MHCP PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

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

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

No new policies for September 1, 2023

POLICIES REVISED

• Program Summary: Accrufer (ferric maltol)

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
82300063000120	Accrufer	Ferric Maltol Cap	30 MG	60	Capsules	30	DAYS				01-01-2022	12-31-9999

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Target Agent(s) will be approved when ALL of the following are met: 1. ONE of the following: A. The prescriber has provided information that ALL other forms of iron available over the counter (e.g., ferrous sulfate, ferrous gluconate, ferrous fumarate) are not clinically appropriate for the patient (medical records required) **OR** B. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** C. BOTH of the following: 1. The patient's medication history includes another form of iron available over the counter (e.g., ferrous sulfate, ferrous gluconate, ferrous fumarate) as indicated by ONE of the following: A. Evidence of a paid claim(s) **OR** B. The presciber has stated that the patient has tried another form of iron available over the counter **AND** 2. ONE of the following: A. The other form of iron available over the counter 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 ALL other forms of iron available over the counter **OR** D. The prescriber has provided documentation that ALL other forms of iron available over the counter (e.g., ferrous sulfate, ferrous gluconate, ferrous fumarate) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**

Module	Clinical Criteria for Approval
	B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months Note: If Quantity Limit applies, please refer to Quantity Limit Criteria **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent (e.g., stable or improvement in hemoglobin) **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Bempedoic Acid

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
39380020000320	Nexletol	Bempedoic Acid Tab 180 MG	180 MG	30	Tablets	30	DAYS				10-01-2020	
39991002200320	Nexlizet	Bempedoic Acid-Ezetimibe Tab 180-10 MG	180-10 MG	30	Tablets	30	DAYS				10-01-2020	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. BOTH of the following: 1. The patient has ONE of the following: A. A diagnosis of heterozygous familial hypercholesterolemia (HeFH) confirmed by ONE of the following: 1. Genetic confirmation of one mutant allele at the LDLR, Apo-B, PCSK9, or ARH adaptor protein 1/LDLRAP1 gene locus **OR** 2. BOTH of the following: A. ONE of the following: 1. History of total cholesterol greater than 290 mg/dL (greater than 7.5 mmol/L) (pretreatment or highest level while on treatment) **OR** 2. History of LDL-C greater than 190 mg/dL (greater than 4.9 mmol/L) (pretreatment or highest level while on treatment) **AND** B. History of tendon xanthomas in ONE of the following: 1. The patient **OR** 2. The patient's first degree relative (i.e., parent, sibling, or child) **OR** 3. The patient's second degree relative (e.g., grandparent, uncle, or aunt) **OR** 3. The Patient has a Dutch Lipid Clinic Network Criteria score of greater than 5 **OR** B. A diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) defined as having 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 **AND** 2. ONE of the following: A. The patient is on maximally tolerated statin therapy **OR** B. The patient has an intolerance or hypersensitivity to statin therapy **OR** C. The patient has an FDA labeled contraindication to ALL statins **OR** B. The patient has another FDA approved indication for the requested agent and route of administration **OR** C. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia

Module	Clinical Criteria for Approval
	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 criteria are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. If the patient has ASCVD or HeFH, then ONE of the following: A. The patient is on maximally tolerated statin therapy **OR** B. The patient has an intolerance or hypersensitivity to statin therapy **OR** C. The patient has an FDA labeled contraindication to ALL statins **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.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

● 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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
6650007000E5	Actemra	tocilizumab subcutaneous soln prefilled syringe	162 MG/0.9 ML	4	Syringes	28	DAYS					
6650007000D520	Actemra actpen	Tocilizumab Subcutaneous Soln Auto-injector 162 MG/0.9ML	162 MG/0.9 ML	4	Pens	28	DAYS					
6627001510D520	Amjevita	adalimumab-atto soln auto-injector	40 MG/0.8 ML	2	Pens	28	DAYS				02-27-2023	
6627001510E505	Amjevita	adalimumab-atto soln prefilled syringe	10 MG/0.2 ML	2	Syringes	28	DAYS					
6627001510E510	Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.4 ML	2	Syringes	28	DAYS				02-27-2023	
6627001510E520	Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.8 ML	2	Syringes	28	DAYS				02-27-2023	
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/0.5 ML	1	Syringe	28	DAYS					
9025057500E520	Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe 150 MG/ML	150 MG/ML	1	Syringe	28	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
9025057500D530	Cosentyx sensoready pen	Secukinumab Subcutaneous Auto-inj 150 MG/ML (300 MG Dose)	150 MG/ML	2	Pens	28	DAYS					
9025057500D520	Cosentyx sensoready pen	Secukinumab Subcutaneous Soln Auto-injector 150 MG/ML	150 MG/ML	1	Pen	28	DAYS					
6627001505F520	Cyltezo	adalimumab-adbm auto-injector kit	40 MG/0.8 ML	2	Pens	28	DAYS			00597037597		
6627001505F805	Cyltezo	adalimumab-adbm prefilled syringe kit	10 MG/0.2 ML	2	Syringes	28	DAYS					
6627001505F810	Cyltezo	adalimumab-adbm prefilled syringe kit	20 MG/0.4 ML	2	Syringes	28	DAYS					
6627001505F820	Cyltezo	adalimumab-adbm prefilled syringe kit	40 MG/0.8 ML	2	Syringes	28	DAYS					
6627001505F520	Cyltezo starter package for psoriasis	adalimumab-adbm auto-injector kit	40 MG/0.8 ML	6	Pens	180	DAYS			00597037523		
6627001505F520	Cyltezo starter package for crohn's disease/UC/HS	adalimumab-adbm auto-injector kit	40 MG/0.8 ML	4	Pens	180	DAYS			00597037516		
66290030002120	Enbrel	Etanercept For Subcutaneous Inj 25 MG	25 MG	8	Vials	28	DAYS					
66290030002015	Enbrel	Etanercept Subcutaneous Inj 25 mg/0.5ml	25 MG/0.5 ML	8	Vials	28	DAYS					
6629003000E525	Enbrel	Etanercept Subcutaneous Soln Prefilled Syringe 25 MG/0.5ML	25 MG/0.5 ML	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					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
6629003000D530	Enbrel sureclick	Etanercept Subcutaneous Solution Auto-injector 50 MG/ML	50 MG/ML	4	Syringes	28	DAYS					
6627001520E510	Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.4 ML	2	Syringes	28	DAYS					
6627001520E520	Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.8 ML	2	Syringes	28	DAYS					
6627001520D510	Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.4 ML	2	Pens	28	DAYS					
6627001520D520	Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.8 ML	2	Pens	28	DAYS					
6627001535F520	Hulio	adalimumab-fkjp auto-injector kit	40 MG/0.8 ML	2	Syringes	28	DAYS					
6627001535F810	Hulio	adalimumab-fkjp prefilled syringe kit	20 MG/0.4 ML	2	Syringes	28	DAYS					
6627001535F820	Hulio	adalimumab-fkjp prefilled syringe kit	40 MG/0.8 ML	2	Syringes	28	DAYS					
6627001500F804	Humira	Adalimumab Prefilled Syringe Kit 10 MG/0.1ML	10 MG/0.1 ML	2	Syringes	28	DAYS					
6627001500F809	Humira	Adalimumab Prefilled Syringe Kit 20 MG/0.2ML	20 MG/0.2 ML	2	Syringes	28	DAYS					
6627001500F830	Humira	Adalimumab Prefilled Syringe Kit 40 MG/0.4ML	40 MG/0.4 ML	2	Syringes	28	DAYS					
6627001500F820	Humira	Adalimumab Prefilled Syringe Kit 40 MG/0.8ML	40 MG/0.8 ML	2	Syringes	28	DAYS					
6627001500F840	Humira pediatric crohns disease	Adalimumab Prefilled Syringe Kit 80 MG/0.8ML	80 MG/0.8 ML	1	Kit	180	DAYS					
6627001500F880	Humira pediatric crohns disease	Adalimumab Prefilled Syringe Kit 80	80 MG/0.8 ML &	1	Kit	180	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		MG/0.8ML & 40 MG/0.4ML	40MG/0.4ML									
6627001500F440	Humira pen	adalimumab pen-injector kit	80 MG/0.8 ML	2	Pens	28	DAYS			00074012402		
6627001500F420	Humira pen	Adalimumab Pen-injector Kit; adalimumab pen-injector kit	40 MG/0.8 ML	2	Pens	28	DAYS			00074433902; 50090448700		
6627001500F430	Humira pen	Adalimumab Pen-injector Kit 40 MG/0.4ML	40 MG/0.4 ML	2	Pens	28	DAYS					
6627001500F420	Humira pen; Humira pen-cd/uc/hs starter	Adalimumab Pen-injector Kit; adalimumab pen-injector kit	40 MG/0.8 ML	1	Kit	180	DAYS			00074433906; 50090448700		
6627001500F420	Humira pen; Humira pen-ps/uv starter	Adalimumab Pen-injector Kit; adalimumab pen-injector kit	40 MG/0.8 ML	1	Kit	180	DAYS			00074433907; 50090448700		
6627001500F440	Humira pen-cd/uc/hs starter pack	adalimumab pen-injector kit	80 MG/0.8 ML	1	Kit	180	DAYS			00074012403		
6627001500F440	Humira pen-pediatric uc starter pack	adalimumab pen-injector kit	80 MG/0.8 ML	1	Kit	180	DAYS			00074012404		
6627001500F450	Humira pen-ps/uv starter	Adalimumab Pen-injector Kit 80 MG/0.8ML & 40 MG/0.4ML	80 MG/0.8 ML & 40MG/0.4ML	1	Kit	180	DAYS					
6627001504D515	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.4 ML	2	Pens	28	DAYS					
6627001504D540	Hyrimoz	adalimumab-adaz soln auto-injector	80 MG/0.8 ML	2	Pens	28	DAYS			61314045420		
6627001504E508	Hyrimoz	adalimumab-adaz soln prefilled syringe	10 MG/0.1 ML	2	Syringes	28	DAYS					
6627001504E513	Hyrimoz	adalimumab-adaz soln prefilled syringe	20 MG/0.2 ML	2	Syringes	28	DAYS					

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

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
666030100003	Olumiant	baricitinib tab	1 MG ; 2 MG ; 4 MG	30	Tablets	30	DAYS					
6640001000E520	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 125 MG/ML	125 MG/ML	4	Syringes	28	DAYS					
6640001000E510	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 50 MG/0.4ML	50 MG/0.4 ML	4	Syringes	28	DAYS					
6640001000E515	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 87.5 MG/0.7ML	87.5 MG/0.7 ML	4	Syringes	28	DAYS					
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					
9025052000E5	Siliq	brodalumab subcutaneous soln prefilled syringe	210 MG/1.5 ML	2	Syringes	28	DAYS					
6627004000D540	Simponi	Golimumab Subcutaneous Soln Auto-injector 100 MG/ML	100 MG/ML	1	Syringe	28	DAYS					
6627004000D520	Simponi	Golimumab Subcutaneous Soln Auto-injector 50 MG/0.5ML	50 MG/0.5 ML	1	Syringe	28	DAYS					
6627004000E540	Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 100 MG/ML	100 MG/ML	1	Syringe	28	DAYS					
6627004000E520	Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 50 MG/0.5ML	50 MG/0.5 ML	1	Syringe	28	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
9025057070F820	Skyrizi	Risankizumab-rzaa Sol Prefilled Syringe 2 x 75 MG/0.83ML Kit	75 MG/0.83 ML	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/1.2 ML	1	Cartridge	56	DAYS					
5250406070E220	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	360 MG/2.4 ML	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/0.5 ML	1	Vial	84	DAYS					
9025058500E520	Stelara	Ustekinumab Soln Prefilled Syringe 45 MG/0.5ML	45 MG/0.5 ML	1	Syringe	84	DAYS					
9025058500E540	Stelara	Ustekinumab Soln Prefilled Syringe 90 MG/ML	90 MG/ML	1	Syringe	56	DAYS					
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					
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					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
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	adalimumab-aaty auto-injector kit	40 MG/0.4 ML	2	Pens	28	DAYS					
6627001509D240	Yusimry	adalimumab-aqvh soln pen-injector	40 MG/0.8 ML	2	Pens	28	DAYS					
66603072007530	Rinvoq	Upadacitinib Tab ER	30 MG	30	Tablets	30	DAYS					

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Module	Clinical Criteria for Approval

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, and Xeljanz Immediate Release tablets.

Disease State	PDL Preferred Agents	PDL Non-Preferred Agents
Ankylosing Spondylitis (AS)	SQ: Enbrel, Humira Oral: Xeljanz	SQ: Cimzia, Cosentyx, Simponi, Taltz 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: Actemra, Orencia Oral: Xeljanz solution

Module	Clinical Criteria for Approval		
	Psoriatic Arthritis (PsA)	SQ: Enbrel, Humira Oral: Xeljanz	SQ: Cimzia, Cosentyx, Orencia, Simponi, Skyrizi, Stelara, Taltz, Tremfya Oral: Rinvoq, Xeljanz XR
	Rheumatoid Arthritis	SQ: Enbrel, Humira Oral: Xeljanz	SQ: Actemra, Cimzia, Kevzara, Kineret, Orencia, Simponi Oral: Olumiant, Rinvoq, Xeljanz XR
	Hidradenitis Suppurativa (HS)	SQ: Humira	N/A
	Psoriasis (PS)	SQ: Enbrel, Humira	SQ: Cimzia, Cosentyx, Siliq, Skyrizi, Stelara, Taltz, Tremfya
	Crohn's Disease	SQ: Humira	SQ: Cimzia, Skyrizi, Stelara
	Ulcerative Colitis	SQ: Humira Oral: Xeljanz	SQ: Simponi, Stelara Oral: Rinvoq, Xeljanz XR
	Uveitis	SQ: Humira	N/A
	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
	*Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product		

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

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	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** 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**

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	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 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**

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	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: 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**

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	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** 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** 5. The prescriber has provided documentation that BOTH oral corticosteroids and

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	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 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

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	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 documented medical condition or comorbid condition that is likely to cause an 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**

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	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** 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:

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	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 a 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 of the conventional agents used in the treatment of PJIA **OR** 3. The patient has an FDA labeled contraindication ALL of the conventional agents used in the treatment of PJIA **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of PJIA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive 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 PJIA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** K. The patient has a diagnosis of active systemic juvenile idiopathic arthritis (SJIA) AND ONE of the following: 1. The patient's medication history includes at least ONE NSAIDs (e.g., ibuprofen, celecoxib) used in the treatment of SJIA AND ONE of the following: A. The patient has had an inadequate response to at least ONE NSAIDs (e.g., ibuprofen, celecoxib) used in the treatment of SJIA **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over NSAIDs (e.g., ibuprofen, celecoxib) used in the treatment of SJIA **OR** 2. The patient has an intolerance or hypersensitivity to NSAIDs used in the treatment of SJIA **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of SJIA **OR** 4. The patient has tried and had an inadequate response to another conventional agent (i.e., methotrexate, leflunomide, systemic corticosteroids) used in the treatment of SJIA **OR** 5. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of SJIA **OR**

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	6. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of SJIA **OR** 7. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of SJIA **OR** 8. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 9. The prescriber has provided documentation that ALL of the conventional agents used in the treatment of SJIA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** L. The patient has a diagnosis of moderate to severe hidradenitis suppurativa (HS) AND ONE of the following: 1. The patient'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

