 tablets
Xpovio (selinexor)			
40 mg once weekly therapy pack (20 mg tablets)	2156006000B712	M, N, O, or Y	8 tablets (1 box)/28 days

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
40 mg once weekly therapy pack (40 mg tablets)	2156006000B760	M, N, O, or Y	4 tablets (1 box)/28 days
40 mg twice weekly therapy pack (20 mg tablets)	2156006000B715	M, N, O, or Y	16 tablets (1 box)/28 days
40 mg twice weekly therapy pack (40 mg tablets)	2156006000B765	M, N, O, or Y	8 tablets (1 box)/28 days
60 mg once weekly therapy pack (20 mg tablets)	2156006000B750	M, N, O, or Y	12 tablets (1 box)/28 days
60 mg once weekly therapy pack (60 mg tablets)	2156006000B780	M, N, O, or Y	4 tablets (1 box)/28 days
60 mg twice weekly therapy pack (20 mg tablets)	2156006000B755	M, N, O, or Y	24 tablets (1 box)/28 days
80 mg once weekly therapy pack (20 mg tablets)	2156006000B740	M, N, O, or Y	16 tablets (1 box)/28 days
80 mg once weekly therapy pack (40 mg tablets)	2156006000B770	M, N, O, or Y	8 tablets (1 box)/28 days
80 mg twice weekly therapy pack (20 mg tablets)	2156006000B720	M, N, O, or Y	32 tablets (1 box)/28 days
100 mg once weekly therapy pack (20 mg tablets)	2156006000B730	M, N, O, or Y	20 tablets (1 box)/28 days
100 mg once weekly therapy pack (50 mg tablets)	2156006000B775	M, N, O, or Y	8 tablets (1 box)/28 days
Xtandi (enzalutamide)			
40 mg capsule	21402430000120	M, N, O, or Y	4 capsules
40 mg tablet	21402430000320	M, N, O, or Y	4 tablets
80 mg tablet	21402430000340	M, N, O, or Y	2 tablets
Yonsa (abiraterone acetate)			
125 mg tablet	21406010250310	M, N, O, or Y	4 tablets
Zejula (niraparib)			
100 mg capsule	21535550200120	M, N, O, or Y	3 capsules
100 mg tablet	21535550200320	M, N, O, or Y	1 tablet
200 mg tablet	21535550200330	M, N, O, or Y	1 tablet
300 mg tablet	21535550200340	M, N, O, or Y	1 tablet
Zelboraf (vemurafenib)			
240 mg tablet	21532080000320	M, N, O, or Y	8 tablets
Zolinza (vorinostat)			
100 mg capsule	21531575000120	M, N, O, or Y	4 capsules
Zydelig (idelalisib)			
100 mg tablet	21538040000320	M, N, O, or Y	2 tablets
150 mg tablet	21538040000330	M, N, O, or Y	2 tablets
Zykadia (ceritinib)			
150 mg tablet	21530514000330	M, N, O, or Y	3 tablets
Zytiga (abiraterone)[a]			
250 mg tablet	21406010200320	M, N, O, or Y	4 tablets
500 mg tablet	21406010200330	M, N, O, or Y	2 tablets

a-generic available

±Agents with variable dosing based on the patient's weight, body surface area, blood concentration etc are not subject to quantity limit

^Calculation is based on 4.5 mg/m^2 with a standard BSA of 2.0 and rounding up to nearest full dose.[1,2]

¥ Quantity limit of 91 tablets per 28 days includes 63 tablets of ribociclib and 28 tablets of letrozole

PRIOR AUTHORIZATION WITH QUANTITY LIMIT CRITERIA FOR APPROVAL

Initial Evaluation

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

1. ONE of the following:
    A. Information has been provided that indicates the patient is currently being treated with the requested agent within the past 180 days
    OR
    B. The prescriber states the patient is being treated with the requested agent within the past 180 days AND is at risk if therapy is changed
    OR
    C. ALL of the following:
        i. ONE of the following:
            a. The patient has an FDA approved indication for the requested agent
            OR
            b. The patient has an indication that is supported by NCCN Compendium™ level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) [i.e., this indication must be supported by ALL requirements in the compendia (e.g., performance status, disease severity, previous failures, monotherapy vs combination therapy, etc.)] for the requested agent
        AND
        ii. ONE of the following:
            a. The patient's age is within FDA labeling for the requested indication for the requested agent
            OR
            b. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication
        AND
        iii. ONE of the following:
            a. ALL of the following:
                1. The requested indication requires genetic/specific diagnostic testing per FDA labeling or compendia (NCCN Compendium™ level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested agent
                AND
                2. Genetic/specific diagnostic testing has been completed
                AND
                3. The results of the genetic/specific diagnostic testing indicate therapy with the requested agent is appropriate
            OR
            b. The requested indication does NOT require genetic/specific diagnostic testing per FDA labeling or compendia (NCCN Compendium™ level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested agent
        AND
        iv. ONE of the following:
            a. The requested agent is being used as monotherapy AND is approved for use as monotherapy in the FDA labeling or supported by compendia (NCCN Compendium™ level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested indication
            OR
            b. The requested agent will be used as combination therapy with all agent(s) and/or treatments (e.g., radiation) listed for concomitant use in the FDA labeling or compendia (NCCN Compendium™ level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested indication

