COMMERCIAL PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: March 1, 2024 Notification Posted: January 15, 2024

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

No new policies for March 1, 2024

POLICIES REVISED

• Program Summary: Amifampridine

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
76000012100320	Firdapse	Amifampridine Phosphate Tab 10 MG (Base Equivalent)	10 MG	240	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. The prescriber has provided information supporting that the patient has a diagnosis of Lambert Eaton myasthenic syndrome (LEMS) confirmed by at least ONE of the following: (medical records required) A. Decreased amplitude of compound muscle action potential (CMAP) to a single supramaximal stimulus **OR** B. Positive antibody test against voltage-gated calcium channels (VGCC) **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 has weakness that interferes with normal function **AND** 4. The patient does NOT have a history of seizures **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months Note: If Quantity Limit applies, please see Quantity Limit criteria **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for an amifampridine containing agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with an amifampridine containing agent [e.g., improved weakness, improved fatigue, improvement in activities of daily living (ADLs)] **AND** 3. The patient has not developed a history of seizures while using the requested medication **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**

Module	Clinical Criteria for Approval
	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 see Quantity Limit criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limits** for the **Target Agent(s)** will be approved when the requested quantity (dose) does NOT exceed the program quantity limit **Length of Approval:** 6 months for initial 12 months for renewal

• Program Summary: Ampyra (dalfampridine)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
62406030007420	Ampyra	Dalfampridine Tab ER 12HR 10 MG	10 MG	60	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of multiple sclerosis (MS) AND ALL of the following: 1. ONE of the following: A. The patient will be using a disease modifying agent for the treatment of MS (e.g., Aubagio, Avonex, Bafiertam, Betaseron, Briumvi, Copaxone, Extavia, Gilenya, Glatopa, Kesimpta, Lemtrada, Mavenclad, Mayzent, Ocrevus, Plegridy, Ponvory, Rebif, Rituxan, Tascenso ODT, Tecfidera, Tysabri, Vumerity, Zeposia) in combination with the requested agent **OR** B. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to ALL disease modifying agent drug classes used for the treatment of MS (see MS disease modifying agents drug class table) **OR** C. 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** D. The prescriber has provided documentation that ALL disease modifying agents FDA labeled for the treatment of MS 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. Information has been provided that the patient has significant limitations attributable to slow ambulation **AND**
3. The patient is ambulatory with a baseline (prior to therapy with the requested agent) timed 25-foot walk of 8 to 45 seconds **AND**
4. Information has been provided that the patient has a current EDSS score less than 7 **OR**

B. The patient has another FDA approved indication for the requested agent and route of administration **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 prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
5. If the requested agent 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
Ampyra	dalfampridine

   D. BOTH of the following:
      1. The prescriber has stated that the patient has tried the generic equivalent **AND**
      2. A 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

Length of Approval: 6 months for MS and 12 months for another FDA approved diagnosis

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

Module	Clinical Criteria for Approval
	Renewal Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization Review process **AND** 2. ONE of the following: A. The patient has a diagnosis of multiple sclerosis (MS) AND ALL of the following: 1. Information has been provided that the patient has had stabilization or improvement from baseline (before treatment with requested agent) in timed walking speed or EDSS score with the requested agent **AND** 2. The patient is ambulatory **AND** 3. Information has been provided that the patient has a current EDSS score of less than 7 **AND** 4. ONE of the following: A. BOTH of the following: 1. The patient is currently treated with a disease modifying agent for the treatment of MS (e.g., Aubagio, Avonex, Bafiertam, Betaseron, Briumvi, Copaxone, Extavia, Gilenya, Glatopa, Kesimpta, Lemtrada, Mavenclad, Mayzent, Ocrevus, Plegridy, Ponvory, Rebif, Rituxan, Tascenso ODT, Tecfidera, Tysabri, Vumerity, Zeposia) **AND** 2. The patient will continue a disease modifying agent for the treatment of MS in combination with the requested agent **OR** B. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to ALL disease modifying agent drug classes used for the treatment of MS (see MS disease modifying agents drug class table) **OR** C. 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** D. The prescriber has provided documentation that ALL disease modifying agents FDA labeled for the treatment of MS cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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 has had stabilization or clinical improvement with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following: 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**

Module	Clinical Criteria for Approval
	<table><tr><th>Brand</th><th>Generic Equivalent</th></tr><tr><td>Ampyra</td><td>dalfampridine</td></tr></table> D. BOTH of the following: 1. The prescriber has stated that the patient has tried the generic equivalent **AND** 2. A 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 **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• 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	Targeted NDCs When Exclusions Exist	Age Limit	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	**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 month period **AND** 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

Module	Clinical Criteria for Approval
	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 and all other indications 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** 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:

Module	Clinical Criteria for Approval
	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: 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, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**

Module	Clinical Criteria for Approval
	B. 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: 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**

Module	Clinical Criteria for Approval
	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 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, 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 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

Module	Clinical Criteria for Approval
	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: 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	**Vivjoa (oteseconazole)** will be approved when BOTH of the following are met: 1. ONE of the following: A. ALL 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 month 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

Module	Clinical Criteria for Approval
	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

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td>Brexafemme, Vivjoa</td><td>Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:

1. The requested quantity (dose) does NOT exceed the program quantity limit OR
2. ALL of the following:
A. The requested quantity (dose) exceeds the program quantity limit AND
B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND
C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit OR
3. ALL of the following:
A. The requested quantity (dose) exceeds the program quantity limit AND
B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication AND
C. The prescriber has provided information in support of therapy with a higher dose for the requested indication

Length of Approval:
<table><tr><td rowspan="3">Brexafemme</td><td>3 months for treatment of vulvovaginal candidiasis</td></tr><tr><td>6 months for recurrent vulvovaginal candidiasis</td></tr><tr><td>6 months for all other indications</td></tr><tr><td>Vivjoa</td><td>4 months</td></tr></table></td></tr>
</table>

• Program Summary: ATTR Amyloidosis

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6270104010E520	Tegsedi	Inotersen Sod Subcutaneous Pref Syr 284 MG/1.5ML (Base Eq)	284 MG/1.5ML	4	Syringes	28	DAYS				
40550080000120	Vyndamax	Tafamidis Cap 61 MG	61 MG	30	Capsules	30	DAYS				
40550080200120	Vyndaqel	Tafamidis Meglumine (Cardiac) Cap 20 MG	20 MG	120	Capsules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has ONE of the following: A. ALL of the following: 1. A diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis confirmed by testing (e.g., genetic testing, biopsy) **AND** 2. The requested agent is FDA approved for use in polyneuropathy of hereditary transthyretin-mediated amyloidosis **AND** 3. The patient has clinical manifestations of polyneuropathy (e.g., neuropathic pain, altered sensation, numbness, tingling, impaired balance, motor disability) **OR** B. ALL of the following: 1. A diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis confirmed by testing [e.g., stannous pyrophosphate (PYP) scanning, monoclonal antibody studies, biopsy, scintigraphy, genetic testing (TTR genotyping)] **AND** 2. The requested agent is FDA approved for use in cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis **AND** 3. The patient has clinical manifestations of cardiomyopathy (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema) **OR** C. The patient has another FDA approved indication for the requested agent and route of administration **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient has NOT received a liver transplant **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, geneticist, neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient will NOT be using the requested agent in combination with another agent targeted in this program, Onpattro (patisiran), OR Amvuttra (vutrisiran) for the requested indication **AND**

Module	Clinical Criteria for Approval
	6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, geneticist, neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient has NOT received a liver transplant **AND** 5. The patient will NOT be using the requested agent in combination with another agent targeted in this program, Onpattro (patisiran), OR Amvuttra (vutrisiran) for the requested indication **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6650007000E5	Actemra	tocilizumab subcutaneous soln prefilled syringe	162 MG/0.9ML	4	Syringes	28	DAYS				
6650007000D5	Actemra actpen	tocilizumab subcutaneous soln auto-injector	162 MG/0.9ML	4	Pens	28	DAYS				
6627001510D520	Amjevita	adalimumab-atto soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS				
6627001510E505	Amjevita	adalimumab-atto soln prefilled syringe	10 MG/0.2ML	2	Syringes	28	DAYS				
6627001510E510	Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001510E520	Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS				
525050201064	Cimzia	certolizumab pegol for inj kit	200 MG	2	Kits	28	DAYS				
5250502010F840	Cimzia	Certolizumab Pegol Prefilled Syringe Kit	200 MG/ML	2	Kits	28	DAYS				
5250502010F860	Cimzia starter kit	Certolizumab Pegol Prefilled Syringe Kit	200 MG/ML	1	Kit	180	DAYS				
9025057500E530	Cosentyx	Secukinumab Subcutaneous Pref Syr 150 MG/ML (300 MG Dose)	150 MG/ML	2	Syringes	28	DAYS				
9025057500E510	Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe	75 MG/0.5ML	1	Syringe	28	DAYS				
9025057500E520	Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe 150 MG/ML	150 MG/ML	1	Syringe	28	DAYS				
9025057500D530	Cosentyx sensoready pen	Secukinumab Subcutaneous Auto-inj 150 MG/ML (300 MG Dose)	150 MG/ML	2	Pens	28	DAYS				
9025057500D520	Cosentyx sensoready pen	Secukinumab Subcutaneous Soln Auto-injector 150 MG/ML	150 MG/ML	1	Pen	28	DAYS				
9025057500D550	Cosentyx unoready	secukinumab subcutaneous soln	300 MG/2ML	1	Pen	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		auto-injector									
6627001505F520	Cyltezo	adalimumab-adbm auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS	00597037597; 00597054522			
6627001505F805	Cyltezo	adalimumab-adbm prefilled syringe kit	10 MG/0.2ML	2	Syringes	28	DAYS				
6627001505F810	Cyltezo	adalimumab-adbm prefilled syringe kit	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001505F820	Cyltezo	adalimumab-adbm prefilled syringe kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001505F520	Cyltezo starter package for crohn's, UC, HS	adalimumab-adbm auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00597037516; 00597054566			
6627001505F520	Cyltezo starter package for psoriasis/psoriasis, UV	adalimumab-adbm auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00597037523; 00597054544			
662900300021	Enbrel	etanercept for subcutaneous inj	25 MG	8	Vials	28	DAYS				
66290030002015	Enbrel	Etanercept Subcutaneous Inj 25 mg/0.5ml	25 MG/0.5ML	8	Vials	28	DAYS				
6629003000E525	Enbrel	Etanercept Subcutaneous Soln Prefilled Syringe 25 MG/0.5ML	25 MG/0.5ML	4	Syringes	28	DAYS				
6629003000E530	Enbrel	Etanercept Subcutaneous Soln Prefilled Syringe 50 MG/ML	50 MG/ML	4	Syringes	28	DAYS				
6629003000E2	Enbrel mini	etanercept subcutaneous solution cartridge	50 MG/ML	4	Cartridges	28	DAYS				
6629003000D5	Enbrel sureclick	etanercept subcutaneous solution auto-injector	50 MG/ML	4	Pens	28	DAYS				
5250308000D220	Entyvio	vedolizumab soln pen-injector	108 MG/0.68ML	2	Pens	28	DAYS				
6627001520E510	Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001520E520	Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001520D510	Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				
6627001520D520	Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS				
6627001535F520	Hulio	adalimumab-fkjp	40 MG/0.8ML	2	Pens	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		auto-injector kit									
6627001535F810	Hulio	adalimumab-fkjp prefilled syringe kit	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001535F820	Hulio	adalimumab-fkjp prefilled syringe kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001500F804	Humira	Adalimumab Prefilled Syringe Kit 10 MG/0.1ML	10 MG/0.1ML	2	Syringes	28	DAYS				
6627001500F809	Humira	Adalimumab Prefilled Syringe Kit 20 MG/0.2ML	20 MG/0.2ML	2	Syringes	28	DAYS				
6627001500F830	Humira	Adalimumab Prefilled Syringe Kit 40 MG/0.4ML	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001500F820	Humira	Adalimumab Prefilled Syringe Kit 40 MG/0.8ML	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001500F840	Humira pediatric crohns d	Adalimumab Prefilled Syringe Kit 80 MG/0.8ML	80 MG/0.8ML	1	Kit	180	DAYS				
6627001500F880	Humira pediatric crohns d	Adalimumab Prefilled Syringe Kit 80 MG/0.8ML & 40 MG/0.4ML	80 MG/0.8ML & 40MG/0.4ML	1	Kit	180	DAYS				
6627001500F440	Humira pen	adalimumab pen-injector kit	80 MG/0.8ML	2	Pens	28	DAYS	00074012402			
6627001500F430	Humira pen	Adalimumab Pen-injector Kit 40 MG/0.4ML	40 MG/0.4ML	2	Pens	28	DAYS				
6627001500F420	Humira pen ; Humira pen-cd/uc/hs start	Adalimumab Pen-injector Kit; adalimumab pen-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00074433906; 50090448700			
6627001500F420	Humira pen ; Humira pen-ps/uv starter	Adalimumab Pen-injector Kit; adalimumab pen-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00074433907; 50090448700			
6627001500F440	Humira pen-cd/uc/hs starter	adalimumab pen-injector kit	80 MG/0.8ML	1	Kit	180	DAYS	00074012403			
6627001500F440	Humira pen-pediatric uc starter	adalimumab pen-injector kit	80 MG/0.8ML	4	Pens	180	DAYS	00074012404			
6627001500F450	Humira pen-ps/uv starter	Adalimumab Pen-injector Kit 80 MG/0.8ML & 40 MG/0.4ML	80 MG/0.8ML & 40MG/0.4ML	1	Kit	180	DAYS				
6627001504D515	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				
6627001504D515	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6627001504D520	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS				
6627001504D540	Hyrimoz	adalimumab-adaz soln auto-injector	80 MG/0.8ML	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/0.2ML	2	Syringes	28	DAYS				
6627001504E515	Hyrimoz	adalimumab-adaz soln prefilled syringe	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001504E520	Hyrimoz	adalimumab-adaz soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001504D540	Hyrimoz crohn's disease and UC	adalimumab-adaz soln auto-injector	80 MG/0.8ML	1	Starter Kit	180	DAYS	61314045436			
6627001504E560	Hyrimoz pediatric crohn's starter	adalimumab-adaz soln prefilled syr	80 MG/0.8ML & 40MG/0.4ML	2	Syringes	180	DAYS				
6627001504E540	Hyrimoz pediatric crohns starter	adalimumab-adaz soln prefilled syringe	80 MG/0.8ML	3	Syringes	180	DAYS				
6627001504D560	Hyrimoz plaque psoriasis	adalimumab-adaz soln auto-injector	80 MG/0.8ML & 40MG/0.4ML	1.6	Starter Kit	180	DAYS				
6627001502F540	Idacio	adalimumab-aacf auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS	65219055408; 65219061299			
6627001502F840	Idacio	adalimumab-aacf prefilled syringe kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001502F540	Idacio starter package	adalimumab-aacf auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	65219055438; 65219061299			
6627001502F540	Idacio starter package	adalimumab-aacf auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	65219055428; 65219061299			
6650006000E5	Kevzara	sarilumab subcutaneous soln prefilled syringe	150 MG/1.14ML; 200 MG/1.14ML	2	Syringes	28	DAYS				
6650006000D5	Kevzara	sarilumab subcutaneous solution auto-injector	150 MG/1.14ML; 200 MG/1.14ML	2	Pens	28	DAYS				
6626001000E5	Kineret	anakinra subcutaneous soln prefilled syringe	100 MG/0.67ML	28	Syringes	28	DAYS				
90731060100120	Litfulo	ritlecitinib tosylate cap	50 MG	28	Capsules	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
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/0.4ML	4	Syringes	28	DAYS				
6640001000E515	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 87.5 MG/0.7ML	87.5 MG/0.7ML	4	Syringes	28	DAYS				
6640001000D5	Orencia clickject	abatacept subcutaneous soln auto-injector	125 MG/ML	4	Syringes	28	DAYS				
66603072007530	Rinvoq	Upadacitinib Tab ER	30 MG	30	Tablets	30	DAYS				
66603072007540	Rinvoq	Upadacitinib Tab ER	45 MG	84	Tablets	365	DAYS				
66603072007520	Rinvoq	Upadacitinib Tab ER 24HR 15 MG	15 MG	30	Tablets	30	DAYS				
9025052000E5	Siliq	brodalumab subcutaneous soln prefilled syringe	210 MG/1.5ML	2	Syringes	28	DAYS				
6627004000D540	Simponi	Golimumab Subcutaneous Soln Auto-injector 100 MG/ML	100 MG/ML	1	Syringe	28	DAYS				
6627004000D520	Simponi	Golimumab Subcutaneous Soln Auto-injector 50 MG/0.5ML	50 MG/0.5ML	1	Syringe	28	DAYS				
6627004000E540	Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 100 MG/ML	100 MG/ML	1	Syringe	28	DAYS				
6627004000E520	Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 50 MG/0.5ML	50 MG/0.5ML	1	Syringe	28	DAYS				
9025057070F8	Skyrizi	risankizumab-rzaa sol prefilled syringe	75 MG/0.83ML	1	Box	84	DAYS				
9025057070E5	Skyrizi	risankizumab-rzaa soln prefilled syringe	150 MG/ML	1	Injection Device	84	DAYS				
5250406070E210	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	180 MG/1.2ML	1	Cartridges	56	DAY				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
5250406070E220	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	360 MG/2.4ML	1	Cartridges	56	DAYS				
9025057070D5	Skyrizi pen	risankizumab-rzaa soln auto-injector	150 MG/ML	1	Pen	84	DAYS				
90250524000320	Sotyktu	Deucravacitinib Tab	6 MG	30	Tablets	30	DAYS				
90250585002020	Stelara	Ustekinumab Inj 45 MG/0.5ML	45 MG/0.5ML	1	Vial	84	DAYS				
9025058500E520	Stelara	Ustekinumab Soln Prefilled Syringe 45 MG/0.5ML	45 MG/0.5ML	1	Syringe	84	DAYS				
9025058500E540	Stelara	Ustekinumab Soln Prefilled Syringe 90 MG/ML	90 MG/ML	1	Syringe	56	DAYS				
9025055400D5	Taltz	ixekizumab subcutaneous soln auto-injector	80 MG/ML	1	Syringe	28	DAYS				
9025055400E5	Taltz	ixekizumab subcutaneous soln prefilled syringe	80 MG/ML	1	Syringe	28	DAYS				
9025054200D2	Tremfya	guselkumab soln pen-injector	100 MG/ML	1	Pen	56	DAYS				
9025054200E5	Tremfya	guselkumab soln prefilled syringe	100 MG/ML	1	Syringe	56	DAYS				
66603065102020	Xeljanz	Tofacitinib Citrate Oral Soln	1 MG/ML	240	mLs	30	DAYS				
66603065100330	Xeljanz	Tofacitinib Citrate Tab 10 MG (Base Equivalent)	10 MG	240	Tablets	365	DAYS				
66603065100320	Xeljanz	Tofacitinib Citrate Tab 5 MG (Base Equivalent)	5 MG	60	Tablets	30	DAYS				
66603065107530	Xeljanz xr	Tofacitinib Citrate Tab ER 24HR 11 MG (Base Equivalent)	11 MG	30	Tablets	30	DAYS				
66603065107550	Xeljanz xr	Tofacitinib Citrate Tab ER 24HR 22 MG (Base Equivalent)	22 MG	120	Tablets	365	DAYS				
6627001503F530	Yuflyma 1-pen kit; Yuflyma 2-pen kit	adalimumab-aaty auto-injector kit	40 MG/0.4ML	2	Pens	28	DAYS				
6627001503F830	Yuflyma 2-syringe kit	adalimumab-aaty prefilled syringe kit	40 MG/0.4ML	1	Kit	28	DAYS				
6627001509D240	Yusimry	adalimumab-aqvh soln pen-injector	40 MG/0.8ML	2	Pens	28	DAYS				

PREFERRED AGENTS

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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

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

Module	Clinical Criteria for Approval						
	Dermatological Disorder						
	Hidradenitis Suppurativa (HS)	SQ: Amjevita, Cosentyx, Hadlima, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, 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, Yuflyma**, 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**, Yuflyma**. 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**, Entyvio, Hulio**, Hyrimoz**, Idacio**, Yuflyma**. Yusimry**
	Other						
	Uveitis	SQ: Amjevita, Hadlima, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**. Yusimry**
	Indications Without Prerequisite Biologic Immunomodulators Required						
	Alopecia Areata Atopic	N/A	N/A	N/A	N/A	N/A	N/A

Module	Clinical Criteria for Approval

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)						

*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

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

Initial Evaluation

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

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

Module	Clinical Criteria for Approval

Agents Eligible for Continuation of Therapy
All target agents EXCEPT the following are eligible for continuation of therapy
Abrilada
Cyltezo, Adalimumab-adbm
Entyvio
Hulio, Adalimumab-fkjp
Hyrimoz, Adalimumab-adaz
Idacio
Omvoh
Yuflyma
Yusimry

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

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

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	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,

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	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

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	taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL 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,

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	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:

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

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	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**

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

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

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	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

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

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	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

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	cause an 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:

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

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

Module	Clinical Criteria for Approval
	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 hidradenitis suppurativa **OR** C. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks for at least 3-months **AND** 8. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND**

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

Module	Clinical Criteria for Approval
	quantity of a higher strength and/or package size that does NOT exceed the program quantity limit **OR** B. ALL of the following: 1. The requested quantity (dose) exceeds the FDA maximum labeled dose **AND** 2. The patient has tried and had an inadequate response to at least a 3 month trial of the maximum FDA labeled dose (medical records required) **AND** 3. ONE of the following: A. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum compendia supported dose for the requested indication **AND** 2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does NOT exceed the program quantity limit **OR** B. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose AND the maximum compendia supported dose for the requested indication **AND** 2. The prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required) **OR** 2. The patient has a compendia supported indication for the requested agent, AND ONE of the following: A. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum compendia supported dose for the requested indication **AND** 2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does NOT exceed the program quantity limit **OR** B. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum compendia supported dose for the requested indication **AND** 2. The prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required) **OR** 3. The patient does NOT have an FDA labeled indication NOR a compendia supported indication for the requested agent AND BOTH of the following: A. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit **AND** B. The prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

Module	Clinical Criteria for Approval
	Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** **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 **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) Enbrel (etanercept) Entyvio (vedolizumab) Fasenra (benralizumab) Hadlima (adalimumab-bwwd) Hulio (adalimumab-fkjp) Humira (adalimumab) Hyrimoz (adalimumab-adaz) Idacio (adalimumab-aacf) Ilaris (canakinumab) Ilumya (tildrakizumab-asmn) Inflectra (infliximab-dyyb) Infliximab Kevzara (sarilumab) Kineret (anakinra) Litfulo (ritlecitinib) Nucala (mepolizumab)

Contraindicated as Concomitant Therapy
Olumiant (baricitinib) 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: Buprenorphine, Buprenorphine/Naloxone for Opioid Dependence

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
65200010100760		Buprenorphine HCl SL Tab 2 MG (Base Equiv)	2 MG	6	Tablets	90	DAYS				
65200010100780		Buprenorphine HCl SL Tab 8 MG (Base Equiv)	8 MG	6	Tablets	90	DAYS				
65200010200720		Buprenorphine HCl-Naloxone HCl SL Tab 2-0.5 MG (Base Equiv)	2-0.5 MG	120	Tablets	30	DAYS				
65200010200740		Buprenorphine HCl-Naloxone HCl SL Tab 8-2 MG (Base Equiv)	8-2 MG	90	Tablets	30	DAYS				
65200010208250	Suboxone	Buprenorphine HCl-Naloxone HCl SL Film 12-3 MG (Base Equiv)	12-3 MG	60	Films	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
65200010208220	Suboxone	Buprenorphine HCl-Naloxone HCl SL Film 2-0.5 MG (Base Equiv)	2-0.5 MG	120	Films	30	DAYS				
65200010208230	Suboxone	Buprenorphine HCl-Naloxone HCl SL Film 4-1 MG (Base Equiv)	4-1 MG	60	Films	30	DAYS				
65200010208240	Suboxone	Buprenorphine HCl-Naloxone HCl SL Film 8-2 MG (Base Equiv)	8-2 MG	60	Films	30	DAYS				
65200010200710	Zubsolv	Buprenorphine HCl-Naloxone HCl SL Tab 0.7-0.18 MG (Base Eq)	0.7-0.18 MG	30	Tablets	30	DAYS				
65200010200715	Zubsolv	Buprenorphine HCl-Naloxone HCl SL Tab 1.4-0.36 MG (Base Eq)	1.4-0.36 MG	90	Tablets	30	DAYS				
65200010200760	Zubsolv	Buprenorphine HCl-Naloxone HCl SL Tab 11.4-2.9 MG (Base Eq)	11.4-2.9 MG	30	Tablets	30	DAYS				
65200010200725	Zubsolv	Buprenorphine HCl-Naloxone HCl SL Tab 2.9-0.71 MG (Base Eq)	2.9-0.71 MG	30	Tablets	30	DAYS				
65200010200732	Zubsolv	Buprenorphine HCl-Naloxone HCl SL Tab 5.7-1.4 MG (Base Eq)	5.7-1.4 MG	30	Tablets	30	DAYS				
65200010200745	Zubsolv	Buprenorphine HCl-Naloxone HCl SL Tab 8.6-2.1 MG (Base Eq)	8.6-2.1 MG	60	Tablets	30	DAYS				

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL Standalone	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. If the requested agent is buprenorphine sublingual tablets, then ONE of the following: 1. The patient is pregnant **OR** 2. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to naloxone or naltrexone **OR** B. 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** C. 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**

Module	Clinical Criteria for Approval
	D. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval:** • Buprenorphine sublingual tablets: Approve for up to 12 months. For increased quantities, the quantity requested up to a maximum dose of 32 mg buprenorphine may be approved. • Buprenorphine/naloxone sublingual tablets and films: Approve for up to 6 months. NOTE: For increased quantities, the quantity requested up to a maximum dose of 32 mg buprenorphine may be approved. • Zubsolv: Approve for up to 6 months NOTE: For increased quantities, the quantity requested up to a maximum dose of 22.8 mg buprenorphine may be approved.

• 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	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
45302030003002	Kalydeco	ivacaftor packet	5.8 MG	60	Packets	30	DAYS				
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 MG	150 MG	60	Tablets	30	DAYS				
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	50-75 & 75 MG	60	Tablets	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		75 MG Tab TBPK									
4530990340B120	Trikafta	elexacaf-tezacaf-ivacaf	80-40-60 & 59.5 MG	56	Packs	28	DAYS				
4530990340B140	Trikafta	elexacaf-tezacaf-ivacaf	100-50-75 & 75 MG	56	Packs	28	DAYS				
4530990340B720	Trikafta	Elexacaf-Tezacaf-Ivacaf	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), 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. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient will NOT be using the requested agent in combination with 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

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

• Program Summary: Hyperhidrosis

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
90970030204320	Qbrexza	Glycopyrronium Tosylate Pad 2.4% (Base Equivalent)	2.4%	30	Each	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of primary axillary hyperhidrosis defined by BOTH the following: A. Focal, visible, excessive sweating of at least 6 months duration without apparent cause **AND** B. TWO of the following characteristics: bilateral and relatively symmetric, impairs daily activities, frequency of at least one episode per week, age of onset less than 25 years, positive family history, cessation of focal sweating during sleep **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to 20% aluminum based topical antiperspirant (e.g., Drysol, OTC) **OR** B. The patient has an intolerance or hypersensitivity to 20% aluminum based topical antiperspirant **OR** C. The patient has an FDA labeled contraindication to 20% aluminum based topical antiperspirant **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 20% aluminum based topical antiperspirant cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Hypoactive Sexual Desire Disorder (HSDD)

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

POLICY AGENT SUMMARY QUANTITY LIMITS

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
62175030000320	Addyi	Flibanserin Tab 100 MG	100 MG	30	Tablets	30	DAYS				
6217351510D520	Vyleesi	Bremelanotide Acet Subcutaneous Soln Auto-Inj 1.75 MG/0.3ML	1.75 MG/0.3ML	6	Pens	30	DAYS				

ADDITIONAL QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
6217351510D520	Vyleesi	Bremelanotide Acet Subcutaneous Soln Auto-Inj 1.75 MG/0.3ML	1.75 MG/0.3ML	Quantity limit for Vyleesi will allow for 6 doses per 30 days.			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient's benefit plan covers the requested agent **AND** 2. The patient is premenopausal **AND** 3. The patient has had a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) and

Module	Clinical Criteria for Approval
	BOTH of the following: A. The patient's diagnosis is characterized by low sexual desire that causes marked distress or interpersonal difficulty **AND** B. The patient's symptoms of low sexual desire have been present for at least 6 months **AND** 4. The HSDD is NOT due to ANY of the following: A. A co-existing medical or psychiatric condition **OR** B. Problems within the relationship **OR** C. The effects of a medication or other drug substance **AND** 5. The patient has tried and had an inadequate response to other treatment modalities (e.g., education, couples counseling, office-based counseling, cognitive behavioral therapy) **AND** 6. The patient will NOT be using the requested agent in combination with another target agent in this program **AND** 7. 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. **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's benefit plan covers the requested agent **AND** 3. The patient is premenopausal **AND** 4. The patient has had clinical benefit with the requested agent (e.g., HSDD symptoms have improved) **AND** 5. The patient will NOT be using the requested agent in combination with another target agent in this program **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity limit for the Target Agent(s)** will be approved when the requested quantity (dose) does NOT exceed the program quantity limit **Length of Approval:** Initial: 8 weeks; Renewal: 12 months

• Program Summary: Inhaled Antibiotics Duplicate Therapy

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

POLICY AGENT SUMMARY QUANTITY LIMITS

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

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
07000070002530	Bethkis	Tobramycin Nebu Soln 300 MG/4ML	300 MG/4ML	56	Ampules	56	DAYS				
16140010402120	Cayston	Aztreonam Lysine For Inhal Soln 75 MG (Base Equivalent)	75 MG	84	Vials	56	DAYS				
07000070002520	Kitabis pak; Tobi	Tobramycin Nebu Soln 300 MG/5ML	300 MG/5ML	56	Ampules	56	DAYS				
07000070002520	Kitabis pak; Tobi	Tobramycin Nebu Soln 300 MG/5ML	300 MG/5ML	56	Ampules	56	DAYS				
07000070000120	Tobi podhaler	Tobramycin Inhal Cap 28 MG	28 MG	28	Blisters	56	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	TARGET AGENT(S) **Preferred and Non-Preferred Agent(s) - to be determined by client** **<u>Preferred Inhaled Antibiotic Agent(s):</u>** **Generic tobramycin inhalation solution 300 mg/5 mL ampules (neb)** **<u>Non-Preferred Inhaled Antibiotic Agent(s):</u>** **TOBI Podhaler** (tobramycin inhalation powder) **<u>Standalone Inhaled Antibiotic Agent(s):</u>** **Bethkis** (tobramycin inhalation solution) **Cayston** (aztreonam inhalation solution) **Kitabis Pak** (tobramycin inhalation solution) **TOBI** (tobramycin inhalation solution) **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of cystic fibrosis with *Pseudomonas aeruginosa* respiratory infection **AND** 2. ONE of the following: A. The patient is NOT currently (within the past 60 days) being treated with another inhaled antibiotic (e.g., Arikayce, inhaled aztreonam, inhaled tobramycin) **OR** B. The patient is currently (within the past 60 days) being treated with another inhaled antibiotic (e.g., Arikayce, inhaled aztreonam, inhaled tobramycin) AND ONE of the following: 1. The prescriber has confirmed that the other inhaled antibiotic will be discontinued and that therapy will be continued only with the requested agent **OR** 2. The prescriber has provided information in support of another inhaled antibiotic therapy used concurrently with or alternating with (i.e., continuous alternating therapy) the requested agent **AND** 3. If the client has preferred inhaled antibiotic agent(s) [preferred and non-preferred agent(s) to be determined by client], then ONE of the following: **Preferred Inhaled Antibiotic Agent(s)** Generic tobramycin inhalation solution 300 mg/5 mL ampules (neb)

Module	Clinical Criteria for Approval
	A. The requested agent is Bethkis, Cayston, Kitabis Pak, or TOBI **OR** B. The requested agent is a preferred inhaled antibiotic agent **OR** C. 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 include the required prerequisite/preferred agent(s) as indicated by: A. Evidence of a paid claim(s) **OR** B. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) days AND the required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR** 3. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Ketorolac

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

POLICY AGENT SUMMARY QUANTITY LIMITS

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
66100037100320		Ketorolac Tromethamine Tab 10 MG	10 MG	20	Tablets	5	DAYS				
66100037102090	Sprix	Ketorolac Tromethamine Nasal Spray 15.75 MG/SPRAY	15.75 MG/SPRAY	5	Bottles	5	DAYS				

ADDITIONAL QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
66100037100320		Ketorolac Tromethamine Tab 10 MG	10 MG	The quantity limit will allow for 20 tablets or 5 bottles of nasal spray per prescription to follow product labeling recommendations for no more than 5 days of therapy with no more than 4 doses/day			
66100037102090	Sprix	Ketorolac Tromethamine Nasal Spray 15.75 MG/SPRAY	15.75 MG/SPRAY	The quantity limit will allow for 20 tablets or 5 bottles of nasal spray per prescription to follow product labeling recommendations for no more than 5 days of therapy with no more than 4 doses/day			

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **Length of Approval**: up to 12 months

• Program Summary: Nasal Antiepileptics

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

POLICY AGENT SUMMARY QUANTITY LIMITS

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
72100060002010	Nayzilam	Midazolam Nasal Spray Soln 5 MG/0.1 ML	5 MG/0.1ML	10	Bottles	30	DAYS				
72100030000930	Valtoco 10 mg dose	Diazepam Nasal Spray 10 MG/0.1 ML	10 MG/0.1ML	5	Boxes	30	DAYS				
7210003000C440	Valtoco 15 mg dose	Diazepam Nasal Spray Ther Pack 2 x 7.5 MG/0.1ML (15 MG Dose)	7.5 MG/0.1ML	5	Boxes	30	DAYS				
7210003000C450	Valtoco 20 mg dose	Diazepam Nasal Spray Ther Pack 2 x 10 MG/0.1ML (20 MG Dose)	10 MG/0.1ML	5	Boxes	30	DAYS				
72100030000920	Valtoco 5 mg dose	Diazepam Nasal Spray 5 MG/0.1 ML	5 MG/0.1ML	5	Boxes	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) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 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: Nasal Inhalers

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

POLICY AGENT SUMMARY QUANTITY LIMITS

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
42401015102020		Azelastine HCl Nasal Spray 0.1% (137 MCG/SPRAY)	0.1%; 137 MCG/SPRAY	2	Bottles	30	DAYS				
42200030002005		Flunisolide Nasal Soln 25 MCG/ACT (0.025%)	0.025%	3	Bottles	30	DAYS				
42300040102010		Ipratropium Bromide Nasal Soln 0.03% (21 MCG/SPRAY)	0.03%	2	Bottles	30	DAYS				
42300040102020		Ipratropium Bromide Nasal Soln 0.06% (42 MCG/SPRAY)	0.06%	3	Bottles	30	DAYS				
42200032301810	Allergy nasal spray 24 hour; Allergy relief; Clarispray; CVS fluticasone propionate; CVS fluticasone proprionate; Eq allergy relief ; Eql fluticasone propionate; Flonase allergy relief; Flonase allergy relief ch; GNP fluticasone propionate; Goodsense 24-hour allergy; HM allergy relief nasals; Kls aller-flo; Qc allergy relief ; Sm allergy relief nasal spray	Fluticasone Propionate Nasal Susp 50 MCG/ACT	50 MCG/ACT	1	Bottle	30	DAYS				
42401015102030	Astepro; Astepro childrens	Azelastine HCl Nasal Spray 0.15% (205.5 MCG/SPRAY)	0.15%; 205.5 MCG/SPRAY	2	Bottles	30	DAYS				
42200010321810	Beconase aq	Beclomethasone Dipropionate Monohyd Nasal Susp 42 MCG/SPRAY	42 MCG/SPRAY	2	Bottles	30	DAYS				
42995502151820	Dymista	Azelastine HCl-Fluticasone Prop Nasal Spray 137-50 MCG/ACT	137-50 MCG/ACT	1	Bottle	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
42200045101820	Nasonex 24hr	Mometasone Furoate Nasal Susp 50 MCG/ACT	50 MCG/ACT	2	Bottles	30	DAYS				
42200018001820	Omnaris	Ciclesonide Nasal Susp 50 MCG/ACT	50 MCG/ACT	1	Bottle	30	DAYS				
42401060102020	Patanase	Olopatadine HCl Nasal Soln 0.6%	0.6%	1	Bottle	30	DAYS				
42200010303430	Qnasl	Beclomethasone Dipropionate Nasal Aerosol 80 MCG/ACT	80 MCG/ACT	1	Canister	30	DAYS				
42200010303408	Qnasl childrens	Beclomethasone Dipropionate Nasal Aerosol 40 MCG/ACT	40 MCG/ACT	1	Canister	30	DAYS				
42995502601820	Ryaltris	Olopatadine HCl-Mometasone Furoate Nasal Susp	665-25 MCG/ACT	1	Bottle	30	DAYS				
42200018003420	Zetonna	Ciclesonide Nasal Aerosol Soln 37 MCG/ACT (50 MCG/Valve)	37 MCG/ACT	1	Canister	30	DAYS				

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Oral Immunotherapy

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

POLICY AGENT SUMMARY QUANTITY LIMITS

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
201000480007	Grastek	timothy grass pollen allergen ext sl tab	2800 BAU	30	Tablets	30	DAYS				
201099022207	Odactra	*dust mite mixed ext sl tab	12 SQ-HDM	30	Tablets	30	DAYS				
20109905200730	Oralair ; Oralair adult starter pac	*Grass Mixed Pollen Ext SL Tab 300 IR (Index of Reactivity)*	300 IR	30	Tablets	30	DAYS				
20109905200720	Oralair children/adolesce	*Grass Mixed Pollen Ext SL Tab 100 IR (Index of Reactivity)*	100 IR	1	Pack	180	DAYS				
201000602007	Ragwitek	short ragweed pollen allergen extract sl tab	12 AMB A 1-U	30	Tablets	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. The patient has a diagnosis of allergic rhinitis, with or without conjunctivitis **AND** 2. The patient's diagnosis is confirmed with ONE of the following: A. Positive skin test to ONE of the pollen extracts included in the requested agent (Grastek, Oralair, or Ragwitek) or licensed house dust mite allergen extracts (Odactra) **OR** B. IgE specific antibodies to ONE of the extracts included in the requested agent: 1. Grastek: Timothy grass or cross-reactive grass 2. Odactra: *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* 3. Oralair: Sweet vernal, orchard, perennial rye, Timothy, or Kentucky blue grass 4. Ragwitek: Short Ragweed **AND** 3. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested 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., allergy or immunology) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. ONE of the following: A. The patient has tried and had an inadequate response to an intranasal corticosteroid AND one other standard allergy agent (e.g., oral or intranasal antihistamines, oral or intranasal corticosteroids, leukotriene inhibitors; note:two separate intranasal corticosteroids meet this criteria) **OR** B. The patient has an intolerance or hypersensitivity to therapy with an intranasal corticosteroid AND one other standard allergy agent **OR** C. The patient has an FDA labeled contraindication to ALL intranasal corticosteroids AND other standard allergy therapies **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following:

Module	Clinical Criteria for Approval
	1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on 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 intranasal corticosteroids AND other standard allergy therapies (e.g., oral or intranasal antihistamines, oral or intranasal corticosteroids, leukotriene inhibitors) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 6. The patient will NOT be using the requested agent in combination with subcutaneous injectable immunotherapy for the requested indication **AND** 7. If the requested agent is Grastek, Oralair, or Ragwitek: The product will be started, or has already been started, 3 to 4 months before the expected onset of the applicable pollen season **AND** 8. The first dose is given in the clinic/hospital under direct supervision from the provider for a period of at least 30 minutes **AND** 9. The patient has been prescribed epinephrine auto-injector for at home emergency use **AND** 10. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Oral Inhalers

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

POLICY AGENT SUMMARY QUANTITY LIMITS

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
44209902708020	Advair diskus; Wixela inhub	Fluticasone-Salmeterol Aer Powder BA 100-50 MCG/DOSE	100-50 MCG/ACT	1	Inhaler	30	DAYS				
44209902708030	Advair diskus; Wixela inhub	Fluticasone-Salmeterol Aer Powder BA 250-50 MCG/DOSE	250-50 MCG/ACT	1	Inhaler	30	DAYS				
44209902708040	Advair diskus; Wixela inhub	Fluticasone-Salmeterol Aer Powder BA 500-50 MCG/DOSE	500-50 MCG/ACT	1	Inhaler	30	DAYS				
44209902703260	Advair hfa	Fluticasone-Salmeterol Inhal Aerosol 115-21 MCG/ACT	115-21 MCG/ACT	1	Inhaler	30	DAYS				
44209902703270	Advair hfa	Fluticasone-Salmeterol Inhal Aerosol 230-21 MCG/ACT	230-21 MCG/ACT	1	Inhaler	30	DAYS				
44209902703250	Advair hfa	Fluticasone-Salmeterol Inhal Aerosol 45-21 MCG/ACT	45-21 MCG/ACT	1	Inhaler	30	DAYS				
44209902718030	Airduo digihaler 113/14	Fluticasone-Salmeterol Aer Powder BA	113-14 MCG/ACT	1	Inhaler	30	DAYS				
44209902718040	Airduo digihaler 232/14	Fluticasone-Salmeterol Aer Powder BA	232-14 MCG/ACT	1	Inhaler	30	DAYS				
44209902718020	Airduo digihaler 55/14	Fluticasone-Salmeterol Aer Powder BA	55-14 MCG/ACT	1	Inhaler	30	DAYS				
44209902708015	Airduo respiclick 113/14	Fluticasone-Salmeterol Aer Powder BA 113-14 MCG/ACT	113-14 MCG/ACT	1	Inhaler	30	DAYS				
44209902708025	Airduo respiclick 232/14	Fluticasone-Salmeterol Aer Powder BA 232-14 MCG/ACT	232-14 MCG/ACT	1	Inhaler	30	DAYS				
44209902708010	Airduo respiclick 55/14	Fluticasone-Salmeterol Aer Powder BA 55-14 MCG/ACT	55-14 MCG/ACT	1	Inhaler	30	DAYS				
44209902783220	Airsupra	albuterol-budesonide	90-80	3	Inhalers	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		inhalation aerosol	MCG/ACT								
44400017003440	Alvesco	Ciclesonide Inhal Aerosol 160 MCG/ACT	160 MCG/ACT	2	Inhalers	30	DAYS				
44400017003420	Alvesco	Ciclesonide Inhal Aerosol 80 MCG/ACT	80 MCG/ACT	1	Inhaler	30	DAYS				
44209902958020	Anoro ellipta	Umeclidinium-Vilanterol Aero Powd BA 62.5-25 MCG/INH	62.5-25 MCG/ACT	1	Inhaler	30	DAYS				
44400033218020	Armonair digihaler	Fluticasone Propionate Aer Pow BA	55 MCG/ACT	1	Inhaler	30	DAYS				
44400033218030	Armonair digihaler	Fluticasone Propionate Aer Pow BA	113 MCG/ACT	1	Inhaler	30	DAYS				
44400033218040	Armonair digihaler	Fluticasone Propionate Aer Pow BA	232 MCG/ACT	1	Inhaler	30	DAYS				
44400033108020	Arnuity ellipta	Fluticasone Furoate Aerosol Powder Breath Activ 100 MCG/ACT	100 MCG/ACT	1	Inhaler	30	DAYS				
44400033108030	Arnuity ellipta	Fluticasone Furoate Aerosol Powder Breath Activ 200 MCG/ACT	200 MCG/ACT	1	Inhaler	30	DAYS				
44400033108010	Arnuity ellipta	Fluticasone Furoate Aerosol Powder Breath Activ 50 MCG/ACT	50 MCG/ACT	1	Inhaler	30	DAYS				
44400036203220	Asmanex hfa	Mometasone Furoate Inhal Aerosol Suspension 100 MCG/ACT	100 MCG/ACT	1	Inhaler	30	DAYS				
44400036203230	Asmanex hfa	Mometasone Furoate Inhal Aerosol Suspension 200 MCG/ACT	200 MCG/ACT	1	Inhaler	30	DAYS				
44400036203210	Asmanex hfa	Mometasone Furoate Inhal Aerosol Suspension 50 MCG/ACT	50 MCG/ACT	1	Inhaler	30	DAYS				
44400036208020	Asmanex twisthaler 120 me; Asmanex twisthaler 14 met; Asmanex twisthaler 30 met; Asmanex twisthaler 60 met	Mometasone Furoate Inhal Powd 220 MCG/INH (Breath Activated)	220 MCG/INH	1	Inhaler	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
44400036208010	Asmanex twisthaler 30 met; Asmanex twisthaler 7 mete	Mometasone Furoate Inhal Powd 110 MCG/INH (Breath Activated)	110 MCG/INH	1	Inhaler	30	DAYS				
44100030123420	Atrovent hfa	Ipratropium Bromide HFA Inhal Aerosol 17 MCG/ACT	17 MCG/ACT	2	Inhalers	30	DAYS				
44209902543220	Bevespi aerosphere	Glycopyrrolate-Formoterol Fumarate Aerosol 9-4.8 MCG/ACT	9-4.8 MCG/ACT	1	Inhaler	30	DAYS				
44209902758010	Breo ellipta	fluticasone furoate-vilanterol aero powd ba	50-25 MCG/INH	1	Inhalers	30	DAYS				
44209902758020	Breo ellipta	Fluticasone Furoate-Vilanterol Aero Powd BA 100-25 MCG/INH	100-25 MCG/ACT	1	Inhaler	30	DAYS				
44209902758030	Breo ellipta	Fluticasone Furoate-Vilanterol Aero Powd BA 200-25 MCG/INH	200-25 MCG/ACT	1	Inhaler	30	DAYS				
44209902413240	Breyna; Symbicort	Budesonide-Formoterol Fumarate Dihyd Aerosol 160-4.5 MCG/ACT	160-4.5 MCG/ACT	3	Inhalers	30	DAYS				
44209902413220	Breyna; Symbicort	Budesonide-Formoterol Fumarate Dihyd Aerosol 80-4.5 MCG/ACT	80-4.5 MCG/ACT	3	Inhalers	30	DAYS				
44209903303220	Breztri aerosphere	Budesonide-Glycopyrrolate-Formoterol Aers	160-9-4.8 MCG/ACT	1	Inhaler	30	DAYS				
44209902013420	Combivent respimat	Ipratropium-Albuterol Inhal Aerosol Soln 20-100 MCG/ACT	20-100 MCG/ACT	2	Inhalers	30	DAYS				
44209902268030	Duaklir pressair	Aclidinium Br-Formoterol Fum Aero Pow Br Act 400-12 MCG/ACT	400-12 MCG/ACT	1	Inhaler	30	DAYS				
44209902903220	Dulera	Mometasone Furoate-Formoterol Fumarate Aerosol 100-5 MCG/ACT	100-5 MCG/ACT	3	Inhalers	30	DAYS				
44209902903240	Dulera	Mometasone Furoate-Formoterol Fumarate Aerosol 200-5 MCG/ACT	200-5 MCG/ACT	3	Inhalers	30	DAYS				
44209902903210	Dulera	Mometasone Furoate-Formoterol Fumarate Aerosol 50-5 MCG/ACT	50-5 MCG/ACT	3	Inhalers	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
44400033208020	Flovent diskus	Fluticasone Propionate Aer Pow BA 100 MCG/BLISTER	100 MCG/ACT; 100 MCG/BLIST	1	Inhaler	30	DAYS				
44400033208030	Flovent diskus	Fluticasone Propionate Aer Pow BA 250 MCG/BLISTER	250 MCG/ACT; 250 MCG/BLIST	4	Inhalers	30	DAYS				
44400033208010	Flovent diskus	Fluticasone Propionate Aer Pow BA 50 MCG/BLISTER	50 MCG/ACT; 50 MCG/BLIST	1	Inhaler	30	DAYS				
44400033223230	Flovent hfa	Fluticasone Propionate HFA Inhal Aer 110 MCG/ACT (125/Valve)	110 MCG/ACT	1	Inhaler	30	DAYS				
44400033223240	Flovent hfa	Fluticasone Propionate HFA Inhal Aer 220 MCG/ACT (250/Valve)	220 MCG/ACT	2	Inhalers	30	DAYS				
44400033223220	Flovent hfa	Fluticasone Propionate HFA Inhal Aero 44 MCG/ACT (50/Valve)	44 MCG/ACT	1	Inhaler	30	DAYS				
44100090208030	Incruse ellipta	Umeclidinium Br Aero Powd Breath Act 62.5 MCG/INH (Base Eq)	62.5 MCG/INH	1	Inhaler	30	DAYS				
44201010128020	Proair digihaler	Albuterol Sulfate Aer Pow BA	108 MCG/ACT	2	Inhalers	30	DAYS				
44201010103410	Proair hfa; Proventil hfa; Ventolin hfa	Albuterol Sulfate Inhal Aero 108 MCG/ACT (90MCG Base Equiv)	108 MCG/ACT	2	Inhalers	30	DAYS				
44201010108020	Proair respiclick	Albuterol Sulfate Aer Pow BA 108 MCG/ACT (90 MCG Base Equiv)	108 MCG/ACT	2	Inhalers	30	DAYS				
44400015008018	Pulmicort flexhaler	Budesonide Inhal Aero Powd 180 MCG/ACT (Breath Activated)	180 MCG/ACT	2	Inhalers	30	DAYS				
44400015008009	Pulmicort flexhaler	Budesonide Inhal Aero Powd 90 MCG/ACT (Breath Activated)	90 MCG/ACT	1	Inhaler	30	DAYS				
44400010128120	Qvar redihaler	Beclomethasone Diprop HFA Breath Act Inh Aer 40 MCG/ACT	40 MCG/ACT	1	Inhaler	30	DAYS				
44400010128140	Qvar redihaler	Beclomethasone Diprop HFA Breath	80 MCG/ACT	2	Inhalers	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		Act Inh Aer 80 MCG/ACT									
44201058108020	Serevent diskus	Salmeterol Xinafoate Aer Pow BA 50 MCG/DOSE (Base Equiv)	50 MCG/DOSE	1	Inhaler	30	DAYS				
44100080100120	Spiriva handihaler	Tiotropium Bromide Monohydrate Inhal Cap 18 MCG (Base Equiv)	18 MCG	30	Capsules	30	DAYS				
44100080103410	Spiriva respimat	Tiotropium Bromide Monohydrate Inhal Aerosol 1.25 MCG/ACT	1.25 MCG/ACT	1	Inhaler	30	DAYS				
44100080103420	Spiriva respimat	Tiotropium Bromide Monohydrate Inhal Aerosol 2.5 MCG/ACT	2.5 MCG/ACT	1	Inhaler	30	DAYS				
44209902923420	Stiolto respimat	Tiotropium Br-Olodaterol Inhal Aero Soln 2.5-2.5 MCG/ACT	2.5-2.5 MCG/ACT	1	Inhaler	30	DAYS				
44201052203410	Striverdi respimat	Olodaterol HCl Inhal Aerosol Soln 2.5 MCG/ACT (Base Equiv)	2.5 MCG/ACT	1	Inhaler	30	DAYS				
44209903408040	Trelegy ellipta	Fluticasone-Umeclidinium-Vilanterol AEPB	200-62.5-25 MCG/ACT	1	Inhaler	30	DAYS				
44209903408020	Trelegy ellipta	Fluticasone-Umeclidinium-Vilanterol AEPB 100-62.5-25 MCG/INH	100-62.5-25 MCG/ACT	1	Inhaler	30	DAYS				
44100007108020	Tudorza pressair	Aclidinium Bromide Aerosol Powd Breath Activated 400 MCG/ACT	400; 400 MCG/ACT	1	Inhaler	30	DAYS				
44201045503220	Xopenex hfa	Levalbuterol Tartrate Inhal Aerosol 45 MCG/ACT (Base Equiv)	45 MCG/ACT	2	Inhalers	30	DAYS				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Advair Diskus	**TARGET AGENT(S)** / **PREREQUISITE AGENT(S)** Advair Diskus* / fluticasone propionate-salmeterol aerosol powder generic *generic available **Target Agent(s)** will be approved when ONE of the following is met: 1. The patient's medication history include ONE prerequisite agent as indicated by:

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td></td><td>A. Evidence of a paid claim(s) OR
B. The prescriber has stated that the patient has tried ONE prerequisite agent AND ONE prerequisite agent was discontinued due to lack of effectiveness or an adverse event OR
2. The patient is currently being treated with the requested agent as indicated by ALL of the following:
A. A statement by the prescriber that the patient is currently taking the requested agent AND
B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent AND
C. The prescriber states that a change in therapy is expected to be ineffective or cause harm OR
3. The prescriber has provided documentation that 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.</td></tr>
<tr><td>Alvesco, Flovent/fluticasone</td><td>
<table>
<tr><th>TARGET AGENT(S)</th><th>PREREQUISITE AGENT(S)</th><th>REQUIRED NUMBER OF PREREQUISITES AND LOOK BACK TIMEFRAME</th></tr>
<tr><td>Alvesco
Flovent Diskus
Flovent HFA
Fluticasone propionate aerosol inhalation</td><td>Arnuity Ellipta
Asmanex HFA
Asmanex Twisthaler
Qvar HFA</td><td>1 prerequisite within the past 90 days</td></tr>
</table>
Target Agent(s) will be approved when ONE of the following is met:
1. The patient’s medication history includes ONE prerequisite agent as indicated by:
A. Evidence of a paid claim(s) OR
B. The prescriber has stated that the patient has tried ONE prerequisite agent AND ONE prerequisite agent was discontinued due to lack of effectiveness or an adverse event OR
2. The patient is currently being treated with the requested agent as indicated by ALL of the following:
A. A statement by the prescriber that the patient is currently taking the requested agent AND
B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent AND
C. The prescriber states that a change in therapy is expected to be ineffective or cause harm OR
3. The prescriber has provided documentation that 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.</td></tr>
</table>

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

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

• Program Summary: Oxybate

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

POLICY AGENT SUMMARY QUANTITY LIMITS

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
62450060203020	Lumryz	sodium oxybate pack for oral er susp	4.5 GM	30	Packets	30	DAYS				
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

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

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

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

● Program Summary: Pain Medications

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

POLICY AGENT SUMMARY QUANTITY LIMITS

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
64991002120105		Butalbital-Acetaminophen Cap 50-300 MG	50-300 MG	180	Capsules	30	DAYS				
64991003300120		Butalbital-Aspirin-Caffeine Cap 50-325-40 MG	50-325-40 MG	180	Capsules	30	DAYS				
64991002120304	Allzital	Butalbital-Acetaminophen Tab 25-325 MG	25 MG; 25-325 MG	360	Tablets	30	DAYS				
64991003100310	Bac; Esgic	Butalbital-Acetaminophen-Caffeine Tab 50-325-40 MG	50-325-40 MG	180	Tablets	30	DAYS				
64991002120308	Bupap	Butalbital-Acetaminophen Tab 50-300 MG	50-300 MG	180	Tablets	30	DAYS				
64991002120310	Tencon	Butalbital-Acetaminophen Tab 50-325 MG	50-325 MG	180	Tablets	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
64991003102020	Vtol lq	Butalbital-Acetaminophen-Caffeine Soln 50-325-40 MG/15ML	50-325-40 MG/15ML	2700	mLs	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) exceeds the program quantity limit AND BOTH of the following: A. ONE of the following: 1. BOTH of the following: A. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** B. Information has been provided to support therapy with a higher dose for the requested indication **OR** 2. BOTH of the following: A. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** B. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. BOTH of the following: A. The requested quantity (dose) exceeds 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 **AND** B. If the requested agent contains acetaminophen, the daily dose of acetaminophen does NOT exceed over 4 grams per 24 hours **Length of Approval**: Approval duration is 1 month for dose titration requests and up to 6 months for all other requests

• Program Summary: Pseudobulbar Affect (PBA)

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

POLICY AGENT SUMMARY QUANTITY LIMITS

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
62609902300120	Nuedexta	Dextromethorphan HBr-Quinidine Sulfate Cap 20-10 MG	20-10 MG	60	Capsules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of pseudobulbar affect (PBA) **AND** 2. The patient has a diagnosis of amyotrophic lateral sclerosis (ALS) or multiple sclerosis (MS) **AND** 3. The prescriber has determined a baseline (prior to therapy with the requested agent) number of laughing and/or crying episodes experienced by the patient **AND** 4. ONE of the following: A. The patient has tried and had an inadequate response to a tricyclic antidepressant (TCA) (e.g., amitriptyline, clomipramine, desipramine, doxepin, imipramine, nortriptyline) OR a selective serotonin reuptake inhibitor (SSRI) (e.g., citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline) used for the requested indication **OR** B. The patient has an intolerance or hypersensitivity to TCA or SSRI therapy **OR** C. The patient has an FDA labeled contraindication to ALL TCAs AND SSRIs **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 TCAs AND SSRIs cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, neuropsychologist, 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:** 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has a diagnosis of pseudobulbar affect (PBA) **AND** 3. The patient has a diagnosis of amyotrophic lateral sclerosis (ALS) or multiple sclerosis (MS) **AND** 4. The patient has had clinical benefit with the requested agent as indicated by a decrease in laughing and/or crying episodes from baseline (prior to therapy with the requested agent) **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, neuropsychologist, 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 NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Transmucosal Immediate Release Fentanyl (TIRF)

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

POLICY AGENT SUMMARY QUANTITY LIMITS

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
65100025108475	Actiq	Fentanyl Citrate Lozenge on a Handle 1200 MCG	1200 MCG	120	Lozenges	30	DAYS				
65100025108485	Actiq	Fentanyl Citrate Lozenge on a Handle 1600 MCG	1600 MCG	120	Lozenges	30	DAYS				
65100025108450	Actiq	Fentanyl Citrate Lozenge on a Handle 200 MCG	200 MCG	120	Lozenges	30	DAYS				
65100025108455	Actiq	Fentanyl Citrate Lozenge on a Handle 400 MCG	400 MCG	120	Lozenges	30	DAYS				
65100025108460	Actiq	Fentanyl Citrate Lozenge on a Handle 600 MCG	600 MCG	120	Lozenges	30	DAYS				
65100025108465	Actiq	Fentanyl Citrate Lozenge on a Handle 800 MCG	800 MCG	120	Lozenges	30	DAYS				
65100025100310	Fentora	Fentanyl Citrate Buccal Tab 100 MCG (Base Equiv)	100 MCG	120	Tablets	30	DAYS				
65100025100320	Fentora	Fentanyl Citrate Buccal	200 MCG	120	Tablets	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		Tab 200 MCG (Base Equiv)									
65100025100330	Fentora	Fentanyl Citrate Buccal Tab 400 MCG (Base Equiv)	400 MCG	120	Tablets	30	DAYS				
65100025100340	Fentora	Fentanyl Citrate Buccal Tab 600 MCG (Base Equiv)	600 MCG	120	Tablets	30	DAYS				
65100025100350	Fentora	Fentanyl Citrate Buccal Tab 800 MCG (Base Equiv)	800 MCG	120	Tablets	30	DAYS				
65100025102050	Lazanda	Fentanyl Citrate Nasal Spray 100 MCG/ACT (Base Equiv)	100 MCG/ACT	30	Bottles	30	DAYS				
65100025102060	Lazanda	Fentanyl Citrate Nasal Spray 400 MCG/ACT (Base Equiv)	400 MCG/ACT	30	Bottles	30	DAYS				
65100025000910	Subsys	Fentanyl Sublingual Spray 100 MCG	100 MCG	120	Sprays	30	DAYS				
65100025000960	Subsys	Fentanyl Sublingual Spray 1200 MCG (600 MCG X 2)	1200 MCG	240	Sprays	30	DAYS				
65100025000970	Subsys	Fentanyl Sublingual Spray 1600 MCG (800 MCG X 2)	1600 MCG	240	Sprays	30	DAYS				
65100025000920	Subsys	Fentanyl Sublingual Spray 200 MCG	200 MCG	120	Sprays	30	DAYS				
65100025000930	Subsys	Fentanyl Sublingual Spray 400 MCG	400 MCG	120	Sprays	30	DAYS				
65100025000940	Subsys	Fentanyl Sublingual Spray 600 MCG	600 MCG	120	Sprays	30	DAYS				
65100025000950	Subsys	Fentanyl Sublingual Spray 800 MCG	800 MCG	120	Sprays	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Through Generic	**Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of chronic cancer pain due to active malignancy **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 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 is currently opioid tolerant (taking, for one week or longer, around-the-clock medicine consisting of at least 60 mg of oral morphine per day, at least 25 mcg per hour of transdermal fentanyl, at least 30 mg of oral oxycodone per day, at least 8 mg of oral hydromorphone per day, at least 25 mg oral

Module	Clinical Criteria for Approval
	oxymorphone per day, at least 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid daily) **AND** 4. The patient is taking a long-acting opioid concurrently with the requested TIRF agent **AND** 5. The patient will NOT be using the requested agent with any other TIRF agent in any other strength **AND** 6. ONE of the following: A. The request is for a generic TIRF agent **OR** B. The request is for a brand TIRF agent AND ONE of the following: 1. The patient's medication history includes use of at least ONE generic TIRF agent **OR** 2. BOTH of the following: A. The prescriber has stated that the patient has tried a generic TIRF agent **AND** B. The generic TIRF agent was discontinued due to lack of effectiveness or an adverse event **OR** 3. Information has been provided that indicates the patient is currently being treated with the requested agent within the past 90 days **OR** 4. The prescriber states the patient is currently being treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The patient has an intolerance or hypersensitivity to at least ONE generic TIRF agent that is not expected to occur with the requested agent **OR** 7. The patient has an FDA labeled contraindication to ALL generic TIRF agents that is not expected to occur with the requested agent **OR** 8. The prescriber has provided documentation that ALL generic TIRF 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** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** • 1 month for increased dose requests during a dose titration period • Up to 6 months for all other requests

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. ALL of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose **AND** 2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **AND** 3. Episodes of breakthrough pain cannot be controlled by modifying the dose of the

Module	Clinical Criteria for Approval
	maintenance long-acting opioid used for underlying persistent pain **AND** 4. The prescriber has provided information in support of therapy with a higher quantity (dose) **OR** B. ALL of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose **AND** 2. Episodes of breakthrough pain cannot be controlled by modifying the dose of the maintenance long-acting opioid used for underlying persistent pain **AND** 3. The prescriber has provided information in support of therapy with a higher quantity (dose) **Length of Approval:** • 1 month for increased dose requests during a dose titration period • Up to 6 months for all other requests

• 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] **OR** B. ornithine transcarbamylase deficiency [OTCD] **OR**

Module	Clinical Criteria for Approval
	C. argininosuccinic acid synthetase deficiency [ASSD] **OR** D. argininosuccinic acid lyase deficiency [ASLD] **OR** 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 or Olpruva, 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** 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**

Module	Clinical Criteria for Approval
	8. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 9. The requested quantity (dose) is within FDA labeled dosing 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** 5. ONE of the following: A. If the requested agent is Buphenyl or Olpruva, 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**

Module	Clinical Criteria for Approval
	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) is within FDA labeled dosing for the requested indication **Length of Approval:** 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 LIMITS

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	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				
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 titratIon	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 Austedo/deutetrabenazine, Austedo XR/deutetrabenazine ER, or 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 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** B. 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

Module	Clinical Criteria for Approval
	daily activities or cause physical or mental harm **AND** 3. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., 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** 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, 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 patient has a diagnosis of tardive dyskinesia AND has had improvements or stabilization from baseline in their Abnormal Involuntary Movement Scale (AIMS) score **OR** B. The patient has a diagnosis other than tardive dyskinesia 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

Module	Clinical Criteria for Approval
	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** 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) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: Initial: tardive dyskinesia - 3 months, all other indications - 12 months Renewal: 12 months

• Program Summary: Xhance

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

POLICY AGENT SUMMARY QUANTITY LIMITS

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
4220003230G720	Xhance	Fluticasone Propionate Nasal Exhaler Susp 93 MCG/ACT	93 MCG/ACT	2	Bottles	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 chronic rhinosinusitis with nasal polyps (CRSwNP) **OR** B. The patient has another FDA approved indication for the requested agent **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response with ONE generic OR OTC intranasal corticosteroid **OR** B. The patient has an intolerance or hypersensitivity to therapy with ONE generic or OTC intranasal corticosteroid that is not expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to ALL generic AND OTC intranasal corticosteroids that is not expected to occur with the requested agent **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL generic AND OTC intranasal corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months Note: If Quantity Limit applies, please refer to Quantity Limit criteria.

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

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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