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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** M. BOTH of the following: 1. The patient has a diagnosis of systemic sclerosis associated interstitial lung disease (SSc-ILD) **AND** 2. The patient's diagnosis has been confirmed on high-resolution computed tomography (HRCT) or chest radiography scans **OR** N. The patient has a diagnosis of active enthesitis related arthritis (ERA) and ONE of the following: 1. The patient'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** O. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following: 1. ONE of the following: A. The patient has at least 10% body surface area involvement **OR** B. The patient has involvement of the palms and/or soles of the feet **AND** 2. ONE of the following: A. The patient's medication history includes at least a mid-potency topical steroid used in the treatment of AD **AND** a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD AND ONE of the following:

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	1. The patient has had an inadequate response to at least a mid- potency topical steroid 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 mid- potency topical steroids 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 mid- potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive 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 mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. ONE of the following: A. The patient's medication history includes a systemic immunosuppressant, including a biologic, used in the treatment of AD AND ONE of the following: 1. The patient has had an inadequate response to a systemic immunosuppressant, including a biologic, 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 a systemic immunosuppressant, including a biologic, used in the treatment of AD **OR** B. The patient has an intolerance or hypersensitivity to therapy with systemic immunosuppressants, including a biologic, used in the treatment of AD **OR**

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	C. The patient has an FDA labeled contraindication to ALL systemic immunosuppressants, including biologics, used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive 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 systemic immunosuppressants, including biologics, used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The prescriber has documented the patient's baseline pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **AND** 5. BOTH of the following: A. The patient is currently treated with topical emollients and practicing good skin care **AND** B. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent **OR** P. BOTH of the following: 1. The patient has a diagnosis of severe alopecia areata (AA) **AND** 2. The patient has at least 50% scalp hair loss that has lasted 6 months or more **OR** Q. The patient has a diagnosis of polymyalgia rheumatica (PMR) AND ONE of the following: 1. The patient'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 tosystemic 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**

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	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** 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 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) within the past 999 days **OR** 2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) in the past 999 days **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

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	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 every 4 weeks is requested as maintenance dosing, ONE of the following: A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis **OR** B. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks for at least 3-months **AND** 4. If Skyrizi is requested for the treatment of Crohn's disease, the patient received Skyrizi IV for induction therapy **AND** 5. If Stelara is requested for the treatment of Crohn's disease or ulcerative colitis, the patient received Stelara IV for induction therapy **AND** 4. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 5. If Stelara 90 mg is requested, ONE of the following: A. The patient has a diagnosis of psoriasis AND weighs >100kg **OR** B. The patient has a dual diagnosis of psoriasis AND psoriatic arthritis AND the patient is >100kg **OR** C. The patient has a diagnosis of Crohn's disease or ulcerative colitis **AND** 6. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND** 7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or has consulted with a specialist in the area of the patient's diagnosis **AND** 8. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, i.e., clinical trials, phase III studies, guidelines required) **AND** 9. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 10. The patient has been tested for latent tuberculosis (TB) when required by the prescribing information for the requested agent AND if positive the patient has begun therapy for latent TB **Length of Approval:** 12 months for all agents EXCEPT adalimumab containing products for ulcerative colitis (UC), Rinvoq for atopic dermatitis (AD), Siliq for plaque psoriasis (PS), Xeljanz and Xeljanz XR for induction therapy for UC, and the agents with indications that require loading doses for new starts. NOTE: For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of the 12 months. Adalimumab containing products for UC may be approved for 12 weeks, Rinvoq for AD may be approved for 6 months, Siliq for PS may be approved for 16 weeks, and Xeljanz and Xeljanz XR for UC may be approved for 16 weeks. **Compendia Allowed:** CMS Approved Compendia

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

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	B. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks for at least 3-months **AND** 8. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND** 9. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** 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

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

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	A. The requested quantity (dose) does NOT exceed the maximum compendia supported dose for the requested indication **AND** B. If the requested quantity (dose) is greater than the maximum FDA labeled dose, the patient has tried and had an inadequate response to at least a 3 month trial of the maximum FDA labeled dose (medical records required) **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit **OR** 4. If the requested agent is NOT Xeljanz/Xeljanz XR for a diagnosis of ulcerative colitis or polyarticular course juvenile idiopathic arthritis, then ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) is greater than the maximum FDA labeled dose AND the maximum compendia supported dose for the requested indication **AND** C. The patient has tried and had an inadequate response to at least a 3 month trial of the maximum FDA labeled dose (medical records required) **AND** D. The prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy required; e.g., clinical trials, phase III studies, guidelines required) **Length of Approval:** • Initial Approval with PA: 12 months for all agents EXCEPT adalimumab containing products for ulcerative colitis (UC), Rinvoq for atopic dermatitis (AD), Siliq for plaque psoriasis (PS), Xeljanz and Xeljanz XR for induction therapy for UC, and the agents with indications that require loading doses for new starts. NOTE: For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of the 12 months. Adalimumab containing products for UC may be approved for 12 weeks, Rinvoq for AD may be approved for 6 months, Siliq for PS may be approved for 16 weeks, and Xeljanz and Xeljanz XR for UC may be approved for 16 weeks. • Renewal Approval with PA: 12 months **Compendia Allowed:** CMS Approved Compendia **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable.
QL All Program Type	**Quantities above the program quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. If the requested agent is Xeljanz/Xeljanz XR for a diagnosis of ulcerative colitis, then BOTH of the following: A. The prescriber has provided information in support of therapy for the dose exceeding the quantity limit [e.g., patient has lost response to the FDA labeled maintenance dose (i.e., 5 mg twice daily or 11 mg once daily) during maintenance treatment; requires restart of induction therapy] (medical records required **AND** B. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit **OR** 2. If the requested agent is Xeljanz oral solution for a diagnosis of polyarticular course juvenile idiopathic arthritis, then ONE of the following: A. BOTH of the following: 1. The requested quantity (dose) does not exceed the maximum FDA labeled dose (i.e., 5 mg twice daily) NOR the maximum compendia supported dose **AND** 2. The prescriber has provided information stating why the patient cannot take Xeljanz 5 mg tablets **OR** B. The requested quantity (dose) is greater than the maximum FDA labeled dose but does NOT exceed the maximum compendia supported dose for the requested indication **OR**

Module	Clinical Criteria for Approval
	C. BOTH of the following: 1. The requested quantity (dose) is greater than the maximum FDA labeled dose AND the maximum compendia supported dose for the requested indication **AND** 2. The prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy required; i.e., clinical trials, phase III studies, guidelines required) **OR** 3. If the requested agent is NOT Xeljanz/Xeljanz XR for a diagnosis of ulcerative colitis or polyarticular course juvenile idiopathic arthritis, then ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. If the patient has an FDA labeled indication for the requested agent, then ONE of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose **OR** 2. BOTH of the following: A. The requested quantity (dose) does NOT exceed the maximum compendia supported dose for the requested indication **AND** B. If the requested quantity (dose) is greater than the maximum FDA labeled dose, the patient has tried and had an inadequate response to at least a 3 month trial of the maximum FDA labeled dose (medical records required) **AND** C. If the patient has a compendia supported indication for the requested agent, the requested quantity (dose) does NOT exceed the maximum compendia supported dose for the requested indication **AND** D. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit **OR** 4. If the requested agent is NOT Xeljanz/Xeljanz XR for a diagnosis of ulcerative colitis or polyarticular course juvenile idiopathic arthritis, then ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) is greater than the maximum FDA labeled dose AND the maximum compendia supported dose for the requested indication **AND** C. The patient has tried and had an inadequate response to at least a 3 month trial of the maximum FDA labeled dose (medical records required) **AND** D. The prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy required; i.e., clinical trials, phase III studies, guidelines required) **Length of Approval:** • Initial Approval with PA: 12 months for all agents EXCEPT adalimumab containing products for ulcerative colitis (UC), Rinvoq for atopic dermatitis (AD), Siliq for plaque psoriasis (PS), Xeljanz and Xeljanz XR for induction therapy for UC, and the agents with indications that require loading doses for new starts. NOTE: For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of the 12 months. Adalimumab containing products for UC may be approved for 12 weeks, Rinvoq for AD may be approved for 6 months, Siliq for PS may be approved for 16 weeks, and Xeljanz and Xeljanz XR for UC may be approved for 16 weeks. • Renewal Approval with PA: 12 months • Standalone QL approval: 12 months or through the remainder of an existing authorization, whichever is shorter **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable.

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly
Adbry (tralokinumab-ldrm) Actemra (tocilizumab) Amjevita (adalimumab-atto) Arcalyst (rilonacept) Avsola (infliximab-axxq) Benlysta (belimumab) Cibinqo (abrocitinib) Cimzia (certolizumab) Cinqair (reslizumab) Cosentyx (secukinumab) Dupixent (dupilumab) Enbrel (etanercept) Entyvio (vedolizumab) Fasenra (benralizumab) Humira (adalimumab) Ilaris (canakinumab) Ilumya (tildrakizumab-asmn) Inflectra (infliximab-dyyb) Infliximab Kevzara (sarilumab) Kineret (anakinra) Nucala (mepolizumab) Olumiant (baricitinib) Opzelura (ruxolitinib) Orencia (abatacept) Otezla (apremilast) Remicade (infliximab) Renflexis (infliximab-abda) Riabni (rituximab-arrx) Rinvoq (upadacitinib) Rituxan (rituximab) Rituxan Hycela (rituximab/hyaluronidase human) Ruxience (rituximab-pvvr) Siliq (brodalumab) Simponi (golimumab) Simponi ARIA (golimumab) Skyrizi (risankizumab-rzaa) Sotyktu (deucravacitinib) Stelara (ustekinumab) Taltz (ixekizumab) Tezspire (tezepelumab-ekko) Tremfya (guselkumab) Truxima (rituximab-abbs) Tysabri (natalizumab) Xeljanz (tofacitinib) Xeljanz XR (tofacitinib extended release) Xolair (omalizumab) Zeposia (ozanimod)

● Program Summary: Cibinqo (abrocitinib)

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
90272005000320	Cibinqo	Abrocitinib Tab	50 MG	30	Tablets	30	DAYS				09-01-2022	
90272005000325	Cibinqo	Abrocitinib Tab	100 MG	30	Tablets	30	DAYS				09-01-2022	
90272005000330	Cibinqo	Abrocitinib Tab	200 MG	30	Tablets	30	DAYS				09-01-2022	

PRIOR AUTHORIZATION 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. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**
   - B. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR**
   - C. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following:
     1. ONE of the following:
        - A. The patient has at least 10% body surface area involvement **OR**
        - B. The patient has involvement of the palms and/or soles of the feet **AND**
     2. ONE of the following:
        - A. The patient's medication history includes at least a mid- potency topical steroid 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 mid- potency topical steroids AND a topical calcineurin inhibitors (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) **OR**
          2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over mid- potency topical steroids and topical calcineurin inhibitors (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) **OR**
        - B. The patient has an intolerance or hypersensitivity to at least a mid- potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR**
        - C. The patient has an FDA labeled contraindication to ALL mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors used in the treatment of AD **OR**
        - D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
          1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
          2. A statement by the prescriber that the patient is currently receiving a positive 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 mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

3. ONE of the following**:**

A. The patient's medication history includes a systemic immunosuppressant, including a biologic AND ONE of the following:

1. The patient has had an inadequate response to a systemic immunosuppressant, including a biologic **OR**
2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over systemic immunosuppressant, including a biologic **OR**

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

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

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

1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
2. A statement by the prescriber that the patient is currently receiving a positive 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 systemic immunosuppressants, including biologics, used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

4. The prescriber has assessed 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) **AND**
5. The patient will be using standard maintenance therapy (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR**

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

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

2. If the patient has an FDA approved indication, ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
   B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**
3. The patient has been tested for latent tuberculosis (TB) AND if positive the patient has begun therapy for latent TB **AND**
4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
5. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):
   A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**

B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
    1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**
    2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND**
6. The patient does NOT have any FDA labeled contraindications to the requested agent

Compendia Allowed: CMS Approved Compendia

Length of Approval: 6 months

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

Renewal Evaluation

Target Agent(s) will be approved when ALL of the following are met:
1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND**
2. ONE of the following:
    A. The patient has a diagnosis of moderate-to-severe atopic dermatitis AND BOTH of the following:
        1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following:
            A. Affected body surface area **OR**
            B. Flares **OR**
            C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **AND**
        2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR**
    B. The patient has a diagnosis other than moderat-to-severe atopic dermatitis 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., dermatologist, allergist, immunologist) 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. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., 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. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **Length of Approval**: Initial - 6 months Renewal - 12 months

CONTRAINDICATION AGENTS

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

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

• Program Summary: Egrifta (tesamorelin)

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
30150085102130	Egrifta; Egrifta sv	Tesamorelin Acetate For Inj 2 MG (Base Equiv)	2; 2 MG	30	Vials	30	DAYS				10-15-2019	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of human immunodeficiency virus (HIV) infection **AND** 2. The requested agent is being prescribed to reduce excess abdominal fat in HIV-associated lipodystrophy **AND** 3. If the patient has an FDA approved indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 4. The prescriber has measured and recorded baseline (prior to initiating therapy with the requested agent) visceral adipose tissue (VAT) and waist circumference **AND** 5. The patient is currently being treated with anti-retroviral therapy (ART) **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., infectious disease, HIV specialist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**

Module	Clinical Criteria for Approval
	7. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months NOTE if Quantity Limit applies, please refer to Quantity Limit criteria **Renewal Evaluation** **Target Agent(s)** will be approved when ALL the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient is currently being treated with anti-retroviral therapy (ART) **AND** 3. The patient has had improvements or stabilization with the requested agent as indicated by ONE of the following: A. The patient has achieved or maintained an 8% decrease in visceral adipose tissue (VAT) from baseline (prior to initiating therapy with the requested agent) **OR** B. The patient has maintained or decreased waist circumference from baseline (prior to initiating therapy with the requested agent) **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., infectious disease, HIV specialist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

● Program Summary: Elagolix/Relugolix

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
24993503800320	Myfembree	Relugolix-Estradiol-Norethindrone Acetate Tab	40-1-0.5 MG	30	Tablets	30	DAYS					
2499350340B220	Oriahnn	Elagolix-Estrad-Noreth 300-1-0.5MG & Elagolix 300MG Cap Pack	300-1-0.5 & 300 MG	56	Capsules	28	DAYS					
30090030100320	Orilissa	Elagolix Sodium Tab 150 MG (Base Equiv)	150 MG	30	Tablets	30	DAYS					
30090030100330	Orilissa	Elagolix Sodium Tab 200 MG (Base Equiv)	200 MG	60	Tablets	30	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Oriahnn and Myfembree	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. All of the following: 1. The patient has a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) **AND** 2. The patient's diagnosis of uterine fibroids was confirmed via imaging (e.g., ultrasound) **AND** 3. The patient has NOT had a hysterectomy **AND** 4. The requested agent is FDA approved for the requested indication **OR** B. BOTH of the following: 1. The patient has a diagnosis of moderate to severe pain associated with endometriosis **AND** 2. The requested agent is FDA approved for the requested indication **AND** 2. The patient is premenopausal (e.g., less than 12 months since last menstrual period) **AND** 3. The prescriber has confirmed the patient's bone health allows for initiating therapy with the requested agent **AND** 4. ONE of the following: A. The patient's medication history includes at least ONE hormonal contraceptive used in the treatment of heavy menstrual bleeding or moderate to severe pain associated with endometriosis AND ONE of the following: 1. The patient has had an inadequate response to maximally tolerated at least ONE hormonal contraceptive used in the treatment of heavy menstrual bleeding or moderate to severe pain associated with endometriosis **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over hormonal contraceptives