AND

v. ONE of the following:
   a. The requested agent will be used as a first-line agent AND is FDA labeled or supported by compendia (NCCN Compendium™ level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) as a first-line agent for the requested indication
   OR
   b. The patient has tried and had an inadequate response to the appropriate number and type(s) of prerequisite agent(s) listed in FDA labeling or compendia (NCCN Compendium™ level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested indication
   OR
   c. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to the appropriate number and type(s) of prerequisite agent(s) listed in the FDA labeling or compendia (NCCN Compendium™ level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested indication
   OR
   d. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      1. A statement by the prescriber that the patient is currently taking the requested agent
      AND
      2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
      AND
      3. The prescriber states that a change in therapy is expected to be ineffective or cause harm

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

AND

2. The patient does not have any FDA labeled contraindications to the requested agent
AND
3. The patient does not have any FDA labeled limitation(s) of use that is otherwise not supported in NCCN to the requested agent
AND
4. ONE of the following:
   A. Quantity limit does NOT apply to the requested agent
   OR
   B. The requested quantity (dose) does NOT exceed the program quantity limit
   OR
   C. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
      AND
      ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
      AND
      iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

   OR
   D. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
      AND

ii. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
AND
iii. The prescriber has provided information in support of therapy with a higher dose for the requested indication

Length of Approval: Up to 3 months for dose titration requests and Vitrakvi
Up to 12 months for all other requests, approve starter packs and loading doses where appropriate and maintenance dose for the remainder of the authorization

Renewal Evaluation

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

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process
AND
2. ONE of the following:
   A. The requested agent is Vitrakvi AND the patient has experienced clinical benefit (i.e., partial response, complete response, or stable disease) with the requested agent
   OR
   B. The requested agent is NOT Vitrakvi
AND
3. The patient does not have any FDA labeled contraindications to the requested agent
AND
4. The patient does not have any FDA labeled limitation(s) of use that is otherwise not supported in NCCN to the requested agent
AND
5. ONE of the following:
   A. Quantity limit does NOT apply to the requested agent
   OR
   B. The requested quantity (dose) does NOT exceed the program quantity limit
   OR
   C. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
      AND
      ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
      AND
      iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
   OR
   D. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
      AND
      ii. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
      AND
      iii. The prescriber has provided information in support of therapy with a higher dose for the requested indication

Length of Approval: Up to 12 months

FDA Companion Diagnostics: https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools

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

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

Sodium-glucose Co-transporter (SGLT) Inhibitors and Combinations Step Therapy – 2-Step Edit

TARGET AGENT(S)
Invokana® (canagliflozin)
Invokamet™ (canagliflozin/metformin)
Invokamet XR™ (canagliflozin/metformin ER)
Inpefa™ (sotagliflozin)
Qtern® (dapagliflozin/saxagliptin)
Segluromet™ (ertugliflozin/metformin)
Steglatro™ (ertugliflozin)
Steglujan™ (ertugliflozin/sitagliptin)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

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

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

    OR
2. The patient's medication history includes use of Glyxambi or Trijardy XR

    OR
3. BOTH of the following:
    A. The prescriber has stated that the patient has tried Glyxambi or Trijardy XR **AND**
    B. Glyxambi or Trijardy XR was discontinued due to lack of effectiveness or an adverse event

    OR
4. The patient has an intolerance or hypersensitivity to BOTH Glyxambi and Trijardy XR

    OR
5. The patient has an FDA labeled contraindication to BOTH Glyxambi and Trijardy XR

