COMMERCIAL PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: October 1, 2024 Notification Posted: August 17, 2024

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

• Program Summary: Eohilia

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
22100012001820	Eohilia	budesonide oral suspension	2 MG/10ML	1800	mLs	90	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of eosinophilic esophagitis (EoE) AND the patient's diagnosis was confirmed by ALL of the following: A. Chronic symptoms of esophageal dysfunction **AND** B. Greater than or equal to 15 eosinophils per high-power field on esophageal biopsy **AND** C. Other causes that may be responsible for or contributing to symptoms and esophageal eosinophilia have been ruled out **AND** 2. ONE of the following: A. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** B. The patient has tried and had an inadequate response to ONE standard corticosteroid therapy used in the treatment of EoE (i.e., budesonide oral suspension, swallowed budesonide, nebulizer suspension, swallowed fluticasone MDI) **OR** C. The patient has an intolerance or hypersensitivity to standard corticosteroid therapy used in the treatment of EoE **OR** D. The patient has an FDA labeled contraindication to ALL standard corticosteroid therapies used in the treatment of EoE **OR** E. The prescriber has provided documentation that ALL standard corticosteroid therapies used in the treatment of EoE cannot be used due to a documented medical condition or comorbid condition that is

	likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** F. The patient has tried and had an inadequate response to ONE proton pump inhibitor (PPI) used in the treatment of EoE **OR** G. The patient has an intolerance or hypersensitivity to PPI therapy used in the treatment of EoE **OR** H. The patient has an FDA labeled contraindication to ALL PPI therapies used in the treatment of EoE **OR** I. The prescriber has provided documentation that ALL PPI therapies used in the treatment of EoE cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 6. ONE of the following: A. The patient has not previously been treated with a course of therapy (12 weeks) with the requested agent **OR** B. The patient has previously been treated with a course of therapy with the requested agent, AND there is support for an additional course of therapy with the requested agent **Length of Approval:** 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Filsuvez (birch triterpenes)

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
	909440200040	Filsuvez	birch triterpenes gel	10 %	M ; N ; O ; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Initial Evaluation

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

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

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

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

   B. The patient has a diagnosis of dystrophic or junctional epidermolysis bullosa as confirmed by ONE of the following: (medical records required)
      1. Immunofluorescence mapping (IFM) **OR**
      2. Transmission electron microscopy (TEM) **OR**
      3. Genetic testing **OR**

   C. The patient has another FDA labeled 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. There is support for using the requested agent for the patient's age for the requested indication **AND**
3. The patient does NOT have current evidence or a history of squamous cell carcinoma in the area that will undergo treatment **AND**
4. The patient does NOT have an active infection in the area that will undergo treatment **AND**
5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, geneticist) 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: 4 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 criteria [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient does NOT have current evidence or a history of squamous cell carcinoma in the area that will undergo treatment **AND** 4. The patient does NOT have an active infection in the area that will undergo treatment **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, geneticist) 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

• Program Summary: IBS-D

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
52554015100310	Lotronex	Alosetron HCl Tab 0.5 MG (Base Equiv)	0.5 MG	60	Tablets	30	DAYS				
52554015100320	Lotronex	Alosetron HCl Tab 1 MG (Base Equiv)	1 MG	60	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Alosetron	**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 irritable bowel syndrome with severe diarrhea (IBS-D) **AND** 2. The patient has an onset of IBS-D symptoms starting at least 6 months prior **AND** 3. The patient exhibits at least ONE of the following: A. Frequent and severe abdominal pain/discomfort **OR** B. Frequent bowel urgency or fecal incontinence **OR** C. Disability or restriction of daily activities due to IBS **AND** 4. The patient will NOT be using the requested agent in combination with another agent from this program for IBS-D **AND** 5. ONE of the following: A. The patient's sex is female **OR** B. The requested agent is medically appropriate for the patient's sex **AND** 6. The patient has had anatomic or biochemical abnormalities of the gastrointestinal tract excluded **AND** 7. ONE of the following: A. The patient has tried and had an inadequate response to at least ONE conventional therapy **OR** B. The patient has an intolerance or hypersensitivity to ONE conventional therapy **OR**

	C. The patient has an FDA labeled contraindication to ALL conventional therapies **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that conventional therapies cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has another FDA labeled indication for the requested agent **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient will NOT be using the requested agent in combination with another agent from this program for a diagnosis of IBS-D **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

	B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

● Program Summary: Spevigo (spesolimab-sbzo)

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
9025057770E530	Spevigo	spesolimab-sbzo subcutaneous soln pref syr	150 MG/ML	2	Syringes	28	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of generalized pustular psoriasis (GPP) AND ALL of the following: 1. The patient has moderate to severe GPP **AND** 2. The patient has a history of 2 or more flares **AND** 3. The patient is NOT currently experiencing an acute flare **OR** B. The patient has another FDA labeled indication for the requested agent **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following: A. The patient does NOT have active or latent tuberculosis (TB) **OR** B. The patient has latent tuberculosis (TB) and the patient has begun or completed therapy for latent TB prior to initiating with the requested agent **AND** 5. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:

	1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (copy of support required, i.e., clinical trials, phase III studies, guidelines) **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months **Note: If patient is NOT transitioning from IV to SC maintenance:** Approve Spevigo loading dose for 1 month, then maintenance dose can be approved for the remainder of 12 months. **Patient IS transitioning from IV to SC maintenance dosing due to a recent flare:** Approve 12 months for maintenance therapy. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (copy of support required, i.e., clinical trials, phase III studies, guidelines) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

	1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

CONTRAINDICATION AGENTS

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

Contraindicated as Concomitant Therapy
Rinvoq (upadacitinib) Rituxan (rituximab) Rituxan Hycela (rituximab/hyaluronidase human) Ruxience (rituximab-pvvr) Siliq (brodalumab) Simlandi (adalimumab-ryvk) Simponi (golimumab) Simponi ARIA (golimumab) Skyrizi (risankizumab-rzaa) Sotyktu (deucravacitinib) Spevigo (spesolimab-sbzo) Stelara (ustekinumab) Taltz (ixekizumab) Tezspire (tezepelumab-ekko) Tofidence (tocilizumab-bavi) Tremfya (guselkumab) Truxima (rituximab-abbs) Tyenne (tocilizumab-aazg) Tysabri (natalizumab) Velsipity (etrasimod) Wezlana (ustekinumab-auub) Xeljanz (tofacitinib) Xeljanz XR (tofacitinib extended release) Xolair (omalizumab) Yuflyma (adalimumab-aaty) Yusimry (adalimumab-aqvh) Zeposia (ozanimod) Zymfentra (infliximab-dyyb)

• Program Summary: Voydeya (danicopan)

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
85808520000320	Voydeya	danicopan tab	100 MG	180	Tablets	30	DAYS				
8580852000B720	Voydeya	danicopan tab therapy pack	50 & 100 MG	1	Box	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) AND ALL of the following: 1. The diagnosis was confirmed by flow cytometry with at least 2 independent flow cytometry reagents on at least 2 cell lineages (e.g., RBCs and WBCs) demonstrating that the patient's

	peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI) – linked proteins (lab tests required) **AND** 2. The patient has clinically significant extravascular hemolysis (EVH) as indicated by BOTH of the following: A. Hemoglobin less than or equal to 9.5 g/dL (lab tests required) **AND** B. Absolute reticulocyte count greater than or equal to 120 x 10^9/L with or without transfusion support (lab tests required) **AND** 3. BOTH of the following: A. The patient has been treated on a stable dose of Soliris (eculizumab) or Ultomiris (ravulizumab-cwvz) for at least the previous 6 months **AND** B. The patient will be using the requested agent as add-on therapy to Soliris (eculizumab) or Ultomiris (ravulizumab-cwvz) **OR** B. The patient has another FDA labeled indication for the requested agent **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient will NOT be using the requested agent in combination with Empaveli (pegcetacoplan) or Fabhalta (iptacopan) for the requested indication **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient will be using the requested agent as add-on therapy to Soliris (eculizumab) or Ultomiris (ravulizumab-cwvz) **AND** 5. The patient will NOT be using the requested agent in combination with Empaveli (pegcetacoplan) or Fabhalta (iptacopan) 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
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR**

	2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• Program Summary: Zelsuvmi (berdazimer)

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
TBD	Zelsuvmi gel	TBD		2	Kits	84	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 molluscum contagiosum (MC) **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to a conventional therapy (e.g., cantharidin, cryotherapy, curettage, podofilox) **OR** B. The patient has an intolerance or hypersensitivity to a conventional therapy **OR** C. The patient has an FDA labeled contraindication to ALL conventional therapy **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that conventional therapies are not recommended for the patient or cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist) 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 conventional therapy (e.g., cantharidin, cryotherapy, curettage, podofilox) for the requested indication **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 weeks NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

POLICIES REVISED

• Program Summary: Afrezza (regular human insulin, inhaled)

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
27104010002990	Afrezza	Insulin Regular (Human) Inh Powd 4 & 8 & 12 Unit/Cart (60)	60x4 &60x8 & 60x12 UNIT	1260	Cartridges	30	DAYS				
27104010002988	Afrezza	Insulin Regular (Human) Inh Powd 90 x 8 Unit & 90 x 12 Unit	90 x 8 UNIT & 90x12 UNIT	1080	Cartridges	30	DAYS				
27104010002978	Afrezza	Insulin Regular (Human) Inhal Powd 90 x 4 Unit & 90 x 8 Unit	90 x 4 UNIT & 90x8 UNIT	1800	Cartridges	30	DAYS				
27104010002955	Afrezza	Insulin Regular (Human) Inhalation Powder 12 Unit/Cartridge	12 UNIT	900	Cartridges	30	DAYS				
27104010002940	Afrezza	Insulin Regular (Human) Inhalation Powder 4 Unit/Cartridge	4 UNIT	2520	Cartridges	30	DAYS				
27104010002950	Afrezza	Insulin Regular (Human) Inhalation Powder 8 Unit/Cartridge	8 UNIT	1260	Cartridges	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Preferred Agent(s)	Non-Preferred Agent(s)
Fiasp (insulin aspart) **Humalog** (insulin lispro) **Humalog U200** (insulin lispro) **Lyumjev** (insulin lispro-aabc) **NovoLog** (insulin aspart)	**Admelog** (insulin lispro) **Apidra** (insulin glulisine) **Insulin aspart** **Insulin lispro**

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 diabetes mellitus type 1 AND the patient is currently on long acting insulin therapy **OR**
   B. The patient has a diagnosis of diabetes mellitus type 2 **AND**
2. The patient has received ALL of the following to identify any potential lung disease:
   A. Detailed medical history review **AND**
   B. Physical examination **AND**
   C. Spirometry with Forced Expiratory Volume in 1 second (FEV1) **AND**
3. The patient has not smoked in the past 6 months **AND**
4. If the patient has an FDA labeled indication, then ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
   B. There is support for using the requested agent for the patient's age for the requested indication **AND**
5. ONE of the following:
   A. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
      2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
      3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
   B. The patient's medication history includes a preferred rapid acting insulin agent as indicated by:
      1. Evidence of a paid claim(s) **OR**
      2. The prescriber has stated that the patient has tried a preferred rapid acting insulin agent AND the preferred rapid acting insulin agent was discontinued due to lack of effectiveness or an adverse event **OR**
   C. The patient has an intolerance or hypersensitivity to a preferred rapid acting insulin agent that is not expected to occur with the requested agent **OR**
   D. The patient has an FDA labeled contraindication to a preferred rapid acting insulin agent **OR**
   E. There is support that the patient has a physical or a mental disability that would prevent them from using a preferred rapid acting insulin agent(s) **OR**
   F. The patient has a documented needle phobia **OR**
   G. The prescriber has provided documentation that preferred rapid acting insulin products cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
6. The patient does not have any FDA labeled contraindications to the requested agent

Length of Approval: 12 months

	NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient has received ALL of the following to identify any potential lung disease: A. Detailed medical history review **AND** B. Physical examination **AND** C. Spirometry with Forced Expiratory Volume in 1 second (FEV1) **AND** 4. The patient has not smoked in the past 6 months **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 **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of Approval:** up to 12 months

• Program Summary: Agamree (vamorolone, Emflaza (deflazacort)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
22100075001820	Agamree	vamorolone oral susp	40 MG/ML	3	Bottles	30	DAYS				
22100017000350	Emflaza	Deflazacort Tab 18 MG	18 MG	30	Tablets	30	DAYS				
22100017000340	Emflaza	Deflazacort Tab 6 MG	6 MG	60	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. The patient has been treated with the requested agent (starting on samples is not approvable) with the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. ALL of the following: 1. ONE of the following: A. The patient has a diagnosis of Duchenne Muscular Dystrophy confirmed by genetic analysis (i.e., dystrophin deletion or duplication mutation) (genetic test required) **OR** B. The patient has another FDA labeled indication for the requested agent and route of administration **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for the use of the requested agent for the patient's age for the requested indication **AND** 3. ONE of the following: A. The prescriber has provided information that the patient has tried and failed a generic prednisone (or prednisolone) **OR** B. The prescriber has provided information that the patient has an intolerance or hypersensitivity to generic prednisone (or prednisolone) that is NOT expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to generic prednisone (or prednisolone) **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that generic prednisone (or prednisolone) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., pediatric neurologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose based on the patient's weight

	Length of Approval: 6 months for Agamree, 12 months for Emflaza NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [NOTE: Patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had improvements or stabilization with the requested agent (e.g., slowed disease progression, improved strength, timed motor function, pulmonary function; reduced need for scoliosis surgery) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., pediatric neurologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose based on the patient's weight **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested agent strength does not have a program quantity limit **OR** 3. The request agent is Emflaza and ONE of the following: A. The requested agent is Emflaza SUSPENSION **OR** B. BOTH of the following: 1. The requested quantity (dose) exceeds the program quantity limit **AND** 2. The requested quantity (dose) cannot be achieved with a lower quantity of any combination of the four Emflaza tablet strengths **OR** 4. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Approval Length:** up to 12 months

• Program Summary: Antiemetic Agents

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

STEP THERAPY WITH QUANTITY LIMIT TARGET AGENT(S)
Ondansetron ODT 16 mg
Sancuso® (granisetron)
Zuplenz® (ondansetron)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL
Target Agent(s) will be approved when ONE of the following is met:

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

OR

2. The patient's medication history includes use of ONE generic oral 5HT-3 antiemetic agent (e.g., granisetron, ondansetron)
   OR
3. BOTH of the following:
   A. The prescriber has stated that the patient has tried at least ONE generic oral 5HT-3 antiemetic agent
   AND
   B. Generic oral 5HT-3 antiemetic agents were discontinued due to lack of effectiveness or an adverse event

OR

4. The patient has an intolerance or hypersensitivity to ONE generic oral 5HT-3 antiemetic agent (e.g., granisetron, ondansetron)
   OR
5. The patient has an FDA labeled contraindication to ALL generic oral 5HT-3 antiemetic agents
   OR
6. The prescriber has provided documentation that ALL generic oral 5HT-3 antiemetic 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 section.

ANTIEMETIC AGENTS QUANTITY LIMIT TARGET AGENT(S)
Akynzeo® (netupitant/palonosetron)
Anzemet® (dolasetron)
Emend® (aprepitant)[c]
granisetron[b]
Ondansetron ODT[a]
Sancuso® (granisetron)
Varubi® (rolapitant)
Zofran® (ondansetron)[a]
Zuplenz® (ondansetron)

a - generic available and included in quantity limit program
b - available as generic only
c - Emend 40 mg capsules are not included in this program due to use for postoperative nausea and vomiting only

QUANTITY LIMIT TARGET AGENT(S) - RECOMMENDED LIMITS (Limits allow for at least 7 days of cancer chemotherapy or radiotherapy)

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
Akynzeo (netupitant/palonosetron)			
300 mg / 0.5 mg capsule	50309902290120	M, N, O, or Y	2 capsules/30 days
Anzemet (dolasetron)			
50 mg tablet	50250025200320	M, N, O, or Y	7 tablets/30 days
100 mg tablet	50250025200330	M, N, O, or Y	7 tablets/30 days
Emend (aprepitant)[c]			
80 mg capsule[a]	50280020000120	M, N, O, or Y	4 capsules/30 days
125 mg capsule[a]	50280020000130	M, N, O, or Y	2 capsules/30 days
Emend Therapy Pack (1x125 mg capsule, 2x80 mg capsules)[a]	50280020006320	M, N, O, or Y	6 capsules (2 therapy packs)/30 days
125mg/5mL oral suspension	50280020001930	M, N, O, or Y	6 single-use kits/30 days
granisetron[b]			
1 mg tablet	50250035100310	M, N, O, or Y	14 tablets/30 days
Ondansetron ODT			
4 mg orally disintegrating tablet[b]	50250065007220	M, N, O, or Y	21 tablets/30 days
8 mg orally disintegrating tablet[b]	50250065007240	M, N, O, or Y	21 tablets/30 days
16 mg orally disintegrating tablet	50250065007260	M, N, O, or Y	1 tablet/30 days
Sancuso (granisetron)			
3.1 mg/24 hours patch	50250035005920	M, N, O, or Y	2 patches/30 days
Varubi (rolapitant)			
90 mg tablet	5028005020B720	M, N, O, or Y	4 tablets/30 days
Zofran (ondansetron)[a]			
4 mg tablet	50250065050310	M, N, O, or Y	21 tablets/30 days
8 mg tablet	50250065050320	M, N, O, or Y	21 tablets/30 days
24 mg tablet[b]	50250065050340	M, N, O, or Y	1 tablet/30 days
4 mg/5 mL oral solution	50250065052070	M, N, O, or Y	
Zuplenz (ondansetron)			
4 mg oral soluble film	50250065008220	M, N, O, or Y	20 films (2 boxes of 10)/30 days
8 mg oral soluble film	50250065008240	M, N, O, or Y	20 films (2 boxes of 10)/30 days

a - generic available and included in quantity limit program
b - available as generic only
c - Emend 40 mg capsules are not included in this program due to use for postoperative nausea and vomiting only

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Quantity limit for **Anzemet, granisetron, Zofran/ondansetron/ondansetron ODT, or Zuplenz** will be approved when ONE of the following is met:

1. The requested quantity (dose) does NOT exceed the program quantity limit **OR**
2. The patient has cancer chemotherapy related nausea and vomiting and will be receiving chemotherapy more than 7 days per month
   OR
3. The patient has delayed emesis in highly emetogenic chemotherapy
   OR
4. The patient has hyperemesis gravidarum
   OR
5. The patient has radiation therapy induced nausea and vomiting for radiation treatment that extends beyond 7 days per month
   OR
6. The prescriber has provided information supporting the use of the requested agent for the requested diagnosis and quantity

Length of Approval: 12 months

Quantity limit for **Sancuso** will be approved when ONE of the following is met:

1. The requested quantity (dose) does NOT exceed the program quantity limit **OR**
2. The patient has cancer chemotherapy related nausea and vomiting and will be receiving chemotherapy more than 14 days per month
   OR
3. The prescriber has provided information supporting the use of the requested agent for the requested diagnosis and quantity

Length of Approval: 12 months

Quantity limit for **Akynzeo**, **Emend/aprepitant, or Varubi** will be approved when ONE of the following is met:

1. The requested quantity (dose) does NOT exceed the program quantity limit **OR**
2. The patient has cancer chemotherapy related nausea and vomiting and the patient will be receiving chemotherapy more than 7 days per month
   OR
3. The prescriber has provided information supporting the use of the requested agent for the requested diagnosis and quantity

Length of Approval: 12 months

● Program Summary: Anti-Obesity non-GLP-1

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

TARGET AGENT(S)
Adipex-P® (phentermine)[a]
Contrave® (naltrexone/bupropion)
Diethylpropion[a]
Lomaira™ (phentermine)
Phendimetrazine[a]
Phentermine[a]
Qsymia® (phentermine/topiramate)
Xenical® (orlistat)
a – Generic equivalent available

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
Adipex-P (phentermine)[a]			
37.5 mg capsule	61200070100120	M, N, or O	1 capsule
37.5 mg tablet	61200070100310	M, N, or O	1 tablet
Contrave (naltrexone/bupropion)			
8 mg / 90 mg tablet	61259902507420	M, N, O, or Y	4 tablets
Diethylpropion[a]			
75 mg extended-release tablet	61200020107510	M, N, O, or Y	1 tablet
Phendimetrazine[a]			
105 mg extended-release capsule	61200050107010	M, N, O, or Y	1 capsule
Phentermine[a]			
15 mg capsule	61200070100110	M, N, or O	1 capsule
30 mg capsule	61200070100115	M, N, or O	1 capsule
Qsymia (phentermine/topiramate)			
3.75mg/23mg capsule	61209902307020	M, N, O, or Y	1 capsule
7.5mg/46mg capsule	61209902307030	M, N, O, or Y	1 capsule

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
11.25mg/69mg capsule	61209902307040	M, N, O, or Y	1 capsule
15mg/92mg capsule	61209902307050	M, N, O, or Y	1 capsule
Xenical (orlistat)			
120 mg capsule	61253560000120	M, N, O, or Y	3 capsules

a – Generic equivalent available

FORMULARY EXCEPTION CRITERIA FOR APPROVAL

Initial Evaluation

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

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

1. The requested agent is not excluded under the patient's current benefit plan
   AND
2. ONE of the following:
   A. The patient is 17 years of age or over and ALL of the following:
      i. ONE of the following:
         a. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 30 kg/m^2 OR a BMI greater than or equal to 25 kg/m^2 if the patient is of South Asian, Southeast Asian, or East Asian descent
            OR
         b. The patient has a BMI greater than or equal to 27 kg/ m^2 with at least one weight-related comorbidity/risk factor/complication (e.g., diabetes, dyslipidemia, coronary artery disease)
            AND
      ii. The patient has been on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications for a minimum of 6 months prior to initiating therapy with the requested agent
      AND
      iii. The patient did not achieve a weight loss of 1 pound or more per week while on the weight loss regimen prior to initiating therapy with the requested agent
      AND
      iv. The patient is currently on and will continue a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications
      OR
   B. The patient is 12 to 16 years of age and ALL of the following:
      i. ONE of the following:
         a. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 95th percentile for age and gender
            OR
         b. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 30 kg/m^2
            OR
         c. The patient has a BMI greater than or equal to 85th percentile for age and gender AND at least one severe weight-related comorbidity/risk factor/complication
      AND
      ii. The patient has been on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications for a minimum of 6 months (prior to initiating therapy with the requested agent)
      AND
      iii. The patient has a weight loss of less than 1 pound per week while on the weight loss regimen (prior to initiating therapy with the requested agent)
      AND
      iv. The patient is currently on and will continue a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications

   AND
3. If the patient has an FDA labeled indication, then ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent
      OR

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

AND

4. ONE of the following:
   A. The patient has not tried a targeted weight loss agent in the past 12 months
      OR
   B. BOTH of the following:
      i. The patient has tried a targeted weight loss agent for a previous course of therapy in the past 12 months
         AND
      ii. The prescriber anticipates success with repeating therapy with any targeted weight loss agent

AND

5. ONE of the following:
   A. The requested agent is diethylpropion, phendimetrazine, or phentermine
      OR
   B. The requested agent is Qsymia AND ONE of the following:
      i. The requested dose is 3.75mg/23mg
         OR
      ii. The patient is currently being treated with Qsymia, the requested dose is greater than 3.75 mg/23 mg AND ONE of the following:
         a. ONE of the following:
            1. For adults, the patient has demonstrated and maintained a weight loss of greater than or equal to 5% from baseline (prior to the initiation of requested agent)
               OR
            2. For pediatric patients aged 12 years and older, the patient has experienced a reduction of at least 5% of baseline BMI (prior to initiation of the requested agent)
         OR
         b. The patient received less than 14 weeks of therapy
            OR
         c. The patient's dose is being titrated upward
            OR
         d. The patient has received less than 12 weeks (3 months) of therapy on the 15mg/92mg strength
      OR
      iii. There is support for therapy for the requested dose for this patient
   OR
   C. The requested agent is Contrave AND ONE of the following:
      i. The patient is newly starting therapy
         OR
      ii. The patient is currently being treated and has received less than 16 weeks (4 months) of therapy
         OR
      iii. The patient has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of requested agent)
   OR
   D. The requested agent is Xenical or Orlistat AND ONE of the following:
      i. The patient is 12 to 16 years of age and ONE of the following:
         a. The patient is newly starting therapy
            OR
         b. The patient is currently being treated and has received less than 12 weeks (3 months) of therapy
            OR
         c. The patient has achieved and maintained a weight loss of greater than 4% from baseline (prior to initiation of requested agent)
      OR
      ii. The patient is 17 years of age or over and ONE of the following:
         a. The patient is newly starting therapy
            OR
         b. The patient is currently being treated and has received less than 12 weeks (3 months) of therapy

OR

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

AND

6. The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication
   AND
7. The patient does NOT have any FDA labeled contraindications to the requested agent
   AND
8. ONE of the following:
   A. The patient has tried and failed at least three (or as many as available, if fewer than three) formulary alternatives
      OR
   B. The prescriber has indicated that available formulary alternatives are contraindicated, likely to be less effective, or likely to cause an adverse reaction or other harm

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

      OR

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

      OR

      iii. BOTH of the following:
         a. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication
            AND
         b. There is support for therapy with a higher dose for the requested indication

Length of Approval: For Contrave: 4 months
For all other agents: 3 months

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

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

1. The requested agent is not excluded under the patient's current benefit plan
   AND
2. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review]
   AND
3. The patient meets ONE of the following:
   A. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of requested agent)
      OR

B. The requested agent is Qsymia AND ONE of the following:
    i. For a pediatric patient aged 12 years and older, the patient has achieved and maintained a reduction of greater than or equal to 5% of baseline BMI (prior to initiation of the requested agent)
    OR
    ii. The patient has achieved and maintained a weight loss less than 5% from baseline (prior to initiation of requested agent) for adults, or a reduction in BMI less than 5% from baseline (prior to initiation of the requested agent) for pediatric patients aged 12 years or older, AND BOTH of the following:
        a. The patient's dose is being titrated upward (for the 3.75 mg/23 mg, 7.5 mg/46 mg or 11.25 mg/69 mg strengths only)
        AND
        b. The patient has received less than 12 weeks of therapy on the 15mg/92mg strength
        c. **OR**

C. The requested agent is Xenical or Orlistat AND ONE of the following:
    i. The patient 12 to 16 years of age AND has achieved and maintained a weight loss greater than 4% from baseline (prior to initiation of requested agent)
    OR
    ii. The patient is 17 years of age or over AND has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of requested agent)

AND

4. If the patient is 12 to less than 18 years of age, the current BMI is greater than 85th percentile for age and gender
AND
5. The patient is currently on and will continue to be on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications
AND
6. The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication
7. The patient does NOT have any FDA labeled contraindications to the requested agent
AND
8. ONE of the following:
    A. The patient has tried and failed at least three (or as many as available, if fewer than three) formulary alternatives
    OR
    B. The prescriber has indicated that available formulary alternatives are contraindicated, likely to be less effective, or likely to cause an adverse reaction or other harm

AND

9. ONE of the following:
    A. The requested quantity (dose) does NOT exceed the program quantity limit
    OR
    B. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following:
        i. BOTH of the following:
            a. The requested agent does NOT have a maximum FDA labeled dose for the requested indication
            AND
            b. There is support for therapy with a higher dose for the requested indication
        OR
        ii. BOTH of the following:
            a. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
            AND
            b. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit
        OR
        iii. BOTH of the following:
            a. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication
            AND

b. There is support for therapy with a higher dose for the requested indication

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

● Program Summary: ARB/Renin Inhibitors

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
369930027003		telmisartan-amlodipine tab	40-10 MG ; 40-5 MG ; 80-10 MG ; 80-5 MG	30	Days	30	DAYS				
36150080002025		Valsartan Oral Soln	4 MG/ML	240	mLs	30	DAYS				
36150020100330	Atacand	Candesartan Cilexetil Tab 16 MG	16 MG	60	Tablets	30	DAYS				
36150020100340	Atacand	Candesartan Cilexetil Tab 32 MG	32 MG	30	Tablets	30	DAYS				
36150020100310	Atacand	Candesartan Cilexetil Tab 4 MG	4 MG	60	Tablets	30	DAYS				
36150020100320	Atacand	Candesartan Cilexetil Tab 8 MG	8 MG	60	Tablets	30	DAYS				
369940022003	Atacand hct	candesartan cilexetil-hydrochlorothiazide tab	16-12.5 MG ; 32-12.5 MG ; 32-25 MG	30	Tablets	30	DAYS				
369940023003	Avalide	irbesartan-hydrochlorothiazide tab	150-12.5 MG ; 300-12.5 MG	30	Tablets	30	DAYS				
361500300003	Avapro	irbesartan tab	150 MG ; 300 MG ; 75 MG	30	Tablets	30	DAYS				
369930020503	Azor	amlodipine besylate-olmesartan medoxomil tab	10-20 MG ; 10-40 MG ; 5-20 MG ; 5-40 MG	30	Tablets	30	DAYS				
36150055200340	Benicar	Olmesartan Medoxomil Tab 20 MG	20 MG	30	Tablets	30	DAYS				
36150055200360	Benicar	Olmesartan Medoxomil Tab 40 MG	40 MG	30	Tablets	30	DAYS				
36150055200320	Benicar	Olmesartan Medoxomil Tab 5 MG	5 MG	60	Tablets	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
369940025003	Benicar hct	olmesartan medoxomil-hydrochlorothiazide tab	20-12.5 MG ; 40-12.5 MG ; 40-25 MG	30	Tablets	30	DAYS				
36150040200340	Cozaar	Losartan Potassium Tab 100 MG	100 MG	30	Tablets	30	DAYS				
36150040200320	Cozaar	Losartan Potassium Tab 25 MG	25 MG	60	Tablets	30	DAYS				
36150040200330	Cozaar	Losartan Potassium Tab 50 MG	50 MG	60	Tablets	30	DAYS				
36150080000330	Diovan	Valsartan Tab 160 MG	160 MG	60	Tablets	30	DAYS				
36150080000340	Diovan	Valsartan Tab 320 MG	320 MG	30	Tablets	30	DAYS				
36150080000310	Diovan	Valsartan Tab 40 MG	40 MG	60	Tablets	30	DAYS				
36150080000320	Diovan	Valsartan Tab 80 MG	80 MG	60	Tablets	30	DAYS				
369940027003	Diovan hct	valsartan-hydrochlorothiazide tab	160-12.5 MG ; 160-25 MG ; 320-12.5 MG ; 320-25 MG ; 80-12.5 MG	30	Tablets	30	DAYS				
361500102003	Edarbi	azilsartan medoxomil tab	40 MG ; 80 MG	30	Tablets	30	DAYS				
369940021003	Edarbyclor	azilsartan medoxomil-chlorthalidone tab	40-12.5 MG ; 40-25 MG	30	Tablets	30	DAYS				
369930021003	Exforge	amlodipine besylate-valsartan tab	10-160 MG ; 10-320 MG ; 5-160 MG ; 5-320 MG	30	Tablets	30	DAYS				
369945032003	Exforge hct	amlodipine-valsartan-hydrochlorothiazide tab	10-160-12.5 MG ; 10-160-25 MG ; 10-320-25 MG ; 5-160-12.5 MG ; 5-160-25 MG	30	Tablets	30	DAYS				
369940024503	Hyzaar	losartan potassium & hydrochlorothiazide tab	100-12.5 MG ; 100-25 MG ; 50-12.5 MG	30	Tablets	30	DAYS				
361500700003	Micardis	telmisartan tab	20 MG ; 40 MG ; 80 MG	30	Tablets	30	DAYS				
36994002600320	Micardis hct	Telmisartan-Hydrochlorothiazide Tab 40-12.5 MG	40-12.5 MG	30	Tablets	30	DAYS				
36994002600340	Micardis hct	Telmisartan-Hydrochlorothiazide Tab 80-12.5 MG	80-12.5 MG	60	Tablets	30	DAYS				
36994002600345	Micardis hct	Telmisartan-Hydrochlorothiazide Tab 80-25 MG	80-25 MG	30	Tablets	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
361700101003	Tekturna	aliskiren fumarate tab	150 MG ; 300 MG	30	Days	30	DAYS				
369960021503	Tekturna hct	aliskiren-hydrochlorothiazide tab	150-12.5 MG ; 150-25 MG ; 300-12.5 MG ; 300-25 MG	30	Tablets	30	DAYS				
369945034503	Tribenzor	olmesartan-amlodipine-hydrochlorothiazide tab	20-5-12.5 MG ; 40-10-12.5 MG ; 40-10-25 MG ; 40-5-12.5 MG ; 40-5-25 MG	30	Tablets	30	DAYS				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
1-Step	

TARGET AGENT(S)	PREREQUISITE AGENT(S)
Atacand (candesartan) tablet* **Atacand HCT** (candesartan/hydrochlorothiazide) tablet* **Avapro** (irbesartan) tablet* **Avalide** (irbesartan/hydrochlorothiazide) tablet* **Azor** (olmesartan/amlodipine) tablet* **Benicar** (olmesartan) tablet* **Benicar HCT** (olmesartan/hydrochlorothiazide) tablet* **Cozaar** (losartan) tablet* **Diovan** tablet***, Valsartan** oral suspension^ **Diovan HCT** (valsartan/hydrochlorothiazide) tablet* **Edarbi** (azilsartan) tablet **Edarbyclor** (azilsartan/chlorthalidone) tablet **Exforge** (valsartan/amlodipine) tablet* **Exforge HCT** (valsartan/amlodipine/hydrochlorothiazide) tablet* **Hyzaar** (losartan/hydrochlorothiazide) tablet* **Micardis** (telmisartan) tablet* **Micardis HCT** (telmisartan/hydrochlorothiazide) tablet* **Tekturna** (aliskiren) tablet* **Tekturna HCT** (aliskiren/HCTZ) tablet **Tribenzor** (olmesartan/amlodipine/hydrochlorothiazide) tablet* **Telmisartan/Amlodipine** tablet*	Any generic ACEI or ACEI combination OR any generic ARB or ARB combination OR any generic renin inhibitor or generic renin inhibitor combination

* Available as generic; included as a prerequisite in the step therapy program
^ Branded generic products available; targeted in the step therapy program

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

1. The patient is currently being treated with the requested agent within the past 90 days **OR**
2. The prescriber states the patient is currently being treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR**

	3. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 4. The patient's medication history includes use of a generic ACEI, generic ACEI combination, generic ARB, generic ARB combination, generic renin inhibitor, or generic renin inhibitor combination **OR** 5. The patient has an intolerance or hypersensitivity to a generic ACEI, generic ACEI combination, generic ARB, generic ARB combination, generic renin inhibitor, or generic renin inhibitor combination **OR** 6. The patient has an FDA labeled contraindication to ALL generic ACEIs, generic ACEI combinations, generic ARBs, generic ARB combinations, generic renin inhibitor, or generic renin inhibitor combinations **OR** 7. BOTH of the following: A. The prescriber has stated that the patient has tried a generic ACEI, generic ACEI combination, generic ARB, generic ARB combination, generic renin inhibitor, or generic renin inhibitor combination **AND** B. A generic ACEI, generic ACEI combination, generic ARB, generic ARB combination, generic renin inhibitor, or generic renin inhibitor combination was discontinued due to lack of effectiveness or an adverse event **OR** 8. The prescriber has provided documentation that ALL generic ACEI, generic ACEI combination, generic ARB, generic ARB combination, generic renin inhibitor, or generic renin inhibitor combinations cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Biologic Immunomodulators

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

This program applies to FocusRx, FlexRx Closed, FlexRx Open, GenRx Closed, GenRx Open, Health Insurance Marketplace, and KeyRx.

This is a FlexRx Standard and GenRx Standard program.

There are two criteria modules, Option A and Option B, with different preferred adalimumab products. These options are based on a member's formulary.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

For target agents that are not yet available on the market, PA and QL will apply upon launch

POLICY AGENT SUMMARY QUANTITY LIMIT

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

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6627001510E510	Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001510E517	Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001510E520	Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS				
9025051800D520	Bimzelx	bimekizumab-bkzx subcutaneous soln auto-injector	160 MG/ML	2	Pens	56	DAYS				
9025051800E520	Bimzelx	bimekizumab-bkzx subcutaneous soln prefilled syr	160 MG/ML	2	Syringes	56	DAYS				
525050201064	Cimzia	certolizumab pegol for inj kit	200 MG	2	Kits	28	DAYS				
5250502010F840	Cimzia	Certolizumab Pegol Prefilled Syringe Kit	200 MG/ML	2	Kits	28	DAYS				
5250502010F860	Cimzia starter kit	Certolizumab Pegol Prefilled Syringe Kit	200 MG/ML	1	Kit	180	DAYS				
9025057500E530	Cosentyx	Secukinumab Subcutaneous Pref Syr 150 MG/ML (300 MG Dose)	150 MG/ML	2	Syringes	28	DAYS				
9025057500E510	Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe	75 MG/0.5ML	1	Syringe	28	DAYS				
9025057500E520	Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe 150 MG/ML	150 MG/ML	1	Syringe	28	DAYS				
9025057500D530	Cosentyx sensoready pen	Secukinumab Subcutaneous Auto-inj 150 MG/ML (300 MG Dose)	150 MG/ML	2	Pens	28	DAYS				
9025057500D520	Cosentyx sensoready pen	Secukinumab Subcutaneous Soln Auto-injector 150 MG/ML	150 MG/ML	1	Pen	28	DAYS				
9025057500D550	Cosentyx unoready	secukinumab subcutaneous soln auto-injector	300 MG/2ML	1	Pen	28	DAYS				

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
6627001505F515	Cyltezo	adalimumab-adbm auto-injector kit	40 MG/0.4ML	2	Pens	28	DAYS	00597049550 ; 00597057550;;82009014422			
6627001505F520	Cyltezo	adalimumab-adbm auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS	00597037597 ; 00597054522; 82009014822			
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				
6627001505F815	Cyltezo	adalimumab-adbm prefilled syringe kit	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001505F820	Cyltezo	adalimumab-adbm prefilled syringe kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001505F515	Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.4ML	1	Kit	180	DAYS	00597049560 ; 00597057560;;			
6627001505F515	Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.4ML	1	Kit	180	DAYS	00597049540 ; 00597057540;;			
6627001505F520	Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00597037516 ; 00597054566			
6627001505F520	Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00597037523 ; 00597054544			
662900300021	Enbrel	etanercept for subcutaneous inj	25 MG	8	Vials	28	DAYS				
66290030002015	Enbrel	Etanercept Subcutaneous Inj 25 mg/0.5ml	25 MG/0.5ML	8	Vials	28	DAYS				
6629003000E525	Enbrel	Etanercept Subcutaneous Soln Prefilled Syringe 25 MG/0.5ML	25 MG/0.5ML	4	Syringes	28	DAYS				
6629003000E530	Enbrel	Etanercept Subcutaneous Soln Prefilled Syringe 50 MG/ML	50 MG/ML	4	Syringes	28	DAYS				
6629003000E2	Enbrel mini	etanercept subcutaneous solution cartridge	50 MG/ML	4	Cartridges	28	DAYS				
6629003000D5	Enbrel sureclick	etanercept subcutaneous	50 MG/ML	4	Pens	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		solution auto-injector									
5250308000D220	Entyvio	vedolizumab soln pen-injector	108 MG/0.68 ML	2	Pens	28	DAYS				
6627001520E510	Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001520E520	Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001520D510	Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				
6627001520D520	Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS				
6627001535F520	Hulio	adalimumab-fkjp auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS				
6627001535F810	Hulio	adalimumab-fkjp prefilled syringe kit	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001535F820	Hulio	adalimumab-fkjp prefilled syringe kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001500F804	Humira	Adalimumab Prefilled Syringe Kit 10 MG/0.1ML	10 MG/0.1ML	2	Syringes	28	DAYS				
6627001500F809	Humira	Adalimumab Prefilled Syringe Kit 20 MG/0.2ML	20 MG/0.2ML	2	Syringes	28	DAYS				
6627001500F830	Humira	Adalimumab Prefilled Syringe Kit 40 MG/0.4ML	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001500F820	Humira	Adalimumab Prefilled Syringe Kit 40 MG/0.8ML	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001500F840	Humira pediatric crohns d	Adalimumab Prefilled Syringe Kit 80 MG/0.8ML	80 MG/0.8ML	1	Kit	180	DAYS				
6627001500F880	Humira pediatric crohns d	Adalimumab Prefilled Syringe Kit 80 MG/0.8ML & 40 MG/0.4ML	80 MG/0.8ML & 40MG/0.4ML	1	Kit	180	DAYS				
6627001500F440	Humira pen	adalimumab pen-injector kit	80 MG/0.8ML	2	Pens	28	DAYS	00074012402;83457012402			

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
6627001500F430	Humira pen	Adalimumab Pen-injector Kit 40 MG/0.4ML	40 MG/0.4ML	2	Pens	28	DAYS				
6627001500F440	Humira pen-cd/uc/hs start	adalimumab pen-injector kit	80 MG/0.8ML	1	Kit	180	DAYS	00074012403			
6627001500F420	Humira pen-cd/uc/hs start	Adalimumab Pen-injector Kit ; adalimumab pen-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00074433906			
6627001500F440	Humira pen-pediatric uc s	adalimumab pen-injector kit	80 MG/0.8ML	4	Pens	180	DAYS	00074012404			
6627001500F420	Humira pen-ps/uv starter	Adalimumab Pen-injector Kit ; adalimumab pen-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00074433907			
6627001500F450	Humira pen-ps/uv starter	Adalimumab Pen-injector Kit 80 MG/0.8ML & 40 MG/0.4ML	80 MG/0.8ML & 40MG/0.4ML	1	Kit	180	DAYS				
6627001504D515	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				
6627001504D515	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				
6627001504D520	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS				
6627001504E508	Hyrimoz	adalimumab-adaz soln prefilled syringe	10 MG/0.1ML	2	Syringes	28	DAYS				
6627001504E513	Hyrimoz	adalimumab-adaz soln prefilled syringe	20 MG/0.2ML	2	Syringes	28	DAYS				
6627001504E515	Hyrimoz	adalimumab-adaz soln prefilled syringe	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001504E520	Hyrimoz	adalimumab-adaz soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001504D540	Hyrimoz ; Hyrimoz sensoready pens	adalimumab-adaz soln auto-injector	80 MG/0.8ML	2	Pens	28	DAYS	61314045420 ; 83457010701			
6627001504D540	Hyrimoz crohn's disease a ; Hyrimoz sensoready pens	adalimumab-adaz soln auto-injector	80 MG/0.8ML	1	Starter Kit	180	DAYS	61314045436 ; 83457011301			

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
6627001504E560	Hyrimoz pediatric crohn's	adalimumab-adaz soln prefilled syr	80 MG/0.8ML & 40MG/0.4ML	2	Syringes	180	DAYS				
6627001504E540	Hyrimoz pediatric crohns	adalimumab-adaz soln prefilled syringe	80 MG/0.8ML	3	Syringes	180	DAYS				
6627001504D560	Hyrimoz plaque psoriasis	adalimumab-adaz soln auto-injector	80 MG/0.8ML & 40MG/0.4ML	1.6	Starter Kit	180	DAYS				
6627001502F540	Idacio (2 pen)	adalimumab-aacf auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS	65219055408 ; 65219061299			
6627001502F840	Idacio (2 syringe)	adalimumab-aacf prefilled syringe kit	40 MG/0.8ML	1	Kit	28	DAYS				
6627001502F540	Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	65219055438			
6627001502F540	Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	65219055428			
6650006000E5	Kevzara	sarilumab subcutaneous soln prefilled syringe	150 MG/1.14 ML ; 200 MG/1.14 ML	2	Syringes	28	DAYS				
6650006000D5	Kevzara	sarilumab subcutaneous solution auto-injector	150 MG/1.14 ML ; 200 MG/1.14 ML	2	Pens	28	DAYS				
6626001000E5	Kineret	anakinra subcutaneous soln prefilled syringe	100 MG/0.67 ML	28	Syringes	28	DAYS				
90731060100120	Litfulo	ritlecitinib tosylate cap	50 MG	28	Capsules	28	DAYS				
666030100003	Olumiant	baricitinib tab	1 MG ; 2 MG ; 4 MG	30	Tablets	30	DAYS				
5250405040E520	Omvoh	mirikizumab-mrkz subcutaneous sol prefill syringe	100 MG/ML	2	Syringes	28	DAYS				
5250405040D520	Omvoh	mirikizumab-mrkz subcutaneous soln auto-injector	100 MG/ML	2	Pens	28	DAYS				
6640001000E520	Orencia	Abatacept Subcutaneous	125 MG/ML	4	Syringes	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		Soln Prefilled Syringe 125 MG/ML									
6640001000E510	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 50 MG/0.4ML	50 MG/0.4ML	4	Syringes	28	DAYS				
6640001000E515	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 87.5 MG/0.7ML	87.5 MG/0.7ML	4	Syringes	28	DAYS				
6640001000D5	Orencia clickject	abatacept subcutaneous soln auto-injector	125 MG/ML	4	Syringes	28	DAYS				
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				
66603072002020	Rinvoq lq	upadacitinib oral soln	1 MG/ML	360	mLs	30	DAYS				
9025052000E5	Siliq	brodalumab subcutaneous soln prefilled syringe	210 MG/1.5ML	2	Syringes	28	DAYS				
6627001540F520	Simlandi 1-pen kit ; Simlandi 2-pen kit	adalimumab-ryvk auto-injector kit	40 MG/0.4ML	2	Pens	28	DAYS				
6627004000D540	Simponi	Golimumab Subcutaneous Soln Auto-injector 100 MG/ML	100 MG/ML	1	Syringe	28	DAYS				
6627004000D520	Simponi	Golimumab Subcutaneous Soln Auto-injector 50 MG/0.5ML	50 MG/0.5ML	1	Syringe	28	DAYS				
6627004000E540	Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 100 MG/ML	100 MG/ML	1	Syringe	28	DAYS				
6627004000E520	Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 50 MG/0.5ML	50 MG/0.5ML	1	Syringe	28	DAYS				
9025057070F8	Skyrizi	risankizumab-rzaa sol prefilled syringe	75 MG/0.83 ML	1	Box	84	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
9025057070E5	Skyrizi	risankizumab-rzaa soln prefilled syringe	150 MG/ML	1	Injection Device	84	DAYS				
5250406070E210	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	180 MG/1.2ML	1	Cartridges	56	DAY				
5250406070E220	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	360 MG/2.4ML	1	Cartridges	56	DAYS				
9025057070D5	Skyrizi pen	risankizumab-rzaa soln auto-injector	150 MG/ML	1	Pen	84	DAYS				
90250524000320	Sotyktu	Deucravacitinib Tab	6 MG	30	Tablets	30	DAYS				
90250585002020	Stelara	Ustekinumab Inj 45 MG/0.5ML	45 MG/0.5ML	1	Vial	84	DAYS				
9025058500E520	Stelara	Ustekinumab Soln Prefilled Syringe 45 MG/0.5ML	45 MG/0.5ML	1	Syringe	84	DAYS				
9025058500E540	Stelara	Ustekinumab Soln Prefilled Syringe 90 MG/ML	90 MG/ML	1	Syringe	56	DAYS				
9025055400D5	Taltz	ixekizumab subcutaneous soln auto-injector	80 MG/ML	1	Syringe	28	DAYS				
9025055400E5	Taltz	ixekizumab subcutaneous soln prefilled syringe	80 MG/ML	1	Syringe	28	DAYS				
9025054200D2	Tremfya	guselkumab soln pen-injector	100 MG/ML	1	Pen	56	DAYS				
9025054200E5	Tremfya	guselkumab soln prefilled syringe	100 MG/ML	1	Syringe	56	DAYS				
6650007017D520	Tyenne	tocilizumab-aazg subcutaneous soln auto-inj	162 MG/0.9ML	4	Pens	28	DAYS				
6650007017E520	Tyenne	tocilizumab-aazg subcutaneous soln pref syr	162 MG/0.9ML	4	Syringes	28	DAYS				
52504525100350	Velsipity	etrasimod arginine tab	2 MG	30	Tablets	30	DAYS				
66603065102020	Xeljanz	Tofacitinib Citrate Oral Soln	1 MG/ML	240	mLs	30	DAYS				
66603065100330	Xeljanz	Tofacitinib Citrate Tab 10 MG (Base Equivalent)	10 MG	240	Tablets	365	DAYS				
66603065100320	Xeljanz	Tofacitinib Citrate Tab 5 MG (Base Equivalent)	5 MG	60	Tablets	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
66603065107530	Xeljanz xr	Tofacitinib Citrate Tab ER 24HR 11 MG (Base Equivalent)	11 MG	30	Tablets	30	DAYS				
66603065107550	Xeljanz xr	Tofacitinib Citrate Tab ER 24HR 22 MG (Base Equivalent)	22 MG	120	Tablets	365	DAYS				
6627001503F530	Yuflyma 1-pen kit	adalimumab-aaty auto-injector kit	40 MG/0.4ML	2	Pens	28	DAYS	72606002209 ; 72606003009			
6627001503F560	Yuflyma 1-pen kit	adalimumab-aaty auto-injector kit	80 MG/0.8ML	2	Pens	28	DAYS	72606002304 ; 72606004004			
6627001503F530	Yuflyma 2-pen kit	adalimumab-aaty auto-injector kit	40 MG/0.4ML	2	Pens	28	DAYS	72606002210 ; 72606003010			
6627001503F820	Yuflyma 2-syringe kit	adalimumab-aaty prefilled syringe kit	20 MG/0.2ML	2	Syringes	28	DAYS				
6627001503F830	Yuflyma 2-syringe kit	adalimumab-aaty prefilled syringe kit	40 MG/0.4ML	1	Kit	28	DAYS				
6627001503F560	Yuflyma cd/uc/hs starter	adalimumab-aaty auto-injector kit	80 MG/0.8ML	1	Kit	180	DAYS	72606002307			
6627001509D240	Yusimry	adalimumab-aqvh soln pen-injector	40 MG/0.8ML	2	Pens	28	DAYS				
5250504020F530	Zymfentra 1-pen	infliximab-dyyb soln auto-injector kit	120 MG/ML	2	Pens	28	DAYS	72606002501			
5250504020F530	Zymfentra 2-pen	infliximab-dyyb soln auto-injector kit	120 MG/ML	2	Pens	28	DAYS	72606002502			
5250504020F830	Zymfentra 2-syringe	infliximab-dyyb soln prefilled syringe kit	120 MG/ML	2	Syringes	28	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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

Disease State	Step 1		Step 2 (Directed to ONE step 1 agent)	Step 3a (Directed to TWO step 1 agents)	Step 3b (Directed to TWO agents from step 1 and/or step 2)	Step 3c (Direct THREE step 1 a
	Step 1a	Step 1b (Directed to ONE TNF inhibitor) NOTE:				

		Please see Step 1a for preferred TNF inhibitors				
Rheumatoid Disorders						
Ankylosing Spondylitis (AS)	SQ: Cosentyx, Enbrel, Hadlima, Humira, Simlandi	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Simponi, Taltz	N/A	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**, 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: Enbrel, Hadlima, Humira, Simlandi	Oral: Rinvoq, Rinvoq LQ, Xeljanz	SQ: Actemra (Hadlima, Humira, or Simlandi is a required Step 1 agent)	N/A	SQ: Orencia	SQ: Abrilada**, Adalimuma -ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**,Kevzara, Tyenne, Yuflyma**, Yusimry**
Psoriatic Arthritis (PsA)	SQ: Cosentyx, Enbrel, Hadlima, Humira, Simlandi, Skyrizi, Stelara, Tremfya Oral: Otezla	Oral: Rinvoq, Rinvoq LQ, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Orencia, Simponi, Taltz	N/A	SQ: Abrilada**, Adalimuma -ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
Rheumatoid Arthritis (RA)	SQ: Enbrel, Hadlima, Humira, Simlandi	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Actemra (Hadlima, Humira, or Simlandi is a required Step 1 agent)	Oral: Olumiant SQ: Cimzia, Kevzara, Kineret, Orencia, Simponi	N/A	SQ: Abrilada**, Adalimuma -ryvk**, Amjevita**, Cyltezo**,

						Hulio**, Hyrimoz**, Idacio**, Tyenne, Yuflyma**, Yusimry**
Systemic Juvenile Idiopathic Arthritis (SJIA)	SQ: Actemra	N/A	SQ: Tyenne			
Dermatological Disorder						
Hidradenitis Suppurativa (HS)	SQ: Cosentyx, Hadlima, Humira, Simlandi	N/A	N/A	N/A	N/A	SQ: Abrilada**, Adalimuma -ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
Psoriasis (PS)	SQ: Cosentyx, Enbrel, Hadlima, Humira, Simlandi, Skyrizi, Stelara, Tremfya Oral: Otezla	N/A	Oral: Sotyktu	SQ: Cimzia, Ilumya	N/A	SQ: Abrilada**, Adalimuma -ryvk**, Amjevita**, Bimzelx, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Siliq, Taltz, Yuflyma**, Yusimry**
Inflammatory Bowel Disease						
Crohn's Disease (CD)	SQ: Hadlima, Humira, Simlandi, Skyrizi, Stelara	Oral: Rinvoq	N/A	SQ: Cimzia (Hadlima, Humira, or Simlandi is a required Step 1 agent)	SQ: Entyvio	SQ: Abrilada**, Adalimuma -ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**, Zymfentra

Ulcerative Colitis (UC)	SQ: Hadlima, Humira, Simlandi, Skyrizi, Stelara	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Hadlima, Humira, or Simlandi is a required Step 1 agent)	N/A	SQ: Entyvio, Omvoh Oral: Zeposia (Hadlima, Humira, Rinvoq, Simlandi, Skyrizi, Stelara, OR Xeljanz/Xeljanz XR are required Step agents)	SQ: Abrilada**, Adalimuma -ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**, Zymfentra Oral: Velsipity
Other						
Giant Cell Arteritis (GCA)	SQ: Actemra	N/A	SQ: Tyenne			
Uveitis	SQ: Hadlima, Humira, Simlandi	N/A	N/A	N/A	N/A	SQ: Abrilada**, Adalimuma -ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
Indications Without Prerequisite Biologic Immunomodulators Required						
Alopecia Areata (AA) Atopic Dermatitis (AD) Deficiency of IL-1 Receptor Antagonist (DIRA) Enthesitis Related Arthritis (ERA) Juvenile Psoriatic Arthritis (JPsA) Neonatal-Onset Multisystem	N/A	N/A	N/A	N/A	N/A	N/A

Inflammatory Disease (NOMID) Polymyalgia Rheumatica (PMR) Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)						

**Hadlima, Humira, and Simlandi are required Step 1 agents

Note: For Xeljanz products (Xeljanz and Xeljanz XR) and Rinvoq products (Rinvoq and Rinvoq LQ), a trial of either or both dosage forms collectively counts as ONE product
Note: Branded generic available for Cyltezo, Idacio, Hulio, Hyrimoz, and Yuflyma and are included as a target at the same step level in this program

Initial Evaluation

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

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

Agents Eligible for Continuation of Therapy
All target agents EXCEPT the following are eligible for continuation of therapy: Abrilada Adalimumab-ryvk Amjevita Cyltezo, Adalimumab-adbm Hulio, Adalimumab-fkjp Hyrimoz, Adalimumab-adaz Idacio, Adalimumab-aacf Tyenne Yuflyma, Adalimumab-aaty Yusimry Zymfentra

1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**

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

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

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

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

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

8. The prescriber has provided documentation that ALL conventional agents (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

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

E. The patient has a diagnosis of moderately to severely active ulcerative colitis (UC) AND ONE of the following:
   1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC after at least a 3-month duration of therapy **OR**
   2. The patient has severely active ulcerative colitis **OR**
   3. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of UC **OR**
   4. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of UC **OR**
   5. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of UC **OR**
   6. The patient is currently being treated with the requested agent as indicated by ALL of the following:

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

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

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

uveitis, posterior uveitis, or panuveitis after at least a 3-month duration of therapy **OR**

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

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

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

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

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

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

J. The patient has a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) AND ONE of the following:

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

K. The patient has a diagnosis of moderate to severe hidradenitis suppurativa (HS) AND ONE of the following:
1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., oral tetracyclines [doxycycline, minocycline, tetracycline]; oral contraceptives [females only]; metformin [females only]; finasteride [females only]; spironolactone [females only]; intralesional corticosteroids [triamcinolone]; clindamycin in combination with rifampin; combination of rifampin, moxifloxacin, and metronidazole; cyclosporine; oral retinoids) used in the treatment of HS after at least a 3-month duration of therapy **OR**
2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of HS **OR**
3. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of HS **OR**
4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of HS **OR**
5. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
    B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND**
    C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
6. The prescriber has provided documentation that ALL conventional agents (i.e., oral tetracyclines [doxycycline, minocycline, tetracycline]; oral contraceptives [females only]; metformin [females only]; finasteride [females only]; spironolactone [females only]; intralesional corticosteroids [triamcinolone]; clindamycin in combination with rifampin; combination of rifampin, moxifloxacin, and metronidazole; cyclosporine, oral retinoids) used in the

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

L. BOTH of the following:
    1. The patient has a diagnosis of systemic sclerosis associated interstitial lung disease (SSc-ILD) **AND**
    2. The patient's diagnosis has been confirmed on high-resolution computed tomography (HRCT) or chest radiography scans **OR**

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

N. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following:
    1. ONE of the following:
        A. The patient has at least 10% body surface area involvement **OR**
        B. The patient has involvement of body sites that are difficult to treat with prolonged topical corticosteroid therapy (e.g., hands, feet, face, neck, scalp, genitals/groin, skin folds) **OR**
        C. The patient has an Eczema Area and Severity Index (EASI) score greater than or equal to 16 **OR**
        D. The patient has an Investigator Global Assessment (IGA) score greater than or equal to 3 **AND**
    2. ONE of the following:
        A. The patient has tried and had an inadequate response to at least a medium-potency topical corticosteroid used in the treatment of AD after at least a 4-week duration of therapy **AND** a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD after at least a 6-week duration of therapy **OR**
        B. The patient has an intolerance or hypersensitivity to at least a medium-potency topical corticosteroid used in the treatment of AD **AND** a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR**

C. The patient has an FDA labeled contraindication to ALL medium-, high-, and super-potency topical corticosteroids used in the treatment of AD **AND** topical calcineurin inhibitors used in the treatment of AD **OR**
D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND**
3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
E. The prescriber has provided documentation that ALL medium-, high-, and super-potency topical corticosteroids used in the treatment of AD **AND** topical calcineurin inhibitors used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

3. The prescriber has documented the patient's baseline (prior to therapy with the requested agent) pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **OR**

O. BOTH of the following:
1. The patient has a diagnosis of severe alopecia areata (AA) **AND**
2. The patient has at least 50% scalp hair loss that has lasted 6 months or more **OR**

P. The patient has a diagnosis of polymyalgia rheumatica (PMR) AND ONE of the following:
1. The patient has tried and had an inadequate response to systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR after at least an 8-week duration of therapy **OR**
2. The patient is currently treated with systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone and cannot tolerate a corticosteroid taper **OR**
3. The patient is currently being treated with the requested agent as indicated by ALL of the following:
A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND**
C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
4. The prescriber has provided documentation that ALL systemic corticosteroids used in the treatment of PMR cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

Q. The patient has a diagnosis of juvenile psoriatic arthritis (JPsA) AND ONE of the following:

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

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

2. ONE of the following (reference Step Table):
    A. The requested indication does NOT require any prerequisite biologic immunomodulator agents **OR**
    B. The requested agent is a Step 1a agent for the requested indication **OR**
    C. If the requested agent is a Step 1b agent for the requested indication, then ONE of the following:
        1. The patient has tried and had an inadequate response to ONE Tumor Necrosis Factor (TNF) inhibitor for the requested indication after at least a 3-month duration of therapy (See Step 1a for preferred TNF inhibitors) **OR**
        2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to therapy with a TNF inhibitor for the requested indication **OR**
        3. The patient has an FDA labeled contraindication to ALL TNF inhibitors for the requested indication **OR**
        4. BOTH of the following:
            A. ALL TNF inhibitors are not clinically appropriate for the patient **AND**
            B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR**
        5. The patient is currently being treated with the requested agent as indicated by ALL of the following:
            A. A statement by the prescriber that the patient is currently taking the requested agent **AND**

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

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

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

E. If the requested agent is a Step 3a agent for the requested indication, then ONE of the following (medical records required):
1. The patient has tried and had an inadequate response to TWO of the Step 1 agents for the requested indication after at least a 3-month trial per agent (See Step 3a) **OR**
2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration or hypersensitivity to TWO of the Step 1 agents for the requested indication **OR**
3. The patient has an FDA labeled contraindication to ALL of the Step 1 agents for the requested indication **OR**
4. BOTH of the following:
A. ALL of the Step 1 agents are not clinically appropriate for the patient **AND**
B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR**
5. The patient is currently being treated with the requested agent as indicated by ALL of the following:

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

6. The prescriber has provided documentation that ALL of the Step 1 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

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

G. If the requested agent is a Step 3c agent for the requested indication, then ONE of the following (medical records required):
1. The patient has tried and had an inadequate response to THREE of the Step 1 agents for the requested indication after at least a 3-month trial per agent (See Step 3c) **OR**
2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to THREE of the Step 1 agents for the requested indication **OR**
3. The patient has an FDA labeled contraindication to ALL of the Step 1 agents for the requested indication **OR**
4. BOTH of the following:
A. ALL of the Step 1 agents are not clinically appropriate for the patient **AND**

B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR**

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

3. If Cosentyx 300 mg is requested as maintenance dosing, then ONE of the following:
    A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis AND the requested dose is 300 mg every 4 weeks **OR**
    B. The patient has a diagnosis of hidradenitis suppurativa AND ONE of the following:
        1. The requested dose is 300 mg every 4 weeks **OR**
        2. The requested dose is 300 mg every 2 weeks AND the patient has tried and had an inadequate response to Cosentyx 300 mg every 4 weeks after at least a 3-month duration of therapy **OR**
    C. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND BOTH of the following:
        1. The requested dose is 300 mg every 4 weeks **AND**
        2. The patient has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks after at least a 3-month duration of therapy **AND**
4. If Omvoh is requested for the treatment of ulcerative colitis, then ONE of the following:
    A. the patient has received Omvoh IV for induction therapy **OR**
    B. The patient is new to therapy and will receive Omvoh IV for induction therapy **AND**
5. If Entyvio is requested for the treatment of ulcerative colitis or Crohn's disease, then ONE of the following:
    A. The patient has received at least 2 doses of Entyvio IV therapy **OR**
    B. The patient is new to therapy and will receive 2 doses of Entyvio IV therapy **AND**
6. If Skyrizi is requested for the treatment of Crohn's disease or ulcerative colitis, then ONE of the following
    A. The patient received Skyrizi IV for induction therapy **OR**
    B. The patient is new to therapy and will receive Skyrizi IV for induction therapy **AND**
7. If an ustekinumab product is requested for the treatment of Crohn's disease or ulcerative colitis, then ONE of the following:
    A. The patient received an ustekinumab IV product for induction therapy **OR**
    B. The patient is new to therapy and will receive an ustekinumab IV product for induction therapy **AND**
8. If Zymfentra is requested for the treatment of Crohn's disease or ulcerative colitis, then ONE of the following:
    A. The patient received an infliximab IV product for induction therapy **OR**
    B. The patient is new to therapy and will receive an infliximab IV product for induction therapy **AND**
9. If the patient has an FDA labeled indication, then ONE of the following:
    A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**

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

4. If an ustekinumab 90 mg product is requested, then ONE of the following:
   A. The patient has a diagnosis of psoriasis AND weighs >100kg **OR**
   B. The patient has a dual diagnosis of psoriasis AND psoriatic arthritis AND the patient is >100kg **OR**
   C. The patient has a diagnosis of Crohn's disease or ulcerative colitis **AND**
5. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND**
6. If Kevzara is requested for a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA), the patient weighs 63 kg or greater **AND**
7. If the patient has a diagnosis of moderate-to-severe atopic dermatitis (AD), then BOTH of the following:
   A. The patient is currently treated with topical emollients and practicing good skin care **AND**
   B. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent **AND**
8. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or has consulted with a specialist in the area of the patient's diagnosis **AND**
9. ONE of the following (please refer to "Agents NOT to be used Concomitantly" table):
   A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**
   B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
      1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**
      2. There is support for the use of combination therapy (submitted copy of support required, i.e., clinical trials, phase III studies, guidelines required) **AND**
10. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
11. The patient has been tested for latent tuberculosis (TB) when required by the prescribing information for the requested agent AND if positive the patient has begun therapy for latent TB

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

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

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

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

Renewal Evaluation

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

1. The request is NOT for use of Olumiant or Actemra in the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or

extracorporeal membrane oxygenation (ECMO) *NOTE: This indication is not covered under the pharmacy benefit **AND**

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

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

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

Length of Approval: 12 months

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

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

Option B - FlexRx

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: Cosentyx, Cyltezo, Enbrel, Humira	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Simponi, Taltz	N/A	SQ: Abrilada**, Adalimumab-adbm**, Amjevita**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, 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: Cyltezo, Enbrel, Humira	Oral: Rinvoq, Rinvoq LQ, Xeljanz	SQ: Actemra (Cyltezo, or Humira is a required Step 1 agent)	N/A	SQ: Orencia	SQ: Abrilada**, Adalimumab-adbm**, Amjevita**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Kevzara, Simlandi**, Tyenne, Yuflyma**, Yusimry**

Psoriatic Arthritis (PsA)	SQ: Cosentyx, Cyltezo, Enbrel, Humira, Skyrizi, Stelara, Tremfya Oral: Otezla	Oral: Rinvoq, Rinvoq LQ, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Orencia, Simponi, Taltz	N/A	SQ: Abrilada**, Adalimumab-adbm**, Amjevita*, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
Rheumatoid Arthritis (RA)	SQ: Cyltezo, Enbrel, Humira	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Actemra (Cyltezo, or Humira is a required Step 1 agent)	Oral: Olumiant SQ: Cimzia, Kevzara, Kineret, Orencia, Simponi	N/A	SQ: Abrilada**, Adalimumab-adbm**, Amjevita**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Tyenne, Yuflyma**, Yusimry**
Systemic Juvenile Idiopathic Arthritis (SJIA)	SQ: Actemra	N/A	SQ: Tyenne			
Dermatological Disorder						
Hidradenitis Suppurativa (HS)	SQ: Cosentyx, Cyltezo, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Adalimumab-adbm**, Amjevita**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
Psoriasis (PS)	SQ: Cosentyx, Cyltezo, Enbrel, Humira, Skyrizi,	N/A	Oral: Sotyktu	SQ: Cimzia, Ilumya	N/A	SQ: Abrilada**, Adalimumab-adbm**, Amjevita**, Bimzelx,

	Stelara, Tremfya Oral: Otezla					Hadlima**, Hulio**, Hyrimoz**, Idacio**, Siliq, Simlandi**, Taltz, Yuflyma**, Yusimry**
Inflammatory Bowel Disease						
Crohn's Disease (CD)	SQ: Cyltezo, Humira, Skyrizi, Stelara	Oral: Rinvoq	N/A	SQ: Cimzia (Cyltezo, or Humira is a required Step 1 agent)	SQ: Entyvio	SQ: Abrilada**, Adalimumab-adbm**, Amjevita**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**, Zymfentra
Ulcerative Colitis (UC)	SQ: Cyltezo, Humira, Skyrizi, Stelara	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Cyltezo, or Humira is a required Step 1 agent)	N/A	SQ: Entyvio, Omvoh Oral: Zeposia (Cyltezo, Humira, Rinvoq, Skyrizi, Stelara, OR Xeljanz/Xeljanz XR are required Step agents)	SQ: Abrilada**, Adalimumab-adbm**, Amjevita**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**, Zymfentra Oral: Velsipity
Other						
Giant Cell Arteritis (GCA)	SQ: Actemra	N/A	SQ: Tyenne			
Uveitis	SQ: Cyltezo, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Adalimumab-adbm**,

						Amjevita**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
Indications Without Prerequisite Biologic Immunomodulators Required						
Alopecia Areata (AA) Atopic Dermatitis (AD) Deficiency of IL-1 Receptor Antagonist (DIRA) Enthesitis Related Arthritis (ERA) Juvenile Psoriatic Arthritis (JPsA) Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Polymyalgia Rheumatica (PMR) Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)	N/A	N/A	N/A	N/A	N/A	N/A

**Cyltezo and Humira are required Step 1 agents

Note: For Xeljanz products (Xeljanz and Xeljanz XR) and Rinvoq products (Rinvoq and Rinvoq LQ), a trial of either or both dosage forms collectively counts as ONE product
Note: Branded generic available for Idacio, Hulio, Hyrimoz, Simlandi, and Yuflyma and are included as a target at the same step level in this program

Initial Evaluation

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

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

Agents Eligible for Continuation of Therapy
All target agents EXCEPT the following are eligible for continuation of therapy: Abrilada Adalimumab-adbm Amjevita Hadlima Hulio, Adalimumab-fkjp Hyrimoz, Adalimumab-adaz Idacio, Adalimumab-aacf Simlandi Tyenne Yuflyma, Adalimumab-aaty Yusimry Zymfentra

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

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

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

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

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

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

D. The patient has a diagnosis of moderately to severely active Crohn's disease (CD) AND ONE of the following:
    1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD after at least a 3-month duration of therapy **OR**
    2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of CD **OR**
    3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of CD **OR**
    4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of CD **OR**
    5. The patient is currently being treated with the requested agent as indicated by ALL of the following:

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

6. The prescriber has provided documentation that ALL conventional agents (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

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

F. The patient has a diagnosis of non-infectious intermediate uveitis, posterior uveitis, or panuveitis AND ONE of the following:
1. BOTH of the following:
A. ONE of the following:
1. The patient has tried and had an inadequate response to oral corticosteroids used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis after at least a 2-week duration of therapy **OR**
2. The patient has tried and had an inadequate response to periocular or intravitreal corticosteroid injections in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR**

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

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

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

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

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

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

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

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

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

K. The patient has a diagnosis of moderate to severe hidradenitis suppurativa (HS) AND ONE of the following:

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

L. BOTH of the following:
1. The patient has a diagnosis of systemic sclerosis associated interstitial lung disease (SSc-ILD) **AND**
2. The patient's diagnosis has been confirmed on high-resolution computed tomography (HRCT) or chest radiography scans **OR**

M. The patient has a diagnosis of active enthesitis related arthritis (ERA) and ONE of the following:
1. The patient has tried and had an inadequate response to TWO different NSAIDs used in the treatment of ERA after at least a 4-week total trial **OR**
2. The patient has an intolerance or hypersensitivity to TWO different NSAIDs used in the treatment of ERA **OR**
3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of ERA **OR**
4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of ERA **OR**
5. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
    B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND**

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

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

N. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following:
   1. ONE of the following:
      A. The patient has at least 10% body surface area involvement **OR**
      B. The patient has involvement of body sites that are difficult to treat with prolonged topical corticosteroid therapy (e.g., hands, feet, face, neck, scalp, genitals/groin, skin folds) **OR**
      C. The patient has an Eczema Area and Severity Index (EASI) score greater than or equal to 16 **OR**
      D. The patient has an Investigator Global Assessment (IGA) score greater than or equal to 3 **AND**
   2. ONE of the following:
      A. The patient has tried and had an inadequate response to at least a medium-potency topical corticosteroid used in the treatment of AD after at least a 4-week duration of therapy **AND** a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD after at least a 6-week duration of therapy **OR**
      B. The patient has an intolerance or hypersensitivity to at least a medium-potency topical corticosteroid used in the treatment of AD **AND** a topical calcineurin inhibitor used in the treatment of AD **OR**
      C. The patient has an FDA labeled contraindication to ALL medium-, high-, and super-potency topical corticosteroids used in the treatment of AD **AND** topical calcineurin inhibitors used in the treatment of AD **OR**
      D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
         1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
         2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND**
         3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
      E. The prescriber has provided documentation that ALL medium-, high-, and super-potency topical corticosteroids **AND** topical calcineurin inhibitors used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
   3. The prescriber has documented the patient's baseline (prior to therapy with the requested agent) pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **OR**

O. BOTH of the following:
   1. The patient has a diagnosis of severe alopecia areata (AA) **AND**

2. The patient has at least 50% scalp hair loss that has lasted 6 months or more **OR**

P. The patient has a diagnosis of polymyalgia rheumatica (PMR) AND ONE of the following:
   1. The patient has tried and had an inadequate response to systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR after at least an 8-week duration of therapy **OR**
   2. The patient is currently treated with systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone and cannot tolerate a corticosteroid taper **OR**
   3. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
      B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND**
      C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
   4. The prescriber has provided documentation that ALL systemic corticosteroids used in the treatment of PMR cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

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

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

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

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

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

6. The prescriber has provided documentation that ALL required Step 1 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

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

F. If the requested agent is a Step 3b agent for the requested indication, then ONE of the following (medical records required):
1. The patient has tried and had an inadequate response to TWO agents from Step 1 and/or Step 2 for the requested indication after at least a 3-month trial per agent (See Step 3b) **OR**
2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to TWO agents from Step 1 and/or Step 2 for the requested indication **OR**
3. The patient has an FDA labeled contraindication to ALL of the Step 1 AND Step 2 agents for the requested indication **OR**
4. BOTH of the following:
A. ALL of the Step 1 AND Step 2 agents are not clinically appropriate for the patient **AND**
B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR**
5. The patient is currently being treated with the requested agent as indicated by ALL of the following:

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

6. The prescriber has provided documentation that ALL of the Step 1 AND Step 2 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

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

3. If Cosentyx 300 mg is requested as maintenance dosing, then ONE of the following:
A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis AND the requested dose is 300 mg every 4 weeks **OR**
B. The patient has a diagnosis of hidradenitis suppurativa AND ONE of the following:
1. The requested dose is 300 mg every 4 weeks **OR**
2. The requested dose is 300 mg every 2 weeks AND the patient has tried and had an inadequate response to Cosentyx 300 mg every 4 weeks after at least a 3-month duration of therapy **OR**
C. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND BOTH of the following:
1. The requested dose is 300 mg every 4 weeks **AND**
2. The patient has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks after at least a 3-month duration of therapy **AND**

4. If Omvoh is requested for the treatment of ulcerative colitis, then ONE of the following:
    A. The patient has received Omvoh IV for induction therapy **OR**
    B. The patient is new to therapy and will receive Omvoh IV for induction therapy **AND**
5. If Entyvio is requested for the treatment of ulcerative colitis or Crohn's disease, then ONE of the following:
    A. The patient has received at least 2 doses of Entyvio IV therapy **OR**
    B. The patient is new to therapy and will receive at least 2 doses of Entyvio IV therapy **AND**
6. If Skyrizi is requested for the treatment of Crohn's disease or ulcerative colitis, then ONE of the following:
    A. The patient received Skyrizi IV for induction therapy **OR**
    B. The patient is new to therapy and will receive Skyrizi IV for induction therapy **AND**
7. If an ustekinumab product is requested for the treatment of Crohn's disease or ulcerative colitis, then ONE of the following:
    A. The patient received an ustekinumab IV product for induction therapy **OR**
    B. The patient is new to therapy and will receive an ustekinumab IV product for induction therapy **AND**
8. If Zymfentra is requested for the treatment of Crohn's disease or ulcerative colitis, then ONE of the following:
    A. The patient received an infliximab IV product for induction therapy **OR**
    B. The patient is new to therapy and will receive an infliximab IV product for induction therapy **AND**
9. If the patient has an FDA labeled indication, then ONE of the following:
    A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
    B. There is support for using the requested agent for the patient's age for the requested indication **AND**

4. If an ustekinumab 90 mg product is requested, ONE of the following:
    A. The patient has a diagnosis of psoriasis AND weighs >100kg **OR**
    B. The patient has a dual diagnosis of psoriasis AND psoriatic arthritis AND the patient is >100kg **OR**
    C. The patient has a diagnosis of Crohn's disease or ulcerative colitis **AND**
5. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND**
6. If Kevzara is requested for a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA), the patient weighs 63 kg or greater **AND**
7. If the patient has a diagnosis of moderate-to-severe atopic dermatitis (AD), then BOTH of the following:
    1. The patient is currently treated with topical emollients and practicing good skin care **AND**
    2. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent **AND**
8. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or has consulted with a specialist in the area of the patient's diagnosis **AND**
9. ONE of the following (please refer to "Agents NOT to be used Concomitantly" table):
    A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**
    B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
        1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**
        2. There is support for the use of combination therapy (submitted copy of support required, i.e., clinical trials, phase III studies, guidelines required) **AND**
10. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**

11. The patient has been tested for latent tuberculosis (TB) when required by the prescribing information for the requested agent AND if positive the patient has begun therapy for latent TB

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

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

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

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

Renewal Evaluation

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

1. The request is NOT for use of Olumiant or Actemra in the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) *NOTE: This indication is not covered under the pharmacy benefit **AND**
2. The request is for use in Alopecia Areata and Alopecia Areata is NOT restricted from coverage under the patient's benefit **AND**
3. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (*please note ustekinumab product renewal must be for the same strength as the initial approval) [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**
4. ONE of the following:
    A. The patient has a diagnosis of moderate to severe atopic dermatitis AND BOTH of the following:
        1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following:
            A. Affected body surface area **OR**
            B. Flares **OR**
            C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **OR**
            D. A decrease in the Eczema Area and Severity Index (EASI) score **OR**
            E. A decrease in the Investigator Global Assessment (IGA) score **AND**
        2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR**
    B. The patient has a diagnosis of polymyalgia rheumatica AND BOTH of the following:
        1. The patient has had clinical benefit with the requested agent **AND**
        2. If the requested agent is Kevzara, the patient does NOT have any of the following:
            A. Neutropenia (ANC less than 1,000 per mm^3 at the end of the dosing interval) **AND**
            B. Thrombocytopenia (platelet count is less than 100,000 per mm^3) **AND**
            C. AST or ALT elevations 3 times the upper limit of normal **OR**
    C. The patient has a diagnosis other than moderate to severe atopic dermatitis or polymyalgia rheumatica AND the patient has had clinical benefit with the requested agent **AND**
5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist

	for SSc-ILD; allergist, immunologist for AD) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): 1. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** 2. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (submitted copy of support required, i.e., clinical trials, phase III studies, guidelines required) **AND** 7. If Cosentyx 300 mg is requested as maintenance dosing, then ONE of the following: A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis AND the requested dose is 300 mg every 4 weeks **OR** B. The patient has a diagnosis of hidradenitis suppurativa AND ONE of the following: 1. The requested dose is 300 mg every 4 weeks **OR** 2. The requested dose is 300 mg every 2 weeks AND the patient has tried and had an inadequate response to Cosentyx 300 mg every 4 weeks after at least a 3-month duration of therapy **OR** C. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND BOTH of the following: 1. The requested dose is 300 mg every 4 weeks **AND** 2. The patient has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks after at least a 3-month duration of therapy **AND** 8. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND** 9. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL All Program Type	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. The requested agent is Xeljanz/Xeljanz XR for a diagnosis of ulcerative colitis, AND BOTH of the following: 1. There is support for therapy for the dose exceeding the quantity limit (e.g., patient has lost response to the FDA labeled maintenance dose [i.e., 5 mg twice daily or 11 mg once daily] during maintenance treatment; requires restart of induction therapy) (medical records required) **AND** 2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit **OR** B. The requested agent is Xeljanz oral solution for a diagnosis of polyarticular course juvenile idiopathic arthritis, AND ONE of the following: 1. BOTH of the following:

A. The requested quantity (dose) does not exceed the maximum FDA labeled dose (i.e., 5 mg twice daily) NOR the maximum compendia supported dose for the requested indication **AND**
B. There is support for why the patient cannot take Xeljanz 5 mg tablets **OR**

2. The requested quantity (dose) exceeds the maximum FDA labeled dose but does NOT exceed the maximum compendia supported dose for the requested indication **OR**
3. BOTH of the following:
A. The requested quantity (dose) exceeds the maximum FDA labeled dose AND the maximum compendia supported dose for the requested indication **AND**
B. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required) **OR**

C. The requested agent is NOT Xeljanz/Xeljanz XR for a diagnosis of ulcerative colitis or polyarticular course juvenile idiopathic arthritis, AND ONE of the following:
1. The patient has an FDA labeled indication for the requested agent, AND ONE of the following:
A. BOTH of the following:
1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**
2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does NOT exceed the program quantity limit **OR**

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

B. BOTH of the following:
1. The requested quantity (dose) exceeds the maximum FDA labeled dose AND the maximum compendia supported dose for the requested indication **AND**
2. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required) **OR**

2. The patient has a compendia supported indication for the requested agent, AND ONE of the following:
A. BOTH of the following:
1. The requested quantity (dose) does NOT exceed the maximum compendia supported dose for the requested indication **AND**
2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does NOT exceed the program quantity limit **OR**

B. BOTH of the following:
1. The requested quantity (dose) exceeds the maximum compendia supported dose for the requested indication **AND**

	2. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required) **OR** 3. The patient does NOT have an FDA labeled indication NOR a compendia supported indication for the requested agent AND BOTH of the following: A. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit **AND** B. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required) **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** Initial Approval with PA: up to 12 months for all agents EXCEPT adalimumab containing products for ulcerative colitis (UC), Rinvoq for atopic dermatitis (AD), Siliq for plaque psoriasis (PS), Xeljanz and Xeljanz XR for induction therapy for UC, and the agents with indications that require loading doses for new starts. NOTE: For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of the length of approval. Adalimumab containing products for UC may be approved for up to 12 weeks, Rinvoq for AD may be approved for up to 6 months, Siliq for PS may be approved for up to 16 weeks, and Xeljanz and Xeljanz XR for UC may be approved for up to 16 weeks. **Renewal Approval with PA:** up to 12 months **Standalone QL approval:** up to 12 months or through the remainder of an existing authorization, whichever is shorter **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable.

CONTRAINDICATION AGENTS

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

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

• Program Summary: Corticotropin

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
	30300010004010	Acthar ; Cortrophin	Corticotropin Inj Gel 80 Unit/ML	80 UNIT/ML	M ; N ; O ; Y				
	3030001000D4	Acthar gel	corticotropin subcutaneous gel auto-injector	40 UNIT/0.5ML ; 80 UNIT/ML	M ; N ; O ; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Preferred Target Agents	Non-Preferred Target Agents
Acthar Gel (repository corticotropin)	Purified Cortrophin Gel (repository corticotropin)

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

1. The patient has a diagnosis of infantile spasms **AND**
2. The patient is less than 24 months of age **AND**
3. ONE of the following:
   - A. The requested agent is a preferred agent **OR**
   - B. The patient has tried and had an inadequate response to the preferred agent **OR**
   - C. The patient has an intolerance or hypersensitivity to the preferred agent(s) that is NOT expected to occur with the requested agent **OR**
   - D. The patient has an FDA labeled contraindication to the preferred agent(s) that is NOT expected to occur with the requested agent **OR**
   - E. The patient is currently being treated with the requested agent as indicated by ALL of the following:
     1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
     2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
     3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
   - F. The prescriber has provided documentation that preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
5. The requested quantity (dose) is within FDA labeled dosing for the requested indication

Length of Approval: 6 months

Target Agent(s) will NOT be approved and are NOT medically necessary for all other indications including but not limited to:

1. Multiple Sclerosis
2. Rheumatic Disorders

	3. Collagen diseases 4. Dermatologic diseases 5. Allergic states 6. Ophthalmic diseases 7. Respiratory diseases 8. Edematous states The effectiveness of repository corticotropin has not been demonstrated as clinically superior to conventional corticosteroids and/or immunosuppressive therapy for uses other than infantile spasms.

• Program Summary: Coverage Exception with Quantity Limit – Health Insurance Marketplace

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

This program applies to individual and small group plans, on- and off-Exchange, that are fully insured and non-grandfathered.

Please note, this program applies to clinical appropriateness. Please see the Clinical Review process flows for determination of exigency as defined per the regulation.

These criteria apply to any request for medication that is not included on the Essential Health Benefit covered drug list.

Weight loss agents must use the Saxenda Wegovy Zepbound Coverage Exception and Formulary Exception criteria.

Objective

These criteria apply to any request for agents that are included on the covered agents list and can be used to treat a medical condition/disease state that is not otherwise excluded from coverage under the pharmacy benefit.

EXCEPTION CRITERIA FOR APPROVAL

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

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

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

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

         OR
       - b. BOTH of the following:
         1. If the requested agent is a brand product with an available formulary generic equivalent, then ONE of the following:

A. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent

OR

B. The patient has an intolerance or hypersensitivity to a formulary generic equivalent agent that is not expected to occur with the requested agent

OR

C. The patient has an FDA labeled contraindication to ALL formulary generic equivalent agent(s) that is not expected to occur with the requested agent

AND

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

      AND

      ii. There is support that the requested aspirin agent is medically necessary

      AND

      iii. The patient is pregnant, at high risk of preeclampsia, and using the requested agent after 12 weeks of gestation

   OR

   B. The requested agent is a bowel prep agent AND ALL of the following:
      i. There is support that the requested bowel prep agent is medically necessary

      AND

      ii. The prescriber has indicated the requested agent will be used for the preparation of colorectal cancer screening using fecal occult blood testing, sigmoidoscopy, or colonoscopy

      AND

      iii. The patient is 45 years of age or over

   OR

   C. The requested agent is a breast cancer primary prevention agent AND ALL of the following:
      i. There is support that the requested breast cancer primary prevention agent is medically necessary

      AND

      ii. The requested agent is tamoxifen, raloxifene, or aromatase inhibitor (anastrozole, exemestane, letrozole)

      AND

      iii. The patient is 35 years of age or over

      AND

      iv. The agent is requested for the primary prevention of breast cancer

   OR

   D. The requested agent is a fluoride supplement AND BOTH of the following:
      i. There is support that the requested fluoride supplement is medically necessary

      AND

      ii. The patient is 6 months to 16 years of age

   OR

   E. The requested agent is a folic acid agent AND ALL of the following:
      i. There is support that the requested folic acid supplement is medically necessary

      AND

      ii. The requested folic acid supplement contains 0.4-0.8 mg of folic acid

      AND

      iii. The requested folic acid supplement is to be used in support of pregnancy

   OR

F. The requested agent is an HIV infection pre-exposure prophylaxis (PrEP) agent being used for PREP AND ALL of the following:
   i. There is support that the requested PrEP agent is medically necessary
   AND
   ii. The requested PrEP agent is ONE of the following:
      a. Tenofovir disoproxil fumarate and emtricitabine combination ingredient agent
      OR
      b. Tenofovir alafenamide and emtricitabine combination ingredient agent
      OR
      c. Cabotegravir
   AND
   iii. The patient has increased risk for HIV infection
   AND
   iv. The patient has recently tested negative for HIV

OR

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

OR

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

OR

I. The requested agent is a statin AND ALL of the following:
   i. There is support that the requested statin is medically necessary
   AND
   ii. The requested statin is for use in the primary prevention of cardiovascular disease (CVD)
   AND
   iii. The patient is 40-75 years of age (inclusive)
   AND
   iv. The patient has at least one of the following risk factors:
      a. Dyslipidemia
      OR
      b. Diabetes
      OR
      c. Hypertension
      OR
      d. Smoking
   AND
   v. The patient has a calculated 10-year risk of a cardiovascular event of 10% or greater per the American College of Cardiology and American Heart Association's Atherosclerotic Cardiovascular Disease (ASCVD) calculator

OR

J. The requested agent is a tobacco cessation agent AND BOTH of the following:
   i. The patient is a non-pregnant adult
   AND
   ii. There is support that the requested tobacco cessation agent is medically necessary

OR

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

OR

B. ALL of the following:
   i. ONE of the following:
      a. The requested agent is in an ACA Preventive Care category AND did NOT meet the preventive service requirements
      OR
      b. BOTH of the following:
         1. ONE of the following:
            A. The requested agent is NOT in an ACA Preventive Care category
            OR
            B. The member's benefit does NOT include ACA Preventive Care for the category requested

         AND

         2. ONE of the following:
            A. The request is for a drug that is on BCBS MN's "CE Formulary Alternative Supplement List" AND BOTH of the following:
               i. The patient has an FDA labeled indication for the requested agent or an indication supported in AHFS, DrugDex with 1 or 2a level of evidence, or NCCN with 1 or 2a level of evidence (for oncology agents also accept NCCN Compendium™ level of evidence 2B, DrugDex 2B, Wolters Kluwer Lexi-Drugs level A, and Clinical Pharmacology) for the requested agent
               AND
               ii. The patient has tried and failed ALL formulary alternatives for the diagnosis being treated with the requested agent

            OR

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

Excluded from Coverage on the Pharmacy Benefit
Alcohol Swabs
Blood Component (not including Hemophilia Factor)
Bulk Powders* (Defined as those products containing the third-party restriction code of B (BULK CHEMICALS) in the product file in RxClaim)
Clinic Packs* (Y in the Clinic Pack field)
Cosmetic Alteration*
Diagnostic Agents (not including glucose test strips)
Dietary and Herbal Supplements
General Anesthetic
Infertility Agents* For the treatment of infertility

Institutional Packs* Those that contain any one of the following modifier codes in the product file in RXClaims i. MODIFIER AAAD31 INSTITUTIONAL/HOSP. PACK ii. MODIFIER BBAD9A INSTITUTIONAL iii. MODIFIER TTAAJQ INSTITUTIONAL iv. MODIFIER TTAA5V INSTITUTIONAL USE ONLY v. MODIFIER AAAB9A HOSPITAL PACK vi. MODIFIER AAADQQ HUD (HOSPITAL UNIT DOSE) vii. MODIFER AAAD6T HOSPITAL USE ONLY
Investigative, experimental, or not medically necessary
Medical Devices and Supplies (not including spacers, lancets, needles, syringes, continuous glucose monitor/sensor/transmitter/receiver) (Defined by GPI 97**********)
Medical devices approved through a different FDA-approval process than drugs (Defined by one of the following: 1) Drug Application File Marketing Category 15 – Premarket Application 2) Drug Application File Marketing Category 16 – Premarket Notification)
Non-FDA Approved Agents* (Refer to all tiers on Formulary ID 220 or reject messaging of 'Non-FDA Approved Drug')
Over-The-Counter Medications* (not including glucose test strips, insulin, ACA required drugs, lancets, syringes) (Defined as indicated by O or P in the Rx-OTC indicator code field in the Product file in RxClaim)
Repackagers (not including Veterans Administration and Department of Defense Claims)* (Defined as indicated as Y in Repkg code field in the product file in RxClaim)
Self-Administered Contraceptives* (2510**********, 2540**********, 2596**********, 2597**********, 2599**********, 260000301003**) (ONLY when not covered in BET AND is being requested exclusively for the use of pregnancy prevention)
Sexual Dysfunction Agents* (Addyi, Viagra, Cialis, Levitra, Staxyn, Caverject, Edex, Muse) for treatment of sexual dysfunction
Surgical Supplies/Medical Devices/Ostomy (not including spacers, lancets, needles, syringes, continuous glucose monitor/sensor/transmitter/receiver) (Defined as indicated by the third-party restriction code 3 (SURGICAL SUPPLY/MEDICAL DEVICE/OSTOMY) in the product file in RxClaim)
Syringes other than insulin syringes
Weight Loss Agents* (GPI: 6120**********, 6125**********) for the treatment of weight loss

*Category specific denial reasons apply

AND

ii. ONE of the following:

a. The requested agent is a CGM/Sensor/Transmitter/Receiver AND ONE of the following:

1. Patient has a visual impairment
   OR
2. Patient uses an insulin pump that is only compatible with one specific CGM/sensor/transmitter/receiver
   OR
3. Patient has a physical or a mental disability

OR

b. The requested agent is a glucose cartridge, test strip, or all-in-one glucose meter system AND ONE of the following:

1. Patient has visual impairment
   OR
2. Patient uses an insulin pump OR continuous glucose monitor that is not accommodated with a preferred glucose cartridge, test strip, or all-in-one glucose meter system
   OR

3. Patient has a physical or a mental disability

OR

c. The requested agent is a rapid, regular, Humalog 50/50, Mix, or NPH insulin agent and ONE of the following:
    1. BOTH of the following:
        A. The requested agent is a rapid insulin
        AND
        B. There is information that the patient is currently using an insulin pump that has an incompatibility with the preferred rapid insulin agent that is not expected to occur with the requested agent

    OR

    2. The request is for Humalog Mix 50/50 AND ONE of the following:
        A. The patient is currently using Humalog Mix 50/50 AND the prescriber stated the patient is at risk if switched to a different insulin
        OR
        B. The patient has tried and failed a preferred insulin mix (e.g., Novolin, Novolog)

    OR

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

    OR

    4. There is information that the patient has a physical or a mental disability that would prevent him/her from using a preferred insulin agent

    OR

    5. The patient is pregnant

OR

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

OR

e. The requested agent is part of the Brand for Generic strategy (i.e., Agents with the following reject message: #NDC NOT COVERED, USE XXX#) AND BOTH of the following:
    1. There is support that the available formulary (any formulary tier) brand equivalents to the requested agent are contraindicated, are likely to be less effective, or will cause an adverse reaction or other harm for the patient

    AND

    2. ONE of the following:
        A. The patient has tried and failed at least three formulary alternatives (any formulary tier), if available, for the diagnosis being treated with the requested agent
        OR
        B. There is support that ALL available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient
        OR
        C. The prescriber stated that the patient is currently stabilized on for a minimum of 90 days the requested agent and switching could potentially cause harm or a health risk (starting on samples is not approvable)

OR

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

OR

g. The requested agent is a Self-Administered Contraceptive Agent (e.g., 2510**********, 2540**********, 2596**********, 2597**********, 2599**********, 260000301003**) AND the agent is being prescribed for an allowable diagnosis

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

OR

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

i. The requested agent is an HIV infection post-exposure prophylaxis (PEP) agent being used for PEP and ALL of the following:
    1. There is support that the requested PEP agent is medically necessary
    AND
    2. The requested PEP agent is ONE of the following (agent AND strength must match):
        A. Emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada)
        OR
        B. Tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread)
        OR
        C. Emtricitabine 200 mg single ingredient agent (Emtriva)
        OR
        D. Raltegravir 400 mg single ingredient agent (Isentress)
        OR
        E. Dolutegravir 50 mg single ingredient agent (Tivicay)
        OR
        F. Darunavir 800 mg single ingredient agent (Prezista)
        OR
        G. Ritonavir 100 mg single ingredient agent (Norvir)
    AND
    3. The patient is at high risk of HIV infection
    AND
    4. The patient is initiating or has initiated PEP within 72 hours of suspected exposure to HIV

OR

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

OR

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

OR

3. BOTH of the following:
    A. ONE of the following:
        i. The patient has an FDA labeled indication for the requested agent

        OR

        ii. The patient has an indication supported in AHFS, DrugDex with 1 or 2a level of evidence, or NCCN with 1 or 2a level of evidence (for oncology agents also accept NCCN Compendium™ level of evidence 2B, DrugDex 2B, Wolters Kluwer Lexi-Drugs level A, and Clinical Pharmacology) for the requested agent

        OR

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

    AND

    B. ONE of the following:
        i. The requested agent has formulary alternatives (any formulary tier) for the diagnosis being treated by the requested agent AND BOTH of the following:
            a. If the requested agent is a brand product with an available formulary generic equivalent AND ONE of the following:
                1. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent

                OR

                2. There is support that ALL available formulary (any formulary tier) generic equivalents to the requested agent are contraindicated, are likely to be less effective, or will cause an adverse reaction or other harm for the patient

            AND

            b. ONE of the following:
                1. The patient has tried and failed at least three formulary alternatives (any formulary tier), if available, for the diagnosis being treated with the requested agent

                OR

                2. There is support that ALL available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

        OR

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

        OR

        iii. The prescriber stated that the patient is currently stabilized on for a minimum of 90 days the requested agent and switching could potentially cause harm or a health risk (starting on samples is not approvable)

AND

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

AND

3. ONE of the following:

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

ACA Length of Approval:
- Aspirin 81 mg: 9 months
- Infant eye ointment: 3 months
- All other indications: 12 months
- Apply $0 copay if ACA criteria met

HIV PEP Length of Approval:
- 12 months
- Apply $0 copay if HIV PEP criteria is met

Coverage Exception Length of Approval: 12 months

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

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
27992502690320		sitagliptin free base-metformin hcl tab	50-500 MG	60	Tablets	30	DAYS				
27992502690330		sitagliptin free base-metformin hcl tab	50-1000 MG	60	Tablets	30	DAYS				
279925027003	Janumet	sitagliptin-metformin hcl tab	50-1000 MG ; 50-500 MG	60	Tablets	30	DAYS				
27992502707530	Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 50-1000 MG	50-1000 MG	60	Tablets	30	DAYS				
27992502707520	Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 50-500 MG	50-500 MG	30	Tablets	30	DAYS				
275500701003	Januvia	sitagliptin phosphate tab	100 MG ; 25 MG ; 50 MG	30	Tablets	30	DAYS				
279925024003	Jentadueto	linagliptin-metformin hcl tab	2.5-1000 MG ; 2.5-500 MG ; 2.5-850 MG	60	Tablets	30	DAYS				
27992502407520	Jentadueto xr	Linagliptin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS				
27992502407530	Jentadueto xr	Linagliptin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	30	Tablets	30	DAYS				
279925021003	Kazano	alogliptin-metformin hcl tab	12.5-1000 MG ; 12.5-500 MG	30	Tablets	30	DAYS				
27992502607520	Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS				
27992502607540	Kombiglyze xr	Saxagliptin-Metformin HCl	5-1000 MG	30	Tablets	30	DAYS				

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

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
1-Step Through Preferred	

Preferred Agents	Non-preferred Agents
Januvia (sitagliptin) **Janumet** (sitagliptin/metformin) **Janumet XR** (sitagliptin/metformin ER)	**Alogliptin** **Alogliptin/metformin** **Alogliptin/pioglitazone** **Jentadueto** (linagliptin/metformin) **Jentadueto XR** (linagliptin/metformin ER) **Kazano** (alogliptin/metformin) **Kombiglyze XR** (saxagliptin/metformin ER)* **Nesina** (alogliptin) **Onglyza** (saxagliptin)* **Oseni** (alogliptin/pioglitazone) **Sitagliptin/metformin** **Tradjenta** (linagliptin) **Zituvio** (sitagliptin)

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

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

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

	1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** B. The patient's medication history includes use of a preferred DPP-4 inhibitor agent **OR** C. BOTH of the following: 1. The prescriber has stated that the patient has tried a preferred DPP-4 inhibitor agent **AND** 2. The preferred DPP-4 inhibitor agent was discontinued due to lack of effectiveness or an adverse event **OR** D. The patient has an intolerance or hypersensitivity to sitagliptin that is not expected to occur with the requested agent **OR** E. The patient has an FDA labeled contraindication to sitagliptin that is not expected to occur with the requested agent **OR** F. The prescriber has provided documentation that the preferred DPP-4 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** 2. The patient will NOT be using the requested agent in combination with another DPP-4 inhibitor/combination agent for the requested indication **AND** 3. The patient will NOT be using the requested agent in combination with a GLP-1 agent **Length of Approval:** 12 months NOTE: If Quantity Limit program also applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Dry Eye Disease – *Note program name change from 'Ophthalmic Immunomodulators'*

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
86720020002040	Cequa	Cyclosporine (Ophth) Soln 0.09% (PF)	0.09 %	60	Vials	30	DAYS				
86300035101825	Eysuvis	Loteprednol Etabonate Ophth Susp	0.25 %	2	Bottles	90	DAYS				
86807018002020	Miebo	perfluorohexyloctane ophth soln	1.338 GM/ML	1	Bottle	30	DAYS				
86720020001620	Restasis	cyclosporine (ophth) emulsion	0.05 %	60	Vials	30	DAYS	;;;;;;;;;;;;;;;00023916330 ; 00023916360 ; 00378876058 ; 00378876091 ; 10702080803 ; 10702080806;50090124200 ; 50090447600;60505620201 ; 60505620202 ; 68180021430 ; 68180021460 ; 73043000501 ; 73043000502			
86720020001620	Restasis multidose	cyclosporine (ophth) emulsion	0.05 %	1	Bottle	30	DAYS	;;;;;;;;;;;;;;;00023530105;;			
86280080202020	Tyrvaya	Varenicline Tartrate Nasal Soln	0.03 MG/ACT	2	Bottles	30	DAYS				
86720020002043	Vevye	cyclosporine (ophth) soln	0.1 %	1	Bottle	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Initial Evaluation** **Cequa (cyclosporine), Miebo (perfluorohexyloctane), Tyrvaya (varenicline), Vevye (cyclosporine), and Xiidra (lifitegrast)** will be approved when ALL of the following are met: 1. ONE of the following: A. BOTH of the following: 1. The patient has a diagnosis of dry eye disease (i.e., dry eye syndrome, keratoconjunctivitis sicca [e.g., Sjögren's Syndrome]) **AND** 2. ONE of the following: A. The patient has previously tried or is currently using aqueous enhancements (e.g., artificial tears, gels, ointments [target agents not included]) **OR** B. The patient has an intolerance or hypersensitivity to aqueous enhancements (e.g., artificial tears, gels, ointments [target agents not included]) **OR** C. The patient has an FDA labeled contraindication to ALL aqueous enhancements **OR**

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

B. The patient has another FDA labeled indication for the requested agent **OR**
C. The patient has an indication that is supported in compendia for the requested agent and route of administration **AND**

2. The patient will NOT be using the requested agent in combination with Verkazia (cyclosporine) or another target agent in this program (e.g., Cequa, Eysuvis, Miebo, Restasis, Tyrvaya, Vevye, Xiidra) **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: Miebo (perfluorohexyloctane) and Tyrvaya (varenicline) - 2 months; Cequa (cyclosporine), Vevye (cyclosporine), Xiidra (lifitegrast) - 3 months

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

Initial Evaluation

Eysuvis (loteprednol etabonate) will be approved when ALL of the following are met:

1. ONE of the following:
    A. The patient has a diagnosis of dry eye disease (i.e., dry eye syndrome, keratoconjunctivitis sicca [e.g., Sjögren's Syndrome]) AND ONE of the following:
        1. The patient has NOT been previously treated with the requested agent AND ONE of the following:
            A. The patient has tried and had an inadequate response to at least ONE generic ophthalmic corticosteroid **OR**
            B. The patient has an intolerance or hypersensitivity to therapy with generic ophthalmic corticosteroids that is not expected to occur with the requested agent **OR**
            C. The patient has an FDA labeled contraindication to ALL generic ophthalmic 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 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 ophthalmic corticosteroids cannot be used due to a documented medical condition or comorbid

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

2. The patient has been previously treated with the requested agent AND ALL of the following:
    A. ONE of the following:
        1. The patient has tried and had an inadequate response to at least ONE generic ophthalmic corticosteroid **OR**
        2. The patient has an intolerance or hypersensitivity to therapy with generic ophthalmic corticosteroids that is not expected to occur with the requested agent **OR**
        3. The patient has an FDA labeled contraindication to ALL generic ophthalmic corticosteroids that is not expected to occur with the requested agent **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 the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
            C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
        5. The prescriber has provided documentation that ALL generic ophthalmic corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
    B. The patient has had clinical benefit with the requested agent **AND**
    C. The patient's eyes have been examined under magnification (e.g., slit lamp), and the patient's intraocular pressure has been evaluated **OR**
B. The patient has another FDA labeled indication for the requested agent **OR**
C. The patient has an indication that is supported in compendia for the requested agent and route of administration **AND**

2. The patient will NOT be using the requested agent in combination with Verkazia (cyclosporine) or another target agent in this program (e.g., Cequa, Eysuvis, Miebo, Restasis, Tyrvaya, Vevye, Xiidra) **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: 3 months

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

Initial Evaluation

Restasis (cyclosporine ophthalmic emulsion) will be approved when ALL of the following are met:

1. ONE of the following:
    A. ALL of the following:
        1. The patient has a diagnosis of dry eye disease (i.e., dry eye syndrome, keratoconjunctivitis sicca [e.g., Sjögren's Syndrome]) **AND**
        2. The patient will NOT be using the requested agent in combination with punctal plug(s) **AND**
        3. ONE of the following:
            A. The patient has previously tried or is currently using aqueous enhancements (e.g., artificial tears, gels, ointments [target agents not included]) **OR**

	B. The patient has an intolerance or hypersensitivity to aqueous enhancements (e.g., artificial tears, gels, ointments [target agents not included]) **OR** C. The patient has an FDA labeled contraindication to ALL aqueous enhancements **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL aqueous enhancements cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has another FDA labeled indication for the requested agent **OR** C. The patient has an indication that is supported in compendia for the requested agent and route of administration **AND** 2. The patient will NOT be using the requested agent in combination with Verkazia (cyclosporine) or another target agent in this program (e.g., Cequa, Eysuvis, Miebo, Restasis, Tyrvaya, Vevye, Xiidra) **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 NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient will NOT be using the requested agent in combination with Verkazia (cyclosporine) or another target agent in this program (e.g., Cequa, Eysuvis, Miebo, Restasis, Tyrvaya, Vevye, Xiidra) **AND** 4. If the requested agent is Eysuvis (loteprednol etabonate), the patient's eyes have been examined under magnification (e.g., slit lamp), and the intraocular pressure has been evaluated **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** Eysuvis (loteprednol etabonate) - 3 months, all other agents - 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

	2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• Program Summary: Endari

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
	828010200030	Endari	glutamine (sickle cell) powd pack	5 GM	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 sickle cell disease **AND** 2. The patient is using the requested agent to reduce the acute complications of sickle cell disease **AND** 3. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age **AND** 4. ONE of the following: A. The patient has tried and had an inadequate response to hydroxyurea **OR** B. The patient has an intolerance or hypersensitivity to hydroxyurea **OR** C. The patient has an FDA labeled contraindication to hydroxyurea **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that hydroxyurea cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 5. ONE of the following: A. The patient will NOT be using the requested agent in combination with Adakevo (crizanlizumab-tmca) OR Oxbryta (voxelotor) **OR**

	B. There is support for use of the requested agent in combination with Adakveo (crizanlizumab-tmca) or Oxbryta (voxelotor) **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 7. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **Length of Approval:** 12 months **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved through the plan's Prior Authorization process (Note: patients not previously approved for the requested agent will require initial evaluation review) **AND** 2. The patient has had clinical benefit with the requested agent (i.e., reduction in acute complications of sickle cell disease since initiating therapy with the requested agent) **AND** 3. ONE of the following: A. The patient will NOT be using the requested agent in combination with Adakevo (crizanlizumab-tmca) OR Oxbryta (voxelotor) **OR** B. There is support for use of the requested agent in combination with Adakevo (crizanlizumab-tmca) or Oxbryta (voxelotor) **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **Length of Approval:** 12 months

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

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

POLICY AGENT SUMMARY QUANTITY 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
2717005600D230	Adlyxin	Lixisenatide Soln Pen-injector 20 MCG/0.2ML (100 MCG/ML)	20 MCG/0.2 ML	2	Pens	28	DAYS				
2717005600F420	Adlyxin starter pack	Lixisenatide Pen-inj Starter Kit 10 MCG/0.2ML & 20 MCG/0.2ML	10 & 20 MCG/0.2 ML	2	Pens	180	DAYS				
2717002000D420	Bydureon bcise	Exenatide Extended Release Susp Auto-Injector 2 MG/0.85ML	2 MG/0.85 ML	4	Pens	28	DAYS				
2717002000D240	Byetta	Exenatide Soln Pen-injector 10 MCG/0.04ML	10 MCG/0.0 4ML	1	Pen	30	DAYS				
2717002000D220	Byetta	Exenatide Soln Pen-injector 5 MCG/0.02ML	5 MCG/0.0 2ML	1	Pen	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
2717308000D210	Mounjaro	Tirzepatide Soln Pen-injector	2.5 MG/0.5ML	4	Pens	180	DAYS				
2717308000D215	Mounjaro	Tirzepatide Soln Pen-injector	5 MG/0.5ML	4	Pens	28	DAYS				
2717308000D220	Mounjaro	Tirzepatide Soln Pen-injector	7.5 MG/0.5ML	4	Pens	28	DAYS				
2717308000D225	Mounjaro	Tirzepatide Soln Pen-injector	10 MG/0.5ML	4	Pens	28	DAYS				
2717308000D230	Mounjaro	Tirzepatide Soln Pen-injector	12.5 MG/0.5ML	4	Pens	28	DAYS				
2717308000D235	Mounjaro	Tirzepatide Soln Pen-injector	15 MG/0.5ML	4	Pens	28	DAYS				
2717007000D221	Ozempic	Semaglutide Soln Pen-inj	2 MG/3ML	1	Pen	28	DAYS				
2717007000D225	Ozempic	Semaglutide Soln Pen-inj	8 MG/3ML	1	Pen	28	DAYS				
2717007000D222	Ozempic	Semaglutide Soln Pen-inj	4 MG/3ML	1	Pen	28	DAYS				
2717007000D210	Ozempic	Semaglutide Soln Pen-inj 0.25 or 0.5 MG/DOSE (2 MG/1.5ML)	2 MG/1.5ML	1	Pen	28	DAYS				
27170070000330	Rybelsus	Semaglutide Tab 14 MG	14 MG	30	Tablets	30	DAYS				
27170070000310	Rybelsus	Semaglutide Tab 3 MG	3 MG	30	Tablets	180	DAYS				
27170070000320	Rybelsus	Semaglutide Tab 7 MG	7 MG	30	Tablets	30	DAYS				
2717001500D240	Trulicity	Dulaglutide Soln Pen-injector	3 MG/0.5ML	4	Pens	28	DAYS				
2717001500D250	Trulicity	Dulaglutide Soln Pen-injector	4.5 MG/0.5ML	4	Pens	28	DAYS				
2717001500D220	Trulicity	Dulaglutide Soln Pen-injector 0.75 MG/0.5ML	0.75 MG/0.5ML	4	Pens	28	DAYS				
2717001500D230	Trulicity	Dulaglutide Soln Pen-injector 1.5 MG/0.5ML	1.5 MG/0.5ML	4	Pens	28	DAYS				
2717005000D220	Victoza, Liraglutide	Liraglutide Soln Pen-injector 18 MG/3ML (6 MG/ML)	18 MG/3ML	3	Pens	30	DAYS				

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

ADDITIONAL QUANITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
2717005600D230	Adlyxin	Lixisenatide Soln Pen-injector 20 MCG/0.2ML (100 MCG/ML)	20 MCG/0.2ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717005600F420	Adlyxin starter pack	Lixisenatide Pen-inj Starter Kit 10 MCG/0.2ML & 20 MCG/0.2ML	10 & 20 MCG/0.2ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717002000D420	Bydureon bcise	Exenatide Extended Release Susp Auto-Injector 2 MG/0.85ML	2 MG/0.85ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717002000D240	Byetta	Exenatide Soln Pen-injector 10 MCG/0.04ML	10 MCG/0.04ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717002000D220	Byetta	Exenatide Soln Pen-injector 5 MCG/0.02ML	5 MCG/0.02ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717308000D210	Mounjaro	Tirzepatide Soln Pen-injector	2.5 MG/0.5ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717308000D215	Mounjaro	Tirzepatide Soln Pen-injector	5 MG/0.5ML	The patient has a diagnosis of type 2 diabetes mellitus			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
2717308000D220	Mounjaro	Tirzepatide Soln Pen-injector	7.5 MG/0.5ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717308000D225	Mounjaro	Tirzepatide Soln Pen-injector	10 MG/0.5ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717308000D230	Mounjaro	Tirzepatide Soln Pen-injector	12.5 MG/0.5ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717308000D235	Mounjaro	Tirzepatide Soln Pen-injector	15 MG/0.5ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717007000D221	Ozempic	Semaglutide Soln Pen-inj	2 MG/3ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717007000D225	Ozempic	Semaglutide Soln Pen-inj	8 MG/3ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717007000D222	Ozempic	Semaglutide Soln Pen-inj	4 MG/3ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717007000D210	Ozempic	Semaglutide Soln Pen-inj 0.25 or 0.5 MG/DOSE (2 MG/1.5ML)	2 MG/1.5ML	The patient has a diagnosis of type 2 diabetes mellitus			
27170070000330	Rybelsus	Semaglutide Tab 14 MG	14 MG	The patient has a diagnosis of type 2 diabetes mellitus			
27170070000310	Rybelsus	Semaglutide Tab 3 MG	3 MG	The patient has a diagnosis of type 2 diabetes mellitus			
27170070000320	Rybelsus	Semaglutide Tab 7 MG	7 MG	The patient has a diagnosis of type 2 diabetes mellitus			
2717001500D240	Trulicity	Dulaglutide Soln Pen-injector	3 MG/0.5ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717001500D250	Trulicity	Dulaglutide Soln Pen-injector	4.5 MG/0.5ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717001500D220	Trulicity	Dulaglutide Soln Pen-injector 0.75 MG/0.5ML	0.75 MG/0.5ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717001500D230	Trulicity	Dulaglutide Soln Pen-injector 1.5 MG/0.5ML	1.5 MG/0.5ML	The patient has a diagnosis of type 2 diabetes mellitus			
2717005000D220	Victoza, Liraglutide	Liraglutide Soln Pen-injector 18 MG/3ML (6 MG/ML)	18 MG/3ML	The patient has a diagnosis of type 2 diabetes mellitus			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
CoT with Dx check	

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

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

1. The patient has a diagnosis of type 2 diabetes **AND**
2. The patient's diagnosis has been confirmed by lab tests (e.g., A1C greater than or equal to 6.5%) (lab test results required) **AND**
3. ONE of the following:
    A. The requested agent is eligible for continuation of therapy AND ONE of the following:

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

1. The patient has been treated with a preferred agent (starting on samples is not approvable) within the past 90 days **OR**
2. The prescriber states the patient has been treated with a preferred agent within the past 90 days (starting on samples is not approvable) AND is at risk if therapy with a preferred agent is discontinued **OR**

B. BOTH of the following:
1. ONE of the following:
A. The patient has tried and had an inadequate response to an agent containing metformin or insulin **OR**
B. The patient has an intolerance or hypersensitivity to metformin or insulin **OR**
C. The patient has an FDA labeled contraindication to BOTH metformin AND insulin **OR**
D. The patient has a diagnosis of type 2 diabetes with/or at high risk for atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease **OR**
E. The patient is currently being treated with the requested agent as indicated by ALL of the following:
1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
F. The prescriber has provided documentation that metformin and insulin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
2. ONE of the following:
A. The requested agent is a preferred GLP-1 or GLP-1/GIP **OR**
B. The agent is a non-preferred GLP-1 and ONE of the following:
1. TWO of the following:

	A. The patient has tried and had an inadequate response, has an intolerance, has a hypersensitivity, or has an FDA labeled contraindication to semaglutide (Ozempic OR Rybelsus) **OR** B. The patient has tried and had an inadequate response, has an intolerance, has a hypersensitivity, or has an FDA labeled contraindication to dulaglutide (Trulicity) **OR** C. The patient has tried and had an inadequate response , has a hypersensitivity, or has an FDA labeled contraindication to tirzepatide (Mounjaro) **OR** 2. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 3. The prescriber has provided documentation that semaglutide (Ozempic OR Rybelsus), dulaglutide (Trulicity), AND tirzepatide (Mounjaro) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The patient will NOT be using the requested agent in combination with a DPP-4 agent containing agent for the requested indication **AND** 5. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **Length of Approval:** 12 months NOTE: If Quantity Limit program also applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: 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				
90970083204020	Sofdra	sofpironium bromide gel	12.45 %	1	Bottle	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: Hyperpolarization-Activated Cyclic Nucleotide-Gated (HCN) Channel Blocker (Corlanor)

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
40700035102020	Corlanor	Ivabradine HCl Oral Soln 5 MG/5ML (Base Equiv)	5 MG/5ML	600	mL	30	DAYS				
40700035100320	Corlanor	Ivabradine HCl Tab 5 MG (Base Equiv)	5 ; 5 MG	60	Tablets	30	DAYS				
40700035100330	Corlanor	Ivabradine HCl Tab 7.5 MG (Base Equiv)	7.5 ; 7.5 MG	60	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. The patient has a diagnosis of stable symptomatic heart failure (NYHA Class II-IV) due to dilated cardiomyopathy (DCM) AND BOTH of the following: 1. The patient is in sinus rhythm **AND** 2. The patient has an elevated heart rate **OR** C. The patient has a diagnosis of stable symptomatic chronic heart failure (NYHA Class II-IV) AND ALL of the following: 1. The patient has a left ventricular ejection fraction (LVEF) less than or equal to 35% **AND** 2. The patient is in sinus rhythm **AND** 3. The patient has a resting heart rate of greater than or equal to 70 beats per minute **AND** 4. ONE of the following: A. BOTH of the following: 1. The patient is currently treated with a maximally tolerated beta blocker **AND** 2. The patient will continue beta blocker therapy **OR** B. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to beta blocker therapy **OR** D. The patient has another FDA labeled indication for the requested agent and route of administration **OR** E. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist), 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 **Compendia Allowed:** AHFS or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation**

	Target Agent(s) will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

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

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
9027302000D215	Dupixent	Dupilumab Subcutaneous Soln Pen-injector	200 MG/1.14 ML	2	Pens	28	DAYS				
9027302000D220	Dupixent	Dupilumab Subcutaneous Soln Pen-injector 300 MG/2ML	300 MG/2ML	4	Pens	28	DAYS				

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
9027302000E510	Dupixent	Dupilumab Subcutaneous Soln Prefilled Syringe	100 MG/0.67 ML	2	Syringes	28	DAYS				
9027302000E515	Dupixent	Dupilumab Subcutaneous Soln Prefilled Syringe 200 MG/1.14ML	200 MG/1.14 ML	2	Syringes	28	DAYS				
9027302000E520	Dupixent	Dupilumab Subcutaneous Soln Prefilled Syringe 300 MG/2ML	300 MG/2ML	4	Syringes	28	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Initial Evaluation

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

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

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

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

   B. BOTH of the following:
      1. ONE of the following:
         A. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following:
            1. ONE of the following:
               A. The patient has at least 10% body surface area involvement **OR**
               B. The patient has involvement of body sites that are difficult to treat with prolonged topical corticosteroid therapy (e.g., hands, feet, face, neck, scalp, genitals/groin, skin folds) **OR**
               C. The patient has an Eczema Area and Severity Index (EASI) score greater than or equal to 16 **OR**
               D. The patient has an Investigator Global Assessment (IGA) score greater than or equal to 3 **AND**
            2. ONE of the following:
               A. The patient has tried and had an inadequate response to BOTH at least a medium-potency topical corticosteroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR**

B. The patient has an intolerance or hypersensitivity to BOTH at least a medium-potency topical corticosteroid AND a topical calcineurin inhibitor used in the treatment of AD **OR**
C. The patient has an FDA labeled contraindication to ALL medium-, high-, and super-potency topical corticosteroids 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 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 medium-, high-, and super-potency topical corticosteroids AND topical calcineurin inhibitors used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

3. The prescriber has documented the patient's baseline (prior to therapy with the requested agent) pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **OR**

B. The patient has a diagnosis of moderate to severe asthma AND BOTH of the following:
1. ONE of the following:
A. The patient has eosinophilic type asthma AND ONE of the following:
1. The patient has a baseline (prior to therapy with the requested agent) blood eosinophilic count of 150 cells/microliter or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **OR**
2. The patient has a fraction of exhaled nitric oxide (FeNO) of 20 parts per billion or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **OR**
3. The patient has sputum eosinophils 2% or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **OR**
B. The patient has oral corticosteroid dependent type asthma **AND**

2. The patient has a history of uncontrolled asthma while on asthma control therapy as demonstrated by ONE of the following:
A. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months **OR**
B. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months **OR**
C. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered **OR**
D. The patient has baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted **OR**

C. The patient has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) AND ALL of the following:
    1. The patient has at least TWO of the following symptoms consistent with chronic rhinosinusitis (CRS):
        A. Nasal discharge (rhinorrhea or post-nasal drainage)
        B. Nasal obstruction or congestion
        C. Loss or decreased sense of smell (hyposmia)
        D. Facial pressure or pain **AND**
    2. The patient has had symptoms consistent with chronic rhinosinusitis (CRS) for at least 12 consecutive weeks **AND**
    3. The patient's diagnosis was confirmed by ONE of the following:
        A. Anterior rhinoscopy or endoscopy **OR**
        B. Computed tomography (CT) of the sinuses **AND**
    4. ONE of the following:
        A. ONE of the following:
            1. The patient had an inadequate response to sinonasal surgery **OR**
            2. The patient is NOT a candidate for sinonasal surgery **OR**
        B. ONE of the following:
            1. The patient has tried and had an inadequate response to oral systemic corticosteroids **OR**
            2. The patient has an intolerance or hypersensitivity to therapy with oral systemic corticosteroids **OR**
            3. The patient has an FDA labeled contraindication to ALL oral systemic corticosteroids **AND**
    5. ONE of the following:
        A. The patient has tried and had an inadequate response to intranasal corticosteroids (e.g., fluticasone, Sinuva) **OR**
        B. The patient has an intolerance or hypersensitivity to therapy with intranasal corticosteroids (e.g., fluticasone, Sinuva) **OR**
        C. The patient has an FDA labeled contraindication to ALL intranasal corticosteroids **OR**

D. The patient has a diagnosis of eosinophilic esophagitis (EoE) AND BOTH of the following:
    1. The patient's diagnosis was confirmed by ALL of the following:
        A. Chronic symptoms of esophageal dysfunction **AND**
        B. Greater than or equal to 15 eosinophils per high-power field on esophageal biopsy **AND**
        C. Other causes that may be responsible for or contributing to symptoms and esophageal eosinophilia have been ruled out **AND**
    2. ONE of the following:
        A. The patient is currently being treated with the requested agent as indicated by ALL of the following:
            1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
            2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
            3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
        B. The patient has tried and had an inadequate response to ONE standard corticosteroid therapy used in the treatment of EoE (i.e., budesonide oral suspension, swallowed budesonide, nebulizer suspension, swallowed fluticasone MDI) **OR**

C. The patient has an intolerance or hypersensitivity to standard corticosteroid therapy used in the treatment of EoE **OR**
D. The patient has an FDA labeled contraindication to ALL standard corticosteroid therapies used in the treatment of EoE **OR**
E. The prescriber has provided documentation that ALL standard corticosteroid therapies used in the treatment of EoE cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**
F. The patient has tried and had an inadequate response to ONE proton pump inhibitor (PPI) used in the treatment of EoE **OR**
G. The patient has an intolerance or hypersensitivity to PPI therapy used in the treatment of EoE **OR**
H. The patient has an FDA labeled contraindication to ALL PPI therapies used in the treatment of EoE **OR**
I. The prescriber has provided documentation that ALL PPI therapies used in the treatment of EoE cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

E. The patient has a diagnosis of prurigo nodularis (PN) and BOTH of the following:
1. The patient has ALL of the following features associated with PN:
A. Presence of firm, nodular lesions **AND**
B. Pruritus that has lasted for at least 6 weeks **AND**
C. History and/or signs of repeated scratching, picking, or rubbing **AND**
2. ONE of the following:
A. The patient has tried and had an inadequate response to at least a medium-potency topical corticosteroid used in the treatment of PN **OR**
B. The patient has an intolerance or hypersensitivity to therapy with at least a medium-potency topical corticosteroid used in the treatment of PN **OR**
C. The patient has an FDA labeled contraindication to ALL medium-, high-, and super-potency topical corticosteroids used in the treatment of PN **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 medium-, high-, and super-potency topical corticosteroids used in the treatment of PN cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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 labeled indication for the requested agent and route of administration **AND**

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

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

2. If the patient has a diagnosis of moderate-to-severe atopic dermatitis (AD), then BOTH of the following:
   A. The patient is currently treated with topical emollients and practicing good skin care **AND**
   B. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent **AND**
3. If the patient has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP), BOTH of the following:
   A. The patient is currently treated with standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) **AND**
   B. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **AND**
4. If the patient has a diagnosis of moderate to severe asthma, ALL of the following:
   A. ONE of the following:
      1. The patient is NOT currently being treated with the requested agent AND is currently treated with a maximally tolerated inhaled corticosteroid **OR**
      2. The patient is currently being treated with the requested agent AND ONE of the following:
         A. Is currently treated with an inhaled corticosteroid that is adequately dosed to control symptoms **OR**
         B. Is currently treated with a maximally tolerated inhaled corticosteroid **OR**
      3. The patient has an intolerance or hypersensitivity to inhaled corticosteroid therapy **OR**
      4. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids **AND**
   B. ONE of the following:
      1. The patient is currently being treated with ONE of the following:
         A. A long-acting beta-2 agonist (LABA) **OR**
         B. Long-acting muscarinic antagonist (LAMA) **OR**
         C. A leukotriene receptor antagonist (LTRA) **OR**
         D. Theophylline **OR**
      2. The patient has an intolerance or hypersensitivity to therapy with long-acting beta-2 agonists (LABA), long-acting muscarinic antagonists (LAMA), leukotriene receptor antagonist (LTRA), or theophylline **OR**
      3. The patient has an FDA labeled contraindication to ALL long-acting beta-2 agonists (LABA) AND long-acting muscarinic antagonists (LAMA) **AND**
   C. The patient will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **AND**
5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., atopic dermatitis -dermatologist, allergist, immunologist; asthma -allergist, immunologist, pulmonologist; CRSwNP -otolaryngologist, allergist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
6. ONE of the following (please refer to "Agents NOT to be used Concomitantly" table):
   A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**
   B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
      1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**
      2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, guidelines required) **AND**

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

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

Length of Approval: 6 months

NOTE: Initial loading dose is allowed for asthma, atopic dermatitis, or prurigo nodularis only and may require a Quantity Limit review. The loading dose plus maintenance dose may be approved for 1 month, followed by maintenance dosing for the remainder of the length of approval.

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

Renewal Evaluation

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

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**
2. ONE of the following:
    A. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND BOTH of the following:
        1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following:
            A. Affected body surface area **OR**
            B. Flares **OR**
            C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **OR**
            D. A decrease in the Eczema Area and Severity Index (EASI) score **OR**
            E. A decrease in the Investigator Global Assessment (IGA) score **AND**
        2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR**
    B. The patient has a diagnosis of moderate to severe asthma AND BOTH of the following:
        1. The patient has had improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following:
            A. The patient has had an increase in percent predicted Forced Expiratory Volume (FEV1) **OR**
            B. The patient has had a decrease in the dose of inhaled corticosteroids required to control the patient's asthma **OR**
            C. The patient has had a decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma **OR**
            D. The patient has had a decrease in number of hospitalizations, need for mechanical ventilation, or visits to urgent care or emergency room due to exacerbations of asthma **AND**
        2. The patient is currently treated and is compliant with asthma control therapy [e.g., inhaled corticosteroids, ICS/long-acting beta-2 agonist (LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), theophylline] **OR**
    C. The patient has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) AND BOTH of the following:
        1. The patient has had clinical benefit with the requested agent **AND**
        2. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **OR**

	D. The patient has a diagnosis other than moderate-to-severe atopic dermatitis (AD), moderate to severe asthma, or chronic rhinosinusitis with nasal polyps (CRSwNP) AND has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., atopic dermatitis -dermatologist, allergist, immunologist; asthma -allergist, immunologist, pulmonologist; CRSwNP -otolaryngologist, allergist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, guidelines required) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of Approval:** up to 12 months Note: If approving initial loading dose, please approve initial loading dose for asthma, atopic dermatitis, or prurigo nodularis only. The loading dose plus maintenance dose may be approved for 1 month, followed by maintenance dosing for the remainder of the length of approval.

CONTRAINDICATION AGENTS

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

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

Contraindicated as Concomitant Therapy
Tyenne (tocilizumab-aazg) Tysabri (natalizumab) Velsipity (etrasimod) Wezlana (ustekinumab-auub) Xeljanz (tofacitinib) Xeljanz XR (tofacitinib extended release) Xolair (omalizumab) Yuflyma (adalimumab-aaty) Yusimry (adalimumab-aqvh) Zeposia (ozanimod) Zymfentra (infliximab-dyyb)

• Program Summary: Interleukin-13 (IL-13) Antagonist

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
9027308045D530	Adbry	tralokinumab-ldrm subcutaneous soln auto-injector	300 MG/2ML	2	Pens	28	DAYS				
9027308045E520	Adbry	Tralokinumab-ldrm Subcutaneous Soln Prefilled Syr	150 MG/ML	4	Syringes	28	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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

A. The patient has at least 10% body surface area involvement **OR**
B. The patient has involvement of body sites that are difficult to treat with prolonged topical corticosteroid therapy (e.g., hands, feet, face, neck, scalp, genitals/groin, skin folds) **OR**
C. The patient has an Eczema Area and Severity Index (EASI) score greater than or equal to 16 **OR**
D. The patient has an Investigator Global Assessment (IGA) score greater than or equal to 3 **AND**

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

3. ONE of the following:
   A. The patient has tried and had an inadequate response to a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR**
   B. The patient has an intolerance or hypersensitivity to a topical calcineurin inhibitor used in the treatment of AD **OR**
   C. The patient has an FDA labeled contraindication to ALL topical calcineurin inhibitors used in the treatment of AD **OR**
   D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
      2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND**
      3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
   E. The prescriber has provided documentation that ALL topical calcineurin inhibitors used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to

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

4. The prescriber has documented the patient's baseline (prior to therapy with the requested agent) pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **OR**

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

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

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

2. If the patient has a diagnosis of moderate-to-severe atopic dermatitis (AD), then BOTH of the following:
   A. The patient is currently treated with topical emollients and practicing good skin care **AND**
   B. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent **AND**
3. ONE of the following:
   A. The patient is initiating therapy with the requested agent **OR**
   B. The patient has been treated with the requested agent for less than 16 consecutive weeks **OR**
   C. The patient has been treated with the requested agent for at least 16 consecutive weeks AND ONE of the following:
      1. The patient weighs less than 100 kg and ONE of the following:
         A. The patient has achieved clear or almost clear skin AND the patient's dose will be reduced to 300 mg every 4 weeks **OR**
         B. The patient has NOT achieved clear or almost clear skin **OR**
         C. There is support for therapy using 300 mg every 2 weeks **OR**
      2. The patient weighs greater than or equal to 100 kg **AND**
4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
5. ONE of the following (please refer to "Agents NOT to be used Concomitantly" table):
   A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**
   B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
      1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**
      2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, guidelines required) **AND**
6. The patient does NOT have any FDA labeled contraindications to the requested agent

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

Length of Approval: 6 months

Note: Initial loading dose is allowed for Adbry and may require a Quantity Limit review. The loading dose plus maintenance dose may be approved for 1 month, followed by maintenance dosing for the remainder of the length of approval.

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

Renewal Evaluation

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

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**
2. ONE of the following:
    A. The patient has a diagnosis of moderate-to-severe atopic dermatitis AND BOTH of the following:
        1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following:
            A. Affected body surface area **OR**
            B. Flares **OR**
            C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **OR**
            D. A decrease in the Eczema Area and Severity Index (EASI) score **OR**
            E. A decrease in the Investigator Global Assessment (IGA) score **AND**
        2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR**
    B. The patient has a diagnosis other than moderate-to-severe atopic dermatitis AND has had clinical benefit with the requested agent **AND**
3. ONE of the following:
    A. The patient is initiating therapy with the requested agent **OR**
    B. The patient has been treated with the requested agent for less than 16 consecutive weeks **OR**
    C. The patient has been treated with the requested agent for at least 16 consecutive weeks AND ONE of the following:
        1. The patient weighs less than 100 kg and ONE of the following:
            A. The patient has achieved clear or almost clear skin AND the patient's dose will be reduced to 300 mg every 4 weeks **OR**
            B. The patient has NOT achieved clear or almost clear skin **OR**
            C. There is support for therapy using 300 mg every 2 weeks **OR**
        2. The patient weighs greater than or equal to 100 kg **AND**
4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
5. ONE of the following (please refer to "Agents NOT to be used Concomitantly" table):
    A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**
    B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
        1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**
        2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, guidelines required) **AND**
6. The patient does NOT have any FDA labeled contraindications to the requested agent

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

Length of Approval: 12 months

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

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of Approval:** up to 12 months Note: If approving initial loading dose for Adbry, approve quantity for loading dose plus maintenance for 1 month followed by maintenance dose for the remainder of the length of approval. Maintenance dosing begins 2 weeks after patient receives the loading dose.

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)
Cibinqo (abrocitinib)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)

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

• Program Summary: Opioids IR NTT

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

OBJECTIVE

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

SINGLE INGREDIENT AGENT(S)				
Brand (generic)	**GPI**	**Daily Quantity Limit**	**Quantity Equaling <50 MME/day**	**Age Limit**
butorphanol[a]				
10 mg/mL nasal spray	65200020102050	0.25 mL	See note*	NA
Codeine				
15 mg tablet	65100020200305	6 tablets	22 tablets	≥18 years
30 mg tablet[a]	65100020200310	6 tablets	11 tablets	≥18 years
60 mg tablet	65100020200315	6 tablets	5 tablets	≥18 years
Dilaudid (hydromorphone)[a]				
2 mg tablet	65100035100310	6 tablets	5 tablets	NA
4 mg tablet	65100035100320	6 tablets	3 tablets	NA
8 mg tablet	65100035100330	6 tablets	1 tablet	NA
1 mg/mL liquid	65100035100920	48 mL	10 mL	NA
Levorphanol[a]				
2 mg tablet	65100040100305	4 tablets	2 tablets	NA
3 mg tablet	65100040100310	4 tablets	1 tablet	NA
Meperidine				
50 mg tablet	65100045100305	12 tablets	10 tablets	NA
50 mg/5 mL solution	65100045102060	60 mL	50 mL	NA
Dolophine (methadone)[a]				
5 mg tablet	65100050100305	3 tablets	3 tablets	NA
10 mg tablet	65100050100310	3 tablets	1 tablet	NA
Methadose, Methadone[a]				
40 mg soluble tablet	65100050107320	3 tablets	see note*	NA
5 mg/5 mL solution	65100050102010	30 mL	11 mL	NA
10 mg/5 mL solution	65100050102015	15 mL	6 mL	NA
10 mg/mL concentrate	65100050101310	3 mL	1 mL	NA
Morphine sulfate				
15 mg tablet[a]	65100055100310	12 tablets	3 tablets	NA
30 mg tablet[a]	65100055100315	6 tablets	1 tablet	NA
10 mg/5 mL solution	65100055102065	90 mL	25 mL	NA
20 mg/5 mL solution[a]	65100055102070	45 mL	12 mL	NA
20 mg/mL concentrate[a]	65100055102090	9 mL	2 mL	NA
Oxaydo, Roxybond, Roxicodone (oxycodone)				
5 mg capsule[a]	65100075100110	12 capsules	6 capsules	NA
5 mg tablet[a]	65100075100310	12 tablets	6 tablets	NA
5 mg tablet	6510007510A530	12 tablets	6 tablets	NA
7.5 mg tablet	65100075100315	6 tablets	4 tablets	NA
10 mg tablet[a]	65100075100320	6 tablets	3 tablets	NA
15 mg tablet[a]	65100075100325	6 tablets	2 tablets	NA
15 mg tablet	6510007510A540	6 tablets	2 tablets	NA
20 mg tablet[a]	65100075100330	6 tablets	1 tablet	NA
30 mg tablet[a]	65100075100340	6 tablets	1 tablet	NA
30 mg tablet	6510007510A560	6 tablets	1 tablet	NA
5 mg/5 mL solution[a]	65100075102005	180 mL	33 mL	NA
20 mg/mL concentrate[a]	65100075101320	9 mL	1 mL	NA
Opana (oxymorphone)[a]				
5 mg tablet	65100080100305	6 tablets	3 tablets	NA
10 mg tablet	65100080100310	6 tablets	1 tablet	NA

Nucynta (tapentadol)				
50 mg tablet	65100091100320	6 tablets	2 tablets	NA
75 mg tablet	65100091100330	6 tablets	1 tablet	NA
100 mg tablet	65100091100340	6 tablets	1 tablet	NA
Qdolo, Ultram, Tramadol				
25 mg tablet	65100095100310	8 tablets	10 tablets	≥18 years
50 mg tablet[a]	65100095100320	8 tablets	5 tablets	≥18 years
100 mg tablet[a]	65100095100340	4 tablets	3 tablets	≥18 years
5 mg/mL solution	65100095102005	80 mL	50 mL	≥18 years
COMBINATION INGREDIENT AGENT(S)				
Apadaz, Benzhydrocodone/acetaminophen				
4.08/325 mg tablet	65990002020310	12 tablets	11 tablets[‡]	NA
6.12/325 mg tablet	65990002020320	12 tablets	7 tablets[‡]	NA
8.16/325 mg tablet	65990002020330	12 tablets	6 tablets[‡]	NA
Tylenol w/Codeine (acetaminophen/codeine)[a]				
120 mg/12 mg/5 mL solution	65991002052020	90 mL	138 mL[‡]	≥18 years
300 mg/15 mg tablet	65991002050310	12 tablets	22 tablets[‡]	≥18 years
300 mg/30 mg tablet	65991002050315	12 tablets	11 tablets[‡]	≥18 years
300 mg/60 mg tablet	65991002050320	6 tablets	5 tablets[‡]	≥18 years
Fioricet w/Codeine (butalbital/acetaminophen/caffeine/codeine)[a]				
50 mg/300 mg/40 mg/30 mg capsule	65991004100113	6 capsules	11 capsules[‡]	≥18 years
50 mg/325 mg/40 mg/30 mg capsule	65991004100115	6 capsules	11 capsules[‡]	≥18 years
Fiorinal w/Codeine (butalbital/aspirin/caffeine/codeine)[a]				
50 mg/325 mg/40 mg/30 mg capsule	65991004300115	6 capsules	11 capsules[‡]	≥18 years
Trezix, Acetaminophen/caffeine/dihydrocodeine				
320.5 mg/30 mg/16 mg capsule	65991303050115	10 capsules	12 capsules[‡]	≥18 years
325 mg/30 mg/16 mg tablet	65991303050320	10 tablets	12 tablets[‡]	≥18 years
Lortab, Norco, Hydrocodone/acetaminophen				
5 mg/300 mg tablet[a]	65991702100309	8 tablets	10 tablets[‡]	NA
5 mg/325 mg tablet[a]	65991702100356	8 tablets	10 tablets[‡]	NA
7.5 mg/300 mg tablet[a]	65991702100322	6 tablets	6 tablets[‡]	NA
7.5 mg/325 mg tablet[a]	65991702100358	6 tablets	6 tablets[‡]	NA
10 mg/300 mg tablet[a]	65991702100375	6 tablets	5 tablets[‡]	NA
10 mg/325 mg tablet[a]	65991702100305	6 tablets	5 tablets[‡]	NA
7.5 mg/325 mg/15 mL solution[a]	65991702102015	90 mL	100 mL[‡]	NA
10 mg/300 mg/15 mL solution	65991702102024	67.5 mL	74 mL[‡]	NA
Hydrocodone/Ibuprofen				
5 mg/200 mg tablet	65991702500315	5 tablets	10 tablets[‡]	NA
7.5 mg/200 mg tablet[a]	65991702500320	5 tablets	6 tablets[‡]	NA
10 mg/200 mg tablet[a]	65991702500330	5 tablets	5 tablets[‡]	NA
Percocet, Prolate, Oxycodone/acetaminophen, Nalocet, Primlev				
2.5 mg/300 mg tablet	65990002200303	12 tablets	13 tablets[‡]	NA
2.5 mg/325 mg tablet[a]	65990002200305	12 tablets	13 tablets[‡]	NA
5 mg/300 mg tablet	65990002200308	12 tablets	6 tablets[‡]	NA
5 mg/325 mg tablet[a]	65990002200310	12 tablets	6 tablets[‡]	NA

7.5 mg/300 mg tablet	65990002200325	8 tablets	4 tablets‡	NA
7.5 mg/325 mg tablet[a]	65990002200327	8 tablets	4 tablets‡	NA
10 mg/300 mg tablet	65990002200333	6 tablets	3 tablets‡	NA
10 mg/325 mg tablet[a]	65990002200335	6 tablets	3 tablets‡	NA
10 mg/300 mg/5 mL solution	65990002202020	30 mL	15 mL‡	NA
5 mg/325 mg/5 mL solution	65990002202005	60 mL	30 mL‡	NA
Oxycodone/Ibuprofen				
5 mg/400 mg tablet	65990002260320	4 tablets	6 tablets‡	NA
pentazocine/naloxone[a]				
50 mg/0.5 mg tablet	65200040300310	12 tablets	2 tablets‡	NA
Seglentis (celecoxib/tramadol)				
56 mg/44 mg tablet	65995002100320	4 tablets	13 tablets‡	≥18 years
Ultracet (tramadol/acetaminophen)[a]				
37.5 mg/325 mg tablet	65995002200320	8 tablets	7 tablets	≥18 years

a - generic available

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

* - product minimum dosage strength surpasses 50 MME

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

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

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

1. The request exceeds the 7 day supply limit and/or the 50 morphine milligram equivalent per day limit AND ALL of the following:
    A. If the requested agent contains acetaminophen, then the requested dose of acetaminophen does NOT exceed 4 g/day
    AND
    B. If the requested agent contains tramadol, dihydrocodeine, OR codeine, then ONE of the following:
        i. The patient is 12 to less than 18 years of age AND the requested agent will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy
        OR
        ii. The patient is 18 years of age or over
    AND
    C. ONE of the following:
        i. The requested quantity (dose) does NOT exceed the program daily quantity limit AND ONE of the following:
            a. There is information that the patient is NOT new to opioid therapy in the past 120 days
            OR
            b. The prescriber states the patient is NOT new to opioid therapy AND is at risk if therapy is changed
            OR
            c. The patient has a claim for an oncology agent in the past 120 days
            OR
            d. BOTH of the following:
                1. ONE of the following:
                    A. The patient has a diagnosis of chronic cancer pain due to an active malignancy
                    OR
                    B. The patient is eligible for hospice OR palliative care
                    OR
                    C. The patient has a diagnosis of sickle cell disease
                    OR
                    D. The patient is undergoing treatment of non-cancer pain and ALL of the following:

i. The prescriber has provided information in support of use of immediate-release single or combination opioids for an extended duration (>7 days) and/or greater than a 50 morphine milligram equivalents (MME) per day
AND
ii. A formal, consultative evaluation which includes BOTH of the following was conducted:
a. Diagnosis
AND
b. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy
AND
iii. A patient-specific pain management plan is on file for the patient
AND
iv. The prescriber has reviewed the patient's records in the state's prescribing drug monitoring program (PDMP) **AND** has determined that the opioid dosage and combinations within the patient's records do NOT indicate the patient is at high risk for overdose

AND

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

OR

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

AND

b. ONE of the following:
1. The patient has a diagnosis of chronic cancer pain due to an active malignancy
OR
2. The patient is eligible for hospice OR palliative care
OR
3. The patient has a diagnosis of sickle cell disease
OR
4. The patient is undergoing treatment of non-cancer pain and ALL of the following:
A. A formal, consultative evaluation which includes BOTH of the following was conducted:
i. Diagnosis
AND

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

AND

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

AND

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

AND

c. ONE of the following:

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

OR

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

AND

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

AND

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

OR

2. The request does NOT exceed the 7 day supply limit nor the 50 morphine milligram equivalent per day limit; but the requested dose exceeds the program quantity daily limit AND ALL of the following:

A. ONE of the following:

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

OR

ii. The patient is eligible for hospice OR palliative care

OR

iii. The patient has a diagnosis of sickle cell disease

OR

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

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

1. Diagnosis

AND

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

AND

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

AND

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

AND

B. ONE of the following:

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

OR

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

AND

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

AND

D. If the requested agent contains tramadol, dihydrocodeine, OR codeine, then ONE of the following:
   i. The patient is 12 to less than 18 years of age AND the requested agent will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy
   OR
   ii. The patient is 18 years of age or over

AND

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

1. OR

3. The request does NOT exceed the 7 day supply limit nor the 50 morphine milligram equivalent per day limit nor the program quantity daily limit AND the requested agent contains tramadol, dihydrocodeine, OR codeine, then ONE of the following:
   A. The patient is 12 to less than 18 years of age AND the requested agent will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy
   OR
   B. The patient is 18 years of age or over

Length of Approval: 6 months

• Program Summary: Parathyroid Hormone Analog for Osteoporosis

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

POLICY AGENT SUMMARY QUANTITY LIMIT

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

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy

• Program Summary: Proprotein Convertase Subtilisin/Kexin Type 9 (PCKK9)

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
3004407000D2	Forteo, Teriparatide	teriparatide (recombinant) soln pen-inj	600 MCG/2.4ML ; 620 MCG/2.48ML	1	Pen	28	DAYS				
3004400500D2	Tymlos	abaloparatide subcutaneous soln pen-injector	3120 MCG/1.56ML	1	Pen	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
FORTEO - brand non-preferred, generic preferred	**Effective 10/1/2024 for:** **Those who were approved through criteria after 10/1/2024** **Those who have started a new plan year since last authorization** **FORTEO** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is FORTEO generic equivalent AND ONE of the following: 1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. ALL of the following: 1. ONE of the following: A. The patient has a diagnosis of osteoporosis and BOTH of the following: 1. ONE of the following: A. The patient's sex is male and ONE of the following: 1. The patient's age is 50 years or over **OR** 2. The requested agent is medically appropriate for the patient's age and sex **OR** B. The patient's sex is female and ONE of the following: 1. The patient is postmenopausal **OR** 2. The requested agent is medically appropriate for the patient's sex and menopause status **AND** 2. ONE of the following: A. The requested agent is FORTEO generic equivalent **OR** B. The requested agent is brand FORTEO AND BOTH of the following: 1. ONE of the following: A. The patient has tried and had an inadequate response to the FORTEO generic equivalent **OR**

B. The patient has an intolerance or hypersensitivity to the FORTEO generic equivalent that is not expected to occur with the requested agent **OR**
C. The patient has an FDA labeled contraindication to the FORTEO generic equivalent that is not expected to occur with the requested agent **OR**
D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
    2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
    3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
E. The prescriber has provided documentation that the FORTEO 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**

2. ONE of the following:
    A. The patient has tried and had an inadequate response to Tymlos (abaloparatide) **OR**
    B. The patient has an intolerance or hypersensitivity to Tymlos (abaloparatide) **OR**
    C. The patient has an FDA labeled contraindication to Tymlos (abaloparatide) **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 Tymlos (abaloparatide) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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 glucocorticoid-induced osteoporosis and ALL of the following:
    1. The patient is either initiating or currently taking glucocorticoids in a daily dosage equivalent to 5 mg or higher of prednisone **AND**
    2. The patient's expected current course of therapy of glucocorticoids is for a period of at least 3 months **AND**
    3. ONE of the following:
        A. The requested agent is FORTEO generic equivalent **OR**
        B. The requested agent is brand FORTEO AND ONE of the following:
            1. The patient has tried and had an inadequate response to the FORTEO generic equivalent **OR**
            2. The patient has an intolerance or hypersensitivity to the FORTEO generic equivalent that is not expected to occur with the requested agent **OR**
            3. The patient has an FDA labeled contraindication to the FORTEO generic equivalent that is not expected to occur with the requested agent **OR**
            4. The patient is currently being treated with the requested agent as indicated by ALL of the following:
                A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
                B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
                C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
            5. The prescriber has provided documentation that the FORTEO 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**

2. The patient's diagnosis was confirmed by ONE of the following:
    A. A fragility fracture in the hip or spine **OR**
    B. A T-score of -2.5 or lower **OR**
    C. A T-score of -1.0 to -2.5 and ONE of the following:
        1. A fragility fracture of a proximal humerus, pelvis, or distal forearm **OR**
        2. A FRAX 10-year probability for major osteoporotic fracture of greater than or equal to 20% **OR**
        3. A FRAX 10-year probability of hip fracture of greater than or equal to 3% **AND**
3. ONE of the following:
    A. The patient is at a very high fracture risk as defined by ONE of the following:
        1. Patient had a recent fracture (within the past 12 months) **OR**
        2. Patient had fractures while on FDA labeled osteoporosis therapy **OR**
        3. Patient has had multiple fractures **OR**
        4. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) **OR**
        5. Patient has a very low T-score (less than -3.0) **OR**

	6. Patient is at high risk for falls or has a history of injurious falls **OR** 7. Patient has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm **OR** B. ONE of the following: 1. The patient has tried and had an inadequate response to a bisphosphonate (medical records required) **OR** 2. The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required) **OR** 3. The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required) **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation ALL bisphosphonates cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient will NOT be using the requested agent in combination with a bisphosphonate, denosumab (e.g., Prolia, Xgeva), romosozumab-aqqg or another parathyroid hormone analog for osteoporosis (e.g., abaloparatide) **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. ONE of the following: A. The total duration of treatment with parathyroid hormone analog(s) for osteoporosis has NOT exceeded 2 years in lifetime **OR** B. The total duration of treatment with parathyroid hormone analog(s) for osteoporosis has exceeded 2 years in lifetime AND the patient is at high risk of fracture (e.g., shown by T-score, FRAX score, continued use of glucocorticoids at a daily equivalent of 5 mg of prednisone or higher) **Length of approval:** For those who have not yet received a total of 2 years of treatment in their lifetime between FORTEO (teriparatide), Teriparatide, and Tymlos (abaloparatide), approve for up to the remainder of that 2 year therapy which has not yet been received. For those who have already received a total of 2 years of treatment in their lifetime between FORTEO (teriparatide) or Teriparatide AND is at high risk of fracture, approve for up to 1 year. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Forteo preferred	**Effective until 9/30/2025 for those with an original PA date prior to 10/1/2024 seeking reauthorization AND that have not started a new plan year** **Preferred Agent (Forteo)** will be approved when ALL of the following are met: 1. ONE of the following:

A. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**
B. The prescriber states that the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR**
C. The patient has a diagnosis of osteoporosis and ALL of the following:
    1. ONE of the following:
        A. The patient's sex is male and ONE of the following:
            1. The patient's age is 50 years or over **OR**
            2. The requested agent is medically appropriate for the patient's age and sex **OR**
        B. The patient's sex is female and ONE of the following:
            1. The patient is postmenopausal **OR**
            2. The requested agent is medically appropriate for the patient's sex and menopause status **AND**
    2. The patient's diagnosis was confirmed by ONE of the following:
        A. A fragility fracture in the hip or spine **OR**
        B. A T-score of -2.5 or lower **OR**
        C. A T-score of -1.0 to -2.5 and ONE of the following:
            1. A fragility fracture of a proximal humerus, pelvis, or distal forearm **OR**
            2. A FRAX 10-year probability for major osteoporotic fracture of greater than or equal to 20% **OR**
            3. A FRAX 10-year probability of hip fracture of greater than or equal to 3% **AND**
    3. ONE of the following:
        A. The patient is at a very high fracture risk as defined by ONE of the following:
            1. Patient had a recent fracture (within the past 12 months) **OR**
            2. Patient had fractures while on FDA approved osteoporosis therapy **OR**
            3. Patient has had multiple fractures **OR**
            4. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) **OR**
            5. Patient has a very low T-score (less than -3.0) **OR**
            6. Patient is at high risk for falls or has a history of injurious falls **OR**
            7. Patient has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm **OR**
        B. ONE of the following:
            1. The patient has tried and had an inadequate response to a bisphosphonate (medical records required) **OR**
            2. The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required) **OR**
            3. The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required) **OR**
            4. The patient is currently being treated with the requested agent as indicated by ALL of the following:
                A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
                B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
                C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
            5. The prescriber has provided documentation ALL bisphosphonates cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient

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

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

2. The patient will NOT be using the requested agent in combination with a bisphosphonate, denosumab (e.g., Prolia, Xgeva), romosozumab-aqqg or another parathyroid hormone analog (e.g., abaloparatide) **AND**
3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
4. ONE of the following:

	A. The patient has never received treatment with a parathyroid hormone analog (Teriparatide, Forteo, and Tymlos) **OR** B. The patient has been previously treated with parathyroid hormone analog(s) and ONE of the following: 1. The total duration of treatment with Forteo (teriparatide), Teriparatide, and Tymlos (abaloparatide) has NOT exceeded 2 years in lifetime **OR** 2. BOTH of the following: A. The patient has received 2 years or more of parathyroid hormone analog treatment in their lifetime, and is at high risk for fracture (e.g., shown by T-score, FRAX score, continued use of glucocorticoids at a daily equivalent of 5 mg of prednisone or higher) **AND** B. The patient was previously treated with Forteo **Length of approval:** up to a total of 2 years of treatment in lifetime between Forteo (teriparatide), Teriparatide, and Tymlos (abaloparatide). Approve for 1 year if patient has already had 2 years of Forteo (teriparatide) or Teriparatide in lifetime and is at high risk of fracture. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Teriparatide - non-preferred	**Effective 10/1/2024 for:** **Those who were approved through criteria after 10/1/2024** **Those who have started a new plan year since last authorization** **Teriparatide** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of osteoporosis and BOTH of the following: 1. ONE of the following: A. The patient's sex is male and ONE of the following: 1. The patient's age is 50 years or over **OR** 2. The requested agent is medically appropriate for the patient's age and sex **OR** B. The patient's sex is female and ONE of the following: 1. The patient is postmenopausal **OR** 2. The requested agent is medically appropriate for the patient's sex and menopause status **AND** 2. BOTH of the following: A. ONE of the following: 1. The patient has tried and had an inadequate response to the FORTEO generic equivalent **OR** 2. The patient has an intolerance or hypersensitivity to the FORTEO generic equivalent that is not expected to occur with the requested agent **OR** 3. The patient has an FDA labeled contraindication to the FORTEO generic equivalent that is not expected to occur with the requested agent **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that the FORTEO 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**

B. ONE of the following:
1. The patient has tried and had an inadequate response to Tymlos (abaloparatide) **OR**
2. The patient has an intolerance or hypersensitivity to Tymlos (abaloparatide) **OR**
3. The patient has an FDA labeled contraindication to Tymlos (abaloparatide) **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 Tymlos (abaloparatide) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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 glucocorticoid-induced osteoporosis and ALL of the following:
1. The patient is either initiating or currently taking glucocorticoids in a daily dosage equivalent to 5 mg or higher of prednisone **AND**
2. The patient's expected current course of therapy of glucocorticoids is for a period of at least 3 months **AND**
3. ONE of the following:
   A. The patient has tried and had an inadequate response to the FORTEO generic equivalent **OR**
   B. The patient has an intolerance or hypersensitivity to the FORTEO generic equivalent that is not expected to occur with the requested agent **OR**
   C. The patient has an FDA labeled contraindication to the FORTEO generic equivalent that is not expected to occur with the requested agent **OR**
   D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
      2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
      3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
   E. The prescriber has provided documentation that the FORTEO 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**

2. The patient's diagnosis was confirmed by ONE of the following:
   A. A fragility fracture in the hip or spine **OR**
   B. A T-score of -2.5 or lower **OR**
   C. A T-score of -1.0 to -2.5 and ONE of the following:

1. A fragility fracture of a proximal humerus, pelvis, or distal forearm **OR**
2. A FRAX 10-year probability for major osteoporotic fracture of greater than or equal to 20% **OR**
3. A FRAX 10-year probability of hip fracture of greater than or equal to 3% **AND**

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

Length of approval:

For those who have not yet received a total of 2 years of treatment in their lifetime between FORTEO (teriparatide), Teriparatide, and Tymlos (abaloparatide), approve for up to the remainder of that 2 year therapy which has not yet been received.

	For those who have already received a total of 2 years of treatment in their lifetime between FORTEO (teriparatide) or Teriparatide AND is at high risk of fracture, approve for up to 1 year. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Teriparatide through preferred	**Effective until 9/30/2025 for those with an original PA date prior to 10/1/2024 seeking reauthorization AND that have not started a new plan year** **Non-Preferred Agent(s) Teriparatide** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** B. The prescriber states that the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** C. The patient has a diagnosis of osteoporosis AND ALL of the following: 1. ONE of the following: A. The patient's sex is male and ONE of the following: 1. The patient's age is 50 years or over **OR** 2. The requested agent is medically appropriate for the patient's age and sex **OR** B. The patient's sex is female and ONE of the following: 1. The patient is postmenopausal **OR** 2. The requested agent is medically appropriate for the patient's sex and menopause status **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to BOTH of the preferred agents (Forteo AND Tymlos) **OR** B. The patient has an intolerance or hypersensitivity to BOTH of the preferred agents (Forteo AND Tymlos) that is not expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to BOTH of the preferred agent (Forteo AND Tymlos) that is not expected to occur with the requested agent **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation BOTH Forteo AND Tymlos cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The patient's diagnosis was confirmed by ONE of the following: A. A fragility fracture in the hip or spine **OR** B. A T-score of -2.5 or lower **OR** C. A T-score of -1.0 to -2.5 and ONE of the following: 1. A fragility fracture of a proximal humerus, pelvis, or distal forearm **OR** 2. A FRAX 10-year probability for major osteoporotic fracture of greater than or equal to 20% **OR**

3. A FRAX 10-year probability of hip fracture of greater than or equal to 3% **AND**

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

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

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

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

2. The patient will NOT be using the requested agent in combination with a bisphosphonate, denosumab (e.g., Prolia, Xgeva), romosozumab-aqqg or another parathyroid hormone analog (e.g., abaloparatide) **AND**
3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
4. ONE of the following:
    A. The patient has never received treatment with a parathyroid hormone analog (Teriparatide, Forteo, and Tymlos) **OR**

	B. The patient has been previously treated with parathyroid hormone analog(s) AND the total duration of treatment with Forteo (teriparatide), Teriparatide, and Tymlos (abaloparatide) has NOT exceeded 2 years in lifetime **Length of approval:** up to a total of 2 years of treatment in lifetime between Forteo (teriparatide), Teriparatide, and Tymlos (abaloparatide). Approve for 1 year if patient has already had 2 years of Forteo (teriparatide) or Teriparatide in lifetime and is at high risk of fracture. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Tymlos - preferred	**Tymlos** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** B. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** C. The patient has a diagnosis of osteoporosis AND ALL of the following: 1. ONE of the following: A. The patient's sex is male and ONE of the following: 1. The patient's age is 50 years or over **OR** 2. The requested agent is medically appropriate for the patient's age and sex **OR** B. The patient's sex is female and ONE of the following: 1. The patient is postmenopausal **OR** 2. The requested agent is medically appropriate for the patient's sex and menopause status **AND** 2. The patient's diagnosis was confirmed by ONE of the following: A. A fragility fracture in the hip or spine **OR** B. A T-score of -2.5 or lower **OR** C. A T-score of -1.0 to -2.5 and ONE of the following: 1. A fragility fracture of a proximal humerus, pelvis, or distal forearm **OR** 2. A FRAX 10-year probability for major osteoporotic fracture of greater than or equal to 20% **OR** 3. A FRAX 10-year probability of hip fracture of greater than or equal to 3% **AND** 3. ONE of the following: A. The patient is at a very high fracture risk as defined by ONE of the following: 1. Patient had a recent fracture (within the past 12 months) **OR** 2. Patient had fractures while on FDA labeled osteoporosis therapy **OR** 3. Patient has had multiple fractures **OR** 4. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) **OR** 5. Patient has a very low T-score (less than -3.0) **OR** 6. Patient is at high risk for falls or has a history of injurious falls **OR** 7. Patient has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm **OR** B. ONE of the following: 1. The patient has tried and had an inadequate response to a bisphosphonate (medical records required) **OR** 2. The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required) **OR** 3. The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required) **OR**

	4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL bisphosphonates cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient will NOT be using the requested agent in combination with a bisphosphonate, denosumab (e.g., Prolia, Xgeva), romosozumab-aqqg, or another parathyroid hormone analog (e.g., teriparatide) therapy **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. The total duration of treatment with FORTEO (teriparatide), Teriparatide, and Tymlos (abaloparatide) has NOT exceeded 2 years in lifetime **Length of approval:** up to the remainder of a total of 2 years of treatment in lifetime between FORTEO (teriparatide), Teriparatide, and Tymlos (abaloparatide). NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Proton Pump Inhibitors (PPIs)

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

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

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

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

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

This program is a GenRx Standard and FlexRx Standard program.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

Quantity limit applies to FlexRx Closed, FlexRx Open, FocusRx, GenRx Closed, GenRx Open, Health Insurance Marketplace, and KeyRx.

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
492700600065		omeprazole cap delayed release	10 MG ; 20 MG ; 40 MG	60	Capsules	30	DAYS				
492700761068		rabeprazole sodium capsule sprinkle dr	10 MG	30	Capsules	30	DAYS				
492700761006	Aciphex	rabeprazole sodium ec tab	20 MG	60	Tablets	30	DAYS				
492700251065	Cvs esomeprazole magnesiu ; Eq esomeprazole magnesium ; Ft acid reducer ; Gnp esomeprazole magnesiu ; Goodsense esomeprazole ma ; Hm esomeprazole magnesium ; Kls esomeprazole magnesiu ; Nexium ; Nexium 24hr ; Nexium 24hr clear minis ; Qc esomeprazole magnesium ; Ra esomeprazole magnesium ; Sm esomeprazole magnesium	esomeprazole magnesium cap delayed release	20 MG ; 40 MG	60	Capsules	30	DAYS				
492700400065	Cvs lansoprazole ; Eq lansoprazole ; Eql lansoprazole ; Ft acid reducer ; Gnp lansoprazole ; Goodsense lansoprazole ; Hm lansoprazole ; Kls lansoprazole ; Prevacid ; Prevacid 24hr ; Qc lansoprazole ; Sm lansoprazole	lansoprazole cap delayed release	15 MG ; 30 MG	60	Capsules	30	DAYS				
4927004000H3	Cvs lansoprazole ; Goodsense lansoprazole ; Prevacid solutab	lansoprazole tab delayed release orally disintegrating	15 MG ; 30 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
499960026001	Cvs omeprazole/sodium bic ; Goodsense omeprazole/sodi ; Zegerid	omeprazole-sodium bicarbonate cap	20-1100 MG ; 40-1100 MG	60	Capsules	30	DAYS				
492700200065	Dexilant	dexlansoprazole cap delayed release	30 MG ; 60 MG	60	Capsules	30	DAYS				
499960026019	Konvomep	omeprazole-sodium bicarbonate for oral susp	2-84 MG/ML	600	mLs	30	DAYS				
49270025103004	Nexium	Esomeprazole Magnesium For Delayed Release Susp Pack 2.5 MG	2.5 MG	30	Packets	30	DAYS				
49270025103010		Esomeprazole Magnesium For Delayed Release Susp Packet 10 MG	10 MG	60	Packets	30	DAYS				
49270025103020	Nexium	Esomeprazole Magnesium For Delayed Release Susp Packet 20 MG		60	Packets	30	DAYS				
49270025103040	Nexium	Esomeprazole Magnesium For Delayed Release Susp Packet 40 MG	40 MG	60	Packets	30	DAYS				
49270025103007	Nexium	Esomeprazole Magnesium For Delayed Release Susp Packet 5 MG	5 MG	30	Packets	30	DAYS				
49270060103030	Prilosec	Omeprazole Magnesium For Delayed Release Susp Packet 10 MG	10 MG	30	Packets	30	DAYS				
49270060103020	Prilosec	Omeprazole Magnesium For Delayed Release Susp Packet 2.5 MG	2.5 MG	60	Packets	30	DAYS				
492700701006	Protonix	pantoprazole sodium ec tab	20 MG ; 40 MG	60	Tablets	30	DAYS				
492700701030	Protonix	pantoprazole sodium for delayed release susp packet	40 MG	60	Packets	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
492750871003	Voquezna	vonoprazan fumarate tab	10 MG ; 20 MG	30	Tablets	30	DAYS				
499960026030	Zegerid	omeprazole-sodium bicarbonate powd pack for susp	20-1680 MG ; 40-1680 MG	60	Packets	30	DAYS				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

TARGET AGENT(S)*	PREREQUISITE AGENT(S)
Aciphex (rabeprazole) **Dexilant** (dexlansoprazole) **Dexlansoprazole** **Esomeprazole Strontium** **Konvomep™** (Omeprazole/sodium bicarbonate) **Nexium** (esomeprazole) **Prevacid** (lansoprazole) **Prevacid SoluTab™** (lansoprazole) **Prilosec** (omeprazole) **Protonix** (pantoprazole) **Rabeprazole Sprinkle** **Voquezna** (vonoprazan) **Zegerid** (omeprazole/sodium bicarbonate)	Any generic proton pump inhibitor EXCEPT omeprazole/sodium bicarbonate

* - see formulary specific information

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

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

Length of Approval: 12 months

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

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The patient has ONE of the following: A. A diagnosis of a hypersecretory disease (i.e., Zollinger-Ellison Syndrome, Barrett's esophagitis, or esophageal stricture) **OR** B. Inadequate response to FDA labeled dosing with the requested agent **OR** C. A diagnosis of H pylori **OR** 3. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months • Hypersecretory disease (i.e., Zollinger-Ellison Syndrome, Barrett's esophagitis, or esophageal stricture) - up to 12 months • Inadequate response to FDA labeled dosing - up to 12 months H. pylori treatment - one time

• Program Summary: Saxenda Wegovy Zepbound

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

Saxenda Wegovy Zepbound Coverage Exception and Formulary Exception with Quantity Limit
Target Agent(s)
Saxenda® (liraglutide)
Wegovy™ (semaglutide)
Zepbound™ (tirzepatide)

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
Saxenda (liraglutide)			
6 mg/mL, 3 mL/pen	6125205000D220	M, N, O, or Y	0.5 mL
Wegovy (semaglutide)			
0.25 mg/0.5 mL pen*	6125207000D520	M, N, O, or Y	8 pens (4 mL)/180 days
0.5 mg/0.5 mL pen*	6125207000D525	M, N, O, or Y	8 pens (4 mL)/180 days

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
1 mg/0.5 mL pen*	6125207000D530	M, N, O, or Y	8 pens (4 mL)/180 days
1.7 mg/0.75 mL pen	6125207000D535	M, N, O, or Y	4 pens (3 mL)/28 days
2.4 mg/0.75 mL pen	6125207000D540	M, N, O, or Y	4 pens (3 mL)/28 days
Zepbound (tirzepatide)			
2.5 mg/0.5 mL pen*	6125258000D520	M, N, O, or Y	4 pens (2 mL)/180 days
5 mg/0.5 mL pen	6125258000D525	M, N, O, or Y	4 pens (2 mL)/28 days
7.5 mg/0.5 mL pen	6125258000D530	M, N, O, or Y	4 pens (2 mL)/28 days
10 mg/0.5 mL pen	6125258000D535	M, N, O, or Y	4 pens (2 mL)/28 days
12.5 mg/0.5 mL pen	6125258000D540	M, N, O, or Y	4 pens (2 mL)/28 days
15 mg/0.5 mL pen	6125258000D545	M, N, O, or Y	4 pens (2 mL)/28 days

* - These strengths are not approvable for maintenance dosing

COVERAGE EXCEPTION AND FORMULARY EXCEPTION CRITERIA FOR APPROVAL

Initial Evaluation

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

1. ALL of the following:
    A. ONE of the following:
        i. The requested use is to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease (medical records required) and the patient is either obese or overweight AND ALL of the following:
            a. The requested agent is FDA labeled for the requested indication and route of administration **AND**
            b. The patient has a history of ONE of the following: (medical records required)
                1. Myocardial infarction **OR**
                2. Stroke **OR**
                3. Peripheral artery disease as defined by intermittent claudication with ankle-brachial index less than 0.85 at rest, or peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease **AND**
            c. The patient has a BMI greater than or equal to 27 kg/m^2 **AND**
            d. The patient does NOT have type 2 diabetes **AND**
            e. The patient's age is 45 years or over **AND**
            f. ONE of the following:
                1. The patient does not currently use any tobacco products (e.g., cigarettes, chewing tobacco) **OR**
                2. The patient is being managed for tobacco cessation **AND**
            g. ALL of the following:
                1. The patient is currently being treated in the past 90 days with antihypertensive therapy (e.g., ACE inhibitor, angiotensin receptor blocker, beta blocker) **AND**
                2. The patient is currently being treated in the past 90 days with lipid lowering therapy (e.g., any statin, ezetimibe) **AND**
                3. The patient will continue antihypertensive therapy (e.g., ACE inhibitor, angiotensin receptor blocker, beta blocker) AND lipid lowering therapy (e.g., any statin, ezetimibe) in combination with the requested agent **AND**
            h. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **OR**
        ii. The patient is overweight or obese and is using the requested agent for weight management AND ALL of the following:
            a. Weight loss is NOT excluded from coverage under the patient's pharmacy benefit **AND**

b. The patient is new to therapy, new to Prime, or attempting a repeat weight loss course of therapy **AND**
c. ONE of the following:
    1. The patient is 17 years of age or over and has ONE of the following:
        A. A BMI greater than or equal to 30 kg/m^2 **OR**
        B. A BMI greater than or equal to 25 kg/m^2 if the patient is of South Asian, Southeast Asian, or East Asian descent **OR**
        C. A BMI greater than or equal to 27 kg/m^2 with at least one weight-related comorbidity/risk factor/complication (e.g., hypertension, type 2 diabetes mellitus, obstructive sleep apnea, cardiovascular disease, dyslipidemia) **OR**
    2. The patient is 12 to 16 years of age and has ONE of the following:
        A. A BMI greater than or equal to 95th percentile for age and sex **OR**
        B. A BMI greater than or equal to 30 kg/m^2 **OR**
        C. A BMI greater than or equal to 85th percentile for age and sex AND at least one severe weight-related comorbidity/risk factor/complication **AND**
d. BOTH of the following:
    1. The patient has been on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications for a minimum of 6 months **AND**
    2. The patient has experienced weight loss of less than 1 pound per week while on a weight loss regimen from baseline (e.g., low-calorie diet, increased physical activity, and behavioral modifications) prior to any pharmacotherapy **AND**
e. ONE of the following:
    1. The patient has not tried a targeted weight loss agent in the past 12 months **OR**
    2. BOTH of the following:
        A. The patient has tried a targeted weight loss agent for a previous course of therapy in the past 12 months **AND**
        B. The prescriber anticipates success with repeating therapy with any targeted weight loss agent **AND**
f. If the requested agent is Saxenda, then ONE of the following:
    1. The patient is 18 years of age or over AND ONE of the following:
        A. The patient is newly starting therapy **OR**
        B. The patient is currently being treated and has received less than 16 weeks (4 months) of therapy **OR**
        C. The patient has achieved and maintained a weight loss of greater than or equal to 4% from baseline (prior to initiation of pharmacotherapy) **OR**
    2. The patient is pediatric (12 to less than 18 years of age) AND BOTH of the following:
        A. The requested agent is NOT being used to treat type 2 diabetes **AND**
        B. ONE of the following:
            i. The patient is newly starting therapy **OR**
            ii. The patient is currently being treated and has received less than 20 weeks (5 months) of therapy **OR**
            iii. The patient has achieved and maintained a reduction in BMI of greater than or equal to 1% from baseline (prior to initiation of pharmacotherapy) **AND**
g. If the requested agent is Wegovy, then ONE of the following:
    1. The patient is newly starting therapy **OR**
    2. The patient is currently being treated and has received less than 52 weeks (1 year) of therapy **OR**
    3. ONE of the following:
        A. The patient is an adult AND has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR**
        B. The patient is pediatric (12 to less than 18 years of age) AND has achieved and maintained a reduction in BMI of at least 5% from baseline (prior to initiation of pharmacotherapy) **AND**

h. If the requested agent is Zepbound, then ONE of the following:
1. The patient is newly starting therapy **OR**
2. The patient is currently being treated and has received less than 52 weeks (1 year) of therapy **OR**
3. The patient has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR**

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

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

C. BOTH of the following:
i. The patient is currently on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **AND**
ii. The patient will continue the weight loss regimen in combination with the requested agent **AND**

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

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

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

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

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

ii. BOTH of the following:
a. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**
b. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR**

iii. BOTH of the following:
a. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND**
b. There is support for therapy with a higher dose for the requested indication

Length of Approval:

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

Renewal Evaluation

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

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**
2. ALL of the following:
A. ONE of the following:

i. The requested use is to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease (medical records required) and the patient is either obese or overweight AND ALL of the following:
    a. The requested agent is FDA labeled for the requested diagnosis and route of administration **AND**
    b. The patient has a history of ONE of the following: (medical records required)
        1. Myocardial infarction **OR**
        2. Stroke **OR**
        3. Peripheral artery disease as defined by intermittent claudication with ankle-brachial index less than 0.85 at rest, or peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease **AND**
    c. The patient does NOT have type 2 diabetes **AND**
    d. ONE of the following:
        1. The patient does not currently use any tobacco products (e.g., cigarettes, chewing tobacco) **OR**
        2. The patient is being managed for tobacco cessation **AND**
    e. BOTH of the following:
        1. The patient is currently being treated in the past 90 days with antihypertensive therapy (e.g., ACE inhibitor, angiotensin receptor blocker, beta blocker) and/or lipid lowering therapy (e.g., any statin, ezetimibe) **AND**
        2. The patient will continue antihypertensive therapy (e.g., ACE inhibitor, angiotensin receptor blocker, beta blocker) and/or lipid lowering therapy (e.g., any statin, ezetimibe) **AND**
    f. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
    g. The patient has had clinical benefit with the requested agent **OR**

ii. The patient is overweight or obese and is using the requested agent for weight management AND ALL of the following:
    a. Weight loss is NOT excluded from coverage under the patient's pharmacy benefit **AND**
    b. The patient is continuing a current weight loss course of therapy **AND**
    c. If the patient is 12 to less than 18 years of age, then the current BMI is greater than 85th percentile for age and sex **AND**
    d. If the requested agent is Saxenda, then BOTH of the following:
        1. The requested agent is NOT being used to treat type 2 diabetes **AND**
        2. ONE of the following:
            A. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR**
            B. The patient is 18 years of age or over AND the patient has achieved and maintained a weight loss greater than or equal to 4% from baseline (prior to initiation of pharmacotherapy) **OR**
            C. The patient is pediatric (12 to less than 18 years of age) AND the patient has achieved and maintained a reduction in BMI of greater than or equal to 1% from baseline (prior to initiation of pharmacotherapy) **AND**
    e. If the requested agent is Wegovy, then BOTH of the following:
        1. The requested dose is 1.7 mg or 2.4 mg **AND**
        2. ONE of the following:
            A. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR**
            B. The patient is 12 years of age and over AND has received less than 52 weeks of therapy on the maximum-tolerated dose **OR**
            C. The patient is pediatric (12 to less than 18 years of age) AND has achieved and maintained a reduction in BMI of at least 5% from baseline (prior to initiation of pharmacotherapy) **AND**
    f. If the requested agent is Zepbound, then ONE of the following:

1. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR**
2. The patient has received less than 52 weeks of therapy on the maximum-tolerated dose **OR**

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

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

C. BOTH of the following:

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

ii. The patient will continue the weight loss regimen in combination with the requested agent **AND**

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

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

3. ONE of the following:

A. The patient has tried and failed at least three (or as many as available, if fewer than three) formulary alternatives **OR**

B. The prescriber has indicated that available formulary alternatives are contraindicated, likely to be less effective, or likely to cause an adverse reaction or other harm **AND**

4. ONE of the following:

A. The requested quantity (dose) does NOT exceed the program quantity limit **OR**

B. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following:

i. BOTH of the following:

a. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND**

b. There is support for therapy with a higher dose for the requested indication **OR**

ii. BOTH of the following:

a. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**

b. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR**

iii. BOTH of the following:

a. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND**

b. There is support for therapy with a higher dose for the requested indication

Length of Approval: 12 months

• Program Summary: Self-Administered Oncology Agents

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
215315501001				6	Capsules	21	DAYS				
21406010200310		Abiraterone Acetate Tab 125 MG		120	Tablets	30	DAYS				
2156006000B730		Selinexor Tab Therapy Pack 20 MG (100 MG Once Weekly)		20	Tablets	28	DAYS				

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
2156006000B712		Selinexor Tab Therapy Pack 20 MG (40 MG Once Weekly)		8	Tablets	28	DAYS				
2156006000B715		Selinexor Tab Therapy Pack 20 MG (40 MG Twice Weekly)		16	Tablets	28	DAYS				
2156006000B750		Selinexor Tab Therapy Pack 20 MG (60 MG Once Weekly)		12	Tablets	28	DAYS				
2156006000B740		Selinexor Tab Therapy Pack 20 MG (80 MG Once Weekly)		16	Tablets	28	DAYS				
215325300003	Afinitor ; Torpenz	everolimus tab	10 MG ; 2.5 MG ; 5 MG ; 7.5 MG	30	Tablets	30	DAYS				
21532530007310	Afinitor disperz	Everolimus Tab for Oral Susp 2 MG	2 MG	60	Tablets	30	DAYS				
21532530007320	Afinitor disperz	Everolimus Tab for Oral Susp 3 MG	3 MG	90	Tablets	30	DAYS				
21532530007340	Afinitor disperz	Everolimus Tab for Oral Susp 5 MG	5 MG	60	Tablets	30	DAYS				
21409902120320	Akeega	niraparib tosylate-abiraterone acetate tab	50-500 MG	60	Tablets	30	DAYS				
21409902120330	Akeega	niraparib tosylate-abiraterone acetate tab	100-500 MG	60	Tablets	30	DAYS				
215305071001	Alecensa	alectinib hcl cap	150 MG	240	Capsules	30	DAYS				
21530510000330	Alunbrig	Brigatinib Tab	30 MG	120	Tablets	30	DAYS				
21530510000350	Alunbrig	Brigatinib Tab	90 MG	30	Tablets	30	DAYS				
21530510000365	Alunbrig	Brigatinib Tab	180 MG	30	Tablets	30	DAYS				
2153051000B720	Alunbrig	Brigatinib Tab Initiation Therapy Pack	90 & 180 MG	30	Tablets	180	DAYS				
21533865000120	Augtyro	repotrectinib cap	40 MG	240	Capsules	30	DAYS				
214900090003	Ayvakit	avapritinib tab	100 MG ; 200 MG ; 25 MG ; 300 MG ; 50 MG	30	Tablets	30	DAYS				
21532225000325	Balversa	erdafitinib tab	4 MG	60	Tablets	30	DAYS				
21532225000320	Balversa	Erdafitinib Tab 3 MG	3 MG	90	Tablets	30	DAYS				
21532225000330	Balversa	Erdafitinib Tab 5 MG	5 MG	30	Tablets	30	DAYS				
2170007750E520	Besremi	Ropeginterferon alfa-	500 MCG/ML	2	Syringes	28	DAYS				
21531812000120	Bosulif	bosutinib cap	50 MG	30	Capsules	30	DAYS				
21531812000130	Bosulif	bosutinib cap	100 MG	150	Capsules	30	DAYS				
21531812000320	Bosulif	Bosutinib Tab	100 MG	90	Tablets	30	DAYS				
21531812000327	Bosulif	Bosutinib Tab	400 MG	30	Tablets	30	DAYS				

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
21531812000340	Bosulif	Bosutinib Tab	500 MG	30	Tablets	30	DAYS				
215320400001	Braftovi	encorafenib cap	75 MG	180	Capsules	30	DAYS				
21532195000120	Brukinsa	zanubrutinib cap	80 MG	120	Capsules	30	DAYS				
21533010100320	Cabometyx	Cabozantinib S-Malate Tab	20 MG	30	Tablets	30	DAYS				
21533010100330	Cabometyx	Cabozantinib S-Malate Tab	40 MG	30	Tablets	30	DAYS				
21533010100340	Cabometyx	Cabozantinib S-Malate Tab	60 MG	30	Tablets	30	DAYS				
215321030001	Calquence	acalabrutinib cap	100 MG	60	Capsules	30	DAYS				
215321035003	Calquence	acalabrutinib maleate tab	100 MG	60	Tablets	30	DAYS				
21533085000320	Caprelsa	Vandetanib Tab	100 MG	60	Tablets	30	DAYS				
21533085000340	Caprelsa	Vandetanib Tab	300 MG	30	Tablets	30	DAYS				
21533010106470	Cometriq	Cabozantinib S-Mal Cap	80 & 20 MG	1	Carton	28	DAYS				
21533010106480	Cometriq	Cabozantinib S-Mal Cap	3 x 20 MG & 80 MG	1	Carton	28	DAYS				
21533010106460	Cometriq	Cabozantinib S-Malate Cap	20 MG	1	Carton	28	DAYS				
215380300001	Copiktra	duvelisib cap	15 MG ; 25 MG	56	Capsules	28	DAYS				
215335302003	Cotellic	cobimetinib fumarate tab	20 MG	63	Tablets	28	DAYS				
21370030300335	Daurismo	Glasdegib Maleate Tab 100 MG (Base Equivalent)	100 MG	30	Tablets	30	DAYS				
21370030300320	Daurismo	Glasdegib Maleate Tab 25 MG (Base Equivalent)	25 MG	60	Tablets	30	DAYS				
21370070000120	Erivedge	Vismodegib Cap 150 MG	150 MG	30	Capsules	30	DAYS				
21402410000360	Erleada	apalutamide tab	240 MG	30	Tablets	30	DAYS				
21402410000320	Erleada	Apalutamide Tab 60 MG	60 MG	120	Tablets	30	DAYS				
21533076250120	Fotivda	Tivozanib HCl Cap	0.89 MG	21	Capsules	28	DAYS				
21533076250130	Fotivda	Tivozanib HCl Cap	1.34 MG	21	Capsules	28	DAYS				
21335035000120	Fruzaqla	fruquintinib cap	1 MG	84	Capsules	28	DAYS				
21335035000140	Fruzaqla	fruquintinib cap	5 MG	21	Capsules	28	DAYS				
215357500001	Gavreto	pralsetinib cap	100 MG	120	Capsules	30	DAYS				
213600061003	Gilotrif	afatinib dimaleate tab	20 MG ; 30 MG ; 40 MG	30	Tablets	30	DAYS				
21531835100320	Gleevec	Imatinib Mesylate Tab	100 MG	90	Tablets	30	DAYS				
21531835100340	Gleevec	Imatinib Mesylate Tab	400 MG	60	Tablets	30	DAYS				

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
21531060000130	Ibrance	Palbociclib Cap 100 MG	100 MG	21	Capsules	28	DAYS				
21531060000140	Ibrance	Palbociclib Cap 125 MG	125 MG	21	Capsules	28	DAYS				
21531060000120	Ibrance	Palbociclib Cap 75 MG	75 MG	21	Capsules	28	DAYS				
21531060000330	Ibrance	Palbociclib Tab 100 MG	100 MG	21	Tablets	28	DAYS				
21531060000340	Ibrance	Palbociclib Tab 125 MG	125 MG	21	Tablets	28	DAYS				
21531060000320	Ibrance	Palbociclib Tab 75 MG	75 MG	21	Tablets	28	DAYS				
21531875100315	Iclusig	Ponatinib HCl Tab	10 MG	30	Tablets	30	DAYS				
21531875100320	Iclusig	Ponatinib HCl Tab	15 MG	30	Tablets	30	DAYS				
21531875100330	Iclusig	Ponatinib HCl Tab	30 MG	30	Tablets	30	DAYS				
21531875100340	Iclusig	Ponatinib HCl Tab	45 MG	30	Tablets	30	DAYS				
21535030200340	Idhifa	Enasidenib Mesylate Tab 100 MG (Base Equivalent)	100 MG	30	Tablets	30	DAYS				
21535030200320	Idhifa	Enasidenib Mesylate Tab 50 MG (Base Equivalent)	50 MG	30	Tablets	30	DAYS				
21532133000110	Imbruvica	Ibrutinib Cap	70 MG	30	Capsules	30	DAYS				
21532133000120	Imbruvica	ibrutinib cap	140 MG	90	Capsules	30	DAYS				
21532133001820	Imbruvica	Ibrutinib Oral Susp	70 MG/ML	216	mLs	30	DAYS				
215321330003	Imbruvica	ibrutinib tab	140 MG ; 280 MG ; 420 MG ; 560 MG	30	Tablets	30	DAYS				
21335013000320	Inlyta	Axitinib Tab	1 MG	180	Tablets	30	DAYS				
21335013000340	Inlyta	Axitinib Tab	5 MG	120	Tablets	30	DAYS				
219900022503	Inqovi	decitabine-cedazuridine tab	35-100 MG	5	Tablets	28	DAYS				
21537520200120	Inrebic	Fedratinib HCl Cap 100 MG	100 MG	120	Capsules	30	DAYS				
213600300003	Iressa	gefitinib tab	250 MG	30	Tablets	30	DAYS				
21757220300320	Iwilfin	eflornithine hcl tab	192 MG	240	Tablets	30	DAYS				
215375602003	Jakafi	ruxolitinib phosphate tab	10 MG ; 15 MG ; 20 MG ; 25 MG ; 5 MG	60	Tablets	30	DAYS				
21532165000320	Jaypirca	pirtobrutinib tab	50 MG	30	Tablets	30	DAYS				
21532165000330	Jaypirca	pirtobrutinib tab	100 MG	60	Tablets	30	DAYS				
2153107050B720	Kisqali	Ribociclib Succinate Tab Pack 200 MG Daily Dose	200 MG	21	Tablets	28	DAYS				
2153107050B740	Kisqali	Ribociclib Succinate Tab Pack 400 MG Daily Dose (200 MG Tab)	200 MG	42	Tablets	28	DAYS				

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
2153107050B760	Kisqali	Ribociclib Succinate Tab Pack 600 MG Daily Dose (200 MG Tab)	200 MG	63	Tablets	28	DAYS				
2199000260B730	Kisqali femara 200 dose	Ribociclib 200 MG Dose (200 MG Tab) & Letrozole 2.5 MG TBPK	200 & 2.5 MG	49	Tablets	28	DAYS				
2199000260B740	Kisqali femara 400 dose	Ribociclib 400 MG Dose (200 MG Tab) & Letrozole 2.5 MG TBPK	200 & 2.5 MG	70	Tablets	28	DAYS				
2199000260B760	Kisqali femara 600 dose	Ribociclib 600 MG Dose (200 MG Tab) & Letrozole 2.5 MG TBPK	200 & 2.5 MG	91	Tablets	28	DAYS				
21533565500110	Koselugo	Selumetinib Sulfate Cap 10 MG	10 MG	240	Capsules	30	DAYS				
21533565500125	Koselugo	Selumetinib Sulfate Cap 25 MG	25 MG	120	Capsules	30	DAYS				
21532410000320	Krazati	Adagrasib Tab	200 MG	180	Tablets	30	DAYS				
2133505420B220	Lenvima 10 mg daily dose	Lenvatinib Cap Therapy Pack	10 MG	30	Capsules	30	DAYS				
2133505420B223	Lenvima 12mg daily dose	Lenvatinib Cap Therapy Pack	4 MG	90	Capsules	30	DAYS				
2133505420B240	Lenvima 14 mg daily dose	Lenvatinib Cap Therapy Pack	10 & 4 MG	60	Capsules	30	DAYS				
2133505420B244	Lenvima 18 mg daily dose	Lenvatinib Cap Ther Pack	10 MG & 2 x 4 MG	90	Capsules	30	DAYS				
2133505420B230	Lenvima 20 mg daily dose	Lenvatinib Cap Therapy Pack	10 MG	60	Capsules	30	DAYS				
2133505420B250	Lenvima 24 mg daily dose	Lenvatinib Cap Ther Pack	2 x 10 MG & 4 MG	90	Capsules	30	DAYS				
2133505420B210	Lenvima 4 mg daily dose	Lenvatinib Cap Therapy Pack	4 MG	30	Capsules	30	DAYS				
2133505420B215	Lenvima 8 mg daily dose	Lenvatinib Cap Therapy Pack	4 MG	60	Capsules	30	DAYS				
21990002750320	Lonsurf	Trifluridine-Tipiracil Tab 15-6.14 MG	15-6.14 MG	60	Tablets	28	DAYS				
21990002750330	Lonsurf	Trifluridine-Tipiracil Tab 20-8.19 MG	20-8.19 MG	80	Tablets	28	DAYS				
21530556000320	Lorbrena	Lorlatinib Tab	25 MG	90	Tablets	30	DAYS				
21530556000330	Lorbrena	Lorlatinib Tab	100 MG	30	Tablets	30	DAYS				
21532480000340	Lumakras	sotorasib tab	320 MG	90	Tablets	30	DAYS				
21532480000320	Lumakras	Sotorasib Tab	120 MG	240	Tablets	30	DAYS				
215355600003	Lynparza	olaparib tab	100 MG ; 150 MG	120	Tablets	30	DAYS				
2153222800B720	Lytgobi	Futibatinib Tab Therapy Pack	4 MG	84	Tablets	28	DAYS				
2153222800B725	Lytgobi	Futibatinib Tab Therapy Pack	4 MG	112	Tablets	28	DAYS				

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2153222800B730	Lytgobi	Futibatinib Tab Therapy Pack	4 MG	140	Tablets	28	DAYS				
21533570102120	Mekinist	trametinib dimethyl sulfoxide for soln	0.05 MG/ML	1170	mLs	28	DAYS				
21533570100310	Mekinist	Trametinib Dimethyl Sulfoxide Tab 0.5 MG (Base Equivalent)	0.5 MG	90	Tablets	30	DAYS				
21533570100330	Mekinist	Trametinib Dimethyl Sulfoxide Tab 2 MG (Base Equivalent)	2 MG	30	Tablets	30	DAYS				
215335200003	Mektovi	binimetinib tab	15 MG	180	Tablets	30	DAYS				
21533035100320	Nerlynx	Neratinib Maleate Tab	40 MG	180	Tablets	30	DAYS				
21533060400320	Nexavar	Sorafenib Tosylate Tab 200 MG (Base Equivalent)	200 MG	120	Tablets	30	DAYS				
215360451001	Ninlaro	ixazomib citrate cap	2.3 MG ; 3 MG ; 4 MG	3	Capsules	28	DAYS				
21402425000320	Nubeqa	Darolutamide Tab 300 MG	300 MG	120	Tablets	30	DAYS				
213700602001	Odomzo	sonidegib phosphate cap	200 MG	30	Capsules	30	DAYS				
21532350200320	Ogsiveo	nirogacestat hydrobromide tab	50 MG	180	Tablets	30	DAYS				
21532350200330	Ogsiveo	nirogacestat hydrobromide tab	100 MG	56	Tablets	28	DAYS				
21532350200340	Ogsiveo	nirogacestat hydrobromide tab	150 MG	56	Tablets	28	DAYS				
21532075001920	Ojemda	tovorafenib for oral susp	25 MG/ML	8	Bottles	28	DAYS				
21532075000320	Ojemda	tovorafenib tab	100 MG	24	Tablets	28	DAYS				
21537540300320	Ojjaara	momelotinib dihydrochloride tab	100 MG	30	Tablets	30	DAYS				
21537540300330	Ojjaara	momelotinib dihydrochloride tab	150 MG	30	Tablets	30	DAYS				
21537540300340	Ojjaara	momelotinib dihydrochloride tab	200 MG	30	Tablets	30	DAYS				
213000030003	Onureg	azacitidine tab	200 MG ; 300 MG	14	Tablets	28	DAYS				
214055700003	Orgovyx	relugolix tab	120 MG	30	Tablets	30	DAYS				
21403720100320	Orserdu	elacestrant hydrochloride tab	86 MG	90	Tablets	30	DAYS				
21403720100340	Orserdu	elacestrant hydrochloride tab	345 MG	30	Tablets	30	DAYS				
21532260000340	Pemazyre	Pemigatinib Tab 13.5 MG	13.5 MG	14	Tablets	21	DAYS				
21532260000320	Pemazyre	Pemigatinib Tab 4.5 MG	4.5 MG	14	Tablets	21	DAYS				

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21532260000330	Pemazyre	Pemigatinib Tab 9 MG	9 MG	14	Tablets	21	DAYS				
2153801000B720	Piqray 200mg daily dose	Alpelisib Tab Therapy Pack 200 MG Daily Dose	200 MG	28	Tablets	28	DAYS				
2153801000B725	Piqray 250mg daily dose	Alpelisib Tab Pack 250 MG Daily Dose (200 MG & 50 MG Tabs)	200 & 50 MG	56	Tablets	28	DAYS				
2153801000B730	Piqray 300mg daily dose	Alpelisib Tab Pack 300 MG Daily Dose (2x150 MG Tab)	150 MG	56	Tablets	28	DAYS				
214500800001	Pomalyst	pomalidomide cap	1 MG ; 2 MG ; 3 MG ; 4 MG	21	Capsules	28	DAYS				
21533053000320	Qinlock	Ripretinib Tab	50 MG	90	Tablets	30	DAYS				
21535779000120	Retevmo	Selpercatinib Cap	40 MG	180	Capsules	30	DAYS				
21535779000140	Retevmo	Selpercatinib Cap	80 MG	120	Capsules	30	DAYS				
99394050000130	Revlimid	Lenalidomide Cap 10 MG	10 MG	30	Capsules	30	DAYS				
99394050000140	Revlimid	Lenalidomide Cap 15 MG	15 MG	21	Capsules	28	DAYS				
99394050000145	Revlimid	Lenalidomide Cap 20 MG	20 MG	21	Capsules	28	DAYS				
99394050000150	Revlimid	Lenalidomide Cap 25 MG	25 MG	21	Capsules	28	DAYS				
99394050000120	Revlimid	Lenalidomide Cap 5 MG	5 MG	30	Capsules	30	DAYS				
99394050000110	Revlimid	Lenalidomide Caps 2.5 MG	2.5 MG	30	Capsules	30	DAYS				
21534960000120	Rezlidhia	Olutasidenib Cap	150 MG	60	Capsules	30	DAYS				
21533820000120	Rozlytrek	Entrectinib Cap 100 MG	100 MG	30	Capsules	30	DAYS				
21533820000130	Rozlytrek	Entrectinib Cap 200 MG	200 MG	90	Capsules	30	DAYS				
21533820003020	Rozlytrek	entrectinib pellet pack	50 MG	336	Packets	28	DAYS				
21535570200320	Rubraca	Rucaparib Camsylate Tab 200 MG (Base Equivalent)	200 MG	120	Tablets	30	DAYS				
21535570200325	Rubraca	Rucaparib Camsylate Tab 250 MG (Base Equivalent)	250 MG	120	Tablets	30	DAYS				
21535570200330	Rubraca	Rucaparib Camsylate Tab 300 MG (Base Equivalent)	300 MG	120	Tablets	30	DAYS				
21533030000130	Rydapt	Midostaurin Cap 25 MG	25 MG	240	Capsules	30	DAYS				
21531806100320	Scemblix	Asciminib HCl Tab	20 MG	60	Tablets	30	DAYS				
21531806100340	Scemblix	Asciminib HCl Tab	40 MG	300	Tablets	30	DAYS				

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21531806100380	Scemblix	asciminib hcl tab	100 MG	120	Tablets	30	DAYS				
21531820000320	Sprycel	Dasatinib Tab	20 MG	90	Tablets	30	DAYS				
21531820000340	Sprycel	Dasatinib Tab	50 MG	30	Tablets	30	DAYS				
21531820000350	Sprycel	Dasatinib Tab	70 MG	30	Tablets	30	DAYS				
21531820000354	Sprycel	Dasatinib Tab	80 MG	30	Tablets	30	DAYS				
21531820000360	Sprycel	Dasatinib Tab	100 MG	30	Tablets	30	DAYS				
21531820000380	Sprycel	Dasatinib Tab	140 MG	30	Tablets	30	DAYS				
2153305000	Stivarga	regorafenib tab	40 MG	84	Tablets	28	DAYS				
21533070300120	Sutent	Sunitinib Malate Cap 12.5 MG (Base Equivalent)	12.5 MG	90	Capsules	30	DAYS				
21533070300130	Sutent	Sunitinib Malate Cap 25 MG (Base Equivalent)	25 MG	30	Capsules	30	DAYS				
21533070300135	Sutent	Sunitinib Malate Cap 37.5 MG (Base Equivalent)	37.5 MG	30	Capsules	30	DAYS				
21533070300140	Sutent	Sunitinib Malate Cap 50 MG (Base Equivalent)	50 MG	30	Capsules	30	DAYS				
215337162003	Tabrecta	capmatinib hcl tab	150 MG ; 200 MG	120	Tablets	30	DAYS				
215320251001	Tafinlar	dabrafenib mesylate cap	50 MG ; 75 MG	120	Capsules	30	DAYS				
21532025107320	Tafinlar	dabrafenib mesylate tab for oral susp	10 MG	840	Tablets	28	DAYS				
213600682003	Tagrisso	osimertinib mesylate tab	40 MG ; 80 MG	30	Tablets	30	DAYS				
21535580400105	Talzenna	talazoparib tosylate cap	0.1 MG	30	Capsules	30	DAYS				
21535580400112	Talzenna	talazoparib tosylate cap	0.35 MG	30	Capsules	30	DAYS				
21535580400114	Talzenna	Talazoparib Tosylate Cap	0.5 MG	30	Capsules	30	DAYS				
21535580400118	Talzenna	Talazoparib Tosylate Cap	0.75 MG	30	Capsules	30	DAYS				
21535580400110	Talzenna	Talazoparib Tosylate Cap 0.25 MG (Base Equivalent)	0.25 MG	90	Capsules	30	DAYS				
21535580400120	Talzenna	Talazoparib Tosylate Cap 1 MG (Base Equivalent)	1 MG	30	Capsules	30	DAYS				
21360025100320	Tarceva	Erlotinib HCl Tab	25 MG	60	Tablets	30	DAYS				
21360025100330	Tarceva	Erlotinib HCl Tab	100 MG	30	Tablets	30	DAYS				
21360025100360	Tarceva	Erlotinib HCl Tab	150 MG	30	Tablets	30	DAYS				

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215318602001	Tasigna	nilotinib hcl cap	150 MG ; 200 MG ; 50 MG	120	Capsules	30	DAYS				
215336752003	Tazverik	tazemetostat hbr tab	200 MG	240	Tablets	30	DAYS				
21533773100320	Tepmetko	Tepotinib HCl Tab	225 MG	60	Tablets	30	DAYS				
99392070000130	Thalomid	Thalidomide Cap 100 MG	100 MG	120	Capsules	30	DAYS				
99392070000135	Thalomid	Thalidomide Cap 150 MG	150 MG	60	Capsules	30	DAYS				
99392070000140	Thalomid	Thalidomide Cap 200 MG	200 MG	60	Capsules	30	DAYS				
99392070000120	Thalomid	Thalidomide Cap 50 MG	50 MG	90	Capsules	30	DAYS				
21534940000320	Tibsovo	Ivosidenib Tab 250 MG	250 MG	60	Tablets	30	DAYS				
21530320000320	Truqap	capivasertib tab	160 MG	64	Tablets	28	DAYS				
21530320000325	Truqap	capivasertib tab	200 MG	64	Tablets	28	DAYS				
2153223540B235	Truseltiq	Infigratinib Phos Cap Pack	100 & 25 MG	42	Capsules	28	DAYS				
2153223540B220	Truseltiq	infigratinib phos cap ther pack	25 MG	42	Capsules	28	DAYS				
2153223540B225	Truseltiq	Infigratinib Phos Cap Ther Pack	25 MG	63	Capsules	28	DAYS				
2153223540B230	Truseltiq	Infigratinib Phos Cap Ther Pack	100 MG	21	Capsules	28	DAYS				
21170080000320	Tukysa	Tucatinib Tab	50 MG	300	Tablets	30	DAYS				
21170080000340	Tukysa	Tucatinib Tab	150 MG	120	Tablets	30	DAYS				
21533045010110	Turalio	Pexidartinib HCl Cap	125 MG	120	Capsules	30	DAYS				
21533045010120	Turalio	Pexidartinib HCl Cap	200 MG	120	Capsules	30	DAYS				
21533026100320	Tykerb	Lapatinib Ditosylate Tab	250 MG	180	Tablets	30	DAYS				
21533047100320	Vanflyta	quizartinib dihydrochloride tab	17.7 MG	28	Tablets	28	DAYS				
21533047100325	Vanflyta	quizartinib dihydrochloride tab	26.5 MG	56	Tablets	28	DAYS				
21470080000320	Venclexta	Venetoclax Tab 10 MG	10 MG	60	Tablets	30	DAYS				
21470080000360	Venclexta	Venetoclax Tab 100 MG	100 MG	180	Tablets	30	DAYS				
21470080000340	Venclexta	Venetoclax Tab 50 MG	50 MG	30	Tablets	30	DAYS				
2147008000B720	Venclexta starting pack	Venetoclax Tab Therapy Starter Pack 10 & 50 & 100 MG	10 & 50 & 100 MG	1	Pack	180	DAYS				
215310100003	Verzenio	abemaciclib tab	100 MG ; 150 MG ; 200 MG ; 50 MG	60	Tablets	30	DAYS				

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
21533835200150	Vitrakvi	Larotrectinib Sulfate Cap 100 MG (Base Equivalent)	100 MG	60	Capsules	30	DAYS				
21533835200120	Vitrakvi	Larotrectinib Sulfate Cap 25 MG (Base Equivalent)	25 MG	180	Capsules	30	DAYS				
21533835202020	Vitrakvi	Larotrectinib Sulfate Oral Soln 20 MG/ML (Base Equivalent)	20 MG/ML	300	mLs	30	DAYS				
213600190003	Vizimpro	dacomitinib tab	15 MG ; 30 MG ; 45 MG	30	Tablets	30	DAYS				
215375501001	Vonjo	pacritinib citrate cap	100 MG	120	Capsules	30	DAYS				
21533042100320	Votrient	Pazopanib HCl Tab	200 MG	120	Tablets	30	DAYS				
21421020000320	Welireg	Belzutifan Tab	40 MG	90	Tablets	30	DAYS				
215305170001	Xalkori	crizotinib cap	200 MG ; 250 MG	120	Capsules	30	DAYS				
21530517006820	Xalkori	crizotinib cap sprinkle	20 MG	120	Capsules	30	DAYS				
21530517006830	Xalkori	crizotinib cap sprinkle	50 MG	120	Capsules	30	DAYS				
21530517006850	Xalkori	crizotinib cap sprinkle	150 MG	180	Capsules	30	DAYS				
21533020200320	Xospata	Gilteritinib Fumarate Tablet	40 MG	90	Tablets	30	DAYS				
2156006000B760	Xpovio	Selinexor Tab Therapy Pack	40 MG	4	Tablets	28	DAYS				
2156006000B765	Xpovio	Selinexor Tab Therapy Pack	40 MG	8	Tablets	28	DAYS				
2156006000B770	Xpovio	Selinexor Tab Therapy Pack	40 MG	8	Tablets	28	DAYS				
2156006000B775	Xpovio	Selinexor Tab Therapy Pack	50 MG	8	Tablets	28	DAYS				
2156006000B780	Xpovio	Selinexor Tab Therapy Pack	60 MG	4	Tablets	28	DAYS				
2156006000B755	Xpovio 60 mg twice weekly	Selinexor Tab Therapy Pack 20 MG (60 MG Twice Weekly)	20 MG	24	Tablets	28	DAYS				
2156006000B720	Xpovio 80 mg twice weekly	Selinexor Tab Therapy Pack 20 MG (80 MG Twice Weekly)	20 MG	32	Tablets	28	DAYS				
214024300001	Xtandi	enzalutamide cap	40 MG	120	Capsules	30	DAYS				
21402430000320	Xtandi	Enzalutamide Tab	40 MG	120	Tablets	30	DAYS				
21402430000340	Xtandi	Enzalutamide Tab	80 MG	60	Tablets	30	DAYS				
21406010250310	Yonsa	abiraterone acetate tab 125 mg	125 MG	120	Tablets	30	DAYS				
215355502001	Zejula	niraparib tosylate cap	100 MG	90	Capsules	30	DAYS				
215355502003	Zejula	niraparib tosylate tab	100 MG ; 200 MG ; 300 MG	30	Tablets	30	DAYS				

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
21532080000320	Zelboraf	Vemurafenib Tab ; vemurafenib tab	240 MG	240	Tablets	30	DAYS				
21531575000120	Zolinza	Vorinostat Cap 100 MG	100 MG	120	Capsules	30	DAYS				
215380400003	Zydelig	idelalisib tab	100 MG ; 150 MG	60	Tablets	30	DAYS				
215305140003	Zykadia	ceritinib tab	150 MG	90	Tablets	30	DAYS				
21406010200320	Zytiga	Abiraterone Acetate Tab 250 MG	250 ; 250 MG	120	Tablets	30	DAYS				
21406010200330	Zytiga	Abiraterone Acetate Tab 500 MG	500 MG	60	Tablets	30	DAYS				

ADDITIONAL QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
21532530007310	Afinitor disperz	Everolimus Tab for Oral Susp 2 MG	2 MG	Calculation is based on 4.5 mg/m2 with a standard BSA of 2.0 and rounding up to nearest full dose			
214500800001	Pomalyst	pomalidomide cap	1 MG ; 2 MG ; 3 MG ; 4 MG	The quantity limits for Pomalyst are based on dosing for multiple myeloma, which is given daily for 21 days of a 28 day cycle			
99394050000140	Revlimid	Lenalidomide Cap 15 MG	15 MG	The quantity limits for Revlimid 15 mg & 25 mg capsules are based on dosing for multiple myeloma, which is 25 mg daily for 21 days of a 28 day cycle			
99394050000150	Revlimid	Lenalidomide Cap 25 MG	25 MG	The quantity limits for Revlimid 15 mg & 25 mg capsules are based on dosing for multiple myeloma, which is 25 mg daily for 21 days of a 28 day cycle			
2153305000	Stivarga	regorafenib tab	40 MG	based 160 mg daily for 21 days of a 28 day cycle			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA QL	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has been treated with the requested agent within the past 180 days **OR** B. The prescriber states the patient is being treated with the requested agent within the past 180 days AND is at risk if therapy is changed **OR** C. ALL of the following: 1. ONE of the following: A. The patient has an FDA labeled indication for the requested agent **OR** B. The patient has an indication that is supported by compendia [i.e., this indication must be supported by ALL requirements in the compendia (e.g., performance status, disease severity, previous failures, monotherapy vs combination therapy, etc.)] for the requested agent **AND**

2. If the patient has an FDA labeled indication, then ONE of the following:
    A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
    B. There is support for using the requested agent for the patient's age for the requested indication **AND**
3. ONE of the following:
    A. The requested indication does NOT require specific genetic/diagnostic testing per FDA labeling or compendia for the requested agent **OR**
    B. The requested indication requires genetic/specific diagnostic testing per FDA labeling or compendia for the requested agent AND BOTH of the following:
        1. Genetic/specific diagnostic testing has been completed **AND**
        2. The results of the genetic/specific diagnostic testing indicate therapy with the requested agent is appropriate **AND**
4. ONE of the following:
    A. The requested agent is being used as monotherapy AND is approved for use as monotherapy in the FDA labeling or supported by compendia for the requested indication **OR**
    B. The requested agent will be used as combination therapy with all agent(s) and/or treatments (e.g., radiation) listed for concomitant use in the FDA labeling or compendia for the requested indication **AND**
5. ONE of the following:
    A. The requested agent will be used as a first-line agent AND is FDA labeled or supported by compendia as a first-line agent for the requested indication **OR**
    B. The patient has tried and had an inadequate response to the appropriate number and type(s) of prerequisite agent(s) listed in FDA labeling or compendia for the requested indication **OR**
    C. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to the appropriate number and type(s) of prerequisite agent(s) listed in the FDA labeling or compendia for the requested indication **OR**
    D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
        1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
        2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
        3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
    E. The prescriber has provided documentation that the appropriate prerequisite agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

2. The patient does not have any FDA labeled contraindications to the requested agent **AND**
3. The patient does not have any FDA labeled limitation(s) of use that is otherwise not supported in NCCN to the requested agent

Compendia Allowed: NCCN Compendium level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology

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

	NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. ONE of the following: A. The requested agent is Vitrakvi AND the patient has experienced clinical benefit (i.e., partial response, complete response, or stable disease) with the requested agent **OR** B. The requested agent is NOT Vitrakvi **AND** 3. The patient does not have any FDA labeled contraindications to the requested agent **AND** 4. The patient does not have any FDA labeled limitation(s) of use that is otherwise not supported in NCCN to the requested agent **Length of Approval:** Up to 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. FDA Companion Diagnostics: https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Somatostatin Analogs

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
30170070102030		Octreotide Acetate Inj 1000 MCG/ML (1 MG/ML)	1000 MCG/ML	6	Vials	30	DAYS				
30170070102015		Octreotide Acetate Inj 200 MCG/ML (0.2 MG/ML)	1000 MCG/5ML ; 200 MCG/ML	18	Vials	30	DAYS				
3017007010E505		Octreotide Acetate Subcutaneous Soln Pref Syr	50 MCG/ML	90	Syringes	30	DAYS				
3017007010E510		Octreotide Acetate Subcutaneous Soln Pref Syr	100 MCG/ML	90	Syringes	30	DAYS				
3017007010E520		Octreotide Acetate Subcutaneous Soln Pref Syr	500 MCG/ML	90	Syringes	30	DAYS				
30170070106520	Mycapssa	Octreotide Acetate Cap Delayed Release 20 MG	20 MG	120	Capsules	30	DAYS				
30170070102010	Sandostatin	Octreotide Acetate Inj 100 MCG/ML (0.1 MG/ML)	100 MCG/ML	90	Ampules	30	DAYS				
30170070102005	Sandostatin	Octreotide Acetate Inj 50 MCG/ML (0.05 MG/ML)	50 MCG/ML	90	Ampules	30	DAYS				
30170070102020	Sandostatin	Octreotide Acetate Inj 500 MCG/ML (0.5 MG/ML)	500 MCG/ML	90	Ampules	30	DAYS				
30170070106410	Sandostatin lar depot	Octreotide Acetate For IM Inj Kit 10 MG	10 MG	1	Kit	28	DAYS				
30170070106420	Sandostatin lar depot	Octreotide Acetate For IM Inj Kit 20 MG	20 MG	1	Kit	28	DAYS				
30170070106430	Sandostatin lar depot	Octreotide Acetate For IM Inj Kit 30 MG	30 MG	1	Kit	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
30170050102040	Somatuline depot	Lanreotide Acetate Extended Release Inj 120 MG/0.5ML	120 ; 120 MG/0.5ML	1	Syringe	28	DAYS				
30170050102025	Somatuline depot	Lanreotide Acetate Extended Release Inj 60 MG/0.2ML	60 MG/0.2ML	1	Syringe	28	DAYS				
30170050102030	Somatuline depot	Lanreotide Acetate Extended Release Inj 90 MG/0.3ML	90 MG/0.3ML	1	Syringe	28	DAYS				
30180060002120	Somavert	Pegvisomant For Inj 10 MG (As Protein)	10 MG	30	Vials	30	DAYS				
30180060002130	Somavert	Pegvisomant For Inj 15 MG (As Protein)	15 MG	30	Vials	30	DAYS				
30180060002140	Somavert	Pegvisomant For Inj 20 MG (As Protein)	20 MG	30	Vials	30	DAYS				
30180060002150	Somavert	Pegvisomant For Inj 25 MG (As Protein)	25 MG	30	Vials	30	DAYS				
30180060002160	Somavert	Pegvisomant For Inj 30 MG (As Protein)	30 MG	30	Vials	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Mycapssa (octreotide)	**Initial Evaluation** **Target agents** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. Information has been provided that indicates the patient has been treated with the requested agent within the past 180 days **OR** 2. The prescriber states the patient has been treated with the requested agent within the past 180 days AND is at risk if therapy is changed **OR** B. The patient has a diagnosis of acromegaly AND BOTH of the following: 1. ONE of the following: A. The patient has responded to and tolerated treatment with octreotide or lanreotide **OR**

	B. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** C. The prescriber has provided documentation that BOTH octreotide AND lanreotide cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient will NOT be using the requested agent in combination with Signifor LAR (pasireotide) **OR** C. The patient has another FDA approved indication for the requested agent **OR** D. The patient has another indication that is supported in compendia for the requested agent **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, oncologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months **Compendia Allowed:** AHFS, NCCN 1 or 2a recommended use, or DrugDex 1 or 2a level of evidence NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target agent** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent (e.g., decrease in symptom severity/frequency, reduction in tumor size, normalized IGF-1 and/or growth hormone levels) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, oncologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Sandostatin (octreotide)/Octreotide	**Initial Evaluation**

prefilled syringes, vials and ampules

Target agents will be approved when ALL of the following are met:

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

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

      1. Information has been provided that indicates the patient has been treated with the requested agent within the past 180 days **OR**
      2. The prescriber states the patient has been treated with the requested agent within the past 180 days AND is at risk if therapy is changed **OR**

   B. The patient has a diagnosis of acromegaly AND BOTH of the following:
      1. ONE of the following:
         A. The patient had an inadequate response to surgical resection or pituitary radiation therapy as indicated by growth hormone and serum IGF-1 that are above the reference ranges **OR**
         B. The patient is not a candidate for surgical resection **OR**
         C. The requested agent will be used in combination with or following pituitary radiation therapy **AND**
      2. The patient will NOT be using the requested agent in combination with Signifor LAR (pasireotide) **OR**

   C. The patient has flushing and/or diarrhea associated with metastatic carcinoid tumors **OR**
   D. The patient has profuse watery diarrhea associated with Vasoactive Intestinal Peptide (VIP) secreting tumors **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 request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following:

Brand	**Generic Equivalent**
Sandostatin	octreotide

   A. The patient's medication history includes the required generic equivalent as indicated by:
      1. Evidence of a paid claim(s) within the past 999 days **OR**
      2. The prescriber has stated that the patient has tried the generic equivalent AND the generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**

   B. The patient has an intolerance or hypersensitivity to the generic equivalent that is NOT expected to occur with the brand agent **OR**
   C. The patient has an FDA labeled contraindication to the generic equivalent that is NOT expected to occur with the brand agent **OR**
   D. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent **OR**
   E. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      1. A statement by the prescriber that the patient is currently taking the requested agent **AND**

	2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that the generic equivalent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, oncologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months **Compendia Allowed:** AHFS, NCCN 1 or 2a recommended use, or DrugDex 1 or 2a level of evidence NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target agent** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent (e.g., decrease in symptom severity/frequency, reduction in tumor size, normalized IGF-1 and/or growth hormone levels) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, oncologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Sandostatin LAR (octreotide)	**Initial Evaluation** **Target agents** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy

1. Information has been provided that indicates the patient has been treated with the requested agent within the past 180 days **OR**
2. The prescriber states the patient has been treated with the requested agent within the past 180 days AND is at risk if therapy is changed **OR**

B. The patient has a diagnosis of acromegaly AND BOTH of the following:
1. ONE of the following:
A. The patient had an inadequate response to surgical resection or pituitary radiation therapy as indicated by growth hormone and serum IGF-1 that are above the reference ranges **OR**
B. The patient is not a candidate for surgical resection **OR**
C. The requested agent will be used in combination with or following pituitary radiation therapy **AND**
2. The patient will NOT be using the requested agent in combination with Signifor LAR (pasireotide) **OR**

C. The patient has flushing and/or diarrhea associated with metastatic carcinoid tumors **OR**
D. The patient has profuse watery diarrhea associated with Vasoactive Intestinal Peptide (VIP) secreting tumors **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. ONE of the following:
A. The patient has responded to and tolerated Sandostatin (octreotide) **OR**
B. The patient is currently being treated with the requested agent as indicated by ALL of the following:
1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

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

3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, oncologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
4. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 6 months

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

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

Renewal Evaluation

<table>
<tr><td></td><td>Target agent 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 (e.g., decrease in symptom severity/frequency, reduction in tumor size, normalized IGF-1 and/or growth hormone levels) AND
3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, oncologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND
4. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 12 months

NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</td></tr>
<tr><td>Somatuline Depot (lanreotide)/Lanreotide</td><td>Initial Evaluation

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

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

<table><tr><th>Agents Eligible for Continuation of Therapy</th></tr><tr><td>All target agents are eligible for continuation of therapy</td></tr></table>

1. Information has been provided that indicates the patient has been treated with the requested agent within the past 180 days OR
2. The prescriber states the patient has been treated with the requested agent within the past 180 days AND is at risk if therapy is changed OR
B. The patient has a diagnosis of acromegaly AND BOTH of the following:
1. ONE of the following:
A. The patient had an inadequate response to surgical resection or pituitary radiation therapy as indicated by growth hormone and serum IGF-1 that are above the reference ranges OR
B. The patient is not a candidate for surgical resection OR
C. The requested agent will be used in combination with or following pituitary radiation therapy AND
2. The patient will NOT be using the requested agent in combination with Signifor LAR (pasireotide) OR
C. The patient has a diagnosis of gastroenteropancreatic neuroendocrine tumors (GEP-NETs) AND BOTH of the following:
1. The tumors are well differentiated or moderately differentiated AND
2. ONE of the following:
A. The tumors are unresectable locally advanced OR
B. The patient has metastatic disease OR
D. The patient has a diagnosis of carcinoid syndrome (i.e., flushing and/or diarrhea) 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:</td></tr>
</table>

	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., endocrinologist, oncologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months **Compendia Allowed:** AHFS, NCCN 1 or 2a recommended use, or DrugDex 1 or 2a level of evidence NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target agent** 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 (e.g., decrease in symptom severity/frequency, reduction in tumor size, normalized IGF-1 and/or growth hormone levels) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, oncologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
somavert (pegvisomant)	**Initial Evaluation** **Target agents** will be approved when ALL the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. Information has been provided that indicates the patient has been treated with the requested agent within the past 180 days **OR** 2. The prescriber states the patient has been treated with the requested agent within the past 180 days AND is at risk if therapy is changed **OR** B. The patient has a diagnosis of acromegaly AND ALL of the following: 1. ONE of the following:

A. The patient had an inadequate response to surgical resection or pituitary radiation therapy as indicated by growth hormone and serum IGF-1 that are above the reference ranges **OR**
B. The patient is not a candidate for surgical resection **OR**
C. The requested agent will be used in combination with or following pituitary radiation therapy **AND**

2. ONE of the following:
A. The patient has tried and had an inadequate response to Sandostatin LAR (octreotide suspension) or Somatuline Depot (lanreotide) **OR**
B. The patient has an intolerance or hypersensitivity to Sandostatin LAR (octreotide suspension) OR Somatuline Depot (lanreotide) **OR**
C. The patient has an FDA labeled contraindication to BOTH Sandostatin LAR (octreotide suspension) AND Somatuline Depot (lanreotide) **OR**
D. The patient is currently using Sandostatin LAR (octreotide suspension) or Somatuline Depot (lanreotide) and the requested agent will be used as add on (adjunctive) therapy **OR**
E. The prescriber has provided information in support of use of the requested agent over BOTH Sandostatin LAR (octreotide suspension) AND Somatuline Depot (lanreotide) **OR**
F. The patient has tried Signifor LAR (pasireotide) AND had severe hyperglycemia **OR**
G. The patient is currently being treated with the requested agent as indicated by ALL of the following:
1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
H. prescriber has provided documentation that BOTH Sandostatin LAR (octreotide suspension) AND Somatuline Depot (lanreotide) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

3. The patient will NOT be using the requested agent in combination with Signifor LAR (pasireotide) **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 prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, oncologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
3. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 6 months

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

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

	Renewal Evaluation **Target agent** 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 (e.g., decrease in symptom severity/frequency, reduction in tumor size, normalized IGF-1 and/or growth hormone levels) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, oncologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
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 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: Topical Corticosteroids

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
90550005103710		Alclometasone Dipropionate Cream 0.05%	0.05 %	120	Grams	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
90550005104210		Alclometasone Dipropionate Oint 0.05%	0.05 %	120	Grams	30	DAYS				
90550010003705		Amcinonide Cream 0.1%	0.1 %	120	Grams	30	DAYS				
90550010004105		Amcinonide Lotion 0.1%	0.1 %	120	mLs	30	DAYS				
90550010004205		Amcinonide Oint 0.1%	0.1 %	120	Grams	30	DAYS				
90550020053705		Betamethasone Dipropionate Augmented Cream 0.05%	0.05 %	200	Grams	28	DAYS				
90550020054005		Betamethasone Dipropionate Augmented Gel 0.05%	0.05 %	200	Grams	28	DAYS				
90550020054105		Betamethasone Dipropionate Augmented Lotion 0.05%	0.05 %	210	mLs	30	DAYS				
90550020003705		Betamethasone Dipropionate Cream 0.05%	0.05 %	135	Grams	30	DAYS				
90550020004105		Betamethasone Dipropionate Lotion 0.05%	0.05 %	120	mLs	30	DAYS				
90550020004205		Betamethasone Dipropionate Oint 0.05%	0.05 %	135	Grams	30	DAYS				
90550020103710		Betamethasone Valerate Cream 0.1% (Base Equivalent)	0.1 %	135	Grams	30	DAYS				
90550020104105		Betamethasone Valerate Lotion 0.1% (Base Equivalent)	0.1 %	120	mLs	30	DAYS				
90550020104205		Betamethasone Valerate Oint 0.1% (Base Equivalent)	0.1 %	135	Grams	30	DAYS				
90550025103705		Clobetasol Propionate Cream 0.05%	0.05 %	210	Grams	28	DAYS				
90550025104010		Clobetasol Propionate Gel 0.05%	0.05 %	210	Grams	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
90550025104205		Clobetasol Propionate Oint 0.05%	0.05 %	210	Grams	28	DAYS				
90550025102005		Clobetasol Propionate Soln 0.05%	0.05 %	200	mLs	28	DAYS				
90550035004105		Desonide Lotion 0.05%	0.05 %	118	mLs	30	DAYS				
90550035004205		Desonide Oint 0.05%	0.05 %	120	Grams	30	DAYS				
90550050103705		Diflorasone Diacetate Cream 0.05%	0.05 %	120	Grams	30	DAYS				
90550050104205		Diflorasone Diacetate Oint 0.05%	0.05 %	120	Grams	30	DAYS				
90550055103705		Fluocinolone Acetonide Cream 0.01%	0.01 %	120	Grams	30	DAYS				
90550060003705		Fluocinonide Cream 0.05%	0.05 %	120	Grams	30	DAYS				
90550060103705		Fluocinonide Emulsified Base Cream 0.05%	0.05 %	120	Grams	30	DAYS				
90550060004005		Fluocinonide Gel 0.05%	0.05 %	120	Grams	30	DAYS				
90550060004205		Fluocinonide Oint 0.05%	0.05 %	120	Grams	30	DAYS				
90550060002005		Fluocinonide Soln 0.05%	0.05 %	120	mLs	30	DAYS				
90550068103710		Fluticasone Propionate Cream 0.05%	0.05 %	120	Grams	30	DAYS				
90550068104120		Fluticasone Propionate Lotion 0.05%	0.05 %	120	mLs	30	DAYS				
90550068104210		Fluticasone Propionate Oint 0.005%	0.005 %	120	Grams	30	DAYS				
90550073103710		Halobetasol Propionate Cream 0.05%	0.05 %	200	Grams	28	DAYS				
90550073104210		Halobetasol Propionate Oint 0.05%	0.05 %	200	Grams	28	DAYS				
90550075303705		Hydrocortisone Butyrate Cream 0.1%	0.1 %	135	Grams	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
90550075304205		Hydrocortisone Butyrate Oint 0.1%	0.1 %	135	Grams	30	DAYS				
90550075302020		Hydrocortisone Butyrate Soln 0.1%	0.1 %	120	mLs	30	DAYS				
90550075003725		Hydrocortisone Cream 2.5%	2.5 %	454	Grams	30	DAYS				
90550075004120		Hydrocortisone Lotion 2.5%	2.5 %	118	mLs	30	DAYS				
90550075004215		Hydrocortisone Oint 2.5%	2.5 %	454	Grams	30	DAYS				
90550075203705		Hydrocortisone Valerate Cream 0.2%	0.2 %	120	Grams	30	DAYS				
90550075204205		Hydrocortisone Valerate Oint 0.2%	0.2 %	120	Grams	30	DAYS				
90550082103710		Mometasone Furoate Cream 0.1%	0.1 %	135	Grams	30	DAYS				
90550082104210		Mometasone Furoate Oint 0.1%	0.1 %	135	Grams	30	DAYS				
90550082102010		Mometasone Furoate Solution 0.1% (Lotion)	0.1 %	120	mLs	30	DAYS				
90550083003710		Prednicarbate Cream 0.1%		120	Grams	30	DAYS				
90550083004210		Prednicarbate Oint 0.1%	0.1 %	120	Grams	30	DAYS				
90550085103705		Triamcinolone Acetonide Cream 0.025%	0.025 %	454	Grams	30	DAYS				
90550085103710		Triamcinolone Acetonide Cream 0.1%	0.1 %	454	Grams	30	DAYS				
90550085104105		Triamcinolone Acetonide Lotion 0.025%	0.025 %	120	mLs	30	DAYS				
90550085104110		Triamcinolone Acetonide Lotion 0.1%	0.1 %	120	mLs	30	DAYS				
90550085104205		Triamcinolone Acetonide Oint 0.025%	0.025 %	454	Grams	30	DAYS				
90550085104210		Triamcinolone Acetonide Oint 0.1%	0.1 %	454	Grams	30	DAYS				
90550085104215		Triamcinolone Acetonide Oint 0.5%	0.5 %	120	Grams	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
90550075003720	Ala-cort ; Anti-itch maximum strengt ; Aveeno anti-itch maximum ; Cortizone-10 intensive he ; Cortizone-10 intensive mo ; Cortizone-10 overnight ; Cortizone-10 overnight it ; Cortizone-10 plus ; Cortizone-10 sensitive sk ; Cortizone-10 soothing alo ; Cortizone-10 ultra soothi ; Cortizone-10/aloe ; Cvs anti-itch maximum str ; Cvs cortisone intense hea ; Cvs cortisone maximum str ; Cvs hydrocortisone anti-i ; Eq 1% hydrocortisone ; Eq hydrocortisone maximu ; Eql anti-itch intensive h ; Eql anti-itch maximum str ; Ft itch relief maximum st ; Ft itch relief/aloe maxim ; Gnp hydrocortisone plus ; Gnp hydrocortisone/aloe ; Goodsense anti-itch maxim ; Hm hydrocortisone plus ; Hm hydrocortisone/aloe ma ; Hydrocortisone anti-itch ; Hydrocortisone maximum st ; Hydrocortisone plus ; Hydrocortisone ultra-mois ; Hydrocortisone/al	Hydrocortisone Cream 1%	1 %	454	Grams	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
	oe maxim ; Medi-first hydrocortisone ; Medpura hydrocortisone ; Meijer hydrocortisone ; Px hydrocream ; Qc anti-itch/aloe ; Qc hydrocortisone maximum ; Ra anti-itch maximum stre ; Ra hydrocortisone plus ; Ra hydrocortisone plus 12 ; Sb hydrocortisone ; Sm hydrocortisone ; Sm hydrocortisone plus										
90550075004118	Ala-scalp	Hydrocortisone Lotion 2%	2 %	118.4	mLs	30	DAYS				
90550050153705	Apexicon e	Diflorasone Diacetate Emollient Base Cream 0.05%	0.05 %	120	Grams	30	DAYS				
90550075004210	Aquaphor itch relief chil ; Aquaphor itch relief maxi ; Cortizone-10 ; Cortizone-10 water resist ; Cvs cortisone maximum str ; Eql anti-itch maximum str ; Ft itch relief maximum st ; Gnp hydrocortisone maximu ; Goodsense anti-itch maxim ; Hydrocortisone maximum st ; Ra anti-itch/maximum stre ; Sb hydrocortisone maximum ; Sm hydrocortisone maximum	Hydrocortisone Oint 1%	1 %	453.6	Grams	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
90550073104105	Bryhali	Halobetasol Propionate Lotion 0.01%	0.01 %	200	Grams	30	DAYS				
90550055104501	Capex	Fluocinolone Acetonide Shampoo 0.01%	0.01 %	840	mLs	28	DAYS				
90550025153705	Clobetasol propionate e ; Clobetasol propionate emo	Clobetasol Propionate Emollient Base Cream 0.05%	0.05 %	210	Grams	28	DAYS				
90550025104110	Clobex	Clobetasol Propionate Lotion 0.05%	0.05 %	177	mLs	28	DAYS				
90550025100910	Clobex	Clobetasol Propionate Spray 0.05%	0.05 %	236	mLs	28	DAYS				
90550025104520	Clobex ; Clodan	Clobetasol Propionate Shampoo 0.05%	0.05 %	236	mLs	28	DAYS				
90550030103705	Cloderm	Clocortolone Pivalate Cream 0.1%	0.1 %	120	Grams	30	DAYS				
90550065003705	Cordran	Flurandrenolide Cream 0.025%	0.025 %	120	Grams	30	DAYS				
90550065003710	Cordran	Flurandrenolide Cream 0.05%	0.05 %	120	Grams	30	DAYS				
90550065004105	Cordran	Flurandrenolide Lotion 0.05%	0.05 %	120	mLs	30	DAYS				
90550065004210	Cordran	Flurandrenolide Oint 0.05%	0.05 %	120	Grams	30	DAYS				
90550065004605	Cordran	Flurandrenolide Tape 4 MCG/SQCM	4 MCG/SQCM	1	Box	30	DAYS				
90550055101712	Derma-smoothe/fs body	Fluocinolone Acetonide Oil 0.01% (Body Oil)	0.01 %	118.28	mLs	30	DAYS				
90550055101714	Derma-smoothe/fs scalp	Fluocinolone Acetonide Oil 0.01% (Scalp Oil)	0.01 %	118.28	mLs	30	DAYS				
90550035003705	Desowen ; Tridesilon	Desonide Cream 0.05%	0.05 %	120	Grams	30	DAYS				
90550035004020	Desrx	Desonide Gel 0.05%	0.05 %	120	Grams	30	DAYS				
90550020054205	Diprolene	Betamethasone Dipropionate Augmented Oint 0.05%	0.05 %	200	Grams	28	DAYS				
90550070003710	Halog	Halcinonide Cream 0.1%	0.1 %	120	Grams	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
90550070004205	Halog	Halcinonide Oint 0.1%	0.1 %	120	Grams	30	DAYS				
90550070002005	Halog	Halcinonide Soln 0.1%	0.1 %	120	mLs	30	DAYS				
90550025104150	Impeklo	Clobetasol Propionate Lotion	0.15 MG/ACT	204	Grams	28	DAYS				
90550025103703	Impoyz	Clobetasol Propionate Cream 0.025%	0.025 %	200	Grams	30	DAYS				
90550085103400	Kenalog	Triamcinolone Acetonide Aerosol Soln 0.147 MG/GM	0.147 MG/GM	126	Grams	30	DAYS				
90550073103920	Lexette	Halobetasol Propionate Foam 0.05%	0.05 %	200	Grams	28	DAYS				
90550075304120	Locoid	Hydrocortisone Butyrate Lotion 0.1%	0.1 %	118	mLs	30	DAYS				
90550075323705	Locoid lipocream	Hydrocortisone Butyrate Hydrophilic Lipo Base Cream 0.1%	0.1 %	120	Grams	30	DAYS				
90550020103920	Luxiq	Betamethasone Valerate Aerosol Foam 0.12%	0.12 %	150	Grams	30	DAYS				
90550025103920	Olux	Clobetasol Propionate Foam 0.05%	0.05 %	200	Grams	28	DAYS				
90550025203920	Olux-e ; Tovet	Clobetasol Propionate Emulsion Foam 0.05%	0.05 %	200	Grams	28	DAYS				
90550075273720	Pandel	Hydrocortisone Probutate Cream 0.1%	0.1 %	160	Grams	30	DAYS				
90550020001620	Sernivo	Betamethasone Dipropionate Spray Emulsion 0.05% (Base Equiv)	0.05 %	120	mLs	30	DAYS				
90550055103710	Synalar	Fluocinolone Acetonide Cream 0.025%	0.025 %	120	Grams	30	DAYS				
90550055104205	Synalar	Fluocinolone Acetonide Oint 0.025%	0.025 %	120	Grams	30	DAYS				
90550055102005	Synalar	Fluocinolone Acetonide Soln 0.01%	0.01 ; 0.01 %	120	mLs	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
90550075002020	Texacort	Hydrocortisone Soln 2.5%	2.5 %	120	mLs	30	DAYS				
90550040003705	Topicort	Desoximetasone Cream 0.05%	0.05 %	120	Grams	30	DAYS				
90550040003710	Topicort	Desoximetasone Cream 0.25%	0.25 %	120	Grams	30	DAYS				
90550040004005	Topicort	Desoximetasone Gel 0.05%	0.05 %	120	Grams	30	DAYS				
90550040004203	Topicort	Desoximetasone Oint 0.05%	0.05 %	120	Grams	30	DAYS				
90550040004205	Topicort	Desoximetasone Oint 0.25%	0.25 %	120	Grams	30	DAYS				
90550040000910	Topicort	Desoximetasone Spray 0.25%	0.25 %	100	mLs	30	DAYS				
90550085104207	Trianex ; Tritocin	Triamcinolone Acetonide Oint 0.05%	0.05 %	430	Grams	30	DAYS				
90550085103720	Triderm	Triamcinolone Acetonide Cream 0.5%	0.5 %	454	Grams	30	DAYS				
90550073104110	Ultravate	Halobetasol Propionate Lotion 0.05%	0.05 %	240	mLs	30	DAYS				
90550060003710	Vanos	Fluocinonide Cream 0.1%	0.1 %	240	Grams	30	DAYS				
90550035003920	Verdeso	Desonide Foam 0.05%	0.05 %	100	Grams	30	DAYS				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	TARGET AGENT(S) **Super-high potency (group 1)** **Betamethasone dipropionate** augmented gel **Clobex** 0.05% (clobetasol propionate) lotion* **Clobex** 0.05% (clobetasol propionate) shampoo* **Clobex** 0.05% (clobetasol propionate) spray* **Cordran** 4 mcg/cm2 (flurandrenolide) tape **Diprolene** 0.05% (betamethasone dipropionate augmented) ointment* **Halobetasol propionate** 0.05% foam **Impeklo** 0.05% (clobetasol propionate) lotion **Lexette** 0.05% (halobetasol propionate) foam **Olux** 0.05% (clobetasol propionate) foam* **Olux-E** 0.05% (clobetasol propionate) emulsion foam* **Temovate** 0.05% (clobetasol propionate) cream* **Temovate** 0.05% (clobetasol propionate) ointment*

	Ultravate 0.05% (halobetasol propionate) lotion **Vanos** 0.1% (fluocinonide) cream* **High potency (group 2)** **Amcinonide** 0.1% ointment **ApexiCon** E 0.05% (diflorasone diacetate) emollient cream **Bryhali** 0.01% (halobetasol propionate) lotion **Diprolene** AF 0.05% (betamethasone dipropionate) cream* **Halog** 0.1% (halcinonide) cream* **Halog** 0.1% (halcinonide) ointment **Halog** 0.1% (halcinonide) solution **Fluocinonide** 0.05% gel* **Impoyz** 0.025% (clobetasol propionate) cream **Topicort** 0.05% (desoximetasone) gel* **Topicort** 0.25% (desoximetasone) cream* **Topicort** 0.25% (desoximetasone) ointment* **Topicort** 0.25% (desoximetasone) spray* **Mid-High potency (group 3)** **Amcinonide** 0.1% cream **Amcinonide** 0.1% lotion **Diflorasone diacetate** 0.05% cream **Luxiq** 0.12% (betamethasone valerate) foam* **Topicort** 0.05% (desoximetasone) cream* **Topicort** 0.05% (desoximetasone) ointment* **Medium potency (group 4)** **Cloderm** 0.1% (clocortolone pivalate) cream* **Cordran** 0.05% (flurandrenolide) ointment* **Kenalog** 0.147 mg/gm (triamcinolone acetonide) spray* **Sernivo** 0.05% (betamethasone dipropionate) spray **Synalar** 0.025% (fluocinolone acetonide) ointment* **Lower-mid potency (group 5)** **Cordran** 0.025% (flurandrenolide) cream **Cordran** 0.05% (flurandrenolide) cream* **Cordran** 0.05% (flurandrenolide) lotion* **Cutivate** 0.05% (fluticasone propionate) lotion* **Desonate** 0.05% (desonide) gel* **Hydrocortisone butyrate** 0.1% solution **Hydrocortisone butyrate** 0.1% cream **Locoid** 0.1% (hydrocortisone butyrate) lotion* **Locoid Lipocream** 0.1% (hydrocortisone butyrate) cream* **Pandel** 0.1% (hydrocortisone probutate) cream **Prednicarbate** 0.1% cream **Prednicarbate** 0.1% ointment **Synalar** 0.025% (fluocinolone acetonide) cream* **Low potency (group 6)** **Capex** 0.01% (fluocinolone acetonide) shampoo **Derma-Smoothe** 0.01% (fluocinolone acetonide) body oil* **Derma-Smoothe** 0.01% (fluocinolone acetonide) scalp oil* **DesOwen** 0.05% (desonide) cream*

	Fluocinolone 0.01% cream **Synalar** 0.01% (fluocinolone acetonide) solution* **Tridesilon** 0.05% (desonide) cream* **Verdeso** 0.05% (desonide) foam **Least potent (group 7)** **Ala Scalp** 2% (hydrocortisone) lotion **Hydrocortisone** 2.5% lotion **Texacort** 2.5% (hydrocortisone) solution * – available as a generic; included as a prerequisite in the step therapy program **Target Agent(s)** will be approved when ONE of the following is met: 1. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. The patient's medication history includes use of TWO generic topical corticosteroids within the same potency group as indicated by: A. Evidence of a paid claim(s) **OR** B. The prescriber has stated the patient has tried TWO generic topical corticosteroids within the same potency group AND the TWO generic topical corticosteroids were discontinued due to lack of effectiveness or an adverse event **OR** 3. The patient has an intolerance or hypersensitivity to TWO generic topical corticosteroids within the same potency group **OR** 4. The patient has an FDA labeled contraindication to ALL generic topical corticosteroids within the same potency group **OR** 5. The prescriber has provided documentation that ALL generic topical corticosteroids within the same potency group cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	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. Information has been provided that fulfills the criteria listed under the "Allowed exception cases/diagnoses" (if applicable) **OR** 3. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does not have a maximum FDA labeled dose for the requested indication **AND** 2. 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

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy

• Program Summary: Urinary Incontinence

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
541000102075		darifenacin hydrobromide tab er	15 MG ; 7.5 MG	30	Tablets	30	DAYS				
54100045202010		oxybutynin chloride solution	5 MG/5ML	600	mLs	30	DAYS				
54100045200310		oxybutynin chloride tab	2.5 MG	90	Tablets	30	DAYS				
54100045200330		Oxybutynin Chloride Tab 5 MG	5 MG	120	Tablets	30	DAYS				
54100045207540		Oxybutynin Chloride Tab ER 24HR 15 MG	15 MG	60	Tablets	30	DAYS				
541000652070		trospium chloride cap er	60 MG	30	Capsules	30	DAYS				
541000652003		trospium chloride tab	20 MG	60	Tablets	30	DAYS				
541000602003	Detrol	tolterodine tartrate tab	1 MG ; 2 MG	60	Tablets	30	DAYS				
541000602070	Detrol la	tolterodine tartrate cap er	2 MG ; 4 MG	30	Capsules	30	DAYS				
54100045207530	Ditropan xl	Oxybutynin Chloride Tab ER 24HR 10 MG	10 MG	60	Tablets	30	DAYS				
54100045207520	Ditropan xl	Oxybutynin Chloride Tab ER 24HR 5 MG	5 MG	30	Tablets	30	DAYS				

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
541000452040	Gelnique	oxybutynin chloride td gel	10 %	30	Sachets	30	DAYS				
542000800003	Gemtesa	vibegron tab	75 MG	30	Tablets	30	DAYS				
5420005000G2	Myrbetriq	mirabegron granules for oral extended release susp	8 MG/ML	300	mLs	28	DAYS				
542000500075	Myrbetriq	mirabegron tab er	25 ; 25 MG ; 50 ; 50 MG	30	Tablets	30	DAYS				
541000450087	Oxytrol ; Oxytrol for women	oxybutynin td patch twice weekly	3.9 MG/24 HR	8	Patches	28	DAYS				
541000202075	Toviaz	fesoterodine fumarate tab er	4 MG ; 8 MG	30	Tablets	30	DAYS				
541000552003	Vesicare	solifenacin succinate tab	10 MG ; 5 MG	30	Tablets	30	DAYS				
541000552018	Vesicare ls	solifenacin succinate susp	5 MG/5ML	300	mLs	30	DAYS				

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Verkazia - *Note program was formerly in 'Ophthalmic Immunomodulators' program*

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
Verkazia	Cyclosporine (Ophth) Emulsion 0.1%	0.1 %	120	Vials	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 patient has a diagnosis of vernal keratoconjunctivitis (VKC) AND BOTH of the following: 1. ONE of the following: A. The patient has tried and had an inadequate response to combination of a topical ophthalmic mast cell stabilizer AND an antihistamine used in the treatment of VKC **OR** B. The patient has an intolerance or hypersensitivity to combination of a topical ophthalmic mast cell stabilizer AND an antihistamine used in the treatment of VKC **OR** C. The patient has an FDA labeled contraindication to ALL topical ophthalmic mast cell stabilizers AND antihistamines **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL topical ophthalmic mast cell stabilizers AND antihistamines cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to a topical ophthalmic corticosteroid used in the treatment of VKC **OR** B. The patient has an intolerance or hypersensitivity to topical ophthalmic corticosteroid therapy **OR** C. The patient has an FDA labeled contraindication to ALL topical ophthalmic corticosteroids **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND**

	3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL topical ophthalmic corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has another FDA labeled indication for the requested agent **OR** C. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. The patient will NOT be using the requested agent in combination with Cequa, Restasis, Vevye, or Xiidra **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:** 4 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient will NOT be using the requested agent in combination with Cequa, Restasis, Vevye, or Xiidra **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

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

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	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				
62380030007525	Austedo xr	deutetrabenazine tab er	18 MG	30	Tablets	30	DAYS				
62380030007530	Austedo xr	deutetrabenazine tab er	24 MG	60	Tablets	30	DAYS				
62380030007535	Austedo xr	deutetrabenazine tab er	30 MG	30	Tablets	30	DAYS				
62380030007540	Austedo xr	deutetrabenazine tab er	36 MG	30	Tablets	30	DAYS				
62380030007545	Austedo xr	deutetrabenazine tab er	42 MG	30	Tablets	30	DAYS				
62380030007550	Austedo xr	deutetrabenazine tab er	48 MG	30	Tablets	30	DAYS				
6238003000C120	Austedo xr patient titrat	deutetrabenazine tab er titration pack	6 & 12 & 24 MG	42	Tablets	180	DAYS				
6238003000C140	Austedo xr patient titrat	deutetrabenazine tab er titration pack	12 & 18 & 24 & 30 MG	28	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				

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
62380080206830	Ingrezza	valbenazine tosylate capsule sprinkle	40 MG	30	Capsules	30	DAYS				
62380080206850	Ingrezza	valbenazine tosylate capsule sprinkle	60 MG	30	Capsules	30	DAYS				
62380080206870	Ingrezza	valbenazine tosylate capsule sprinkle	80 MG	30	Capsules	30	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 patient is not taking any medications known to cause tardive dyskinesia (i.e., dopamine receptor blocking agents) **OR** 2. The prescriber has reduced the dose or discontinued any medications known to cause tardive dyskinesia **OR** 3. 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 labeled indication for the requested agent and route of administration **OR** 4. The patient has another indication that is supported in compendia for the requested agent and route of administration **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 labeled indication for the requested agent and route of administration **OR** 3. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following: A. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**

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

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

Brand	Generic Equivalent
Xenazine	tetrabenazine

D. BOTH of the following:
   1. The prescriber has stated that the patient has tried the generic equivalent **AND**
   2. The generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**

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

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

3. If the patient has an FDA labeled indication, then ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
   B. There is support for using the requested agent for the patient's age for the requested indication **AND**
4. The 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 [Note: patients not previously approved for the requested agent will require initial evaluation review] **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 has had clinical benefit with the requested agent **AND**
4. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following:
   A. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**

B. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR**
C. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent **OR**

Brand	Generic Equivalent
Xenazine	tetrabenazine

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

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. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months

• Program Summary: Vijoice (alpelisib)

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
99486010003020	Vijoice	alpelisib (pros) oral granules packet	50 MG	28	Packets	28	DAYS				
9948601000B740	Vijoice	Alpelisib (PROS) Pak	200 & 50 MG	56	Tablets	28	DAYS				
9948601000B720	Vijoice	Alpelisib (PROS) Tab Therapy Pack	50 MG	28	Tablets	28	DAYS				
9948601000B730	Vijoice	Alpelisib (PROS) Tab Therapy Pack	125 MG	28	Tablets	28	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Initial Evaluation

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

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

Agents Eligible for Continuation of Therapy
Vijoice

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

   B. ALL of the following:
      1. The patient has a diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS) confirmed by ALL of the following:
         A. Presence of somatic PIK3CA mutation **AND**
         B. Congenital or early childhood onset **AND**
         C. Overgrowth sporadic and mosaic **AND**
         D. ONE of the following:
            1. The patient has at least TWO of the following features:
               A. Overgrowth
               B. Vascular malformations
               C. Epidermal nevus **OR**
            2. The patient has at least ONE of the following features:
               A. Large isolated lymphatic malformations
               B. Isolated macrodactyly OR overgrown splayed feet/hands, overgrown limbs
               C. Truncal adipose overgrowth
               D. Hemimegalencephaly (bilateral)/dysplastic megalencephaly/focal cortical dysplasia
               E. Epidermal nevus

	F. Seborrheic keratoses G. Benign lichenoid keratoses **AND** 2. The patient has severe manifestations of PROS that requires systemic therapy **AND** 3. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., experienced in PROS) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient has NOT had disease progression (e.g., increase in lesion number, increase in lesion volume) with the requested agent (medical records required) **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., experienced in PROS) 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
	Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of Approval**: up to 6 months for initial; up to 12 months for renewal

• Program Summary: Weight Loss Agents

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
61200010100305		Benzphetamine HCl Tab 25 MG		90	Tablets	30	DAYS				
61200010100310		Benzphetamine HCl Tab 50 MG	50 MG	90	Tablets	30	DAYS				
61200020100305		Diethylpropion HCl Tab 25 MG	25 MG	90	Tablet	30	DAYS				
61200020107510		Diethylpropion HCl Tab ER 24HR 75 MG	75 MG	30	Tablets	30	DAYS				
61200050107010		Phendimetrazine Tartrate Cap ER 24HR 105 MG	105 MG	30	Capsules	30	DAYS				
61200050100305		Phendimetrazine Tartrate Tab 35 MG	35 MG	180	Tablets	30	DAYS				
61200070100110		Phentermine HCl Cap 15 MG	15 MG	30	Capsules	30	DAYS				
61200070100115		Phentermine HCl Cap 30 MG	30 MG	30	Capsules	30	DAYS				
61200070100120	Adipex-p	Phentermine HCl Cap 37.5 MG	37.5 MG	30	Capsules	30	DAYS				
61200070100310	Adipex-p	Phentermine HCl Tab 37.5 MG	37.5 MG	30	Tablets	30	DAYS				
61259902507420	Contrave	Naltrexone HCl-Bupropion HCl Tab ER 12HR 8-90 MG	8-90 MG	120	Tablets	30	DAYS				
61200070100305	Lomaira	Phentermine HCl Tab 8 MG	8 MG	90	Tablets	30	DAYS				
61209902307040	Qsymia	Phentermine HCl-Topiramate Cap ER 24HR 11.25-69 MG	11.25-69 MG	30	Capsules	30	DAYS				
61209902307050	Qsymia	Phentermine HCl-Topiramate Cap ER 24HR 15-92 MG	15-92 MG	30	Capsules	30	DAYS				
61209902307020	Qsymia	Phentermine HCl-Topiramate Cap ER 24HR 3.75-23 MG	3.75-23 MG	30	Capsules	30	DAYS				
61209902307030	Qsymia	Phentermine HCl-Topiramate Cap ER 24HR 7.5-46 MG	7.5-46 MG	30	Capsules	30	DAYS				
61253560000120	Xenical	Orlistat Cap 120 MG	120 MG	90	Capsules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation (Patient new to therapy, new to Prime, or attempting a repeat weight loss course of therapy) **Target Agent(s)** will be approved when ALL the following are met: 1. ONE of the following: A. The patient is 17 years of age or over and ALL of the following: 1. ONE of the following: A. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 30 kg/m^2 OR a BMI greater than or equal to 25 kg/m^2 if the patient is of South Asian, Southeast Asian, or East Asian descent **OR** B. The patient has a BMI greater than or equal to 27 kg/m^2 with at least one weight-related comorbidity/risk factor/complication (e.g., diabetes, dyslipidemia, coronary artery disease) **AND** 2. The patient has been on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications for a minimum of 6 months prior to initiating therapy with the requested agent **AND** 3. The patient did not achieve a weight loss of 1 pound or more per week while on the weight loss regimen prior to initiating therapy with the requested agent **AND** 4. The patient is currently on and will continue a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **OR** B. The patient is 12 to 16 years of age and ALL of the following: 1. ONE of the following: A. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 95th percentile for age and gender **OR** B. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 30 kg/m^2 **OR** C. The patient has a BMI greater than or equal to 85th percentile for age and gender AND at least one severe weight-related comorbidity/risk factor/complication **AND** 2. The patient has been on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications for a minimum of 6 months (prior to initiating therapy with the requested agent) **AND** 3. The patient has a weight loss of less than 1 pound per week while on the weight loss regimen (prior to initiating therapy with the requested agent) **AND** 4. The patient is currently on and will continue a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. ONE of the following: A. The patient has not tried a targeted weight loss agent in the past 12 months **OR** B. BOTH of the following: 1. The patient has tried a targeted weight loss agent for a previous course of therapy in the past 12 months **AND** 2. The prescriber anticipates success with repeating therapy with any targeted weight loss agent **AND** 4. ONE of the following: A. The requested agent is benzphetamine, diethylpropion, phendimetrazine, or phentermine **OR** B. The requested agent is Qsymia AND ONE of the following: 1. The requested dose is 3.75mg/23mg **OR**

2. The patient is currently being treated with Qsymia, the requested dose is greater than 3.75 mg/23 mg AND ONE of the following:
    A. ONE of the following:
        1. For adults, the patient has demonstrated and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of the requested agent) **OR**
        2. For pediatric patients aged 12 years and older, the patient has experienced a reduction of at least 5% of baseline BMI (prior to initiation of the requested agent) **OR**
    B. The patient received less than 14 weeks of therapy **OR**
    C. The patient's dose is being titrated upward **OR**
    D. The patient has received less than 12 weeks (3 months) of therapy on the 15mg/92mg strength **OR**
3. There is support for therapy for the requested dose for this patient **OR**

C. The requested agent is Contrave and ONE of the following:
1. The patient is newly starting therapy **OR**
2. The patient is currently being treated and has received less than 16 weeks (4 months) of therapy **OR**
3. The patient has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of requested agent) **OR**

D. The requested agent is Xenical (or Orlistat) and ONE of the following:
1. The patient is 12 to 16 years of age and ONE of the following:
    A. The patient is newly starting therapy **OR**
    B. The patient is currently being treated and has received less than 12 weeks (3 months) of therapy **OR**
    C. The patient has achieved and maintained a weight loss of greater than 4% from baseline (prior to initiation of requested agent) **OR**
2. The patient is 17 years of age or over and ONE of the following:
    A. The patient is newly starting therapy **OR**
    B. The patient is currently being treated and has received less than 12 weeks (3 months) of therapy **OR**
    C. The patient has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of requested agent) **AND**

5. The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication **AND**
6. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 3 months

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

Renewal Evaluation

(Patient continuing a current weight loss course of therapy)

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

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**
2. The patient meets ONE of the following:

	A. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of requested agent) **OR** B. The requested agent is Qsymia AND ONE of the following: 1. For a pediatric patient aged 12 years and older, the patient has achieved and maintained a reduction of greater than or equal to 5% of baseline BMI (prior to initiation of the requested agent) **OR** 2. For an adult, the patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of the requested agent) **OR** 3. BOTH of the following: A. ONE of the following: 1. For a pediatric patient aged 12 years and older, the patient has achieved and maintained less than a 5% reduction of baseline BMI (prior to initiation of the requested agent) **OR** 2. For an adult, the patient has achieved and maintained a weight loss less than 5% from baseline (prior to initiation of requested agent) **AND** B. BOTH of the following: 1. The patient's dose is being titrated upward (for the 3.75 mg/23 mg, 7.5 mg/46 mg or 11.25 mg/69 mg strengths only) **AND** 2. The patient has received less than 12 weeks of therapy on the 15mg/92mg strength **OR** C. The requested agent is Xenical (or Orlistat) AND ONE of the following: 1. The patient 12 to 16 years of age AND has achieved and maintained a weight loss greater than 4% from baseline (prior to initiation of requested agent) **OR** 2. The patient is 17 years of age or over AND has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of requested agent) **AND** 3. If the patient is 12 to less than 18 years of age, the current BMI is greater than 85th percentile for age and gender **AND** 4. The patient is currently on and will continue to be on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **AND** 5. The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** • Qsymia: greater than or equal to 5% weight loss from baseline (adults); greater than or equal to 5% reduction in BMI from baseline (pediatrics): 12 months • Qsymia: less than 5% weight loss from baseline (adults); less than 5% reduction in BMI from baseline (pediatrics): 3 months • All other agents: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

	B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• Program Summary: Weight Management

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6125205000D220	Saxenda	Liraglutide (Weight Mngmt) Soln Pen-Inj 18 MG/3ML (6 MG/ML)	18 MG/3ML	15	mLs	30	DAYS				
6125207000D520	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	0.25 MG/0.5ML	8	Pens	180	DAYS				
6125207000D525	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	0.5 MG/0.5ML	8	Pens	180	DAYS				
6125207000D530	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	1 MG/0.5ML	8	Pens	180	DAYS				
6125207000D535	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	1.7 MG/0.75ML	4	Pens	28	DAYS				
6125207000D540	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	2.4 MG/0.75ML	4	Pens	28	DAYS				
6125258000D520	Zepbound	tirzepatide (weight mngmt) soln auto-injector	2.5 MG/0.5ML	4	Pens	180	DAYS				
6125258000D525	Zepbound	tirzepatide (weight mngmt) soln auto-injector	5 MG/0.5ML	4	Pens	28	DAYS				
6125258000D530	Zepbound	tirzepatide (weight mngmt) soln auto-injector	7.5 MG/0.5ML	4	Pens	28	DAYS				

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
6125258000D535	Zepbound	tirzepatide (weight mngmt) soln auto-injector	10 MG/0.5ML	4	Pens	28	DAYS				
6125258000D540	Zepbound	tirzepatide (weight mngmt) soln auto-injector	12.5 MG/0.5ML	4	Pens	28	DAYS				
6125258000D545	Zepbound	tirzepatide (weight mngmt) soln auto-injector	15 MG/0.5ML	4	Pens	28	DAYS				

ADDITIONAL QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
6125207000D520	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	0.25 MG/0.5ML	*This strength is not approvable for maintenance dosing			
6125207000D525	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	0.5 MG/0.5ML	*This strength is not approvable for maintenance dosing			
6125207000D530	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	1 MG/0.5ML	*This strength is not approvable for maintenance dosing			
6125258000D520	Zepbound	tirzepatide (weight mngmt) soln auto-injector	2.5 MG/0.5ML	*This strength is not approvable for maintenance dosing			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Initial Evaluation** **Target Agent(s)** will be approved when ALL the following are met: 1. ONE of the following: A. The requested use is to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease (medical records required) and the patient is either obese or overweight AND ALL of the following: 1. The requested agent is FDA labeled for the requested indication and route of administration **AND** 2. The patient has a history of ONE of the following: A. Myocardial infarction **OR** B. Stroke **OR** C. Peripheral artery disease as defined by intermittent claudication with ankle-brachial index less than 0.85 at rest, or peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease **AND** 3. The patient has a BMI greater than or equal to 27 kg/m^2 **AND** 4. The patient will use optimized pharmacotherapy for established cardiovascular disease in combination with the requested agent **OR** B. The patient is overweight or obese and is using the requested agent for weight management and ALL of the following: 1. Obesity is NOT restricted from coverage under the patient's benefit **AND**

2. The patient is new to therapy, new to Prime, or attempting a repeat weight loss course of therapy **AND**
3. ONE of the following:
    A. The patient is 17 years of age or over and has ONE of the following:
        1. A BMI greater than or equal to 30 kg/m^2 **OR**
        2. A BMI greater than or equal to 25 kg/m^2 if the patient is of South Asian, Southeast Asian, or East Asian descent **OR**
        3. A BMI greater than or equal to 27 kg/m^2 with at least one weight-related comorbidity/risk factor/complication (e.g., hypertension, type 2 diabetes mellitus, obstructive sleep apnea, cardiovascular disease, dyslipidemia) **OR**
    B. The patient is 12 to 16 years of age and has ONE of the following:
        1. A BMI greater than or equal to 95th percentile for age and sex **OR**
        2. A BMI greater than or equal to 30 kg/m^2 **OR**
        3. A BMI greater than or equal to 85th percentile for age and sex AND at least one severe weight-related comorbidity/risk factor/complication **AND**
4. The patient has been on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications for a minimum of 6 months **AND**
5. ONE of the following:
    A. The patient has not tried a targeted weight loss agent in the past 12 months **OR**
    B. BOTH of the following:
        1. The patient has tried a targeted weight loss agent for a previous course of therapy in the past 12 months **AND**
        2. The prescriber anticipates success with repeating therapy with any targeted weight loss agent **AND**
6. If the requested agent is Saxenda, then ONE of the following:
    A. The patient is 18 years of age or over and ONE of the following:
        1. The patient is newly starting therapy **OR**
        2. The patient is currently being treated and has received less than 16 weeks (4 months) of therapy **OR**
        3. The patient has achieved and maintained a weight loss of greater than or equal to 4% from baseline (prior to initiation of pharmacotherapy) **OR**
    B. The patient is pediatric (12 to less than 18 years of age) AND BOTH of the following:
        1. The requested agent is NOT being used to treat type 2 diabetes **AND**
        2. ONE of the following:
            A. The patient is newly starting therapy **OR**
            B. The patient is currently being treated and has received less than 20 weeks (5 months) of therapy **OR**
            C. The patient has achieved and maintained a reduction in BMI of greater than or equal to 1% from baseline (prior to initiation of pharmacotherapy) **AND**
7. If the requested agent is Wegovy, then ONE of the following:
    A. The patient is newly starting therapy **OR**
    B. The patient is currently being treated and has received less than 52 weeks (1 year) of therapy **OR**
    C. The patient is an adult AND has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR**
    D. The patient is pediatric (12 to less than 18 years of age) AND has achieved and maintained a reduction in BMI of at least 5% from baseline (prior to initiation of pharmacotherapy) **AND**
8. If the requested agent is Zepbound, then ONE of the following:
    A. The patient is newly starting therapy **OR**
    B. The patient is currently being treated and has received less than 52 weeks (1 year) of therapy **OR**

C. The patient has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR**

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

2. The patient will NOT be using the requested agent in combination with another weight loss agent (e.g., Contrave, phentermine, Qsymia, Xenical) for the requested indication **AND**
3. BOTH of the following:
   A. The patient is currently on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **AND**
   B. The patient will continue the weight loss regimen in combination with the requested agent **AND**
4. If the patient has an FDA labeled indication, then ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
   B. There is support for using the requested agent for the patient's age for the requested indication **AND**
5. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND**
6. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval:

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

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

Renewal Evaluation

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

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**
2. ONE of the following:
   A. The requested use is to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease AND BOTH of the following:
      1. The patient will use optimized pharmacotherapy for established cardiovascular disease in combination with the requested agent **AND**
      2. The patient has had clinical benefit with the requested agent **OR**
   B. The patient is overweight or obese and is using the requested agent for weight management and ALL of the following:
      1. Obesity is NOT restricted from coverage under the patient's benefit **AND**
      2. The patient is continuing a current weight loss course of therapy **AND**
      3. If the patient is 12 to less than 18 years of age, then the current BMI is greater than 85th percentile for age and sex **AND**
      4. If the requested agent is Saxenda, then BOTH of the following:
         A. The requested agent is NOT being used to treat type 2 diabetes **AND**
         B. ONE of the following:
            1. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR**
            2. The patient is 18 years of age or over AND has achieved and maintained a weight loss greater than or equal to 4% from baseline (prior to initiation of pharmacotherapy) **OR**

	3. The patient is pediatric (12 to less than 18 years of age) AND has achieved and maintained a reduction in BMI of greater than or equal to 1% from baseline (prior to initiation of pharmacotherapy) **AND** 5. If the requested agent is Wegovy, then BOTH of the following: A. The requested dose is 1.7 mg or 2.4 mg **AND** B. ONE of the following: 1. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR** 2. The patient is 12 years of age and over AND has received less than 52 weeks of therapy on the maximum-tolerated dose **OR** 3. The patient is pediatric (12 to less than 18 years of age) AND has achieved and maintained a reduction in BMI of at least 5% from baseline (prior to initiation of pharmacotherapy) **AND** 6. If the requested agent is Zepbound, then ONE of the following: A. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR** B. The patient has received less than 52 weeks of therapy on the maximum-tolerated dose **OR** C. The patient has another FDA labeled indication for the requested agent and route of administration AND has had clinical benefit with the requested agent **AND** 3. The patient will NOT be using the requested agent in combination with another weight loss agent (e.g., Contrave, phentermine, Qsymia, Xenical) for the requested indication **AND** 4. BOTH of the following: A. The patient is currently on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **AND** B. The patient will continue the weight loss regimen in combination with the requested agent **AND** 5. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

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

• Program Summary: Xhance

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
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
PA	**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 a diagnosis of chronic rhinosinusitis without nasal polyps (CRSsNP) **OR** C. The patient has another FDA labeled indication for the requested agent and route of administration **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. 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.

	Renewal Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient 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. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months

• Program Summary: Xolair (omalizumab)

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

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	446030600021	Xolair	omalizumab for inj	150 MG	M ; N ; O ; Y				
	4460306000D5	Xolair	omalizumab subcutaneous soln auto-injector	150 MG/ML ; 300 MG/2ML ; 75 MG/0.5ML	M ; N ; O ; Y				

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
	4460306000E5	Xolair	omalizumab subcutaneous soln prefilled syringe	150 MG/ML ; 300 MG/2ML ; 75 MG/0.5ML	M ; N ; O ; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** No Target Agents are eligible for continuation of therapy 1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. BOTH of the following: 1. ONE of the following: A. The patient has a diagnosis of moderate to severe persistent asthma AND ALL of the following: 1. ONE of the following: A. The patient is 6 to less than 12 years of age AND BOTH of the following: 1. The pretreatment IgE level is 30 IU/mL to 1300 IU/mL **AND** 2. The patient's weight is 20 kg to 150 kg **OR** B. The patient is 12 years of age or over AND BOTH of the following: 1. The pretreatment IgE level is 30 IU/mL to 700 IU/mL **AND** 2. The patient's weight is 30 kg to 150 kg **AND** 2. Allergic asthma has been confirmed by a positive skin test or in vitro reactivity test to a perennial aeroallergen **AND** 3. The patient has a history of uncontrolled asthma while on asthma control therapy as demonstrated by ONE of the following: A. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months **OR** B. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months **OR** C. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered **OR** D. The patient has baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted **OR** B. The patient has a diagnosis of chronic spontaneous urticaria (CSU) (otherwise known as chronic idiopathic urticaria [CIU]) AND ALL of the following: 1. The patient has had over 6 weeks of hives and itching **AND**

2. If the patient is currently being treated with medications known to cause or worsen urticaria, then ONE of the following:
    A. The prescriber has reduced the dose or discontinued any medications known to cause or worsen urticaria (e.g., NSAIDs) **OR**
    B. A reduced dose or discontinuation of any medications known to cause or worsen urticaria is not appropriate **AND**
3. ONE of the following:
    A. The patient has tried and had an inadequate response to the FDA labeled maximum dose of a second-generation H-1 antihistamine (e.g., cetirizine, levocetirizine, fexofenadine, loratadine, desloratadine) AND ONE of the following:
        1. The patient has tried and had an inadequate response to a dose titrated up to 4 times the FDA labeled maximum dose of a second-generation H-1 antihistamine **OR**
        2. The patient cannot be treated with a dose titrated up to 4 times the FDA labeled maximum dose of a second-generation H-1 antihistamine **OR**
    B. The patient has an intolerance or hypersensitivity to second-generation H-1 antihistamine therapy **OR**
    C. The patient has an FDA labeled contraindication to ALL second-generation H-1 antihistamines **OR**
    D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
        1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
        2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
        3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
    E. The prescriber has provided documentation that ALL second-generation H-1 antihistamines cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

C. The patient has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) AND ALL of the following:
1. The patient has at least TWO of the following symptoms consistent with chronic rhinosinusitis (CRS):
    A. Nasal discharge (rhinorrhea or post-nasal drainage)
    B. Nasal obstruction or congestion
    C. Loss or decreased sense of smell (hyposmia)
    D. Facial pressure or pain **AND**
2. The patient has had symptoms consistent with chronic rhinosinusitis (CRS) for at least 12 consecutive weeks **AND**
3. The patient's diagnosis was confirmed by ONE of the following:
    A. Anterior rhinoscopy or endoscopy **OR**
    B. Computed tomography (CT) of the sinuses **AND**
4. ONE of the following:
    A. The patient has tried and had an inadequate response to intranasal corticosteroids (e.g., fluticasone, Sinuva) **OR**
    B. The patient has an intolerance or hypersensitivity to therapy with intranasal corticosteroids (e.g., fluticasone, Sinuva) **OR**

C. The patient has an FDA labeled contraindication to ALL intranasal corticosteroids **OR**

D. The patient has a diagnosis of IgE-mediated food allergy AND ALL of the following:

1. The patient has a confirmed IgE-mediated food allergy confirmed by an allergy diagnostic test (e.g., skin prick test, serum specific IgE test, oral food challenge) **AND**
2. The patient will avoid known food allergens while treated with the requested agent **AND**
3. The requested agent will NOT be used for the emergency treatment of allergic reactions, including anaphylaxis **OR**

E. The patient has another FDA labeled indication for the requested agent AND the requested dose is within FDA labeled dosing for the requested indication **AND**

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

C. The patient has another indication that is supported in compendia for the requested agent **AND**

2. If the patient has a diagnosis of moderate to severe persistent asthma, ALL of the following:
   A. ONE of the following:
      1. The patient is NOT currently being treated with the requested agent AND is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months **OR**
      2. The patient is currently being treated with the requested agent AND ONE of the following:
         A. Is currently treated with an inhaled corticosteroid for at least 3 months that is adequately dosed to control symptoms **OR**
         B. Is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months **OR**
      3. The patient has an intolerance or hypersensitivity to inhaled corticosteroid therapy **OR**
      4. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids **OR**
      5. The patient is currently being treated with the requested agent as indicated by ALL of the following:
         A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
         B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
         C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
      6. The prescriber has provided documentation that ALL inhaled corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
   B. ONE of the following:
      1. The patient is currently being treated for at least 3 months with ONE of the following:
         A. A long-acting beta-2 agonist (LABA) **OR**
         B. Long-acting muscarinic antagonist (LAMA) **OR**
         C. A Leukotriene receptor antagonist (LTRA) **OR**
         D. Theophylline **OR**
      2. The patient has an intolerance or hypersensitivity to therapy with long-acting beta-2 agonists (LABA), long-acting muscarinic antagonists (LAMA), leukotriene receptor antagonist (LTRA), or theophylline **OR**
      3. The patient has an FDA labeled contraindication to ALL long-acting beta-2 agonists (LABA) AND long-acting muscarinic antagonists (LAMA) **OR**
      4. The patient is currently being treated with the requested agent as indicated by ALL of the following:

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

5. The prescriber has provided documentation that ALL long-acting beta-2 agonists (LABA) AND long-acting muscarinic antagonists (LAMA) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

C. The patient will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **AND**
D. The requested dose is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 375 mg every 2 weeks **AND**

3. If the patient has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP), ALL of the following:
   A. The patient is currently treated with standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) **AND**
   B. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **AND**
   C. The requested dose is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 600 mg every 2 weeks **AND**
4. If the patient has a diagnosis of chronic spontaneous urticaria (CSU) (otherwise known as chronic idiopathic urticaria [CIU]), the requested dose is within FDA labeled dosing AND does NOT exceed 300 mg every 4 weeks **AND**
5. If the patient has a diagnosis of IgE-mediated food allergy, the requested dose is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 600 mg every 2 weeks **AND**
6. If the patient has another FDA labeled indication for the requested agent, the requested dose is within FDA labeled dosing for the requested indication **AND**
7. If the patient has another indication that is supported in compendia for the requested agent, the requested dose is supported in compendia for the requested indication **AND**
8. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, otolaryngologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
9. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):
   A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**
   B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
      1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**
      2. There is support for the use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) **AND**
10. The patient does NOT have any FDA labeled contraindications to the requested agent

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

Length of Approval: 6 months for asthma, chronic idiopathic urticaria, IgE-mediated food allergy, and chronic rhinosinusitis with nasal polyps (CRSwNP)

12 months for all other indications

Renewal Evaluation

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

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**
2. ONE of the following:
    A. The patient has a diagnosis of moderate to severe persistent asthma AND ALL of the following:
        1. The patient has had improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following:
            A. Increase in percent predicted Forced Expiratory Volume (FEV_1) **OR**
            B. Decrease in the dose of inhaled corticosteroid required to control the patient's asthma **OR**
            C. Decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma **OR**
            D. Decrease in the number of hospitalizations, need for mechanical ventilation, or visits to the emergency room or urgent care due to exacerbations of asthma **AND**
        2. The patient is currently treated and is compliant with standard therapy [i.e., inhaled corticosteroids (ICS), ICS/long-acting beta-2 agonist (ICS/LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), theophylline] **AND**
        3. The requested dose is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 375 mg every 2 weeks **OR**
    B. The patient has a diagnosis of chronic spontaneous urticaria (CSU) (otherwise known as chronic idiopathic urticaria [CIU]) AND BOTH of the following:
        1. The patient has had clinical benefit with the requested agent **AND**
        2. The requested dose is within FDA labeled dosing for the requested indication AND does NOT exceed 300 mg every 4 weeks **OR**
    C. The patient has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) AND ALL of the following:
        1. The patient has had clinical benefit with the requested agent **AND**
        2. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **AND**
        3. The requested dose is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 600 mg every 2 weeks **OR**
    D. The patient has a diagnosis of IgE-mediated food allergy, AND the requested dose is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 600 mg every 2 weeks **OR**
    E. The patient has another FDA labeled indication for the requested agent AND BOTH of the following:
        1. The patient has had clinical benefit with the requested agent **AND**
        2. The requested dose is within FDA labeled dosing for the requested indication **OR**
    F. The patient has another indication that is supported in compendia for the requested agent AND BOTH of the following:
        1. The patient has had clinical benefit with the requested agent **AND**
        2. The requested dose is supported in compendia for the requested indication **AND**
3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, otolaryngologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):
    A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**
    B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:

	1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months

CONTRAINDICATED AGENTS

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

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

• Program Summary: Zeposia (ozanimod)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

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

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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

Formulary ID	Step 1a	Step 1b (Directed to ONE TNF	Step 2 (Directed to ONE Step 1 agent)	Step 3a (Directed	Step 3b (Directed to	Step 3c (Directed to THREE step 1 agents)

		inhibitor) NOTE please see Step 1a for preferred TNF inhibitors		**to TWO Step 1 agents)**	**TWO agents from Step 1 and/or Step 2)**	
FlexRx, GenRx, KeyRx, BasicRx	SQ: Hadlima, Humira, Simlandi, Skyrizi, Stelara	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Hadlima, Humira, or Simlandi is a required Step 1 agent)	N/A	SQ: Entyvio, Omvoh Oral: Zeposia (Hadlima, Humira, Rinvoq, Simlandi, Skyrizi, Stelara, OR Xeljanz/Xeljanz XR are required Step agents)	SQ: Abrilada*, Adalimumab-ryvk*, Amjevita*, Cyltezo*, Hulio*, Hyrimoz*, Idacio*, Yuflyma*, Yusimry*, Zymfentra Oral: Velsipity *Hadlima, Humira, and Simlandi are required Step 1 agents <u>Note:</u> Branded generic available for Cyltezo, Idacio, Hulio, Hyrimoz, and Yuflyma and are included as a target at the same step level in this program
FocusRx	SQ: Cyltezo, Humira, Skyrizi, Stelara	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Cyltezo, or Humira is a required Step 1 agent)	N/A	SQ: Entyvio, Omvoh Oral: Zeposia (Cyltezo, Humira, Rinvoq, Skyrizi, Stelara, OR Xeljanz/Xeljanz XR are required Step agents)	SQ: Abrilada*, Adalimumab-adbm*, Amjevita*, Hadlima*, Hulio*, Hyrimoz*, Idacio*, Simlandi*, Yuflyma*, Yusimry*, Zymfentra Oral: Velsipity *Cyltezo, and Humira are required Step 1 agents <u>Note:</u> Branded generic available for Idacio, Hulio,

						Hyrimoz, Simlandi, and Yuflyma and are included as a target at the same step level in this program

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

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

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

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

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

** generic available

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

Initial Evaluation

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

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

Agents Eligible for Continuation of Therapy
Zeposia (ozanimod)

   A. The patient has been treated with the requested agent within the past 90 days **OR**

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

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

3. The patient has a diagnosis of moderately to severely active ulcerative colitis (UC) AND ALL of the following:
   A. ONE of the following:
      1. The patient is currently being treated with the requested agent as indicated by ALL of the following:
         A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
         B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
         C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
      2. The patient has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC **OR**

3. The patient has severely active ulcerative colitis **OR**
4. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of UC **OR**
5. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of UC **OR**
6. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of UC **OR**
7. The prescriber has provided documentation that ALL of the conventional agents (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, steroid suppositories, sulfasalazine) used in the treatment of UC cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

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

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

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

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

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

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

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

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

Renewal Evaluation

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

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**
2. ONE of the following:
    A. The patient has a diagnosis of multiple sclerosis (MS) AND BOTH of the following:
        1. ONE of the following:
            A. The requested agent is eligible for continuation of therapy AND ONE of following:

Agents Eligible for Continuation of Therapy
Zeposia (ozanimod)

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

	2. The patient will not be using the requested agent in combination with another MS disease modifying agent (DMA) (Please refer to "Multiple Sclerosis Disease Modifying Agents" contraindicated use table) **OR** B. The patient has a diagnosis of ulcerative colitis AND ALL of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (see "Immunomodulatory Agents NOT to be used Concomitantly" table) **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
MS Disease Modifying Agents
Aubagio (teriflunomide)
Avonex (interferon b-1a)
Bafiertam (monomethyl fumarate)
Betaseron (interferon b-1b)
Briumvi (ublituximab-xiiy)
Copaxone (glatiramer)
dimethyl fumarate
Extavia (interferon b-1b)
fingolimod
Gilenya (fingolimod)
Glatopa (glatiramer)
glatiramer
Kesimpta (ofatumumab)
Mavenclad (cladribine)

Contraindicated as Concomitant Therapy
Mayzent (siponimod) Plegridy (peginterferon b-1a) Ponvory (ponesimod) Rebif (interferon b-1a) Tascenso ODT (fingolimod) Tecfidera (dimethyl fumarate) Vumerity (diroximel fumarate) Zeposia (ozanimod) **Immunomodulatory Agents NOT to be used concomitantly** Abrilada (adalimumab-afzb) Actemra (tocilizumab) Adalimumab Adbry (tralokinumab-ldrm) Amjevita (adalimumab-atto) Arcalyst (rilonacept) Avsola (infliximab-axxq) Benlysta (belimumab) Bimzelx (bimekizumab-bkzx) Cibinqo (abrocitinib) Cimzia (certolizumab) Cinqair (reslizumab) Cosentyx (secukinumab) Cyltezo (adalimumab-adbm) Dupixent (dupilumab) Enbrel (etanercept) Entyvio (vedolizumab) Fasenra (benralizumab) Hadlima (adalimumab-bwwd) Hulio (adalimumab-fkjp) Humira (adalimumab) Hyrimoz (adalimumab-adaz) Idacio (adalimumab-aacf) Ilaris (canakinumab) Ilumya (tildrakizumab-asmn) Inflectra (infliximab-dyyb) Infliximab Kevzara (sarilumab) Kineret (anakinra) Litfulo (ritlecitinib) Nucala (mepolizumab) Olumiant (baricitinib) Omvoh (mirikizumab-mrkz) Opzelura (ruxolitinib) Orencia (abatacept) Otezla (apremilast) Remicade (infliximab) Renflexis (infliximab-abda) Riabni (rituximab-arrx) Rinvoq (upadacitinib) Rituxan (rituximab) Rituxan Hycela (rituximab/hyaluronidase human)

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

• Program Summary: Zoryve (roflumilast)

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

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	902300600037	Zoryve	roflumilast cream	0.15 %	M ; N ; O ; Y				
	902500450037	Zoryve	roflumilast cream	0.3 %	M ; N ; O ; Y				
	903000450039	Zoryve	roflumilast foam	0.3 %	M ; N ; O ; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is Zoryve cream AND ALL of the following: 1. The patient has a diagnosis of plaque psoriasis **AND**: 2. The patient's affected body surface area (BSA) is less than or equal to 20% **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to a topical corticosteroid **OR** B. The patient has an intolerance or hypersensitivity to therapy with topical corticosteroids **OR** C. The patient has an FDA labeled contraindication to ALL topical corticosteroids **OR**

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

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

B. The requested agent is Zoryve foam AND ALL of the following:
    1. The patient has a diagnosis of seborrheic dermatitis **AND**
    2. ONE of the following:
        A. The patient has tried and had an inadequate response to ONE topical antifungal OR ONE topical corticosteroid **OR**
        B. The patient has an intolerance or hypersensitivity to ONE topical antifungal OR ONE topical corticosteroid **OR**
        C. The patient has an FDA labeled contraindication to ALL topical antifungals AND topical corticosteroids **OR**
        D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
            1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
            2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND**
            3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
        E. The prescriber has provided documentation that topical antifungals AND topical corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to

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

3. ONE of the following:
    A. The patient has seborrheic dermatitis of the scalp **OR**
    B. The patient has tried and had an inadequate response to ONE topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) **OR**
    C. The patient has an intolerance or hypersensitivity to ONE topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) **OR**
    D. The patient has an FDA labeled contraindication to ALL topical calcineurin inhibitors (e.g., pimecrolimus, tacrolimus) **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 the 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 topical calcineurin inhibitors (e.g., pimecrolimus, tacrolimus) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

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

2. If the patient has an FDA labeled indication, then ONE of the following:
    A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
    B. There is support for using the requested agent for the patient's age for the requested indication **AND**
3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
4. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: diagnosis of plaque psoriasis 12 months, diagnosis of seborrheic dermatitis 8 weeks, All other FDA approved indications 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 [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**
2. The patient has had clinical benefit with the requested agent **AND**
3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
4. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 12 months