Module	Clinical Criteria for Approval
	used in the treatment of heavy menstrual bleeding or moderate to severe pain associated with endometriosis **OR** B. The patient has an intolerance or hypersensitivity to at least ONE hormonal contraceptive used in the treatment of heavy menstrual bleeding or moderate to severe pain associated with endometriosis **OR** C. The patient has an FDA labeled contraindication to ALL hormonal contraceptive therapy (i.e., oral, topical patches, implants, injections, IUD) **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 hormonal contraceptive therapy (i.e., oral, topical patches, implants, injections, IUD) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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 GnRH antagonist agent targeted in this program (e.g., elagolix, relugolix) for the requested indication **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 7. ONE of the following: A. The patient is initiating therapy with the requested agent **OR** B. The patient is not initiating therapy with the requested agent and BOTH of the following: 1. The prescriber has provided information indicating the number of months the patient has been on therapy **AND** 2. The total duration of treatment with the requested agent has NOT exceeded 24 months per lifetime **Length of Approval:** Up to 6 months, with a lifetime maximum of 24 months **Renewal Evaluation** **Target Agent** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient is premenopausal (e.g., less than 12 months since last menstrual period) **AND** 3. The patient has had clinical benefit with the requested agent **AND** 4. The prescriber has assessed the patient's bone health AND confirmed the patient's bone health allows for continued therapy with the requested agent **AND** 5. The patient has NOT had a fragility fracture since starting therapy with the requested agent **AND** 6. The patient will NOT be using the requested agent in combination with another GnRH antagonist agent targeted in this program (e.g., elagolix, relugolix) for the requested indication **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 8. BOTH of the following: A. The prescriber has provided information indicating the number of months the patient has been on therapy **AND** B. The total duration of treatment with the requested agent has NOT exceeded 24 months per lifetime **Length of Approval:** Up to 6 months, with a lifetime maximum of 24 months

Module	Clinical Criteria for Approval
Orilissa	**Initial Evaluation** **Target Agent** will be approved when ALL of the following are met: 1. The patient has a diagnosis of moderate to severe pain associated with endometriosis **AND** 2. The patient is premenopausal (e.g., less than 12 months since last menstrual period) **AND** 3. ONE of the following: A. The patient's medication history includes a hormonal contraceptive used for the treatment of moderate to severe pain associated with endometriosis AND ONE of the following: 1. The patient has had an inadequate response to a hormonal contraceptive used for the treatment of moderate to severe pain associated with endometriosis **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over a hormonal contraceptive used for the treatment of moderate to severe pain associated with endometriosis **OR** B. The patient has an intolerance or hypersensitivity to hormonal contraceptive therapy **OR** C. The patient has an FDA labeled contraindication to ALL hormonal contraceptive therapy (i.e., oral, topical patches, implants, injections, IUD) **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 hormonal contraceptive therapy (i.e., oral, topical patches, implants, injections, IUD) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The prescriber has confirmed the patient's bone health allows for initiating therapy with the requested agent **AND** 5. The patient will NOT be using the requested agent in combination with another GnRH antagonist agent targeted in this program (e.g., elagolix, relugolix) for the requested indication **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 7. ONE of the following: A. The patient does NOT have coexisting moderate hepatic impairment (Child-Pugh [CP]/ Child-Turcotte-Pugh [CTP] Class B) AND ONE of the following: 1. The patient is initiating therapy with the requested agent and strength **OR** 2. The patient is not initiating therapy with the requested agent and strength and BOTH of the following: A. The prescriber has provided information indicating the number of months the patient has been on therapy **AND** B. ONE of the following: 1. The requested strength is 150 mg AND the total duration of treatment with the requested strength has NOT exceeded 24 months per lifetime **OR** 2. The requested strength is 200 mg AND the total duration of treatment with the requested strength has NOT exceeded 6 months per lifetime **OR** B. The patient does have coexisting moderate hepatic impairment (Child-Pugh [CP]/ Child-Turcotte-Pugh [CTP] Class B) AND BOTH of the following: 1. The requested strength is 150 mg **AND** 2. ONE of the following: A. The patient is initiating therapy with the requested agent and strength **OR**

Module	Clinical Criteria for Approval
	B. The patient is not initiating therapy with the requested agent and strength and BOTH of the following: 1. The prescriber has provided information indicating the number of months the patient has been on therapy **AND** 2. The total duration of treatment with the requested strength has NOT exceeded 6 months per lifetime **Length of Approval:** Up to 6 months with a lifetime maximum of 24 months with the 150 mg without coexisting moderate hepatic impairment, a lifetime maximum of 6 months with the 150 mg with coexisting moderate hepatic impairment, and a lifetime maximum of 6 months with the 200 mg **Renewal Evaluation** **Target Agent** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (*please note requests for 200 mg strength should always be reviewed under initial criteria) **AND** 2. The patient is premenopausal (e.g., less than 12 months since last menstrual period) **AND** 3. The patient has had clinical benefit with the requested agent **AND** 4. The prescriber has assessed the patient's bone health AND confirmed the patient's bone health allows for continued therapy with the requested agent **AND** 5. The patient has NOT had a fragility fracture since starting therapy with the requested agent **AND** 6. The patient will NOT be using the requested agent in combination with another GnRH antagonist agent targeted in this program (e.g., elagolix, relugolix) for the requested indication **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 8. BOTH of the following: A. The prescriber has provided information indicating the number of months the patient has been on therapy with the requested agent and strength **AND** B. ONE of the following: 1. The patient does NOT have coexisting moderate hepatic impairment (Child-Pugh [CP]/ Child-Turcotte-Pugh [CTP] Class B) AND the total duration of treatment with the requested strength has NOT exceeded 24 months per lifetime **OR** 2. The patient does have coexisting moderate hepatic impairment (Child-Pugh [CP]/ Child-Turcotte-Pugh [CTP] Class B) AND the total duration of treatment with the requested strength has NOT exceeded 6 months per lifetime **Length of Approval:** Up to 6 months with a lifetime maximum of 24 months with the 150 mg without coexisting moderate hepatic impairment OR a lifetime maximum of 6 months with the 150 mg with coexisting moderate hepatic impairment

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL Myfembree and Oriahnn	**Quantity Limit for the Target Agent(s)** will be approved when the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **Length of Approval:** Up to 6 months with a lifetime maximum of 24 months
QL Orilissa	**Quantity Limit for the Target Agent(s)** will be approved when the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit

Module	Clinical Criteria for Approval
	Length of Approval: Up to 6 months with a lifetime maximum of 24 months with the 150 mg without coexisting moderate hepatic impairment, a lifetime maximum of 6 months with the 150 mg with coexisting moderate hepatic impairment, and a lifetime maximum of 6 months with the 200 mg

• Program Summary: Elmiron

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
	565000601001	Elmiron	pentosan polysulfate sodium caps	100 MG	M ; N ; O ; Y				10-01-2018

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of interstitial cystitis (IC) or interstitial cystitis/bladder pain syndrome (IC/BPS) or interstitial cystitis/painful bladder syndrome (IC/PBS) **AND** 2. The patient has tried and had an inadequate response to behavioral modification or self-care practices **AND** 3. ONE of the following: A. The patient's medication history includes amitriptyline, cimetidine, or hydroxyzine AND ONE of the following: 1. The patient has had an inadequate response to amitriptyline, cimetidine, or hydroxyzine **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over amitriptyline, cimetidine, and hydroxyzine **OR** B. The patient has an intolerance or hypersensitivity to amitriptyline, cimetidine, or hydroxyzine **OR** C. The patient has an FDA labeled contraindication to amitriptyline, cimetidine, and hydroxyzine **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that amitriptyline, cimetidine, and hydroxyzine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The patient has had an eye exam with an eye specialist (e.g., optometrist, ophthalmologist) prior to starting the requested agent **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**

Module	Clinical Criteria for Approval
	6. The requested quantity (dose) does not exceed the FDA labeled dose for the requested indication **Length of Approval:** 6 months **Renewal Evaluation** **Target Agent(s)** will be approved for renewal when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent (e.g., decreased bladder pain, decreased frequency or urgency of urination) **AND** 3. The patient has had an eye exam with an eye specialist (e.g., optometrist, ophthalmologist) within the last 12 months **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. The requested quantity (dose) does not exceed the FDA labeled dose for the requested indication **Length of Approval:** 12 months

• Program Summary: Hemlibra (emicizumab-kxwh)

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
85105030202030	Hemlibra	Emicizumab-kxwh Subcutaneous Soln 105 MG/0.7ML (150 MG/ML)	105 MG/0.7ML					Determined by patient weight and dosing interval* *See Hemlibra weight based approvable quantities chart for guidance				
85105030202040	Hemlibra	Emicizumab-kxwh Subcutaneous Soln 150 MG/ML	150 MG/ML					Determined by patient weight and dosing interval* *See Hemlibra weight based approvable quantities chart for guidance				
85105030202010	Hemlibra	Emicizumab-kxwh Subcutaneous Soln 30 MG/ML	30 MG/ML					Determined by patient weight and dosing interval* *See Hemlibra weight based approvable quantities chart for guidance				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
85105030202020	Hemlibra	Emicizumab-kxwh Subcutaneous Soln 60 MG/0.4ML (150 MG/ML)	60 MG/0.4ML					Determined by patient weight and dosing interval* *See Hemlibra weight based approvable quantities chart for guidance				

PRIOR AUTHORIZATION 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
Hemlibra (emicizumab-kxwh)

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

   B. The patient has a diagnosis of hemophilia A with or without inhibitors **AND**
2. The requested agent will be used as prophylaxis to prevent or reduce the frequency of bleeding episodes **AND**
3. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] 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 any of the following while on maintenance dosing with the requested agent:
   A. Prophylaxis with a Factor VIIa product (e.g., NovoSeven RT) **OR**
   B. Prophylaxis with a Factor VIII product (e.g., Advate, Adynovate, Eloctate, Nuwiq, Recombinate, Xyntha) **OR**
   C. Prophylaxis with a bypassing agent (e.g., Feiba, NovoSeven) **OR**
   D. Immune tolerance therapy (ITT) (immune tolerance induction [ITI]) **AND**
5. If the patient is receiving Feiba [activated prothrombin complex concentrate (aPCC)] for breakthrough bleeds, BOTH of the following:
   A. The patient will be monitored for thrombotic microangiopathy and thromboembolism **AND**
   B. The prescriber has counseled the patient on the maximum dosages of Feiba to be used (i.e., no more than 100 u/kg/24 hours) **AND**
6. ONE of the following:
   A. The patient will NOT be using the requested agent in combination with a nonsteroidal anti-inflammatory agent (NSAID) (e.g., aspirin, ibuprofen) other than cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib) NOTE: for the purposes of this criteria COX-2 inhibitors will be accepted for concomitant use **OR**
   B. The prescriber has provided information in support of using an NSAID for this patient **AND**
7. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**

	8. The requested quantity (dose) is within the FDA labeled dosing based on the patient's weight and dosing interval **Length of Approval:** 1 month for induction therapy 6 months for maintenance therapy (or remainder of 6 months if requesting induction therapy and maintenance therapy) NOTE: If Quantity Limit applies, please see Quantity Limit criteria **Renewal Evaluation** **Target Agent(s**) will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. ONE of the following: A. The patient has shown clinical benefit since starting the requested agent (i.e., less breakthrough bleeds as reported in the treatment log and/or chart notes) (medical records including treatment log and/or chart notes required) **OR** B. The prescriber has provided information supporting the continued use of the requested agent (medical record required) **AND** 3. If the patient is receiving Feiba [activated prothrombin complex concentrate (aPCC)] for breakthrough bleeds, the patient will be monitored for thrombotic microangiopathy and thromboembolism **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] 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 any of the following: A. Prophylaxis with a Factor VIIa product (e.g., NovoSeven RT) **OR** B. Prophylaxis with a Factor VIII product (e.g., Advate, Adynovate, Eloctate, Nuwiq, Recombinate, Xyntha) **OR** C. Prophylaxis with a bypassing agent (e.g., Feiba, NovoSeven) OR D. Immune tolerance therapy (ITT) (immune tolerance induction [ITI]) **AND** 6. ONE of the following: A. The patient will NOT be using the requested agent in combination with a nonsteroidal anti-inflammatory agent (NSAID) (e.g., aspirin, ibuprofen) other than cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib) NOTE: for the purposes of this criteria COX-2 inhibitors will be accepted for concomitant use **OR** B. The prescriber has provided information in support of using an NSAID for this patient **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 8. The requested quantity (dose) is within the FDA labeled dosing based on the patient's weight and dosing interval **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please see Quantity Limit criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Quantity Limit for Target Agent(s)** will be approved when ONE of the following is met: 1. The patient is requesting induction therapy only **OR** 2. The patient is requesting induction therapy and maintenance therapy and the requested quantity (dose) for maintenance therapy does not exceed the program quantity limit (see Hemlibra Weight-Based Approvable Quantities chart) **OR**

Module	Clinical Criteria for Approval

3. The patient is requesting maintenance therapy only and the requested quantity (dose) does not exceed the program quantity limit (see the Hemlibra Weight-Based Approvable Quantities chart)

Length of Approval: 1 month for induction therapy 6 months for maintenance therapy (or remainder of 6 months if requesting induction therapy and maintenance therapy)

Renewal Evaluation

Quantity Limit for the Target Agent(s) will be approved when the requested quantity (dose) for maintenance therapy does not exceed the program quantity limit (see the Hemlibra Weight-Based Approvable Quantities chart)

Length of Approval: 12 months

Hemlibra Weight-Based Approvable Quantities (maintenance dosing)

Weight (kg)	Dosing Schedule	30 mg/1 mL vials	60 mg/0.4 mL vials	105 mg/0.7 mL vials	150 mg/1 mL vials
less than or equal to 5 kg	1.5 mg/kg every week	4 mL (4 vials)/28 days	0	0	0
less than or equal to 5 kg	3 mg/kg every 2 weeks	2 mL (2 vials)/28 days	0	0	0
less than or equal to 5 kg	6 mg/kg every 4 weeks	1 mL (1 vial)/28 days	0	0	0
greater than 5 and less than or equal to 10 kg	1.5 mg/kg every week	4 mL (4 vials)/28 days	0	0	0
greater than 5 and less than or equal to 10 kg	3 mg/kg every 2 weeks	2 mL (2 vials)/28 days	0	0	0
greater than 5 and less than or equal to 10 kg	6 mg/kg every 4 weeks	0	0.4 mL (1 vial)/28 days	0	0
greater than 10 and less than or equal to 15 kg	1.5 mg/kg every week	4 mL (4 vials)/28 days	0	0	0
greater than 10 and less than or equal to 15 kg	3 mg/kg every 2 weeks	0	0.8 mL (2 vials)/28 days	0	0

Module	Clinical Criteria for Approval					
	greater than 10 and less than or equal to 15 kg	6 mg/kg every 4 weeks	1 mL (1 vial)/28 days	0.4 mL (1 vial)/28 days	0	0
	greater than 15 and less than or equal to 20 kg	1.5 mg/kg every week	4 mL (4 vials)/28 days	0	0	0
	greater than 15 and less than or equal to 20 kg	3 mg/kg every 2 weeks	0	0.8 mL (2 vials)/28 days	0	0
	greater than 15 and less than or equal to 20 kg	6 mg/kg every 4 weeks	0	0.8 mL (2 vials)/28 days	0	0
	greater than 20 and less than or equal to 25 kg	1.5 mg/kg every week	0	1.6 mL (4 vials)/28 days	0	0
	greater than 20 and less than or equal to 25 kg	3 mg/kg every 2 weeks	2 mL (2 vials)/28 days	0.8 mL (2 vials)/28 days	0	0
	greater than 20 and less than or equal to 25 kg	6 mg/kg every 4 weeks	0	0	0	1 mL (1 vial)/28 days
	greater than 25 and less than or equal to 30 kg	1.5 mg/kg once every week	0	1.6 mL (4 vials)/28 days	0	0
	greater than 25 and less than or equal to 30 kg	3 mg/kg every 2 weeks	2 mL (2 vials)/28 days	0.8 mL (2 vials)/28 days	0	0
	greater than 25 and less than or equal to 30 kg	6 mg/kg every 4 weeks	0	1.2 mL (3 vials)/28 days	0	0
	greater than 30 and less than or equal to 35 kg	1.5 mg/kg once every week	0	1.6 mL (4 vials)/28 days	0	0
	greater than 30 and less than or equal to 35 kg	3 mg/kg every 2 weeks	0	0	1.4 mL (2 vials)/28 days	0

Module	Clinical Criteria for Approval					
	greater than 30 and less than or equal to 35 kg	6 mg/kg every 4 weeks	0	0	1.4 mL (2 vials)/28 days	0
	greater than 35 and less than or equal to 40 kg	1.5 mg/kg once every week	0	1.6 mL (4 vials)/28 days	0	0
	greater than 35 and less than or equal to 40 kg	3 mg/kg every 2 weeks	0	1.6 mL (4 vials)/28 days	0	0
	greater than 35 and less than or equal to 40 kg	6 mg/kg every 4 weeks	0	1.6 mL (4 vials)/28 days	0	0
	greater than 40 and less than or equal to 45 kg	1.5 mg/kg once every week	4 mL (4 vials)/28 days	1.6 mL (4 vials)/28 days	0	0
	greater than 40 and less than or equal to 45 kg	3 mg/kg every 2 weeks	2 mL (2 vials)/28 days	0	1.4 mL (2 vials)/28 days	0
	greater than 40 and less than or equal to 45 kg	6 mg/kg every 4 weeks	0	0.8 mL (2 vials)/28 days	0	1 mL (1 vial)/28 days
	greater than 45 and less than or equal to 50 kg	1.5 mg/kg once every week	4 mL (4 vials)/28 days	1.6 mL (4 vials)/28 days	0	0
	greater than 45 and less than or equal to 50 kg	3 mg/kg every 2 weeks	0	0	0	2 mL (2 vials)/28 days
	greater than 45 and less than or equal to 50 kg	6 mg/kg every 4 weeks	0	0	0	2 mL (2 vials)/28 days
	greater than 50 and less than or equal to 55 kg	1.5 mg/kg once every week	4 mL (4 vials)/28 days	1.6 mL (4 vials)/28 days	0	0
	greater than 50 and less than or equal to 55 kg	3 mg/kg every 2 weeks	0	0.8 mL (2 vials)/28 days	1.4 mL (2 vials)/28 days	0

Module	Clinical Criteria for Approval					
	greater than 50 and less than or equal to 55 kg	6 mg/kg every 4 weeks	0	0.8 mL (2 vials)/28 days	1.4 mL (2 vials)/28 days	0
	greater than 55 and less than or equal to 60 kg	1.5 mg/kg once every week	4 mL (4 vials)/28 days	1.6 mL (4 vials)/28 days	0	0
	greater than 55 and less than or equal to 60 kg	3 mg/kg every 2 weeks	0	2.4 mL (6 vials)/28 days	0	0
	greater than 55 and less than or equal to 60 kg	6 mg/kg every 4 weeks	0	0.4 mL (1 vial)/28 days	0	2 mL (2 vials)/28 days
	greater than 60 and less than or equal to 65 kg	1.5 mg/kg once every week	0	0	2.8 mL (4 vials)/28 days	0
	greater than 60 and less than or equal to 65 kg	3 mg/kg every 2 weeks	2 mL (2 vials)/28 days	0.8 mL (2 vials)/28 days	1.4 mL (2 vials)/28 days	0
	greater than 60 and less than or equal to 65 kg	6 mg/kg every 4 weeks	0	1.6 mL (4 vials)/28 days	0	1 mL (1 vial)/28 days
	greater than 65 and less than or equal to 70 kg	1.5 mg/kg once every week	0	0	2.8 mL (4 vials)/28 days	0
	greater than 65 and less than or equal to 70 kg	3 mg/kg every 2 weeks	0	0	2.8 mL (4 vials)/28 days	0
	greater than 65 and less than or equal to 70 kg	6 mg/kg every 4 weeks	0	0.8 mL (2 vials)/28 days	0	2 mL (2 vials)/28 days
	greater than 70 and less than or equal to 75 kg	1.5 mg/kg once every week	0	3.2 mL (8 vials)/28 days	0	0
	greater than 70 and less than or equal to 75 kg	3 mg/kg every 2 weeks	0	1.6 mL (4 vials)/28 days	1.4 mL (2 vials)/28 days	0

Module	Clinical Criteria for Approval					
	greater than 70 and less than or equal to 75 kg	6 mg/kg every 4 weeks	0	0	0	3 mL (3 vials)/28 days
	greater than 75 and less than or equal to 80 kg	1.5 mg/kg once every week	0	3.2 mL (8 vials)/28 days	0	0
	greater than 75 and less than or equal to 80 kg	3 mg/kg every 2 weeks	0	3.2 mL (8 vials)/28 days	0	0
	greater than 75 and less than or equal to 80 kg	6 mg/kg every 4 weeks	0	0.4 mL (1 vial)/28 days	2.8 mL (4 vials)/28 days	0
	greater than 80 and less than or equal to 85 kg	1.5 mg/kg once every week	4 mL (4 vials)/28 days	0	2.8 mL (4 vials)/28 days	0
	greater than 80 and less than or equal to 85 kg	3 mg/kg every 2 weeks	0	0	1.4 mL (2 vials)/28 days	2 mL (2 vials)/28 days
	greater than 80 and less than or equal to 85 kg	6 mg/kg every 4 weeks	0	0.4 mL (1 vial)/28 days		3 mL (3 vials)/28 days
	greater than 85 and less than or equal to 90 kg	1.5 mg/kg once every week	4 mL (4 vials)/28 days	0	2.8 mL (4 vials)/28 days	0
	greater than 85 and less than or equal to 90 kg	3 mg/kg every 2 weeks	0	1.6 mL (4 vials)/28 days	0	2 mL (2 vials)/28 days
	greater than 85 and less than or equal to 90 kg	6 mg/kg every 4 weeks	0	0.8 mL (2 vials)/28 days	2.8 mL (4 vials)/28 days	0
	greater than 90 and less than or equal to 95 kg	1.5 mg/kg once every week	0	0	0	4 mL (4 vials)/28 days
	greater than 90 and less than or equal to 95 kg	3 mg/kg every 2 weeks	0	2.4 mL (6 vials)/28 days	1.4 mL (2 vials)/28 days	0

Module	Clinical Criteria for Approval					
	greater than 90 and less than or equal to 95 kg	6 mg/kg every 4 weeks	0	0	2.8 mL (4 vials)/28 days	1 mL (1 vial)/28 days
	greater than 95 and less than or equal to 100 kg	1.5 mg/kg once every week	0	0	0	4 mL (4 vials)/28 days
	greater than 95 and less than or equal to 100 kg	3 mg/kg every 2 weeks	0	0	0	4 mL (4 vials)/28 days
	greater than 95 and less than or equal to 100 kg	6 mg/kg every 4 weeks	0	0	0	4 mL (4 vials)/28 days
	greater than 100 and less than or equal to 105 kg	1.5 mg/kg once every week	0	1.6 mL (4 vials)/28 days	2.8 mL (4 vials)/28 days	0
	greater than 100 and less than or equal to 105 kg	3 mg/kg every 2 weeks	0	0	4.2 mL (6 vials)/28 days	0
	greater than 100 and less than or equal to 105 kg	6 mg/kg every 4 weeks	0	0	4.2 mL (6 vials)/28 days	0
	greater than 105 and less than or equal to 110 kg	1.5 mg/kg once every week	0	1.6 mL (4 vials)/28 days	2.8 mL (4 vials)/28 days	0
	greater than 105 and less than or equal to 110 kg	3 mg/kg every 2 weeks	0	1.6 mL (4 vials)/28 days	2.8 mL (4 vials)/28 days	0
	greater than 105 and less than or equal to 110 kg	6 mg/kg every 4 weeks	0	0.4 mL (1 vial)/28 days	0	4 mL (4 vials)/28 days
	greater than 110 and less than or equal to 115 kg	1.5 mg/kg once every week	0	4.8 mL (12 vials)/28 days	0	0
	greater than 110 and less than or equal to 115 kg	3 mg/kg every 2 weeks	0	3.2 mL (8 vials)/28 days	1.4 mL (2 vials)/28 days	0

Module	Clinical Criteria for Approval					
	greater than 110 and less than or equal to 115 kg	6 mg/kg every 4 weeks	0	0.4 mL (1 vial)/28 days	4.2 mL (6 vials)/28 days	0
	greater than 115 and less than or equal to 120 kg	1.5 mg/kg once every week	0	4.8 mL (12 vials)/28 days	0	0
	greater than 115 and ≤less than or equal to 120 kg	3 mg/kg every 2 weeks	0	0.8 mL (2 vials)/28 days	0	4 mL (4 vials)/28 days
	greater than 115 and less than or equal to 120 kg	6 mg/kg every 4 weeks	0	0.8 mL (2 vials)/28 days	0	4 mL (4 vials)/28 days
	greater than 120 and less than or equal to 125 kg	1.5 mg/kg once every week	4 mL (4 vials)/28 days	1.6 mL (4 vials)/28 days	2.8 mL (4 vials)/28 days	0
	greater than 120 and less than or equal to 125 kg	3 mg/kg every 2 weeks	0	0.8 mL (2 vials)/28 days	4.2 mL (6 vials)/28 days	0
	greater than 120 and less than or equal to 125 kg	6 mg/kg every 4 weeks	0	0	0	5 mL (5 vials)/28 days
	greater than 125 and less than or equal to 130 kg	1.5 mg/kg once every week	4 mL (4 vials)/28 days	1.6 mL (4 vials)/28 days	2.8 mL (4 vials)/28 days	0
	greater than 125 and less than or equal to 130 kg	3 mg/kg every 2 weeks	0	3.2 mL (8 vials)/28 days	0	2 mL (2 vials)/28 days
	greater than 125 and less than or equal to 130 kg	6 mg/kg every 4 weeks	0	1.2 mL (3 vials)/28 days	0	4 mL (4 vials)/28 days
	greater than 130 and less than or equal to 135 kg	1.5 mg/kg once every week	0	0	5.6 mL (8 vials)/28 days	0
	greater than 130 and less than or equal to 135 kg	3 mg/kg every 2 weeks	0	0	1.4 mL (2 vials)/28 days	4 mL (4 vials)/28 days

Module	Clinical Criteria for Approval					
	greater than 130 and less than or equal to 135 kg	6 mg/kg every 4 weeks	0	0.4 mL (1 vial)/28 days	0	5 mL (5 vials)/28 days
	greater than 135 and less than or equal to 140 kg	1.5 mg/kg once every week	0	0	5.6 mL (8 vials)/28 days	0
	greater than 135 and less than or equal to 140 kg	3 mg/kg every 2 weeks	0	1.6 mL (4 vials)/28 days	0	4 mL (4 vials)/28 days
	greater than 135 and less than or equal to 140 kg	6 mg/kg every 4 weeks	0	0	5.6 mL (8 vials)/28 days	0
	greater than 140 and less than or equal to 145 kg	1.5 mg/kg once every week	0	3.2 mL (8 vials)/28 days	2.8 mL (4 vials)/28 days	0
	greater than 140 and less than or equal to 145 kg	3 mg/kg every 2 weeks	0	1.6 mL (4 vials)/28 days	4.2 mL (6 vials)/28 days	0
	greater than 140 and less than or equal to 145 kg	6 mg/kg every 4 weeks	0	0.8 mL (2 vials)/28 days		5 mL (5 vials)/28 days
	greater than 145 and less than or equal to 150 kg	1.5 mg/kg once every week	0	3.2 mL (8 vials)/28 days	2.8 mL (4 vials)/28 days	0
	greater than 145 and less than or equal to 150 kg	3 mg/kg every 2 weeks	0	0	0	6 mL (6 vials)/28 days
	greater than 145 and less than or equal to 150 kg	6 mg/kg every 4 weeks	0	0	0	6 mL (6 vials)/28 days
	greater than 150 and less than or equal to 155 kg	1.5 mg/kg once every week	4 mL (4 vials)/28 days	0	5.6 mL (8 vials)/28 days	0
	greater than 150 and less than or equal to 155 kg	3 mg/kg every 2 weeks	0	0.8 mL (2 vials)/28 days	1.4 mL (2 vials)/28 days	4 mL (4 vials)/28 days

Module	Clinical Criteria for Approval					
	greater than 150 and less than or equal to 155 kg	6 mg/kg every 4 weeks	1 mL (1 vial)/28 days	0	0	6 mL (6 vials)/28 days
	greater than 155 and less than or equal to 160 kg	1.5 mg/kg once every week	4 mL (4 vials)/28 days	0	5.6 mL (8 vials)/28 days	0
	greater than 155 and less than or equal to 160 kg	3 mg/kg every 2 weeks	2 mL (2 vials)/28 days	0	0	6 mL (6 vials)/28 days
	greater than 155 and less than or equal to 160 kg	6 mg/kg every 4 weeks	0	0.4 mL (1 vial)/28 days	0	6 mL (6 vials)/28 days
	greater than 160 and less than or equal to 165 kg	1.5 mg/kg once every week	0	0	2.8 mL (4 vials)/28 days	4 mL (4 vials)/28 days
	greater than 160 and less than or equal to 165 kg	3 mg/kg every 2 weeks	0	2.4 mL (6 vials)/28 days	4.2 mL (6 vials)/28 days	0
	greater than 160 and less than or equal to 165 kg	6 mg/kg every 4 weeks	1 mL (1 vial)/28 days	0	1.4 mL (2 vials)/28 days	5 mL (5 vials)/28 days
	greater than 165 and less than or equal to 170 kg	1.5 mg/kg once every week	0	0	2.8 mL (4 vials)/28 days	4 mL (4 vials)/28 days
	greater than 165 and less than or equal to 170 kg	3 mg/kg every 2 weeks	0	0.8 mL (2 vials)/28 days	0	6 mL (6 vials)/28 days
	greater than 165 and less than or equal to 170 kg	6 mg/kg every 4 weeks	0	0.4 mL (1 vial)/28 days	1.4 mL (2 vials)/28 days	5 mL (5 vials)/28 days
	greater than 170 and less than or equal to 175 kg	1.5 mg/kg once every week	0	2.4 mL (4 vials)/28 days	5.6 mL (8 vials)/28 days	0
	greater than 170 and less than or equal to 175 kg	3 mg/kg every 2 weeks	0	0.8 mL (2 vials)/28 days	4.2 mL (6 vials)/28 days	2 mL (2 vials)/28 days

Module	Clinical Criteria for Approval					
	greater than 170 and less than or equal to 175 kg	6 mg/kg every 4 weeks	0	0	0	7 mL (7 vials)/28 days
	greater than 175 and less than or equal to 180 kg	1.5 mg/kg once every week	0	2.4 mL (4 vials)/28 days	5.6 mL (8 vials)/28 days	0
	greater than 175 and less than or equal to 180 kg	3 mg/kg every 2 weeks	2 mL (2 vials)/28 days	0	2.8 mL (4 vials)/28 days	4 mL (4 vials)/28 days
	greater than 175 and less than or equal to 180 kg	6 mg/kg every 4 weeks	1 mL (1 vial)/28 days	0	0	7 mL (7 vials)/28 days
	greater than 180 and less than or equal to 185 kg	1.5 mg/kg once every week	4 mL (4 vials)/28 days	0	2.8 mL (4 vials)/28 days	4 mL (4 vials)/28 days
	greater than 180 and less than or equal to 185 kg	3 mg/kg every 2 weeks	0	0	1.4 mL (2 vials)/28 days	6 mL (6 vials)/28 days
	greater than 180 and less than or equal to 185 kg	6 mg/kg every 4 weeks	0	0.4 mL (1 vial)/28 days	0	7 mL (7 vials)/28 days
	greater than 185 and less than or equal to 190 kg	1.5 mg/kg once every week	4 mL (4 vials)/28 days	0	2.8 mL (4 vials)/28 days	4 mL (4 vials)/28 days
	greater than 185 and less than or equal to 190 kg	3 mg/kg every 2 weeks	0	0.8 mL (2 vials)/28 days	2.8 mL (4 vials)/28 days	4 mL (4 vials)/28 days
	greater than 185 and less than or equal to 190 kg	6 mg/kg every 4 weeks	1 mL (1 vial)/28 days	0	1.4 mL (2 vials)/28 days	6 mL (6 vials)/28 days
	greater than 190 and less than or equal to 195 kg	1.5 mg/kg once every week	0	0	0	8 mL (8 vials)/28 days
	greater than 190 and less than or equal to 195 kg	3 mg/kg every 2 weeks	2 mL (2 vials)/28 days	0	1.4 mL (2 vials)/28 days	6mL (6 vials)/28 days

Module	Clinical Criteria for Approval

greater than 190 and less than or equal to 195 kg	6 mg/kg every 4 weeks	0	0.4 mL (1 vial)/28 days	1.4 mL (2 vials)/28 days	6 mL (6 vials)/28 days
greater than 195 and less than or equal to 200 kg	1.5 mg/kg once every week	0	0	0	8 mL (8 vials)/28 days
greater than 195 and less than or equal to 200 kg	3 mg/kg every 2 weeks	0	0	0	8 mL (8 vials)/28 days
greater than 195 and less than or equal to 200 kg	6 mg/kg every 4 weeks	0	0	0	8 mL (8 vials)/28 days
greater than 200 kg	Approve quantity requested if appropriate for patient weight and dosing interval				

The 60 mg, 105 mg and/or 150 mg vials are the same concentration (150 mg/mL) and may be combined for dosing

The 30 mg vials (30mg/mL) should NOT be combined in the same injection with the 60 mg, 105 mg, or 150 mg vials and should be given as a separate injection

• Program Summary: Hemophilia 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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
Target Agent(s) EXCEPT Coagadex, NovoSeven RT, and Sevenfact												
851000103121	Altuviiio	antihemophilic fact rcmb fc-vwf-xten-ehtl for inj	1000 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 4000 UNIT; 500 UNIT					Dependent on patient weight and number of doses				
851000102521	Advate; Kovaltry	Antihemophilic Factor rAHF-PFM For Inj; antihemophilic factor rahf-pfm for inj; antihemophilic factor recomb (rahf-pfm) for inj	1000; 1000 UNIT; 1500; 1500 UNIT; 2000; 2000 UNIT; 250; 250 UNIT; 3000; 3000 UNIT; 4000 UNIT; 500; 500 UNIT					Dependent on patient weight and number of doses			07-01-2021	
851000104021	Adynovate	antihemophilic factor recomb pegylated for inj	1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT;					Dependent on patient weight and number of doses			07-01-2021	

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
			500 UNIT; 750 UNIT									
851000105564	Afstyla	antihemophilic fact rcmb single chain for inj kit	1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 2500 UNIT; 3000 UNIT; 500 UNIT					Dependent on patient weight and number of doses			07-01-2021	
851000151021	Alphanate; Humate-p	antihemophilic factor/vwf (human) for inj	1000 UNIT; 1000-2400 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 250-600 UNIT; 500 UNIT; 500-1200 UNIT					Dependent on patient weight and number of doses			07-01-2021	
851000280021	Alphanine sd; Mononine	coagulation factor ix for inj	1000 UNIT; 1500 UNIT; 500 UNIT					Dependent on patient weight and number of doses			07-01-2021	
851000284021	Alprolix	coagulation factor ix (recomb) (rfixfc) for inj	1000 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 4000 UNIT; 500 UNIT					Dependent on patient weight and number of doses			07-01-2021	
851000282064	Benefix	coagulation factor ix (recombinant) for inj kit	1000 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 500 UNIT					Dependent on patient weight and number of doses			07-01-2021	
851000310021	Coagadex	coagulation factor x (human) for inj	250 UNIT; 500 UNIT					Dependent on patient weight and number of doses			07-01-2021	
851000330064	Corifact	factor xiii concentrate (human) for inj kit	1000-1600 UNIT					Dependent on patient weight and number of doses			07-01-2021	
851000103021	Eloctate	antihemophilic factor rcmb (bdd-rfviiifc) for inj	1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 4000 UNIT; 500 UNIT; 5000 UNIT; 6000 UNIT; 750 UNIT					Dependent on patient weight and number of doses			07-01-2021	
851000103521	Esperoct	antihemophilic factor recomb glycopeg-exei for inj	1000 UNIT; 1500 UNIT; 2000 UNIT; 3000 UNIT; 500 UNIT					Dependent on patient weight and number of doses			07-01-2021	
851000200021	Feiba	antiinhibitor coagulant complex for iv soln	1000 UNIT; 2500 UNIT; 500 UNIT					Dependent on patient weight and number of doses			07-01-2021	
851000100021	Hemofil m; Koate; Koate-dvi	antihemophilic factor (human) for inj	1000 UNIT; 1700 UNIT; 250 UNIT; 500 UNIT					Dependent on patient weight and number of doses			07-01-2021	

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
851000283521	Idelvion	coagulation factor ix (recomb) (rix-fp) for inj	1000 UNIT; 2000 UNIT; 250 UNIT; 3500 UNIT; 500 UNIT					Dependent on patient weight and number of doses			07-01-2021	
851000282021	Ixinity ; Rixubis	coagulation factor ix (recombinant) for inj	1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 500 UNIT					Dependent on patient weight and number of doses			07-01-2021	
851000104121	Jivi	antihemophil fact rcmb (bdd-rfviii peg-aucl) for inj; antihemophil fact rcmb (bdd-rfviii peg-aucl) for inj	1000 UNIT; 2000 UNIT; 3000 UNIT; 500 UNIT					Dependent on patient weight and number of doses			07-01-2021	
851000102064	Kogenate fs	antihemophilic factor recomb (rfviii) for inj kit	1000 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 500 UNIT					Dependent on patient weight and number of doses			07-01-2021	
851000103321	Novoeight	antihemophilic fact rcmb (bd trunc-rfviii) for inj	1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 500 UNIT					Dependent on patient weight and number of doses			07-01-2021	
851000262021	Novoseven rt	coagulation factor viia (recomb) for inj	1 MG; 2 MG; 5 MG; 8 MG					Dependent on patient weight and number of doses			07-01-2021	
851000102264	Nuwiq	antihemophil fact rcmb (bdd-rfviii,sim) for inj kit; antihemophil fact rcmb (bdd-rfviii,sim) for inj kit	1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 2500 UNIT; 3000 UNIT; 4000 UNIT; 500 UNIT					Dependent on patient weight and number of doses			07-01-2021	
851000102221	Nuwiq	antihemophilic fact rcmb (bdd-rfviii,sim) for inj; antihemophilic factor rcmb (bdd-rfviii,sim) for inj	1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 2500 UNIT; 3000 UNIT; 4000 UNIT; 500 UNIT					Dependent on patient weight and number of doses			07-01-2021	
851000105021	Obizur	antihemophilic factor (recomb porc) rpfviii for inj	500 UNIT					Dependent on patient weight and number of doses			07-01-2021	
851000300021	Profilnine	factor ix complex for inj	1000 UNIT; 1500 UNIT; 500 UNIT					Dependent on patient weight and number of doses			07-01-2021	
851000284521	Rebinyn	coagulation factor ix recomb glycopegylated for inj	1000 UNIT; 2000 UNIT; 3000 UNIT; 500 UNIT					Dependent on patient weight and number of doses			07-01-2021	
851000102021	Recombinate	antihemophilic factor recomb (rfviii) for inj	1241-1800 UNIT; 1801-2400 UNIT; 220-400 UNIT;					Dependent on patient weight and number of doses				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
			401-800 UNIT; 801-1240 UNIT									
851000264021	Sevenfact	coagulation factor viia (recom)-jncw for inj	1 MG; 5 MG					Dependent on patient weight and number of doses			07-01-2021	
851000321021	Tretten	coagulation factor xiii a-subunit for inj	2000-3125 UNIT					Dependent on patient weight and number of doses			07-01-2021	
851000702021	Vonvendi	von willebrand factor (recombinant) for inj	1300 UNIT; 650 UNIT					Dependent on patient weight and number of doses			07-01-2021	
851000151064	Wilate	antihemophilic factor/vwf (human) for inj	1000-1000 UNIT; 500-500 UNIT					Dependent on patient weight and number of doses			07-01-2021	
851000102664	Xyntha; Xyntha solofuse	antihemophil fact rcmb (bdd-rfviii,mor) for inj kit; antihemophil fact rcmb (bdd-rfviii,mor) for inj kit	1000 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 500 UNIT					Dependent on patient weight and number of doses			07-01-2021	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**PRIOR AUTHORIZATION CRITERIA FOR APPROVAL** **Initial Evaluation** **See drug specific criteria below for Coagadex, NovoSeven RT, and Sevenfact** **Target Agent(s) EXCEPT Coagadex, NovoSeven RT, and Sevenfact** will be approved when ALL of the following are met: 1. ONE of the following: A. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** B. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** C. The patient is currently experiencing a bleed AND BOTH of the following: 1. The patient is out of medication **AND** 2. The patient needs to receive a ONE TIME emergency supply of medication **OR** D. The patient has an FDA approved diagnosis for the requested agent including intended use (i.e., prophylaxis, ITT/ITI, on-demand, peri-operative) AND ONE of the following: 1. If the patient has a diagnosis of hemophilia A (also known as Factor VIII deficiency or classic hemophilia) BOTH of the following: A. If the requested agent is being used for prophylaxis OR Immune Tolerance Therapy (ITT)/Immune Tolerance Induction (ITI) the patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **AND** B. If the patient has mild hemophilia A (i.e., factor VIII activity level between 5%-40%) ONE of the following:

Module	Clinical Criteria for Approval
	1. The patient's medication history includes desmopressin (e.g., DDAVP injection, Stimate nasal spray) used for the requested indication AND ONE of the following: A. The patient has had an inadequate response to desmopressin used for the requested indication **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent desmopressin **OR** 2. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 3. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to therapy with desmopressin **OR** 4. The prescriber has provided information supporting why the patient cannot use desmopressin (e.g., shortage in marketplace) **OR** 5. The prescriber has provided documentation that desmopressin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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. If the patient has a diagnosis of Type 1, Type 2A, Type 2M, or Type 2N von Willebrand Disease (VWD) ONE of the following: A. The patient's medication history includes desmopressin (e.g., DDAVP injection, Stimate nasal spray) used for the requested indication AND ONE of the following: 1. The patient has had an inadequate response to desmopressin used for the requested indication **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent desmopressin **OR** B. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** C. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to therapy with desmopressin **OR** D. The prescriber has provided information supporting why the patient cannot use desmopressin (e.g., shortage in marketplace) **OR** E. The prescriber has provided documentation that desmopressin acetate cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. If the patient has an FDA approved indication, then ONE of the following:

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	A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] 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 will NOT be using the requested agent in combination with nonsteroidal anti-inflammatory agents (NSAIDs) (e.g., aspirin, ibuprofen) other than cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib) NOTE: for the purposes of this criteria COX-2 inhibitors will be accepted for concomitant use **OR** B. The prescriber has provided support of using an NSAID for this patient **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 6. The prescriber must provide the actual prescribed dose with ALL of the following: A. Patient's weight **AND** B. Intended use/regimen: prophylaxis, ITT/ITI, on-demand, peri-operative **AND** C. If the patient has a diagnosis of hemophilia A BOTH of the following: 1. Severity of the factor deficiency (i.e., severe is <1% factor activity, moderate is ≥1 to ≤5% factor activity, mild is >5 to 40% factor activity) **AND** 2. Inhibitor status **AND** 7. ONE of the following: A. The patient will NOT be using the requested agent in combination with another agent in the same class included in this program **OR** B. Information has been provided supporting the use of more than one unique agent in the same class (medical record required) **Length of Approval:** One time emergency use: up to 2 weeks Peri-operative dosing: 1 time per request On-demand: up to 3 months Prophylaxis: up to 6 months ITT/ITI: up to 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria. **Renewal Evaluation** **Target Agent(s) EXCEPT Coagadex, NovoSeven RT, and Sevenfact** 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 (if current request is for ONE TIME emergency use or the patient ONLY has previous approval(s) for emergency use, must use Initial Evaluation) **AND** 2. If the patient is using the requested agent for Hemophilia A prophylaxis OR ITT/ITT, the patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] 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 will NOT be using the requested agent in combination with nonsteroidal anti-inflammatory agents (NSAIDs) (e.g., aspirin, ibuprofen) other than cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib) NOTE: for the purposes of this criteria COX-2 inhibitors will be accepted for concomitant use **OR** B. The prescriber has provided support of using an NSAID for this patient **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**

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	6. The prescriber must provide the actual prescribed dose with ALL of the following: A. Patient's weight **AND** B. Intended use/regimen: (e.g., prophylaxis, ITT/ITT, on-demand, peri-operative) **AND** C. If the patient has a diagnosis of hemophilia A BOTH of the following: 1. Severity of the factor deficiency (i.e., severe is <1% factor activity, moderate is ≥1 to ≤5% factor activity, mild is >5 to 40% factor activity) **AND** 2. Inhibitor status **AND** 7. ONE of the following: A. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have >5 on-demand doses on hand **OR** B. The prescriber has provided information in support of the patient having more than 5 on-demand doses on hand **AND** 8. ONE of the following: A. The patient will NOT be using the requested agent in combination with another agent in the same class included in this program **OR** B. Information has been provided supporting the use of more than one unique agent in the same class (medical record required) **AND** 9. If the patient is using Immune Tolerance Therapy (ITT)/Immune Tolerance Induction (ITI), then ONE of the following: A. The patient has NOT had more than 33 months of ITT/ITI therapy **OR** B. Information has been provided supporting the continued use of ITT/ITI therapy (i.e., the patient has had a ≥ 20% decrease in inhibitor level over the last 6 months and needs further treatment to eradicate inhibitors) (medical record required) **Length of Approval:** On-demand: up to 3 months Peri-operative dosing: 1 time per request Prophylaxis: up to 12 months ITT/ITI: up to 6 months, or up to a total of 33 months of ITT/ITI therapy, or requested duration, whichever is shortest NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria. **Evaluation** **Coagadex** will be approved when ALL of the following are met: 1. ONE of the following: A. Information has been provided that indicates the patient has been treated with the requested agent for the requested use (e.g., prophylaxis, on-demand) within the past 90 days **OR** B. The prescriber states the patient has been treated with the requested agent for the requested use (e.g., prophylaxis, on-demand) within the past 90 days AND is at risk if therapy is changed **OR** C. The patient has a diagnosis of hereditary Factor X deficiency AND ONE of the following: 1. The patient is currently experiencing a bleed AND BOTH of the following: A. The patient is out of medication **AND** B. The patient needs to receive a ONE TIME emergency supply of medication **OR** 2. The requested agent will be used for prophylaxis treatment AND ONE of the following: A. The patient has severe or moderate Factor X deficiency (Factor X level ≤ 5%) **OR** B. The patient has mild Factor X deficiency (Factor X level 6-10%) AND the prescriber has provided information supporting prophylaxis use of the requested agent (medical records required) **OR**

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	3. The requested agent will be used as on-demand treatment to control bleeding episodes AND BOTH of the following: A. The prescriber has communicated with the patient (via any means) and has verified that the patient does NOT have more than 5 on-demand doses on hand AND ONE of the following: 1. The patient's medication history includes aminocaproic acid or tranexamic acid used for the requested indication AND ONE of the following: A. The patient has had an inadequate response to aminocaproic acid or tranexamic acid used for the requested indication **OR** B. he prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent aminocaproic acid or tranexamic acid used for the requested indication **OR** 2. The patient has an intolerance or hypersensitivity to aminocaproic acid or tranexamic acid **OR** 3. The patient has an FDA labeled contraindication to BOTH aminocaproic acid AND tranexamic acid **OR** 4. The prescriber has provided information to support the use of the requested agent over BOTH aminocaproic acid AND tranexamic acid **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 BOTH aminocaproic acid AND tranexamic acid cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The requested agent will be used as perioperative management of bleeding AND BOTH of the following: 1. The patient has mild (Factor X level 6-10%) or moderate (Factor X level 1-5%) hereditary Factor X deficiency **AND** 2. ONE of the following: A. The patient's medication history includes aminocaproic acid or tranexamic acid used for the requested indication AND ONE of the following: 1. The patient has had an inadequate response to aminocaproic acid or tranexamic acid used for the requested indication **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent aminocaproic acid or tranexamic acid used for the requested indication **OR**

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	B. The patient has an intolerance or hypersensitivity to aminocaproic acid or tranexamic acid **OR** C. The patient has an FDA labeled contraindication to BOTH aminocaproic acid AND tranexamic acid **OR** D. The prescriber has provided information to support the use of the requested agent over BOTH aminocaproic acid AND tranexamic acid **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 BOTH aminocaproic acid AND tranexamic acid cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The prescriber is a specialist (e.g., hematologist) in the area of the patient's diagnosis or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient does NOT have liver disease **AND** 4. The patient does NOT have vitamin K deficiency **AND** 5. The patient will NOT be using the requested agent in combination with an indirect or direct Factor Xa inhibitor [e.g., apixaban (Eliquis), dalteparin (Fragmin), edoxaban (Savaysa), enoxaparin (Lovenox), fondaparinux (Arixtra), rivaroxaban (Xarelto) or warfarin (Coumadin)] **AND** 6. ONE of the following: A. The patient will NOT be using the requested agent in combination with nonsteroidal anti-inflammatory agents (NSAIDs) (e.g., aspirin, ibuprofen) other than cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib) NOTE: for the purposes of this criteria COX-2 inhibitors will be accepted for concomitant use **OR** B. The prescriber has provided support of using an NSAID for this patient **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** One time emergency use: 1 time Perioperative management of bleeding: 1 time per request On-demand treatment: 3 months Prophylaxis treatment: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria. **Evaluation** **NovoSeven RT** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of hemophilia A AND BOTH of the following: 1. The patient has inhibitors to Factor VIII **AND** 2. The requested agent is being used for ONE of the following: A. On-demand use for bleeds AND ONE of the following:

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	1. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have > 5 on-demand doses on hand **OR** 2. The prescriber has provided information in support of the patient having more than 5 on-demand doses on hand (supportive reasoning required) **OR** B. Prophylaxis AND ALL of the following: 1. ONE of the following: A. The patient has tried and had an inadequate response to Immune Tolerance Induction (ITI) [Immune Tolerance Therapy (ITT)] **OR** B. The patient has an inhibitor level ≥ 200 BU (lab records required) **OR** C. Information has been provided indicating why the patient is not a candidate for ITI **AND** 2. The patient will NOT be using the requested agent in combination with Hemlibra **AND** 3. The patient will NOT be using the requested agent in combination with Feiba [activated prothrombin complex (aPCC)] used for prophylaxis (on-demand use of aPCC is acceptable) **OR** C. Peri-operative management of bleeding **OR** D. As a component of Immune tolerance induction (ITI)/Immune tolerance therapy (ITT) AND ONE of the following: 1. The patient has NOT had more than 33 months of ITT/ITI therapy **OR** 2. Information has been provided supporting the continued use of ITT/ITI therapy (i.e., the patient has had a ≥ 20% decrease in inhibitor level over the last 6 months and needs further treatment to eradicate inhibitors) (medical record required) **OR** B. The patient has a diagnosis of hemophilia B AND BOTH of the following: 1. The patient has inhibitors to Factor IX **AND** 2. The requested agent is being used for ONE of the following: A. On-demand use for bleeds AND ONE of the following: 1. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have > 5 on-demand doses on hand **OR** 2. The prescriber has provided information in support of the patient having more than 5 on-demand doses on hand (supportive reasoning required) **OR** B. Prophylaxis AND BOTH of the following: 1. ONE of the following: A. The patient has tried and had an inadequate response to Immune Tolerance Induction (ITI) [Immune Tolerance Therapy (ITT)] **OR** B. The patient has an inhibitor level ≥ 200 BU (lab records required) **OR** C. Information has been provided indicating why the patient is not a candidate for ITI **AND** 2. The patient will NOT be using the requested agent in combination with Feiba [activated prothrombin complex (aPCC)] used for prophylaxis (on-demand use of aPCC is acceptable) **OR** C. Peri-operative management of bleeding **OR**

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	D. As a component of Immune tolerance induction (ITI)/Immune tolerance therapy (ITT) AND ONE of the following: 1. The patient has NOT had more than 33 months of ITT/ITI therapy **OR** 2. Information has been provided supporting the continued use of ITT/ITI therapy (i.e., the patient has had a ≥ 20% decrease in inhibitor level over the last 6 months and needs further treatment to eradicate inhibitors) (medical records required) **OR** C. The patient has a diagnosis of congenital Factor VII deficiency AND the requested agent will be used for ONE of the following: 1. On-demand use for bleeds AND ONE of the following: A. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have > 5 on-demand doses on hand **OR** B. The prescriber has provided information in support of the patient having more than 5 on-demand doses on hand (supportive reasoning required) **OR** 2. Prophylaxis **OR** 3. Perioperative use **OR** D. The patient has a diagnosis of Glanzmann's thrombasthenia AND BOTH of the following: 1. The patient is refractory to platelet transfusions **AND** 2. The requested agent will be used for ONE of the following: A. On-demand use for bleeds AND ONE of the following: 1. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have > 5 on-demand doses on hand **OR** 2. The prescriber has provided information in support of the patient having more than 5 on-demand doses on hand (supportive reasoning required) **OR** B. Perioperative use **OR** E. The patient has a diagnosis of acquired hemophilia AND the requested agent will be used for ONE of the following: 1. On-demand use for bleeds **AND** ONE of the following: A. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have > 5 on-demand doses on hand **OR** B. The prescriber has provided information in support of the patient having more than 5 on-demand doses on hand (supportive reasoning required) **OR** 2. Perioperative use **OR** F. The patient has another FDA approved indication for the requested agent and route of administration **OR** G. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] 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 another Factor VIIa agent **AND** 5. ONE of the following: A. The patient will NOT be using the requested agent in combination with nonsteroidal anti-inflammatory agents (NSAIDs) (e.g., aspirin, ibuprofen) other than cyclooxygenase-2 (COX-2)

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	inhibitors (e.g., celecoxib) NOTE: for the purposes of this criteria COX-2 inhibitors will be accepted for concomitant use **OR** B. The prescriber has provided information in support of using an NSAID for this patient **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** Peri-operative dosing: 1 time per request On-demand: up to 3 months Prophylaxis: up to 12 months ITT/ITI: up to 6 months, or up to a total of 33 months of ITT/ITI therapy, or requested duration, whichever is shortest 3 months for all other diagnoses NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria. **Evaluation** **Sevenfact** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of hemophilia A AND BOTH of the following: 1. The patient has inhibitors to Factor VIII **AND** 2. The requested agent is being used for on-demand use for bleeds **OR** B. The patient has a diagnosis of hemophilia B AND BOTH of the following: 1. The patient has inhibitors to Factor IX **AND** 2. The requested agent is being used for on-demand use for bleeds **OR** C. The patient has another FDA approved indication for the requested agent and route of administration **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] 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 another Factor VIIa agent **AND** 5. ONE of the following: A. The patient will NOT be using the requested agent in combination with nonsteroidal anti-inflammatory agents (NSAIDs) (e.g., aspirin, ibuprofen) other than cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib) NOTE for the purposes of this criteria COX-2 inhibitors will be accepted for concomitant use **OR** B. The prescriber has provided information in support of using an NSAID for this patient **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 7. ONE of the following: A. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have > 5 on-demand doses on hand **OR** B. The prescriber has provided information in support of the patient having more than 5 on-demand doses on hand (supportive reasoning required) **Length of Approval:** up to 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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Coagadex	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. ONE of the following: A. The requested quantity (dose) does NOT exceed the program quantity limit defined by BOTH of the following: 1. The requested quantity (dose) is within the FDA labeled dosing **AND** 2. The requested quantity (number of doses) is appropriate based on intended use (e.g., on-demand, perioperative management of bleeding, prophylaxis) **OR** B. The prescriber has provided clinical reasoning for exceeding the defined program quantity limit (dose and/or number of doses) (medical records) **Length of Approval:** One time emergency use: 1 time Perioperative management of bleeding: 1 time per request On-demand treatment: 3 months Prophylaxis treatment: 12 months
NovoSeven RT	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. ONE of the following: A. The requested quantity (dose) does NOT exceed the program quantity limit defined by BOTH of the following: 1. The requested dose is within the FDA labeled dosing **AND** 2. The requested quantity (number of doses) is appropriate based on intended use (e.g., on-demand, prophylaxis, perioperative) **OR** B. The prescriber has provided clinical reasoning for exceeding the defined program quantity limit (dose and/or number of doses) (medical records required) **Length of Approval:** Peri-operative dosing: 1 time per request On-demand: up to 3 months Prophylaxis: up to 12 months ITT/ITI: up to 6 months, or up to a total of 33 months of ITT/ITI therapy, or requested duration, whichever is shortest 3 months for all other diagnoses
Sevenfact	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. ONE of the following: 1. The requested quantity (dose) does NOT exceed the program quantity limit defined by BOTH of the following: 1. The requested dose is within the FDA labeled dosing **AND** 2. The requested quantity (number of doses) is appropriate based on intended use (e.g., on-demand) **OR** 2. The prescriber has provided clinical reasoning for exceeding the defined program quantity limit (dose and/or number of doses) (medical records required) **Length of Approval:** up to 3 months
Target Agent(s) EXCEPT Coagadex, NovoSeven	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. ONE of the following: A. The requested quantity (dose) does NOT exceed the program quantity limit defined by BOTH of the following:

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RT, and Sevenfact	1. The requested quantity (dose) is within the FDA labeled dosing **AND** 2. The requested quantity (number of doses) is appropriate based on intended use (e.g., prophylaxis, on-demand, peri-operative) **OR** B. The prescriber has provided clinical reasoning for exceeding the defined program quantity limit (dose and/or number of doses) (medical records required) **Initial Length of Approval:** One time emergency use: up to 2 weeks Peri-operative dosing: 1 time per request On-demand: up to 3 months Prophylaxis: up to 6 months ITT/ITI: up to 6 months **Renewal Length of Approval:** On-demand: up to 3 months Peri-operative dosing: 1 time per request Prophylaxis: up to 12 months ITT/ITI: up to 6 months, or up to a total of 33 months of ITT/ITI therapy, or requested duration, whichever is shortest

● Program Summary: Interleukin-5 (IL-5) 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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
4460402000D520	Fasenra pen	Benralizumab Subcutaneous Soln Auto-injector 30 MG/ML	30 MG/ML	1	Pen	56	DAYS					
4460405500D530	Nucala	Mepolizumab Subcutaneous Solution Auto-injector 100 MG/ML	100 MG/ML					Severe eosinophilic asthma and CRSwNP: 1 syringe/28 days. EGPA and HES: 3 syringes/28 days.				
4460405500E520	Nucala	Mepolizumab Subcutaneous Solution Pref Syringe	40 MG/0.4ML	1	Syringe	28	DAYS					
4460405500E530	Nucala	Mepolizumab Subcutaneous Solution Pref Syringe 100 MG/ML	100 MG/ML					Severe eosinophilic asthma and CRSwNP: 1 syringe/28 days. EGPA				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
								and HES: 3 syringes/28 days.				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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	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 severe eosinophilic asthma and ALL of the following: 1. The patient's diagnosis has been confirmed by ONE of the following: A. 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** B. 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** C. The patient has sputum eosinophils 2% or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **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 **AND** 3. ONE of the following: A. The patient is NOT currently being treated with the requested agent AND is currently treated with a maximally tolerated inhaled corticosteroid **OR** B. The patient is currently being treated with the requested agent AND ONE of the following: 1. Is currently treated with an inhaled corticosteroid that is adequately dosed to control symptoms **OR** 2. Is currently treated with a maximally tolerated inhaled corticosteroid **OR** C. The patient has an intolerance or hypersensitivity to inhaled corticosteroid therapy **OR** D. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids **AND** 4. ONE of the following: A. The patient is currently being treated with ONE of the following: 1. A long-acting beta-2 agonist (LABA) **OR** 2. A leukotriene receptor antagonist (LTRA) **OR** 3. Long-acting muscarinic antagonist (LAMA) **OR** 4. Theophylline **OR**

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	B. The patient has an intolerance or hypersensitivity to therapy with long-acting beta-2 agonists (LABA), leukotriene receptor antagonists (LTRA), long-acting muscarinic antagonists (LAMA), or theophylline **OR** C. The patient has an FDA labeled contraindication to ALL long-acting beta-2 agonists (LABA), leukotriene receptor antagonists (LTRA), long-acting muscarinic antagonists (LAMA), AND theophylline **AND** 5. The patient will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **AND** 6. If the requested agent is Nucala, then ONE of the following: A. The patient's medication history includes use of Fasenra AND ONE of the following: 1. The patient has had an inadequate response to Fasenra **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over Fasenra **OR** B. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to Fasenra **OR** C. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** D. The prescriber has provided documentation that Fasenra cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) and ALL of the following: 1. The requested agent is Nucala **AND** 2. The patient has had a diagnosis of EGPA for at least 6 months with a history of relapsing or refractory disease **AND** 3. The patient's diagnosis of EGPA was confirmed by ONE of the following: A. The patient meets 4 of the following: 1. Asthma (history of wheezing or diffuse high-pitched rales on expiration) 2. Eosinophilia (greater than 10% eosinophils on white blood cell differential count) 3. Mononeuropathy (including multiplex), multiple mononeuropathies, or polyneuropathy attributed to a systemic vasculitis 4. Migratory or transient pulmonary infiltrates detected radiographically 5. Paranasal sinus abnormality 6. Biopsy containing a blood vessel showing the accumulation of eosinophils in extravascular areas **OR** B. The patient meets ALL of the following: 1. Medical history of asthma **AND** 2. Peak peripheral blood eosinophilia greater than 1500 cells/microliter **AND** 3. Systemic vasculitis involving two or more extra-pulmonary organs **AND**

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	4. ONE of the following: A. The patient is currently on maximally tolerated oral corticosteroid therapy **OR** B. The patient has an intolerance or hypersensitivity to oral corticosteroid therapy **OR** C. The patient has an FDA labeled contraindication to ALL oral 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 oral corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 5. ONE of the following: A. The patient's medication history includes use of an oral immunosuppressant (i.e., azathioprine, methotrexate) AND ONE of the following: 1. The patient has had an inadequate response to ONE oral immunosuppressant (i.e., azathioprine, methotrexate, mycophenolate mofetil) **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over oral immunosuppressant therapy **OR** B. The patient has an intolerance or hypersensitivity to oral immunosuppressant therapy **OR** C. The patient has an FDA labeled contraindication to ALL oral immunosuppressants **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 oral immunosuppressants cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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 hypereosinophilic syndrome (HES) and ALL of the following: 1. The requested agent is Nucala **AND** 2. BOTH of the following: A. The patient has had a diagnosis of HES for at least 6 months **AND** B. The patient has a history of at least 2 HES flares within the past 12 months (i.e., worsening of clinical symptoms and/or blood eosinophil counts requiring an escalation in therapy) **AND** 3. The patient's diagnosis of HES was confirmed by BOTH of the following:

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	A. ONE of the following: 1. The patient has a peripheral blood eosinophil count greater than 1500 cells/microliter **OR** 2. The patient has a percentage of eosinophils in bone marrow section exceeding 20% of all nucleated cells **OR** 3. The patient has marked deposition of eosinophil granule proteins found **OR** 4. The patient has tissue infiltration by eosinophils that is extensive in the opinion of a pathologist **AND** B. ALL of the following: 1. Secondary (reactive, non-hematologic) causes of eosinophilia have been excluded (e.g., infection, allergy/atopy, medications, collagen vascular disease, metabolic [e.g., adrenal insufficiency], solid tumor/lymphoma) **AND** 2. There is evidence of hypereosinophilia-related organ damage (e.g., fibrosis of lung, heart, digestive tract, skin, etc; thrombosis with or without thromboembolism; cutaneous erythema, edema/angioedema, ulceration, pruritis, or eczema; peripheral or central neuropathy with chronic or recurrent neurologic deficit; other organ system involvement such as liver, pancreas, kidney) **AND** 3. The patient does NOT have *FIP1L1-PDGFRA*-positive disease **AND** 4. ONE of the following: A. The patient is currently being treated with maximally tolerated oral corticosteroid (OCS) **OR** B. The patient has an intolerance or hypersensitivity to oral corticosteroid (OCS) therapy **OR** C. The patient has an FDA labeled contraindication to ALL oral 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 oral corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 5. ONE of the following: A. The patient is currently being treated with ONE of the following: 1. Hydroxyurea **OR** 2. Interferon-α **OR** 3. Another immunosuppressive agent (e.g., azathioprine, cyclosporine, methotrexate, tacrolimus) **OR** B. The patient has an intolerance or hypersensitivity to therapy with hydroxyurea, interferon-α, or immunosuppressive agents (e.g., azathioprine, cyclosporine, methotrexate, tacrolimus) **OR** C. The patient has an FDA labeled contraindication to hydroxyurea, interferon-α, and ALL immunosuppressive agents (e.g., azathioprine, cyclosporine, methotrexate, tacrolimus) **OR**

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	D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that hydroxyurea, interferon-α, and ALL immunosuppressive agents (e.g., azathioprine, cyclosporine, methotrexate, tacrolimus) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 6. The patient will continue existing HES therapy (e.g., OCS, hydroxyurea, interferon-α, immunosuppressants) in combination with the requested agent **OR** D. The patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND ALL of the following: 1. The requested agent is Nucala **AND** 2. 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** 3. The patient has had symptoms consistent with chronic rhinosinusitis (CRS) for at least 12 consecutive weeks **AND** 4. 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** 5. 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** 6. 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 **AND** 7. BOTH of the following: A. The patient is currently treated with standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) **AND**

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	B. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **OR** E. The patient has another FDA approved indication for the requested agent and route of administration **OR** F. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., 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. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., 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:** 6 months for severe eosinophilic asthma; 12 months for EGPA, HES, CRSwNP, and all other FDA approved indications For Fasenra, approve loading dose for new starts and the maintenance dose for the remainder of the 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. ONE of the following: A. The patient has a diagnosis of severe eosinophilic 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. Increase in percent predicted Forced Expiratory Volume (FEV_1) **OR** B. Decrease in the dose of inhaled corticosteroids 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 number of hospitalizations, need for mechanical ventilation, or visits to urgent care or emergency room due to exacerbations of asthma **AND** 2. The patient is currently treated and is compliant with asthma control therapy (e.g., inhaled corticosteroids (ICS), ICS/long-acting beta-2 agonist (ICS/LABA), leukotriene

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	receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), theophylline) **OR** B. The patient has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) AND ALL of the following: 1. The requested agent is Nucala **AND** 2. 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. Remission achieved with the requested agent **OR** B. Decrease in oral corticosteroid maintenance dose required for control of symptoms related to EGPA **OR** C. Decrease in hospitalization due to symptoms of EGPA **OR** D. Dose of maintenance corticosteroid therapy and/or immunosuppressant therapy was not increased **AND** 3. ONE of the following: A. The patient is currently treated and is compliant with maintenance therapy with oral corticosteroids **OR** B. The patient has an intolerance or hypersensitivity to oral corticosteroid therapy **OR** C. The patient has an FDA labeled contraindication to ALL oral 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 oral corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has a diagnosis of hypereosinophilic syndrome (HES) AND ALL of the following: 1. The requested agent is Nucala **AND** 2. 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. Decrease in incidence of HES flares **OR** B. Escalation of therapy (due to HES-related worsening of clinical symptoms or increased blood eosinophil counts) has not been required **AND** 3. ONE of the following: A. The patient is currently treated and is compliant with oral corticosteroid and/or other maintenance therapy (e.g., hydroxyurea, interferon-α, azathioprine, cyclosporine, methotrexate, tacrolimus) **OR** B. The patient has an intolerance or hypersensitivity to therapy with oral corticosteroids or other maintenance agents (e.g., hydroxyurea, interferon-α, azathioprine, cyclosporine, methotrexate, tacrolimus) **OR** C. The patient has an FDA labeled contraindication to ALL oral corticosteroids AND maintenance agents (e.g., hydroxyurea, interferon-α, azathioprine, cyclosporine, methotrexate, tacrolimus) **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 oral corticosteroids and other maintenance agents (e.g., hydroxyurea, interferon-α, azathioprine, cyclosporine, methotrexate, tacrolimus) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. The patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND ALL of the following: 1. The requested agent is Nucala **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **OR** E. The patient has another FDA approved indication for the requested agent and route of administration AND has had clinical benefit with the requested agent **OR** F. The patient has another indication that is supported in compendia for the requested agent and route of administration 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., 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. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., 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

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

Module	Clinical Criteria for Approval
	C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** Initial: 6 months for severe eosinophilic asthma; 12 months for EGPA, HES, CRSwNP, and all other FDA approved indications; For Fasenra, approve loading dose for new starts and the maintenance dose for the remainder of the 6 months; Renewal: 12 months

CONTRAINDICATION AGENTS

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

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

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

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
9027308045E520	Adbry	Tralokinumab-ldrm Subcutaneous Soln Prefilled Syr	150 MG/ML	4	Syringes	28	DAYS				09-01-2022	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Indication	PDL Preferred Agents
Atopic Dermatitis	Dupixent

Initial Evaluation

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

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

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

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

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	B. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following: 1. ONE of the following: A. The patient has at least 10% body surface area involvement **OR** B. The patient has involvement of the palms and/or soles of the feet **AND** 2. ONE of the following: A. The patient's medication history includes use of an oral systemic immunosuppressant (e.g., methotrexate, azathioprine, mycophenolate mofetil, cyclosporine) OR BOTH at least a mid- potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) AND ONE of the following: 1. The patient has had an inadequate response to an oral systemic immunosuppressant (e.g., methotrexate, azathioprine, mycophenolate mofetil, cyclosporine) used for the treatment of AD **OR** 2. The patient has had an inadequate response to BOTH at least a mid-potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) **OR** 3. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over an oral systemic immunosuppressant (e.g., methotrexate, azathioprine, mycophenolate mofetil, cyclosporine) AND BOTH at least a mid- potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) **OR** B. The patient has an intolerance or hypersensitivity to an oral systemic immunosuppressant **OR** C. The patient has an intolerance or hypersensitivity to BOTH at least a mid-potency topical steroid AND a topical calcineurin inhibitor **OR** D. The patient has an FDA labeled contraindication to ALL oral systemic immunosuppressants, mid-potency topical steroids, AND topical calcineurin inhibitors **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that ALL oral systemic immunosuppressants, mid- potency topical steroids, AND topical calcineurin inhibitors cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The prescriber has assessed 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) **AND** 4. The patient will be using standard maintenance therapy (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** C. The patient has another FDA approved indication for the requested agent and route of administration **OR** D. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND**

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	2. ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. ONE of the following: A. The patient is initiating therapy with the requested agent **OR** B. The patient has been treated with the requested agent for less than 16 consecutive weeks **OR** C. The patient has been treated with the requested agent for at least 16 consecutive weeks **AND** ONE of the following: 1. The patient weighs less than 100 kg and ONE of the following: A. The patient has achieved clear or almost clear skin AND the patient's dose will be reduced to 300 mg every 4 weeks **OR** B. The patient has NOT achieved clear or almost clear skin **OR** C. The prescriber has provided information in support of therapy using 300 mg every 2 weeks **OR** 2. The patient weighs greater than or equal to 100 kg **AND** 4. If the patient has an FDA approved indication, then 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 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. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 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**

Module	Clinical Criteria for Approval
	B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., 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**: Approve Adbry subcutaneous loading dose for 1 month, then maintenance dose can be approved for the remainder of 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. ONE of the following: A. The patient has a diagnosis of moderate-to-severe atopic dermatitis AND BOTH of the following: 1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following: A. Affected body surface area **OR** B. Flares **OR** C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **AND** 2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has a diagnosis other than moderate-to-severe atopic dermatitis AND has had clinical benefit with the requested agent **AND** 3. ONE of the following: A. The patient is initiating therapy with the requested agent **OR** B. The patient has been treated with the requested agent for less than 16 consecutive weeks **OR** C. The patient has been treated with the requested agent for at least 16 consecutive weeks **AND** ONE of the following: 1. The patient weighs less than 100 kg and ONE of the following: A. The patient has achieved clear or almost clear skin AND the patient's dose will be reduced to 300 mg every 4 weeks **OR** B. The patient has NOT achieved clear or almost clear skin **OR** C. The prescriber has provided information in support of therapy using 300 mg every 2 weeks **OR** 2. The patient weighs greater than or equal to 100 kg **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:

Module	Clinical Criteria for Approval
	1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **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. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **Length of Approval**: Initial approval - 6 months Renewal approval - 12 months **Note**: Approve Adbry subcutaneous loading dose for 1 month, then maintenance dose can be approved for the remainder of 6 months

CONTRAINDICATION AGENTS

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

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

● Program Summary: Isturisa

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
30022060600320	Isturisa	Osilodrostat Phosphate Tab 1 MG	1 MG	240	Tablets	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
30022060600340	Isturisa	Osilodrostat Phosphate Tab 10 MG	10 MG	180	Tablets	30	DAYS					
30022060600330	Isturisa	Osilodrostat Phosphate Tab 5 MG	5 MG	360	Tablets	30	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	PRIOR AUTHORIZATION CRITERIA FOR APPROVAL **Initial Evaluation** **Target Agent** will be approved when ALL of the following are met: 1. The patient has a diagnosis of Cushing's disease and ALL of the following: A. ONE of the following: 1. The patient had an inadequate response to pituitary surgery **OR** 2. The patient is NOT a candidate for pituitary surgery **AND** B. The patient's disease is persistent or recurrent as evidenced by ONE of the following: 1. The patient has a mean of three 24 hour urine free cortisol (UFC) >1.3 times the upper limit of normal **OR** 2. Morning plasma adrenocorticotropic hormone (ACTH) above the lower limit of normal **AND** C. ONE of the following: 1. The patient's medication history includes a conventional agent (i.e., mifepristone, Signifor/Signifor LAR [pasireotide], Recorlev [levoketoconazole], cabergoline, metyrapone, Lysodren [mitotane]) AND ONE of the following: A. The patient has had an inadequate response to a conventional agent **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL conventional agents **OR** 2. The patient has an intolerance or hypersensitivity to mifepristone, pasireotide, or levoketoconazole **OR** 3. The patient has an FDA labeled contraindication to mifepristone, pasireotide, or levoketoconazole **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 cabergoline, pasireotide, and mifepristone cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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** D. ONE of the following:

Module	Clinical Criteria for Approval
	1. The patient's medication history includes ketoconazole tablets AND ONE of the following: A. The patient has had an inadequate response to ketoconazole tablets **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ketoconazole tablets **OR** 2. The patient has an intolerance or hypersensitivity to ketoconazole tablets **OR** 3. The patient has an FDA labeled contraindication to ketoconazole tablets **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 ketoconazole tablets cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) 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 glucocorticoid replacement therapy **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 6. ONE of the following: A. The requested quantity (dose) does NOT exceed the program quantity limit **OR** B. ALL of the following: 1. The requested quantity (dose) is greater than the program quantity limit **AND** 2. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 3. 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:** 6 months **Renewal Evaluation** **Target Agent** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient will NOT be using the requested agent in combination with glucocorticoid replacement therapy **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 6. ONE of the following: A. The requested quantity (dose) does NOT exceed the program quantity limit **OR**

Module	Clinical Criteria for Approval
	B. ALL of the following: 1. The requested quantity (dose) is greater than the program quantity limit **AND** 2. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 3. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **Length of Approval:** 12 months

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Multiple Sclerosis Agents

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

TARGET AGENT(S) - Preferred agents are the MN Medicaid Preferred Drug List (PDL) preferred drugs

Preferred Agents

Aubagio® (teriflunomide)
Avonex® (interferon β-1a)
Betaseron® (interferon β-1b)
Copaxone® 20 mg/mL (glatiramer)[a]
dimethyl fumarate
Gilenya® (fingolimod)[a]
Rebif® (interferon β-1a)

Nonpreferred Agents

Bafiertam™ (monomethyl fumarate)
Copaxone® 40 mg/mL (glatiramer)[a]
dimethyl fumarate Starter Pack
Extavia® (interferon β-1b)Glatiramer 20 mg/mL
fingolimod
Glatiramer 40 mg/mL
Glatopa® (glatiramer)[a*]
Kesimpta® (ofatumumab)
Mavenclad® (cladribine)
Mayzent® (siponimod)
Plegridy® (peginterferon β-1a)
Ponvory™ (ponesimod)
Tecfidera® (dimethyl fumarate)[a]
Tascenso ODT™ (fingolimod)

Vumerity® (diroximel fumarate)
a -generic available

FDA Approved Indication	FDA Approved Agent(s)
Clinically Isolated Syndrome (CIS)	Aubagio, Avonex, Bafiertam, Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Kesimpta, Mayzent, Plegridy, Ponvory, Rebif, Tascenso ODT, Tecfidera, Vumerity
Relapsing Remitting Multiple Sclerosis (RRMS)	Aubagio, Avonex, Bafiertam, Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Kesimpta, Mavenclad, Mayzent, Plegridy, Ponvory, Rebif, Tascenso ODT, Tecfidera, Vumerity
Active Secondary Progressive Multiple Sclerosis (SPMS)	Aubagio, Avonex, Bafiertam, Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Kesimpta, Mavenclad, Mayzent, Plegridy, Ponvory, Rebif, Tascenso ODT, Tecfidera, Vumerity

QUANTITY LIMIT

Brand (generic)	GPI (NDC)	Multisource Code	Quantity Limit (per day or as listed)
Aubagio (teriflunomide)[a]			
7 mg tablet	62404070000320	M, N, O, or Y	1 tablet
14 mg tablet	62404070000330	M, N, O, or Y	1 tablet
Avonex (interferon β-1a)			
30 mcg/0.5 mL auto-injector pen	6240306045F530	M, N, O, or Y	1 kit (4 pens)/28 days
30 mcg/0.5 mL prefilled syringe	6240306045F830	M, N, O, or Y	1 kit (4 syringes)/28 days
Bafiertam (monomethyl fumarate)			
95 mg delayed release capsule	62405550006520	M, N, O, or Y	4 capsules
Betaseron (interferon β-1b)			
0.3 mg vial	62403060506420 (50419-0524-01, 50419-0524-35)	M, N, O, or Y	14 vials/28 days
Copaxone (glatiramer)[a]			
20 mg/mL syringe	6240003010E520 (68546-0317-30)	M, N, O, or Y	1 syringe
40 mg/mL syringe	6240003010E540 (68546-0325-06, 68546-0325-12)	M, N, O, or Y	12 syringes/28 days
Extavia (interferon β-1b)			
0.3 mg vial	62403060506420 (00078-0569-12, 00078-0569-61, 00078-0569-99)	M, N, O, or Y	15 vials/30 days
Gilenya (fingolimod)[a]			
0.25 mg capsule	62407025100110	M, N, O, or Y	1 capsule
0.5 mg capsule	62407025100120	M, N, O, or Y	1 capsule
Glatiramer			

Brand (generic)	GPI (NDC)	Multisource Code	Quantity Limit (per day or as listed)
20 mg/mL prefilled syringe	6240003010E520 (00378-6960-32 00378-6960-93)	M, N, O, or Y	1 syringe
40 mg/mL prefilled syringe	6240003010E540 (00378-6961-12 00378-6961-32)	M, N, O, or Y	12 syringes/28 days
Glatopa (glatiramer)			
20 mg/mL prefilled syringe	6240003010E520 (00781-3234-34 00781-3234-71)	M, N, O, or Y	1 syringe
40 mg/mL prefilled syringe	6240003010E540 (00781-3250-71, 00781-3250-89)	M, N, O, or Y	12 syringes/28 days
Kesimpta (ofatumumab)			
20 mg/0.4 mL auto-injector	6240506500D520	M, N, O, or Y	0.4 mL (1 pen)/28 days
Mavenclad (cladribine)			
10 mg (4 tablet pack)	6240101500B718	M, N, O, or Y	8 tablets/301 days
10 mg (5 tablet pack)	6240101500B722	M, N, O, or Y	10 tablets/301days
10 mg (6 tablet pack)	6240101500B726	M, N, O, or Y	12 tablets/301 days
10 mg (7 tablet pack)	6240101500B732	M, N, O, or Y	14 tablets/301 days
10 mg (8 tablet pack)	6240101500B736	M, N, O, or Y	8 tablets/301 days
10 mg (9 tablet pack)	6240101500B740	M, N, O, or Y	9 tablets/301 days
10 mg (10 tablet pack)	6240101500B744	M, N, O, or Y	20 tablets/301 days
Mayzent (siponimod)			
Starter Pack – 0.25 mg tablet	6240707020B710	M, N, O, or Y	1 pack (7 tablets)/180 days
Starter Pack – 0.25 mg tablet	6240707020B720	M, N, O, or Y	1 pack (12 tablets)/180 days
0.25 mg tablet	62407070200320	M, N, O, or Y	4 tablets
1 mg tablet	62407070200330	M, N, O, or Y	1 tablet
2 mg tablet	62407070200340	M, N, O, or Y	1 tablet
Plegridy (peginterferon β-1a)			
125 mcg/0.5mL pen-injector for subcutaneous (SQ) injection	6240307530D220	M, N, O, or Y	2 pens (1 mL)/28 days)
Starter kit- pen-injector for subcutaneous (SQ) injection	6240307530D250	M, N, O, or Y	1 kit/180 days
125 mcg/0.5 mL syringe for subcutaneous (SQ) injection	6240307530E520	M, N, O, or Y	2 syringes (1 mL)/28 days)
Starter kit- syringe for subcutaneous (SQ) injection	6240307530E550	M, N, O, or Y	1 kit/180 days
125 mcg/0.5 mL prefilled syringe for intramuscular (IM) injection	6240307530E521	M, N, O, or Y	2 syringes (1 mL)/28 days
Ponvory (ponesimod)			
Starter pack	6240706000B720	M, N, O, or Y	14 tablets/180 days
20 mg tablet	62407060000320	M, N, O, or Y	1 tablet
Rebif (interferon β-1a)			
22 mcg/0.5 mL prefilled syringe	6240306045E520	M, N, O, or Y	12 syringes (6 mL)/28 days

Brand (generic)	GPI (NDC)	Multisource Code	Quantity Limit (per day or as listed)
44 mcg/0.5 mL prefilled syringe	6240306045E540	M, N, O, or Y	12 syringes (6 mL)/28 days
Titration pack: (6 x 8.8 mcg/0.2 mL + 6 x 22 mcg/0.5 mL) prefilled syringes	6240306045E560	M, N, O, or Y	1 kit (4.2 mL)/180 days
Rebif Rebidose 22 mcg/0.5 mL auto-injector	6240306045D520	M, N, O, or Y	12 syringes (6 mL)/28 days
Rebif Rebidose 44 mcg/0.5 mL auto-injector	6240306045D540	M, N, O, or Y	12 syringes (6 mL)/28 days
Rebif Rebidose Titration Pack auto-injectors	6240306045D560	M, N, O, or Y	1 kit (4.2 mL)/180 days
Tascenso ODT (fingolimod)			
0.25 mg oral disintegrating tablet	62407025207220	M, N, O, or Y	1 tablet
0.5 mg oral disintegrating tablet	62407025207230	M, N, O, or Y	1 tablet
Tecfidera (dimethyl fumarate)[a]			
Starter kit (14 x 120 mg capsules + 46 x 240 mg capsules)	62405525006320	M, N, O, or Y	60 capsules/180 days
120 mg capsule	62405525006520	M, N, O, or Y	56 capsules/180 days
240 mg capsule	62405525006540	M, N, O, or Y	2 capsules
Vumerity (diroximel fumarate)			
231 mg delayed release capsule	62405530006540	M, N, O, or Y	4 capsules

a -generic available

PRIOR AUTHORIZATION WITH QUANTITY LIMIT CRITERIA FOR APPROVAL– THROUGH PREFERRED AGENT(S)

Mavenclad (cladribine) Initial Evaluation

Mavenclad (cladribine) will be approved when ALL of the following are met:

1. ONE of the following:
    A. Information has been provided that the patient has been treated with the requested agent within the past 90 days
    OR
    B. The prescriber states the patient has been treated with the requested agent within the past 90 days AND the patient is at risk if therapy is changed
    OR
    C. The patient has ONE of the following relapsing forms of multiple sclerosis (MS):
        i. Relapsing-remitting disease (RRMS)
        ii. Active secondary progressive disease (SPMS)

    AND
2. ONE of the following:
    A. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following:
        i. 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

ii. The patient's medication history includes two preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) AND ONE of the following:
    a. The patient had an inadequate response to two preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL)
    OR
    b. The prescriber has submitted an evidence-based and peer reviewed clinical practice guideline supporting the use of the requested agent over the preferred agent(s)

OR

iii. The patient has an intolerance or hypersensitivity to two 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

iv. The patient has an FDA labeled contraindication to ALL 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

v. The prescriber has provided information that the required 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

vi. The prescriber has provided information supporting the use of the non-preferred agent over the preferred agent(s)

OR

B. The patient has been previously treated with the requested agent AND BOTH of the following:
    i. The prescriber has provided the number of courses the patient has completed (one course consists of 2 cycles of 4-5 days each)
    AND
    ii. The patient has NOT completed 2 courses of the requested agent (one course consists of 2 cycles of 4-5 days each)

AND

3. A complete CBC with differential including lymphocyte count has been performed

AND

4. The lymphocyte count is within normal limits

AND

5. The prescriber is a specialist in the area of the patient's diagnosis (i.e., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

AND

6. ONE of the following:
    A. The patient will NOT be using the requested agent with an additional disease modifying agent (DMA) for the requested indication
    OR
    B. BOTH of the following:
        i. The patient is currently using the requested agent
        AND
        ii. Information has been provided supporting the use of the additional DMA (e.g., relapse between cycles)

AND

7. ONE of the following:
    A. The patient's age is within FDA labeling for the requested indication for the requested agent
    OR
    B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication

AND

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

AND

9. The requested quantity (dose) does not exceed the FDA labeled maximum dose based on the patient's weight

AND

10. ONE of the following:

A. The requested quantity (dose) does not exceed the program quantity limit
OR
B. BOTH of the following
i. The requested quantity (dose) is greater than the program quantity limit
AND
ii. The requested quantity (dose) cannot be achieved with a lower quantity of packs and a higher pack size (e.g., two 10 tablet packs instead of four 5 tablet packs) that does not exceed the program quantity limit

Length of Approval: 36 weeks for new starts OR if patient is currently taking the requested agent, approve for remainder of the annual course (1 course consists of 2 cycles of 4-5 days)

Mavenclad (cladribine) Renewal Evaluation
Mavenclad (cladribine) will be approved when ALL of the following are met:
1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process
AND
2. The patient has had clinical benefit with the requested agent
AND
3. A complete CBC with differential including lymphocyte count has been performed
AND
4. The patient has a lymphocyte count of at least 800 cells/µL
AND
5. The prescriber is a specialist in the area of the patient's diagnosis (i.e., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis
AND
6. ONE of the following:
A. The patient will NOT be using the requested agent in combination with an additional disease modifying agent (DMA) for the requested indication
OR
B. Information has been provided supporting the use of the additional DMA (e.g., relapse between cycles)
AND
7. The patient does NOT have any FDA labeled contraindications to the requested agent
AND
8. It has been at least 35 weeks but not more than 67 weeks since the last dose of the requested agent
AND
9. BOTH of the following:
A. The prescriber has provided the number of courses the patient has completed (one course consists of 2 cycles of 4-5 days each)
AND
B. The patient has NOT completed 2 courses with the requested agent (one course consists of 2 cycles of 4-5 days)
AND
10. The requested dose does not exceed the maximum FDA labeled dose for the patient's weight
AND
11. ONE of the following:
A. The requested quantity (dose) does not exceed the program quantity limit
OR
B. ALL of the following:
i. The requested quantity (dose) is greater than the program quantity limit
AND
ii. The requested quantity (dose) cannot be achieved with a lower quantity of packs and a higher pack size (e.g., two 10 tablet packs instead of four 5 tablet packs) that does not exceed the program quantity limit

Length of Approval: 3 months

Initial Evaluation
Target Agent(s) (excluding Mavenclad [cladribine]) will be approved when ALL of the following are met:
1. ONE of the following:

A. Information has been provided that the patient has been treated with the requested agent within the past 90 days
OR
B. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed
OR
C. The patient has a diagnosis of a relapsing form of MS AND ALL of the following:
    i. The patient has an FDA labeled indication for the requested agent
    AND
    ii. ONE of the following:
        a. The patient has a diagnosis of clinically isolated syndrome (CIS) AND ALL of the following:
            1. The patient had a single event that lasted at least 24 hours
            AND
            2. The event was not due to fever or infection
            AND
            3. The patient has MS-like brain lesion(s) confirmed by magnetic resonance imaging (MRI)
        OR
        b. The patient has a diagnosis of relapsing remitting multiple sclerosis (RRMS) or secondary progressive multiple sclerosis (SPMS)
    AND
    iii. 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's medication history includes two preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) AND ONE of the following:
            A. The patient had an inadequate response to two preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL)
            OR
            B. The prescriber has submitted an evidence-based and peer reviewed clinical practice guideline supporting the use of the requested agent over the preferred agent(s)
        OR
        3. The patient has an intolerance or hypersensitivity to two 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 patient has an FDA labeled contraindication to ALL 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
        5. The prescriber has provided information that the required 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

6. The prescriber has provided information supporting the use of the non-preferred agent over the preferred agent(s)

AND

iv. If the requested agent is Aubagio (teriflunomide), the prescriber has obtained transaminase and bilirubin levels within 6 months prior to initiating treatment

AND

v. If the requested agent is Gilenya (fingolimod) or Tascenso ODT (fingolimod) the prescriber has performed an electrocardiogram within 6 months prior to initiating treatment

AND

2. The prescriber is a specialist in the area of the patient's diagnosis (i.e., 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 will NOT be using the requested agent in combination with an additional disease modifying agent (DMA) for the requested indication

   OR

   B. The patient will be using the requested agent in combination with another DMA used for the treatment of the requested indication AND BOTH of the following:
      i. The requested agent will be used in combination with Mavenclad (cladribine)

      AND

      ii. Information has been provided supporting the use of the requested agent in combination with Mavenclad (e.g., relapse between cycles of Mavenclad)

AND

4. ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent

   OR

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

AND

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

AND

6. ONE of the following:
   A. The requested quantity (dose) does not exceed the program quantity limit

   OR

   B. ALL of the following
      i. The requested quantity (dose) is greater than the program quantity limit

      AND

      ii. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication

      AND

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

   OR

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

      AND

      ii. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication

      AND

      iii. Information has been provided in support of therapy with a higher dose for the requested indication

Length of Approval: 12 months. **NOTE**: For agents requiring a starter dose for initial use, the starter dose can be approved for the FDA labeled starting dose and the maintenance dose can be approved for the remainder of 12 months.

Renewal Evaluation

Target agent(s) (excluding Mavenclad [cladribine]) will be approved when ALL of the following are met:

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process
   AND
2. The patient has had clinical benefit with the requested agent
   AND
3. The prescriber is a specialist in the area of the patient's diagnosis (i.e., neurologist) 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 will NOT be using the requested agent in combination with an additional disease modifying agent (DMA) for the requested indication
      OR
   B. The patient will be using the requested agent in combination with another DMA used for the requested indication AND BOTH of the following:
      i. The requested agent will be used in combination with Mavenclad cladribine)
         AND
      ii. Information has been provided supporting the use of the requested agent in combination with Mavenclad (e.g., relapse between cycles of Mavenclad)

   AND
5. The patient does NOT have any FDA labeled contraindications to the requested agent
   AND
6. ONE of the following:
   A. The requested quantity (dose) does not exceed the program quantity limit
      OR
   B. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
         AND
      ii. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication
         AND
      iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

      OR
   C. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
         AND
      ii. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
         AND
      iii. Information has been provided in support of therapy with a higher dose for the requested indication

Length of Approval: 12 months

• