MHCP PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

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

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

Program Summary: Eohilia

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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**

Module	Clinical Criteria for Approval
	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's medication history includes at least ONE standard corticosteroid therapy (i.e., swallowed budesonide nebulizer suspension, swallowed fluticasone MDI) used in the treatment of EoE AND ONE of the following: 1. The patient has had an inadequate response to at least ONE standard corticosteroid therapy used in the treatment of EoE **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over standard corticosteroid therapy used in the treatment of EoE **OR** C. The patient has an intolerance or hypersensitivity to standard corticosteroid therapy used in the treatment of EoE that is not expected to occur with the requested agent **OR** D. The patient has an FDA labeled contraindication to ALL standard corticosteroid therapy used in the treatment of EoE **OR** E. The prescriber has provided documentation that ALL standard corticosteroid therapy 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's medication history includes at least ONE proton pump inhibitor (PPI) used in the treatment of EoE AND ONE of the following: 1. The patient has had an inadequate response to at least ONE PPI used in the treatment of EoE **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over PPI therapy 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: Spevigo (spesolimab-sbzo)

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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**

Module	Clinical Criteria for Approval
	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 **<u>Note</u>: 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

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

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

Contraindicated as Concomitant Therapy
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)

Program Summary: Voydeya (danicopan)

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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**

Module	Clinical Criteria for Approval
	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**

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

POLICIES REVISED

• Program Summary: Biologic Immunomodulators

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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
6627001502F540		adalimumab-aacf auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS	65219061299			
66290030002120		Etanercept For Subcutaneous Inj 25 MG		8	Vials	28	DAYS				
6627001507F810	Abrilada	adalimumab-afzb prefilled syringe kit	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001507F820	Abrilada	adalimumab-afzb prefilled syringe kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001507F520	Abrilada 1-pen kit; Abrilada 2-pen kit	adalimumab-afzb auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS				
6650007000E5	Actemra	tocilizumab subcutaneous soln prefilled syringe	162 MG/0.9ML	4	Syringes	28	DAYS				
6650007000D520	Actemra actpen	Tocilizumab Subcutaneous Soln Auto-injector 162 MG/0.9ML	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			02-27-2023	
6627001510D537	Amjevita	adalimumab-atto soln auto-injector	80 MG/0.8ML	2	Pens	28	DAYS				
6627001510E505	Amjevita	adalimumab-atto soln prefilled syringe	10 MG/0.2ML	2	Syringes	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6627001510E508	Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.2ML	2	Syringes	28	DAYS				
6627001510E510	Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.4ML	2	Syringes	28	DAYS			02-27-2023	
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			02-27-2023	
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				
52505020106420	Cimzia	Certolizumab Pegol For Inj Kit 2 X 200 MG	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	4	Pens	180	DAYS	00597037523; 00597054544			
6627001505F520	Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.8ML	6	Pens	180	DAYS	00597037516; 00597054566			
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				
6629003000E230	Enbrel mini	Etanercept Subcutaneous Solution Cartridge 50 MG/ML	50 MG/ML	4	Cartridges	28	DAYS				
6629003000D530	Enbrel sureclick	Etanercept Subcutaneous Solution Auto-injector 50 MG/ML	50 MG/ML	4	Syringes	28	DAYS				
5250308000D220	Entyvio	vedolizumab soln pen-injector	108 MG/0.68ML	2	Pens	28	DAYS				
6627001520E510	Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001520E520	Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS				

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
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	Syringes	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			
6627001500F420	Humira pen	Adalimumab Pen-injector Kit; adalimumab pen-injector kit	40 MG/0.8ML	2	Pens	28	DAYS	00074433902; 50090448700			
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	1	Kit	180	DAYS	00074012404			
6627001500F420	Humira pen-ps/uv starter	Adalimumab Pen-injector Kit;	40 MG/0.8ML	1	Kit	180	DAYS	00074433907			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		adalimumab pen-injector kit									
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				
6627001504D520	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS				
6627001504E508	Hyrimoz	adalimumab-adaz soln prefilled syringe	10 MG/0.1 ML	2	Syringes	28	DAYS				
6627001504E513	Hyrimoz	adalimumab-adaz soln prefilled syringe	20 MG/0.2ML	2	Syringes	28	DAYS				
6627001504E515	Hyrimoz	adalimumab-adaz soln prefilled syringe	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001504E520	Hyrimoz	adalimumab-adaz soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001504D540	Hyrimoz; Hyrimoz sensoready pens	adalimumab-adaz soln auto-injector	80 MG/0.8ML	2	Pens	28	DAYS	61314045420; 83457010701			
6627001504D540	Hyrimoz crohn's disease a; Hyrimoz sensoready pens	adalimumab-adaz soln auto-injector	80 MG/0.8ML	1	Starter Kit	180	DAYS	61314045436; 83457011301			
6627001504E560	Hyrimoz pediatric crohn's	adalimumab-adaz soln prefilled syr	80 MG/0.8ML & 40MG/0.4ML	2	Syringes	180	DAYS				
6627001504E540	Hyrimoz pediatric crohns	adalimumab-adaz soln prefilled syringe	80 MG/0.8ML	3	Syringes	180	DAYS				
6627001504D560	Hyrimoz plaque psoriasis	adalimumab-adaz soln auto-injector	80 MG/0.8ML & 40MG/0.4ML	1	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	Starter Kit	180	DAYS	65219055428			
6627001502F540	Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8ML	1	Starter Kit	180	DAYS	65219055438			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6650006000E5	Kevzara	sarilumab subcutaneous soln prefilled syringe	150 MG/1.14ML; 200 MG/1.14ML	2	Syringes	28	DAYS				
6650006000D5	Kevzara	sarilumab subcutaneous solution auto-injector	150 MG/1.14ML; 200 MG/1.14ML	2	Pens	28	DAYS				
6626001000E5	Kineret	anakinra subcutaneous soln prefilled syringe	100 MG/0.67ML	28	Syringes	28	DAYS				
90731060100120	Litfulo	ritlecitinib tosylate cap	50 MG	28	Capsules	28	DAYS				
666030100003	Olumiant	baricitinib tab	1 MG; 2 MG; 4 MG	30	Tablets	30	DAYS				
5250405040E520	Omvoh	mirikizumab-mrkz subcutaneous sol prefill syringe	100 MG/ML	2	Syringes	28	DAYS				
5250405040D520	Omvoh	mirikizumab-mrkz subcutaneous soln auto-injector	100 MG/ML	2	Pens	28	DAYS				
6640001000E520	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 125 MG/ML	125 MG/ML	4	Syringes	28	DAYS				
6640001000E510	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 50 MG/0.4ML	50 MG/0.4ML	4	Syringes	28	DAYS				
6640001000E515	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 87.5 MG/0.7ML	87.5 MG/0.7ML	4	Syringes	28	DAYS				
6640001000D520	Orencia clickject	Abatacept Subcutaneous Soln Auto-Injector 125 MG/ML	125 MG/ML	4	Syringes	28	DAYS				
66603072007540	Rinvoq	Upadacitinib Tab ER	45 MG	84	Tablets	365	DAYS				
66603072007520	Rinvoq	Upadacitinib Tab ER 24HR 15 MG	15 MG	30	Tablets	30	DAYS				
66603072002020	Rinvoq lq	upadacitinib oral soln	1 MG/ML	360	mLs	30	DAYS				
9025052000E5	Siliq	brodalumab subcutaneous soln prefilled syringe	210 MG/1.5ML	2	Syringes	28	DAYS				
6627001540F520	Simlandi 1-pen kit; Simlandi 2-pen kit	adalimumab-ryvk auto-injector kit	40 MG/0.4ML	2	Pens	28	DAYS				

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
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				
9025057070F820	Skyrizi	Risankizumab-rzaa Sol Prefilled Syringe 2 x 75 MG/0.83ML Kit	75 MG/0.83ML	1	Kit	84	DAYS				
9025057070E540	Skyrizi	Risankizumab-rzaa Soln Prefilled Syringe	150 MG/ML	1	Syringe	84	DAYS				
5250406070E210	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	180 MG/1.2ML	1	Cartridge	56	DAYS				
5250406070E220	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	360 MG/2.4ML	1	Cartridge	56	DAYS				
9025057070D520	Skyrizi pen	Risankizumab-rzaa Soln Auto-injector	150 MG/ML	1	Pen	84	DAYS				
90250524000320	Sotyktu	Deucravacitinib Tab	6 MG	30	Tablets	30	DAYS				
90250585002020	Stelara	Ustekinumab Inj 45 MG/0.5ML	45 MG/0.5ML	1	Vial	84	DAYS				
9025058500E520	Stelara	Ustekinumab Soln Prefilled Syringe 45 MG/0.5ML	45 MG/0.5ML	1	Syringe	84	DAYS				
9025058500E540	Stelara	Ustekinumab Soln Prefilled Syringe 90 MG/ML	90 MG/ML	1	Syringe	56	DAYS				
9025055400D520	Taltz	Ixekizumab Subcutaneous Soln Auto-injector 80 MG/ML	80 MG/ML	1	Injection	28	DAYS				
9025055400E520	Taltz	Ixekizumab Subcutaneous Soln Prefilled Syringe 80 MG/ML	80 MG/ML	1	Syringe	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
9025054200D220	Tremfya	Guselkumab Soln Pen-Injector 100 MG/ML	100 MG/ML	1	Pen	56	DAYS				
9025054200E520	Tremfya	Guselkumab Soln Prefilled Syringe 100 MG/ML	100 MG/ML	1	Syringe	56	DAYS				
6650007017D520	Tyenne	tocilizumab-aazg subcutaneous soln auto-inj	162 MG/0.9ML	4	Pens	28	DAYS				
6650007017E520	Tyenne	tocilizumab-aazg subcutaneous soln pref syr	162 MG/0.9ML	4	Syringes	28	DAYS				
52504525100350	Velsipity	etrasimod arginine tab	2 MG	30	Tablets	30	DAYS				
66603065102020	Xeljanz	Tofacitinib Citrate Oral Soln	1 MG/ML	240	mLs	30	DAYS				
66603065100330	Xeljanz	Tofacitinib Citrate Tab 10 MG (Base Equivalent)	10 MG	240	Tablets	365	DAYS				
66603065100320	Xeljanz	Tofacitinib Citrate Tab 5 MG (Base Equivalent)	5 MG	60	Tablets	30	DAYS				
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			

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
5250504020F830	Zymfentra 2-syringe	infliximab-dyyb soln prefilled syringe kit	120 MG/ML	2	Syringes	28	DAYS				
66603072007530	Rinvoq	Upadacitinib Tab ER	30 MG	30	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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For Medicaid, the preferred products are the MN Medicaid Preferred Drug List (PDL) preferred drugs: Enbrel kits, Enbrel pens, Enbrel syringes, Enbrel vial, Enbrel mini cartridges, Humira kits, Humira pen kits, infliximab intravenous injection, Otezla tablets, and Xeljanz Immediate Release tablets.

Disease State	PDL Preferred Agents	PDL Non-Preferred Agents
Ankylosing Spondylitis (AS)	SQ: Enbrel, Humira Oral: Xeljanz IV: infliximab*	SQ: Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cimzia, Cosentyx, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simponi, Taltz, Yuflyma Oral: Rinvoq, Xeljanz XR
Nonradiographic Axial Spondyloarthritis (nr-axSpA)	N/A	SQ: Cimzia, Cosentyx, Taltz Oral: Rinvoq
Polyarticular Juvenile Idiopathic Arthritis (PJIA)	SQ: Enbrel, Humira Oral: Xeljanz	SQ: Abrilada, Actemra, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Kevzara, Orencia, Yuflyma Oral: Rinvoq, Xeljanz solution
Psoriatic Arthritis (PsA)	SQ: Enbrel, Humira Oral: Otezla, Xeljanz IV: infliximab*	SQ: Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cimzia, Cosentyx, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Orencia, Simponi, Skyrizi, Stelara, Taltz, Tremfya, Yuflyma Oral: Rinvoq, Xeljanz XR
Rheumatoid Arthritis	SQ: Enbrel, Humira Oral: Xeljanz IV: infliximab*	SQ: Abrilada, Actemra, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cimzia, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Kevzara, Kineret, Orencia, Simponi, Yuflyma Oral: Olumiant, Rinvoq, Xeljanz XR
Hidradenitis Suppurativa (HS)	SQ: Humira	SQ: Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma
Psoriasis (PS)	SQ: Enbrel, Humira Oral: Otezla IV: infliximab*	SQ: Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Bimzelx, Cimzia, Cosentyx, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Siliq, Skyrizi, Sotyktu, Stelara, Taltz, Tremfya, Yuflyma

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	Crohn's Disease	SQ: Humira IV: infliximab*	SQ: Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cimzia, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Skyrizi, Stelara, Yuflyma
	Ulcerative Colitis	SQ: Humira Oral: Xeljanz IV: infliximab*	SQ: Abrilada syringe/pen, adalimumab-adaz syringe/pen, adalimumab-adbm syringe/pen, adalimumab-fkjp syringe/pen, Amjevita syringe/autoinjector, Cyltezo syringe/pen, Entyvio, Hadlima, Hulio, Hyrimoz, Idacio, Simponi, Skyrizi, Stelara, Yuflyma Oral: Rinvoq, Xeljanz XR
	Uveitis	SQ: Humira	SQ: Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma
	Alopecia Areata Atopic Dermatitis Deficiency of IL-1 Receptor Antagonist (DIRA) Enthesitis Related Arthritis (ERA) Giant Cell Arteritis (GCA) Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Systemic Juvenile Idiopathic Arthritis (SJIA) Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)	N/A	N/A

* Infliximab is a preferred product on the MN Medicaid Preferred Drug List (PDL) and is locked to the medical benefit

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	** Note: For Xeljanz products (Xeljanz and Xeljanz XR) and Rinvoq products (Rinvoq and Rinvoq LQ), a trial of either or both dosage forms collectively counts as ONE product
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The request is NOT for use of Olumiant or Actemra in the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) *NOTE: This indication is not covered under the pharmacy benefit **AND** 2. If the request is for use in Alopecia Areata and Alopecia Areata is NOT restricted from coverage under the patient's benefit **AND** 3. ONE of the following: A. If the request is for an oral liquid form of a medication, then BOTH of the following: 1. The patient has an FDA labeled indication **AND** 2. The patient uses an enteral tube for feeding or medication administration **OR** B. ALL of the following: 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. 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's medication history includes ONE conventional agent (i.e., maximally tolerated methotrexate [e.g., titrated to 25 mg weekly], hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA AND ONE of the following: 1. The patient has had an inadequate response to a conventional agent used in the treatment of RA **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional agents used in the treatment of RA **OR** B. The patient has an intolerance or hypersensitivity to ONE of the following conventional agents (i.e., maximally tolerated methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR**

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	C. 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** D. 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** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that ALL 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's medication history includes ONE conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA AND ONE of the following: A. The patient has had an inadequate response to a conventional agent used in the treatment of PsA **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional agents used in the treatment of PsA **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PsA **OR**

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	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 therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 8. The prescriber has provided documentation that ALL of the conventional agents 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's medication history includes 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 AND ONE of the following: A. The patient has had an inadequate response to a conventional agent used in the treatment of PS **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional agents used in the treatment of PS **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

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	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 therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 8. The prescriber has provided documentation that 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's medication history includes ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD AND ONE of the following: A. The patient has had an inadequate response to a conventional agent used in the treatment of CD **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional agents used in the treatment of CD **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:

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	A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive 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 of the conventional agents 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's medication history includes ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC AND ONE of the following: A. The patient has had an inadequate response to a conventional agent used in the treatment of UC **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional agents used in the treatment of UC **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 therapeutic 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 of the conventional agents 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**

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	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's medication history includes oral corticosteroids OR periocular or intravitreal corticosteroid injections used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis AND ONE of the following: A. The patient has had an inadequate response to oral corticosteroids OR periocular or intravitreal corticosteroid injections used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over oral corticosteroids OR periocular or intravitreal corticosteroid injections used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 2. 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** 3. The patient has an FDA labeled contraindication to BOTH oral corticosteroids and periocular/intravitreal corticosteroids **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

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	5. 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's medication history includes ONE conventional systemic agent (i.e., azathioprine, mycophenolate, methotrexate, cyclosporine, tacrolimus) used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis AND ONE of the following: A. The patient has had an inadequate response to a conventional agent used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **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 therapeutic

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	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's medication history includes systemic corticosteroids (e.g., prednisone, methylprednisolone) used in the treatment of GCA AND ONE of the following: A. The patient has had an inadequate response to systemic corticosteroids (e.g., prednisone, methylprednisolone) used in the treatment of GCA **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over systemic corticosteroids (e.g., prednisone, methylprednisolone) used in the treatment of GCA **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 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 systemic corticosteroids cannot be used due to a

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	documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** H. The patient has a diagnosis of active ankylosing spondylitis (AS) AND ONE of the following: 1. The patient's medication history includes TWO different NSAIDs used in the treatment of AS AND ONE of the following: A. The patient has had an inadequate response to TWO different NSAIDs used in the treatment of AS **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over TWO different NSAIDs used in the treatment of AS **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 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 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's medication history includes two different NSAIDs used in the treatment of nr-axSpA AND ONE of the following: A. The patient has had an inadequate response to TWO different NSAIDs used in the treatment of nr-axSpA **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over TWO different NSAIDs used in the treatment of nr-axSpA **OR**

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	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 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 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's medication history includes ONE conventional agent (i.e., methotrexate, leflunomide) used in the treatment of PJIA AND ONE of the following: A. The patient has had an inadequate response to ONE conventional agent (i.e., methotrexate, leflunomide) used in the treatment of PJIA **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional agents (i.e., methotrexate, leflunomide) used in the treatment of PJIA **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 therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

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	6. The prescriber has provided documentation that ALL of the conventional agents 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's medication history includes 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 AND ONE of the following: A. The patient has had an inadequate response to at a conventional agent used in the treatment of HS **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional agents used in the treatment of HS **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 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 conventional agents 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**

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	M. The patient has a diagnosis of active enthesitis related arthritis (ERA) and ONE of the following: 1. The patient's medication history includes TWO different NSAIDs used in the treatment of ERA AND ONE of the following: A. The patient has had an inadequate response to TWO different NSAIDs used in the treatment of ERA **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over NSAIDs used in the treatment of ERA **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 is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber 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 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** 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 ERA **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 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's medication history includes at least a medium-potency topical corticosteroid used in the treatment of AD **AND** a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus,

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	Protopic/tacrolimus) used in the treatment of AD AND ONE of the following: 1. The patient has had an inadequate response 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** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over at least medium-potency topical corticosteroids used in the treatment of AD **AND** topical calcineurin inhibitors (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR** B. The patient has an intolerance or hypersensitivity to 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** 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 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,

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	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's medication history includes ONE systemic corticosteroid at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR AND ONE of the following: A. The patient has 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 **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR **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 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 prescriber has provided documentation that ALL systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone 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's medication history includes a conventional agent (i.e., methotrexate, leflunomide, sulfasalazine) used in the treatment of JPsA AND ONE of the following: A. The patient has had an inadequate response to ONE conventional agent (i.e., methotrexate, leflunomide, sulfasalazine) used in the treatment of JPsA **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional

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	agents (i.e., methotrexate, leflunomide, sulfasalazine) used in the treatment of JPsA **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 is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber 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 conventional agents (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** 6. 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** 7. 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** 8. 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** R. The patient has a diagnosis not mentioned previously **AND** 2. ONE of the following: A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR** B. The request is for Velsipity, Omvoh, or a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and 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 preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following:

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	A. ONE of the following: 1. Evidence of a paid claim **OR** 2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND** B. ONE of the following: 1. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR** 3. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** 4. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 5. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **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 after at least 3-month duration of therapy **AND** 4. 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 intravenous therapy **OR** B. The patient is new to therapy and will receive 2 doses of Entyvio IV therapy **AND**

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	5. If Omvoh is requested for the treatment of ulcerative colitis, then ONE of the following: A. The patient received Omvoh IV for induction therapy **OR** B. The patient is new to therapy and will receive Omvoh IV for induction 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** 2. 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** 3. 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** 4. If Kevzara is requested for a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA), the patient weighs 63 kg or greater **AND** 5. If the patient has 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** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or has consulted with a specialist in the area of the patient's diagnosis **AND** 7. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support of combination therapy (submitted copy required, i.e., clinical trials, phase III studies, guidelines required) **AND**

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	8. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 9. The patient has been tested for latent tuberculosis (TB) when required by the prescribing information for the requested agent AND if positive the patient has begun therapy for latent TB **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. **Compendia Allowed:** CMS Approved Compendia **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. If the request is for an oral liquid form of a medication, then BOTH of the following: 1. The patient has an FDA labeled indication **AND** 2. The patient uses an enteral tube for feeding or medication administration **OR** B. ALL of the following: 1. 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:

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	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** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, 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** 3. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, guidelines required) **AND** 4. 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 after at least a 3-month duration of therapy **AND** 5. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **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

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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**

Module	Clinical Criteria for Approval
	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:** CMS Approved Compendia **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)

Contraindicated as Concomitant Therapy
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)
Tyenne (tocilizumab-aazg)
Tysabri (natalizumab)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)

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

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

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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				
86807018002020	Miebo	perfluorohexyloctane ophth soln	1.338 GM/ML	1	Bottle	30	DAYS				
86720020001620	Restasis	cyclosporine (ophth) emulsion	0.05; 0.05 %	60	Vials	30	DAYS	00023916330; 00023916360; 00378876058; 00378876091; 10702080803; 10702080806; 50090124200; 50090447600; 60505620201; 60505620202; 68180021430; 68180021460; 73043000501; 73043000502			
86720020001620	Restasis; Restasis multidose	cyclosporine (ophth) emulsion	0.05; 0.05 %	1	Bottle	30	DAYS				
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				
86734050002020	Xiidra	Lifitegrast Ophth Soln 5%	5 %	60	Vials	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Initial Evaluation** **Tyrvaya (varenicline)** will be approved when ALL of the following are met: 1. ONE of the following: A. BOTH of the following:

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	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's medication history includes aqueous enhancements (e.g., artificial tears, gels, ointments [target agents not included]) AND ONE of the following: 1. The patient has had an inadequate response to aqueous enhancements **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL aqueous enhancements **OR** B. The patient has an intolerance or hypersensitivity to aqueous enhancements **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 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 (e.g., artificial tears, gels, ointments [target agents not included]) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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:** CMS approved compendia **Length of Approval:** Tyrvaya (varenicline) - 2 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. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months

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

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
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: Interleukin-4 (IL-4) Inhibitors

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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/1.14ML	2	Pens	28	DAYS				
9027302000D220	Dupixent	Dupilumab Subcutaneous Soln Pen-injector 300 MG/2ML	300 MG/2ML	4	Pens	28	DAYS				
9027302000E510	Dupixent	Dupilumab Subcutaneous Soln Prefilled Syringe	100 MG/0.67ML	2	Syringes	28	DAYS				
9027302000E515	Dupixent	Dupilumab Subcutaneous Soln Prefilled Syringe 200 MG/1.14ML	200 MG/1.14ML	2	Syringes	28	DAYS				
9027302000E520	Dupixent	Dupilumab Subcutaneous Soln	300 MG/2ML	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
		Prefilled Syringe 300 MG/2ML									

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's medication history includes use of 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 AND ONE of the following: 1. The patient has had an inadequate response to BOTH at least a medium-potency topical corticosteroid AND a topical calcineurin inhibitor used in the treatment of AD **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over BOTH at least a medium-potency topical corticosteroid AND a topical calcineurin inhibitor 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**

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	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)

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	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. There is information indicating 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's medication history includes use of ONE standard corticosteroid therapy used in the treatment of EoE (i.e., budesonide oral suspension, swallowed budesonide nebulizer suspension, swallowed fluticasone MDI) AND ONE of the following: 1. The patient has had an inadequate response to ONE standard corticosteroid therapy used in the treatment of EoE **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the

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	requested agent over standard corticosteroid therapies used in the treatment of EoE **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 therapy 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's medication history includes use of ONE proton pump inhibitor (PPI) used in the treatment of EoE AND ONE of the following: 1. The patient has had an inadequate response to ONE PPI used in the treatment of EoE **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over PPIs 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's medication history includes use of at least a medium-potency topical corticosteroid used in the treatment of PN AND ONE of the following: 1. The patient has had an inadequate response to at least a medium-potency topical corticosteroid used in the treatment of PN **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over at least a medium-potency topical corticosteroid used in the treatment of PN **OR** B. The patient has an intolerance or hypersensitivity to 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:

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	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. A 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 a LABA, LAMA, 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/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **AND**

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	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 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:** CMS Approved Compendia **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 (FEV_1) **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**

Module	Clinical Criteria for Approval
	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, 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 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:** CMS Approved Compendia **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

Module	Clinical Criteria for Approval
	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)
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)

Contraindicated as Concomitant Therapy
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: Parathyroid Hormone Analog for Osteoporosis

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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
3004407000D220	Forteo	Teriparatide (Recombinant) Soln Pen-inj 600 MCG/2.4ML	600 MCG/2.4ML	1	Pen	28	DAYS				
3004407000D221	Teriparatide	Teriparatide (Recombinant) Soln Pen-inj 620 MCG/2.48ML	620 MCG/2.48ML	1	Pen	28	DAYS				
3004400500D230	Tymlos	Abaloparatide Subcutaneous Soln Pen-injector 3120 MCG/1.56ML	3120 MCG/1.56ML	1	Pen	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Teriparatide through preferred	**For Medicaid, the preferred product is the MN Medicaid Preferred Drug List (PDL) preferred drug: Forteo**

Module	Clinical Criteria for Approval
	Non-Preferred Agent(s) 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 ONE of the following: 1. The patient's sex is male and ONE of the following: A. The patient's age is 50 years or over **OR** B. The requested agent is medically appropriate for the patient's age and sex **OR** 2. The patient's sex is female and ONE of the following: A. The patient is postmenopausal **OR** B. The requested agent is medically appropriate for the patient's sex and menopause status **OR** B. The patient has a diagnosis of glucocorticoid-induced osteoporosis AND BOTH 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** 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's medication history includes a bisphosphonate AND ONE of the following: A. The patient has had an inadequate response to bisphosphonate therapy (medical records required) **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over bisphosphonates **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**

Module	Clinical Criteria for Approval
	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. ONE of the following: A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR** B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and 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 preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following: A. ONE of the following: 1. Evidence of a paid claim(s) **OR** 2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND** B. ONE of the following: 1. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR** 3. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** 4. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 5. 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** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 7. 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.

Module	Clinical Criteria for Approval
	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.
Tymlos through preferred	**For Medicaid, the preferred product is the MN Medicaid Preferred Drug List (PDL) preferred drug: Forteo** **Non-Preferred Agent(s) Tymlos** will be approved when ALL of the following are met: 1. The patient has a diagnosis of osteoporosis AND ALL of the following: A. ONE of the following: 1. The patient's sex is male and ONE of the following: A. The patient's age is 50 years or over **OR** B. The requested agent is medically appropriate for the patient's age and sex **OR** 2. The patient's sex is female and ONE of the following: A. The patient is postmenopausal **OR** B. The requested agent is medically appropriate for the patient's sex and menopause status **AND** B. The patient's diagnosis was confirmed by ONE of the following: 1. A fragility fracture in the hip or spine **OR** 2. A T-score of -2.5 or lower **OR** 3. A T-score of -1.0 to -2.5 and ONE of the following: A. A fragility fracture of a proximal humerus, pelvis, or distal forearm **OR** B. A FRAX 10-year probability for major osteoporotic fracture of greater than or equal to 20% **OR** C. A FRAX 10-year probability of hip fracture of greater than or equal to 3% **AND** C. ONE of the following: 1. The patient is at a very high fracture risk as defined by ONE of the following: A. Patient had a recent fracture (within the past 12 months) **OR** B. Patient had fractures while on FDA labeled osteoporosis therapy **OR** C. Patient has had multiple fractures **OR** D. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) **OR** E. Patient has a very low T-score (less than -3.0) **OR** F. Patient is at high risk for falls or has a history of injurious falls **OR** G. 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** 2. ONE of the following: A. The patient's medication history includes a bisphosphonate AND ONE of the following: 1. The patient has had an inadequate response to bisphosphonate therapy (medical records required) **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over bisphosphonates **OR** B. The patient has an intolerance or hypersensitivity to bisphosphonate (medical records required) **OR** C. The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required) **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following:

Module	Clinical Criteria for Approval
	1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL 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. ONE of the following: A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR** B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and 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 preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following: A. ONE of the following: 1. Evidence of a paid claim(s) **OR** 2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND** B. ONE of the following: 1. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR** 3. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** 4. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. 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., teriparatide) therapy **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. 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: Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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
3935002000E5	Repatha	evolocumab subcutaneous soln prefilled syringe	140 MG/ML	2	Syringes	28	DAYS				
3935002000E2	Repatha pushtronex system	evolocumab subcutaneous soln cartridge/infusor	420 MG/3.5ML	2	Cartridges	28	DAYS				
3935002000D5	Repatha sureclick	evolocumab subcutaneous soln auto-injector	140 MG/ML	2	Pens	28	DAYS				
3935001000	Praluent	alirocumab subcutaneous solution auto-injector	150 MG/ML; 75 MG/ML	2	Syringes	28	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) and ALL of the following: 1. The patient has a diagnosis of HoFH confirmed by ONE of the following: A. Genetic confirmation of bi-allelic pathogenic/likely pathogenic variants on different chromosomes at the *LDLR, Apo-B, PCSK9,* or *LDLRAP1* genes, or greater than or equal to 2 such variants at different loci **OR** B. History of untreated LDL-C greater than 400 mg/dL (greater than 10 mmol/L) and ONE of the following: 1. The patient had cutaneous or tendon xanthomas before age of 10 years **OR** 2. Untreated elevated LDL-C levels consistent with heterozygous FH in both parents, (or in digenic form, one parent may have normal LDL-C levels and the other may have LDL-C levels consistent with HoFH) **AND** 2. ONE of the following: A. The patient has tried a high-intensity statin (e.g., atorvastatin 40-80 mg, rosuvastatin 20-40 mg daily) for 2 months and had an inadequate response **OR** B. The patient has an intolerance or hypersensitivity to ALL high-intensity statins **OR** C. The patient has an FDA labeled contraindication to ALL high-intensity statins **OR** D. The patient's medication history includes use of high intensity atorvastatin or rosuvastatin therapy, or a drug in the same pharmacological class with the same mechanism of action, AND ONE of the following: 1. High intensity atorvastatin or rosuvastatin or a drug in the same pharmacological class with the same mechanism of action was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over high-intensity rosuvastatin or atorvastatin therapy **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 atorvastatin AND rosuvastatin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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 use other lipid-lowering therapy (e.g., statin, ezetimibe, lipoprotein apheresis, lomitapide, evinacumab) **OR** B. BOTH of the following: 1. ONE of the following: A. The patient has a diagnosis of heterozygous familial hypercholesterolemia (HeFH) AND ONE of the following: 1. Genetic confirmation of one mutant allele at the *LDLR, Apo-B, PCSK9*, or *1/LDLRAP1* gene **OR** 2. Pre-treatment LDL-C greater than 190 mg/dL (greater than 4.9 mmol/L) **OR** 3. The patient has clinical manifestations of HeFH (e.g., cutaneous xanthomas, tendon xanthomas, corneal arcus) **OR** 4. The patient has "definite" or "possible" familial hypercholesterolemia as defined by the Simon Broome criteria **OR** 5. The Patient has a Dutch Lipid Clinic Network Criteria score of greater than 5 **OR**

Module	Clinical Criteria for Approval
	6. The patient has a treated LDL-C level greater than or equal to 100 mg/dL after statin treatment with or without ezetimibe **OR** B. The patient has a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) AND has ONE of the following: 1. Acute coronary syndrome 2. History of myocardial infarction 3. Stable or unstable angina 4. Coronary or other arterial revascularization 5. Stroke 6. Transient ischemic attack 7. Peripheral arterial disease, including aortic aneurysm, presumed to be of atherosclerotic origin **OR** C. The patient has a diagnosis of primary hyperlipidemia AND ONE of the following: 1. The patient has a coronary artery calcium or calcification (CAC) score greater than or equal to 300 Agatston units **OR** 2. The patient has a pre-treatment LDL-C level greater than or equal to 190 mg/dL (greater than or equal to 4.9 mmol/L) **OR** D. The patient has at least a 20% 10-year ASCVD risk AND ONE of the following: 1. The patient has greater than or equal to 40% 10-year ASCVD risk AND BOTH of the following: A. LDL-C greater than or equal to 70 mg/dL while on maximally tolerated statin therapy **AND** B. ONE of the following: 1. The patient has extensive or active burden of ASCVD (i.e., polyvascular ASCVD, which affects all 3 vascular beds—coronary, cerebrovascular, and peripheral arterial; clinical peripheral arterial disease in addition to coronary and/or cerebrovascular disease; a clinical ASCVD event with multivessel coronary artery disease defined as greater than or equal to 40% stenosis in greater than or equal to 2 large vessels; or recurrent myocardial infarction within 2 years of the initial event) in the presence of adverse or poorly controlled cardiometabolic risk factors **OR** 2. Extremely high-risk elevations in cardiometabolic factors with less-extensive ASCVD (i.e., diabetes, LDL-C greater than or equal to 100 mg/dL, less than high–intensity statin therapy, chronic kidney disease, poorly controlled hypertension, high-sensitivity C-reactive protein greater than 3 mg/L, or metabolic syndrome, usually occurring with other extremely high–risk or very-high-risk characteristics), usually with other adverse or poorly controlled cardiometabolic risk factors present. **OR** 3. Patients with ASCVD and LDL-C greater than or equal to 220 mg/dL with greater than or equal to 45% 10- year ASCVD risk despite statin therapy **OR** 2. The patient has 30-39% 10-year ASCVD risk AND ALL of the following: A. LDL-C greater than or equal to 100 mg/dL while on maximally tolerated statin therapy **AND** B. Less-extensive clinical ASCVD (i.e., no polyvascular ASCVD, no clinical peripheral arterial disease, a prior ASCVD event greater than or equal to 2 years prior, and no coronary artery bypass grafting) **AND** C. Adverse or poorly controlled cardiometabolic risk factor(s) including age 65 years or older, current smoking, chronic kidney disease, lipoprotein(a) greater than or equal to 37 nmol/L, high-sensitivity C-

Module	Clinical Criteria for Approval
	reactive protein 1–3 mg/L, metabolic syndrome with a history of myocardial infarction, ischemic stroke, or symptomatic peripheral arterial disease, usually in the presence of other adverse or poorly controlled cardiometabolic risk factors **OR** 3. The patient has 20-29% 10-year ASCVD risk AND BOTH of the following: A. LDL-C greater than or equal to 130 mg/dL while on maximally tolerated statins **AND** B. ONE of the following: 1. The patient has less extensive ASCVD and well-controlled cardiometabolic risk factors (i.e., no diabetes, nonsmoker, on high-intensity statin with LDL-C less than 100 mg/dL, blood pressure less than 140/90 mm Hg, and C-reactive protein less than 1 mg/dL) **OR** 2. The use is for primary prevention with LDL-C greater than or equal to 220 mg/dL AND BOTH of the following: A. No clinical ASCVD or CAC less than 100 Agatston units **AND** B. Poorly controlled cardiometabolic risk factor **AND** 2. ONE of the following: A. The patient has been adherent to high-intensity statin therapy (i.e., atorvastatin 40-80mg, rosuvastatin 20-40 mg daily) for at least 8 consecutive weeks AND ONE of the following: 1. The patient's LDL-C level after this statin therapy remains greater than or equal to 70 mg/dL **OR** 2. The patient has not achieved a 50% reduction in LDL-C from this statin therapy **OR** 3. If the patient has ASCVD at very high risk, ONE of the following: A. The patient's LDL-C level after this statin therapy remains greater than or equal to 55 mg/dL **OR** B. The patient's non HDL-C level after this statin therapy remains greater than or equal to 85 mg/dL **OR** B. The patient has been determined to be statin intolerant by meeting ONE of the following: 1. The patient experienced statin-related rhabdomyolysis **OR** 2. The patient experienced skeletal-related muscle symptoms (e.g., myopathy, myalgia) and BOTH of the following: A. The skeletal-related muscle symptoms occurred while receiving separate trials of both atorvastatin AND rosuvastatin **AND** B. When receiving separate trials of both atorvastatin and rosuvastatin, the skeletal-related muscle symptoms resolved upon discontinuation of each statin **OR** 3. The patient experienced elevations in hepatic transaminase while receiving separate trials of both atorvastatin and rosuvastatin **OR** C. The patient has a hypersensitivity to atorvastatin AND rosuvastatin **OR** D. The patient has an FDA labeled contraindication to atorvastatin AND rosuvastatin **OR** E. The patient's medication history includes use of high intensity atorvastatin or rosuvastatin therapy, or a drug in the same pharmacological class with the same mechanism of action, AND ONE of the following: 1. High intensity atorvastatin or rosuvastatin or a drug in the same pharmacological class with the same mechanism of action was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over high-intensity rosuvastatin or atorvastatin therapy **OR**

Module	Clinical Criteria for Approval
	F. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** G. The prescriber has provided documentation that atorvastatin AND rosuvastatin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has another FDA labeled indication for the requested agent and route of administration **OR** D. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA labeled indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. The patient will NOT be using the requested agent in combination with another PCSK9 agent for the requested indication **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **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 therapy for PCSK9 inhibitors 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 shown clinical benefit with a PCSK9 inhibitor **AND** 3. The patient is currently adherent to therapy with a PCSK9 inhibitor **AND** 4. If the patient has a diagnosis of HoFH, they will continue to use other lipid-lowering therapy (e.g., statin, ezetimibe, lipoprotein apheresis, lomitapide, evinacumab) **AND** 5. If the patient has ASCVD, HeFH, or hyperlipidemia, then ONE of the following: A. The patient is currently adherent to high-intensity statin therapy (i.e., atorvastatin 40-80mg, rosuvastatin 20-40 mg daily) **OR** B. The patient has been determined to be statin intolerant by meeting ONE of the following criteria: 1. The patient experienced statin-related rhabdomyolysis **OR** 2. The patient experienced skeletal-related muscle symptoms (e.g., myopathy, myalgia) and BOTH of the following: A. The skeletal-related muscle symptoms occurred while receiving separate trials of both atorvastatin AND rosuvastatin **AND** B. When receiving separate trials of both atorvastatin and rosuvastatin the skeletal-related muscle symptoms resolved upon discontinuation of each statin **OR**

Module	Clinical Criteria for Approval
	3. The patient experienced elevations in hepatic transaminase while receiving separate trials of both atorvastatin and rosuvastatin **OR** C. The patient has a hypersensitivity to atorvastatin AND rosuvastatin **OR** D. The patient has an FDA labeled contraindication to atorvastatin AND rosuvastatin **OR** E. The patient's medication history includes use of high-intensity rosuvastatin or atorvastatin therapy or a drug in the same pharmacological class with the same mechanism of action AND ONE of the following: 1. High-intensity rosuvastatin or atorvastatin, or a drug in the same pharmacological class with the same mechanism of action, was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over high-intensity rosuvastatin or atorvastatin therapy **OR** F. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** G. The prescriber has provided documentation that atorvastatin and rosuvastatin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 6. The patient will NOT be using the requested agent in combination with another PCSK9 agent for the requested indication **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

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

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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
86720020001630	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's medication history includes combination of a topical ophthalmic mast cell stabilizer AND an antihistamine used in the treatment of VKC AND ONE of the following: 1. The patient has had an inadequate response to the combination of a topical ophthalmic mast cell stabilizer AND an antihistamine used in the treatment of VKC **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the 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 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's medication history includes a topical ophthalmic corticosteroid used in the treatment of VKC AND ONE of the following: 1. The patient has had an inadequate response to a topical ophthalmic corticosteroid used in the treatment of VKC **OR**

Module	Clinical Criteria for Approval
	2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over 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 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:** CMS Approved Compendia **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:

Module	Clinical Criteria for Approval
	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:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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				

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
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				
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**

Module	Clinical Criteria for Approval
	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. ONE of the following: A. The generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested 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. 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:** CMS Approved Compendia **Length of Approval**: Tardive dyskinesia - 3 months, all other indications - 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

Module	Clinical Criteria for Approval
	Renewal Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The 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. ONE of the following: A. The generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested 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** 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:** CMS Approved Compendia **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: Weight Loss Agents

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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				

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
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

Targeted Agents that are part of the MN Medicaid Preferred Drug List (PDL)	
PDL Preferred Agents	**PDL Non-Preferred Agents**
Saxenda Wegovy	orlistat Xenical

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 **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**

Module	Clinical Criteria for Approval
	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 a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR** B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following: 1. The patient is currently being treated with the requested agent and is experiencing a positive therapeutic outcome AND the prescriber provides documentation that switching the member to a preferred drug is expected to cause harm to the member or that the preferred drug would be ineffective **OR** 2. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following: A. ONE of the following: 1. Evidence of a paid claim(s) **OR** 2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND** B. ONE of the following: 1. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR** C. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** D. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse

Module	Clinical Criteria for Approval
	reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** E. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **AND** 5. 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** 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 **Length of Approval:** 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

Module	Clinical Criteria for Approval
	Renewal Evaluation (Patient continuing a current weight loss course of therapy) **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient meets ONE of the following: A. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of requested agent) **OR** B. 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:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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				

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
6125258000D520	Zepbound	tirzepatide (weight mngmt) soln auto-injector	2.5 MG/0.5ML	4	Pens	180	DAYS				
6125258000D525	Zepbound	tirzepatide (weight mngmt) soln auto-injector	5 MG/0.5ML	4	Pens	28	DAYS				
6125258000D530	Zepbound	tirzepatide (weight mngmt) soln auto-injector	7.5 MG/0.5ML	4	Pens	28	DAYS				
6125258000D535	Zepbound	tirzepatide (weight mngmt) soln auto-injector	10 MG/0.5ML	4	Pens	28	DAYS				
6125258000D540	Zepbound	tirzepatide (weight mngmt) soln auto-injector	12.5 MG/0.5ML	4	Pens	28	DAYS				
6125258000D545	Zepbound	tirzepatide (weight mngmt) soln auto-injector	15 MG/0.5ML	4	Pens	28	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL the following are met: 1. ONE of the following: A. The 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 established cardiovascular disease as evidenced by ONE of the following: (medical records required) A. Myocardial infarction **OR** B. Stroke **OR** C. Peripheral artery disease as defined by intermittent claudication with ankle-brachial index less than 0.85 at rest, or peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease **AND** 3. The patient has a BMI greater than or equal to 27 kg/m^2 (medical records required) **AND** 4. The patient does NOT have type 1 or type 2 diabetes **AND** 5. The patient does NOT have a hemoglobin A1C greater than or equal to 6.5% (medical records required) **AND** 6. The patient does NOT have a history of a myocardial infarction, stroke, transient ischemic attack, or hospitalization for unstable angina in the last 60 days **AND** 7. The patient's age is 45 years or over **OR** B. The patient is overweight or obese and is using the requested agent for weight management and ALL of the following: 1. The patient is new to therapy, new to Prime, or attempting a repeat weight loss course of therapy **AND** 2. ONE of the following:

Module	Clinical Criteria for Approval
	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, 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** 3. BOTH of the following: A. The patient has been on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications for a minimum of 6 months **AND** B. The patient has experienced weight loss of less than 1 pound per week while on a weight loss regimen (e.g., low-calorie diet, increased physical activity, and behavioral modifications) prior to any pharmacotherapy **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. ONE of the following: A. 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: 1. The patient is newly starting therapy **OR** 2. The patient is currently being treated and has received less than 20 weeks (5 months) of therapy **OR** 3. The patient has achieved and maintained a reduction in BMI of greater than or equal to 1% from baseline (prior to initiation of pharmacotherapy) **OR** B. If the requested agent is Wegovy, then ONE of the following: 1. The patient is newly starting therapy **OR** 2. The patient is currently being treated and has received less than 52 weeks (1 year) of therapy **OR** 3. ONE of the following: A. The patient is an adult AND has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR** B. The patient is pediatric (12 to less than 18 years of age) AND has achieved and maintained a reduction in BMI of at least 5% from baseline (prior to initiation of pharmacotherapy) **OR** C. If the requested agent is Zepbound, then ONE of the following:

Module	Clinical Criteria for Approval
	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) **AND** 6. 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 **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 patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND** 4. 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 the patient was or 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 does NOT have a history of type 1 or type 2 diabetes **AND** 3. 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. The patient is continuing a current weight loss course of therapy **AND** 2. 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 a weight loss regimen in combination with the requested agent **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. ONE of the following: A. 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:

Module	Clinical Criteria for Approval
	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 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) **OR** B. If the requested agent is Wegovy, then BOTH of the following: 1. The requested dose is 1.7 mg or 2.4 mg **AND** 2. ONE of the following: A. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of pharmacotherapy) **OR** B. The patient is 12 years of age and over AND has received less than 52 weeks of therapy on the maximum-tolerated dose **OR** C. The patient is pediatric (12 to less than 18 years of age) AND has achieved and maintained a reduction in BMI of at least 5% from baseline (prior to initiation of pharmacotherapy) **OR** C. 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 requested agent) **OR** 2. The patient has received less than 52 weeks of therapy on the maximum-tolerated dose **AND** 5. 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 **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 GLP-1 receptor agonist agent **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. 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**

Module	Clinical Criteria for Approval
	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:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☐ Quantity Limit ☐ Step Therapy ☐ 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
	4460306000D5	Xolair	omalizumab subcutaneous soln auto-injector	150 MG/ML; 300 MG/2ML; 75 MG/0.5ML	M; N; O; Y				
	4460306000E5	Xolair	omalizumab subcutaneous soln prefilled syringe	150 MG/ML; 300 MG/2ML; 75 MG/0.5ML	M; N; O; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** 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**

Module	Clinical Criteria for Approval
	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 had an inadequate response to the FDA 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 above the FDA labeled maximum dose (e.g., 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 above the FDA labeled maximum dose of a second-generation H-1 antihistamine **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over second-generation H-1 antihistamine therapy **OR** C. The patient has an intolerance or hypersensitivity to second-generation H-1 antihistamine therapy **OR** D. The patient has an FDA labeled contraindication to ALL second-generation H-1 antihistamines **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

Module	Clinical Criteria for Approval
	F. The prescriber has provided documentation that 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** 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 **AND** B. ONE of the following: 1. The patient is currently being treated for at least 3 months with ONE of the following:

Module	Clinical Criteria for Approval
	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**

Module	Clinical Criteria for Approval
	10. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **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**

Module	Clinical Criteria for Approval
	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:** CMS Approved Compendia **Length of Approval:** 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)

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