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

Length of Approval: 12 months

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

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

OR

B. The patient's medication history includes use of an agent containing dapagliflozin

OR

C. BOTH of the following:
    1. The prescriber has stated that the patient has tried an agent containing dapagliflozin

    AND

    2. The agent containing dapagliflozin was discontinued due to lack of effectiveness or an adverse event

OR

D. The patient has an intolerance or hypersensitivity to dapagliflozin

OR

E. The patient has an FDA labeled contraindication to dapagliflozin

OR

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

AND

2. ONE of the following:
    A. The patient is currently being treated with the requested agent as indicated by ALL of the following:
        1. A statement by the prescriber that the patient is currently taking the requested agent

        AND

        2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent

        AND

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

    OR

    B. The patient's medication history includes use of an agent containing empagliflozin

    OR

    C. BOTH of the following:
        1. The prescriber has stated that the patient has tried empagliflozin

        AND

        2. Empagliflozin was discontinued due to lack of effectiveness or an adverse event

    OR

    D. The patient has an intolerance or hypersensitivity to empagliflozin

    OR

    E. The patient has an FDA labeled contraindication to empagliflozin

    OR

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

Length of Approval: 12 months

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

• Program Summary: Statin

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

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

a - available as a generic

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

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

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

Length of Approval: 12 months

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

• Program Summary: Urea Cycle Disorders

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
	309080600029	Buphenyl	sodium phenylbutyrate oral powder	3 GM/TSP	M ; N ; O ; Y				
	309080600003	Buphenyl	sodium phenylbutyrate tab	500 MG	M ; N ; O ; Y				
	3090806000B1	Olpruva	sodium phenylbutyrate packet for susp	2 GM; 3 GM; 4 GM; 5 GM; 6 GM; 6.67 GM	M ; N ; O ; Y				
	309080600089	Pheburane	sodium phenylbutyrate oral pellets	483 MG/GM	M ; N ; O ; Y				
	309080300009	Ravicti	glycerol phenylbutyrate liquid	1.1 GM/ML	M ; N ; O ; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of hyperammonemia AND ALL of the following: A. The patient has elevated ammonia levels according to the patient's age [Neonate: plasma ammonia level 150 micromol/L (greater than 260 micrograms/dL) or higher; Older child or adult: plasma ammonia level greater than 100 micromol/L (175 micrograms/dL)] **AND** B. The patient has a normal anion gap **AND** C. The patient has a normal blood glucose level **AND** 2. The patient has a diagnosis of ONE of the following urea cycle disorders confirmed by enzyme analysis OR genetic testing: A. carbamoyl phosphate synthetase I deficiency [CPSID] B. ornithine transcarbamylase deficiency [OTCD] C. argininosuccinic acid synthetase deficiency [ASSD] D. argininosuccinic acid lyase deficiency [ASLD] E. arginase deficiency [ARG1D] **AND** 3. The requested agent will NOT be used as treatment of acute hyperammonemia **AND** 4. The patient is unable to maintain a plasma ammonia level within the normal range with the use of a protein restricted diet and, when clinically appropriate, essential amino acid supplementation **AND** 5. The patient will be using the requested agent as adjunctive therapy to dietary protein restriction **AND** 6. ONE of the following: A. If the requested agent is Buphenyl, then ONE of the following: 1. The patient has tried and had an inadequate response to generic sodium phenylbutyrate **OR** 2. The patient has an intolerance or hypersensitivity to generic sodium phenylbutyrate that is not expected to occur with the brand agent **OR** 3. The patient has an FDA labeled contraindication to generic sodium phenylbutyrate that is not expected to occur with the brand agent **OR**

Module	Clinical Criteria for Approval
	4. The prescriber has provided information to support the use of the requested brand agent over generic sodium phenylbutyrate **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that generic sodium phenylbutyrate cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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. If the requested agent is Ravicti, ONE of the following: 1. The patient has tried and had an inadequate response to generic sodium phenylbutyrate AND Pheburane **OR** 2. The patient has an intolerance or hypersensitivity to generic sodium phenylbutyrate AND Pheburane **OR** 3. The patient has an FDA labeled contraindication to generic sodium phenylbutyrate AND Pheburane **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 sodium phenylbutyrate AND Pheburane cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., metabolic disorders) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 8. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 9. 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 for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent (e.g., plasma ammonia level within the normal range) **AND** 3. The requested agent will NOT be used as treatment of acute hyperammonemia **AND** 4. The patient will be using the requested agent as adjunctive therapy to dietary protein restriction **AND**

Module	Clinical Criteria for Approval
	5. ONE of the following: A. If the requested agent is Buphenyl, then ONE of the following: 1. The patient has tried and had an inadequate response to generic sodium phenylbutyrate **OR** 2. The patient has an intolerance or hypersensitivity to generic sodium phenylbutyrate that is not expected to occur with the brand agent **OR** 3. The patient has an FDA labeled contraindication to generic sodium phenylbutyrate that is not expected to occur with the brand agent **OR** 4. The prescriber has provided information to support the use of the requested brand agent over generic sodium phenylbutyrate **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that generic sodium phenylbutyrate cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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. If the requested agent is Ravicti, ONE of the following: 1. The patient has tried and had an inadequate response to generic sodium phenylbutyrate AND Pheburane **OR** 2. The patient has an intolerance or hypersensitivity to generic sodium phenylbutyrate AND Pheburane **OR** 3. The patient has an FDA labeled contraindication to generic sodium phenylbutyrate AND Pheburane **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 sodium phenylbutyrate AND Pheburane cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., metabolic disorders) 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 **AND** 8. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication **Length of Approval:** 12 months

• Program Summary: Urinary Incontinence

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
541000102075		darifenacin hydrobromide tab er	15 MG; 7.5 MG	30	Tablets	30	DAYS					
54100045202010		oxybutynin chloride solution	5 MG/5ML	600	mLs	30	DAYS					
541000452012		oxybutynin chloride syrup	5 MG/5ML	600	mLs	30	DAYS					
54100045200310		oxybutynin chloride tab	2.5 MG	90	Tablets	30	DAYS					
54100045200330		Oxybutynin Chloride Tab 5 MG	5 MG	120	Tablets	30	DAYS					
54100045207540		Oxybutynin Chloride Tab ER 24HR 15 MG	15 MG	60	Tablets	30	DAYS					
541000652070		trospium chloride cap er	60 MG	30	Capsules	30	DAYS					
541000652003		trospium chloride tab	20 MG	60	Tablets	30	DAYS					
541000602003	Detrol	tolterodine tartrate tab	1 MG; 2 MG	60	Tablets	30	DAYS					
541000602070	Detrol la	tolterodine tartrate cap er	2 MG; 4 MG	30	Capsules	30	DAYS					
54100045207530	Ditropan xl	Oxybutynin Chloride Tab ER 24HR 10 MG	10 MG	60	Tablets	30	DAYS					
54100045207520	Ditropan xl	Oxybutynin Chloride Tab ER 24HR 5 MG	5 MG	30	Tablets	30	DAYS					
541000452040	Gelnique	oxybutynin chloride td gel	10%	30	Sachets	30	DAYS					
542000800003	Gemtesa	vibegron tab	75 MG	30	Tablets	30	DAYS					
5420005000G2	Myrbetriq	mirabegron granules for oral extended release susp	8 MG/ML	300	mLs	28	DAYS					
542000500075	Myrbetriq	mirabegron tab er	25 MG; 50 MG	30	Tablets	30	DAYS					
541000450087	Oxytrol ; Oxytrol for women	oxybutynin td patch twice weekly	3.9 MG/24HR	8	Patches	28	DAYS					
541000202075	Toviaz	fesoterodine	4 MG;	30	Tablets	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		fumarate tab er	8 MG									
541000552003	Vesicare	solifenacin succinate tab	10 MG; 5 MG	30	Tablets	30	DAYS					
541000552018	Vesicare ls	solifenacin succinate susp	5 MG/5ML	300	mLs	30	DAYS					

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
62380030000330	Austedo	Deutetrabenazine Tab 12 MG	12 MG	120	Tablets	30	DAYS					
62380030000310	Austedo	Deutetrabenazine Tab 6 MG	6 MG	60	Tablets	30	DAYS					
62380030000320	Austedo	Deutetrabenazine Tab 9 MG	9 MG	120	Tablets	30	DAYS					
62380030007510	Austedo xr	deutetrabenazine tab er	6 MG	30	Tablets	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
62380030007520	Austedo xr	deutetrabenazine tab er	12 MG	30	Tablets	30	DAYS					
62380030007530	Austedo xr	deutetrabenazine tab er	24 MG	60	Tablets	30	DAYS					
6238003000C120	Austedo xr patient titrate	deutetrabenazine tab er titration pack	6 & 12 & 24 MG	42	Tablets	180	DAYS					
62380080200130	Ingrezza	Valbenazine Tosylate Cap	60 MG	30	Capsules	30	DAYS					
62380080200120	Ingrezza	Valbenazine Tosylate Cap 40 MG (Base Equiv)	40 MG	30	Capsules	30	DAYS					
62380080200140	Ingrezza	Valbenazine Tosylate Cap 80 MG (Base Equiv)	80 MG	30	Capsules	30	DAYS					
6238008020B220	Ingrezza	Valbenazine Tosylate Cap Therapy Pack 40 MG (7) & 80 MG (21)	40 & 80 MG	28	Capsules	180	DAYS					
62380070000310	Xenazine	Tetrabenazine Tab 12.5 MG	12.5 MG	240	Tablets	30	DAYS					
62380070000320	Xenazine	Tetrabenazine Tab 25 MG	25 MG	120	Tablets	30	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is Ingrezza/valbenazine AND ONE of the following: 1. The patient has a diagnosis of tardive dyskinesia AND BOTH of the following: A. ONE of the following: 1. The prescriber has reduced the dose or discontinued any medications known to cause tardive dyskinesia (i.e., dopamine receptor blocking agents) **OR** 2. The prescriber has provided clinical rationale indicating that a reduced dose or discontinuation of any medications known to cause tardive dyskinesia is not appropriate **AND** B. The prescriber has documented the patient's baseline Abnormal Involuntary Movement Scale (AIMS) score **OR** 2. The patient has another FDA approved indication for the requested agent **OR** 3. The patient has another indication that is supported in compendia for the requested agent **OR** B. The requested agent is Austedo/deutetrabenazine AND ONE of the following: 1. The patient has a diagnosis of tardive dyskinesia AND BOTH of the following: A. ONE of the following:

Module	Clinical Criteria for Approval

1. The prescriber has reduced the dose or discontinued any medications known to cause tardive dyskinesia (i.e., dopamine receptor blocking agents) **OR**
2. The prescriber has provided clinical rationale indicating that a reduced dose or discontinuation of any medications known to cause tardive dyskinesia is not appropriate **AND**

B. The prescriber has documented the patient's baseline Abnormal Involuntary Movement Scale (AIMS) score **OR**

2. The patient has a diagnosis of chorea associated with Huntington's disease **OR**
3. The patient has another FDA approved indication for the requested agent **OR**
4. The patient has another indication that is supported in compendia for the requested agent **OR**

C. The requested agent is Xenazine/tetrabenazine and ONE of the following:

1. The patient has a diagnosis of chorea associated with Huntington's disease **OR**
2. The patient has another FDA approved indication for the requested agent **OR**
3. The patient has another indication that is supported in compendia for the requested agent **AND**

2. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following:

A. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**

B. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR**

C. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent **OR**

Brand	Generic Equivalent
Xenazine	tetrabenazine

D. 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**

E. The patient is currently being treated with the requested agent as indicated by ALL of the following:

1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

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

3. ONE of the following:

A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**

B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**

4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., psychiatrist, neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
5. The patient will NOT be using the requested agent in combination with another agent included in this prior authorization program **AND**

Module	Clinical Criteria for Approval

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:

Tardive dyskinesia	3 months
Chorea associated with Huntington's Disease	12 months
All other indications	12 months

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

Renewal Evaluation

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

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND**
2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., psychiatrist, neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
3. ONE of the following:
   A. The diagnosis is tardive dyskinesia AND the patient has had stabilization or improvement from baseline in Abnormal Involuntary Movement Scale (AIMS) score **OR**
   B. The diagnosis is another FDA approved indication or another indication that is supported in compendia AND the patient has had clinical benefit with the requested agent **AND**
4. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following:
   A. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**
   B. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR**
   C. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent **OR**

Brand	Generic Equivalent
Xenazine	tetrabenazine

   D. 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**
   E. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
      2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
      3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
   F. The prescriber has provided documentation that the generic equivalent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

Module	Clinical Criteria for Approval
	5. The patient will NOT be using the requested agent in combination with another agent included in this prior authorization program **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**: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

Indication	Initial	Renewal
Tardive dyskinesia	3 months	12 months
Chorea associated with Huntington's Disease	12 months	12 months
All other indications	12 months	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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
624070502001	Zeposia	ozanimod hcl cap	0.92 MG	30	Capsules	30	DAYS					
6240705020B210	Zeposia 7-day starter pac	Ozanimod Cap Pack 4 x 0.23	4 x 0.23MG	7	Capsules	180	DAYS					

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

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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

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

Module	Clinical Criteria for Approval

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

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

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

D. ONE of the following:

1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
2. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**

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

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

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

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

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

Renewal Evaluation

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

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND**
2. ONE of the following:

A. The patient has a diagnosis of multiple sclerosis (MS) AND BOTH of the following:

1. ONE of the following:

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

Agents Eligible for Continuation of Therapy
Zeposia (ozanimod)

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

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

Module	Clinical Criteria for Approval

Length of Approval: 12 months

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

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

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

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

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

** generic available

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

Immunomodulatory Agent Step table****

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

Module	Clinical Criteria for Approval

	Stelara		or Humira are required Step 1 agents)		Rinvoq, Stelara, OR Xeljanz/Xeljanz XR are required step agents)	Idacio**, Yusimry**
FlexRx, GenRx, KeyRx, BasicRx	SQ: Amjevita, Hadlima, Humira, Stelara	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Amjevita, Hadlima, or Humira are required Step 1 agents)	N/A	Zeposia (Amjevita, Humira, Rinvoq, Stelara, OR Xeljanz/Xeljanz XR are required step agents)	SQ: Abrilada***, Cyltezo***, Hulio***, Hyrimoz***, Idacio***, Yusimry***

** Note Amjevita, Cyltezo and Humira are required Step 1 agents

*** Note Amjevita, Hadlima, and Humira are required Step 1 agents

**** Noted preferred status is effective upon launch

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

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)

Contraindicated as Concomitant Therapy
Copaxone (glatiramer) 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)a **Vumerity** (diroximel fumarate) **Zeposia** (ozanimod) **Immunomodulatory Agents NOT to be used concomitantly** **Adbry** (tralokinumab-ldrm) **Actemra** (tocilizumab) **Arcalyst** (rilonacept) **Avsola** (infliximab-axxq) **Benlysta** (belimumab) **Cibinqo** (abrocitinib) **Cimzia** (certolizumab) **Cinqair** (reslizumab) **Cosentyx** (secukinumab) **Dupixent** (dupilumab) **Enbrel** (etanercept) **Entyvio** (vedolizumab) **Fasenra** (benralizumab) **Humira** (adalimumab) **Ilaris** (canakinumab) **Ilumya** (tildrakizumab-asmn) **Inflectra** (infliximab-dyyb) Infliximab **Kevzara** (sarilumab) **Kineret** (anakinra) **Nucala** (mepolizumab) **Olumiant** (baricitinib) **Opzelura** (ruxolitinib) **Orencia** (abatacept) **Otezla** (apremilast) **Remicade** (infliximab) **Renflexis** (infliximab-abda) **Riabni** (rituximab-arrx) **Rinvoq** (upadacitinib) **Rituxan** (rituximab) **Rituxan Hycela** (rituximab/hyaluronidase human) **Ruxience** (rituximab-pvvr) **Siliq** (brodalumab)

Contraindicated as Concomitant Therapy
Simponi (golimumab) **Simponi ARIA** (golimumab) **Sotyktu** (deucravacitinib) **Skyrizi** (risankizumab-rzaa) **Stelara** (ustekinumab) **Taltz** (ixekizumab) **Tezspire** (tezepelumab-ekko) **Tremfya** (guselkumab) **Truxima** (rituximab-abbs) **Xeljanz** (tofacitinib) **Xeljanz XR** (tofacitinib extended release) **Xolair** (omalizumab) **Zeposia** (ozanimod)

• Quantity Limit Program Summary: Quantity Limit Changes for October 1, 2023

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

QUANTITY LIMIT CRITERIA FOR APPROVAL:

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

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

Length of approval: up to 12 months

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

Program: Atypical Antipsychotics - Extended Maintenance Agents

TARGET DRUGS	DOSAGE / STRENGTH	QUANTITY LIMIT (Units/Day or As Noted)
Abilify Asimtufii (aripiprazole extended release)	720 mg suspension syringe	1 syringe/56 days
Abilify Asimtufii (aripiprazole extended release)	960 mg suspension syringe	1 syringe/56 days
Abilify Maintena (aripiprazole extended release)	300 mg reconstituted suspension vial	1 vial/28 days
Abilify Maintena (aripiprazole extended release)	300 mg suspension syringe	1 syringe/28 days
Abilify Maintena (aripiprazole extended release)	400 mg reconstituted suspension vial	1 vial/28 days
Abilify Maintena (aripiprazole extended release)	400 mg suspension syringe	1 syringe/28 days
Aristada (aripiprazole lauroxil injection)	441 mg injection	1 syringe/28 days
Aristada (aripiprazole lauroxil injection)	662 mg injection	1 syringe/28 days
Aristada (aripiprazole lauroxil injection)	882 mg injection	1 syringe/28 days
Aristada (aripiprazole lauroxil injection)	1064 mg injection	1 syringe/56 days
Aristada Initio (aripiprazole lauroxil extended-release injection)	675 mg injection	1 kit/180 days
Invega Hafyera (paliperidone)	1092 mg/3.5 mL extended-release suspension prefilled syringe	1 syringe/180 days
Invega Hafyera (paliperidone)	1560 mg/5 mL extended-release suspension prefilled syringe	1 syringe/180 days
Invega Sustenna (paliperidone)	39 mg/kit extended-release injection	1 kit/28 days
Invega Sustenna (paliperidone)	78 mg/kit extended-release injection	1 kit/28 days
Invega Sustenna (paliperidone)	117 mg/kit extended-release injection	1 kit/28 days
Invega Sustenna (paliperidone)	156 mg/kit extended-release injection	1 kit/28 days
Invega Sustenna (paliperidone)	234 mg/kit extended-release injection	1 kit/28 days
Invega Trinza (paliperidone)	273 mg / 0.88 mL	1 syringe/84 days
Invega Trinza (paliperidone)	410 mg / 1.32 mL	1 syringe/84 days
Invega Trinza (paliperidone)	546 mg / 1.75 mL	1 syringe/84 days
Invega Trinza (paliperidone)	819 mg / 2.63 mL	1 syringe/84 days
Perseris (risperidone)	90 mg kit extended-release injection	1 kit/28 days
Perseris (risperidone)	120 mg kit extended-release injection	1 kit/28 days
Risperdal Consta (risperidone)	12.5 mg/vial long-acting injection	2 vials/28 days
Risperdal Consta (risperidone)	25 mg/vial long-acting injection	2 vials/28 days
Risperdal Consta (risperidone)	37.5 mg/vial long-acting injection	2 vials/28 days
Risperdal Consta (risperidone)	50 mg/vial long-acting injection	2 vials/28 days
Uzedy (risperidone extended release)	50 mg suspension syringe	1 syringe/28 days
Uzedy (risperidone extended release)	75 mg suspension syringe	1 syringe/28 days
Uzedy (risperidone extended release)	100 mg suspension syringe	1 syringe/28 days
Uzedy (risperidone extended release)	125 mg suspension syringe	1 syringe/28 days
Uzedy (risperidone extended release)	150 mg suspension syringe	1 syringe/56 days
Uzedy (risperidone extended release)	200 mg suspension syringe	1 syringe/56 days
Uzedy (risperidone extended release)	250 mg suspension syringe	1 syringe/56 days
Zyprexa Relprevv (olanzapine)	210 mg vial extended-release injection	2 vials/28 days
Zyprexa Relprevv (olanzapine)	300 mg vial extended-release injection	2 vials/28 days
Zyprexa Relprevv (olanzapine)	405 mg vial extended-release injection	1 vial/28 days

Program: Insomnia

TARGET DRUGS	DOSAGE / STRENGTH	QUANTITY LIMIT (Units/Day or As Noted)
Ambien (zolpidem)	5 mg tablet	1 tablet
Ambien (zolpidem)	10 mg tablet	1 tablet
Ambien CR (zolpidem)	6.25 mg extended-release tablet	1 tablet
Ambien CR (zolpidem)	12.5 mg extended-release tablet	1 tablet
Belsomra (suvorexant)	5 mg tablet	1 tablet
Belsomra (suvorexant)	10 mg tablet	1 tablet
Belsomra (suvorexant)	15 mg tablet	1 tablet
Belsomra (suvorexant)	20 mg tablet	1 tablet
Dayvigo (lemborexant)	5 mg tablet	1 tablet
Dayvigo (lemborexant)	10 mg tablet	1 tablet
Edluar (zolpidem)	5 mg orally disintegrating tablet	1 tablet
Edluar (zolpidem)	10 mg orally disintegrating tablet	1 tablet
Intermezzo (zolpidem)	1.75 mg sublingual tablet	1 tablet
Zolpidem	3.5 mg sublingual tablet	1 tablet
Lunesta (eszopiclone)	1 mg tablet	1 tablet
Lunesta (eszopiclone)	2 mg tablet	1 tablet
Lunesta (eszopiclone)	3 mg tablet	1 tablet
Quviviq (daridorexant)	25 mg tablet	1 tablet
Quviviq (daridorexant)	50 mg tablet	1 tablet
Rozerem (ramelteon)	8 mg tablet	1 tablet
Silenor (doxepin)	3 mg tablet	1 tablet
Silenor (doxepin)	6 mg tablet	1 tablet
zaleplon	5 mg capsule	1 capsule
zaleplon	10 mg capsule	1 capsule
zolpidem	7.5 mg capsule	1 capsule
ZolpiMist (zolpidem)	Oral Spray 5 mg/actuation	1 canister (60 actuations)/ 30 days

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

TARGET DRUGS	DOSAGE / STRENGTH	QUANTITY LIMIT (Units/Day or As Noted)
Farxiga (dapagliflozin)	5 mg tablet	1 tablet
Farxiga (dapagliflozin)	10 mg tablet	1 tablet
Glyxambi (empagliflozin/linagliptin)	10 mg / 5 mg	1 tablet
Glyxambi (empagliflozin/linagliptin)	25 mg / 5 mg	1 tablet
Inpefa (sotagliflozin)	200mg	1 tablet
Invokana (canagliflozin)	100 mg tablet	1 tablet
Invokana (canagliflozin)	300 mg tablet	1 tablet
Invokamet (canagliflozin/metformin)	50 mg / 500 mg	2 tablets
Invokamet (canagliflozin/metformin)	50 mg / 1000 mg	2 tablets

TARGET DRUGS	DOSAGE / STRENGTH	QUANTITY LIMIT (Units/Day or As Noted)
Invokamet (canagliflozin/metformin)	150 mg / 500 mg	2 tablets
Invokamet (canagliflozin/metformin)	150 mg / 1000 mg	2 tablets
Invokamet XR (canagliflozin/metformin ER)	50 mg/500 mg tablet	2 tablets
Invokamet XR (canagliflozin/metformin ER)	50 mg/1000 mg tablet	2 tablets
Invokamet XR (canagliflozin/metformin ER)	150 mg/500 mg tablet	2 tablets
Invokamet XR (canagliflozin/metformin ER)	150 mg/1000 mg tablet	2 tablets
Jardiance (empagliflozin)	10 mg	1 tablet
Jardiance (empagliflozin)	25 mg	1 tablet
Qtern (dapagliflozin/saxagliptin)	5 mg/5 mg tablet	1 tablet
Qtern (dapagliflozin/saxagliptin)	10 mg/5 mg tablet	1 tablet
Segluromet (ertugliflozin/metformin)	2.5 mg/500 mg tablet	4 tablets
Segluromet (ertugliflozin/metformin)	2.5 mg/1000 mg tablet	2 tablets
Segluromet (ertugliflozin/metformin)	7.5 mg/500 mg tablet	2 tablets
Segluromet (ertugliflozin/metformin)	7.5 mg/1000 mg tablet	2 tablets
Steglatro (ertugliflozin)	5 mg tablet	2 tablets
Steglatro (ertugliflozin)	15 mg tablet	1 tablet
Steglujan (ertugliflozin/sitagliptin)	5 mg/100 mg tablet	1 tablet
Steglujan (ertugliflozin/sitagliptin)	15 mg/100 mg tablet	1 tablet
Synjardy (empagliflozin/metformin)	5 mg / 500 mg	2 tablets
Synjardy (empagliflozin/metformin)	5 mg / 1000 mg	2 tablets
Synjardy (empagliflozin/metformin)	12.5 mg / 500 mg	2 tablets
Synjardy (empagliflozin/metformin)	12.5 mg / 1000 mg	2 tablets
Synjardy XR (empagliflozin/metformin ER)	5 mg/1000 mg tablet	2 tablets
Synjardy XR (empagliflozin/metformin ER)	10 mg/1000 mg tablet	2 tablets
Synjardy XR (empagliflozin/metformin ER)	12.5 mg/1000 mg tablet	2 tablets
Synjardy XR (empagliflozin/metformin ER)	25 mg/1000 mg tablet	1 tablet
Trijardy XR (empagliflozin/linagliptin/metformin ER)	5 mg/2.5 mg/1000 mg tablet	2 tablets
Trijardy XR (empagliflozin/linagliptin/metformin ER)	10 mg/5 mg/1000 mg tablet	1 tablet
Trijardy XR (empagliflozin/linagliptin/metformin ER)	12.5 mg/2.5 mg/1000 mg tablet	2 tablets
Trijardy XR (empagliflozin/linagliptin/metformin ER)	25 mg/5 mg/1000 mg tablet	1 tablet
Xigduo XR (dapagliflozin/metformin ER)	2.5 mg/1000 mg tablet	2 tablets
Xigduo XR (dapagliflozin/metformin ER)	5 mg / 500 mg tablet	1 tablet
Xigduo XR (dapagliflozin/metformin ER)	5 mg / 1000 mg tablet	2 tablets
Xigduo XR (dapagliflozin/metformin ER)	10 mg / 500 mg tablet	1 tablet
Xigduo XR (dapagliflozin/metformin ER)	10 mg / 1000 mg tablet	1 tablet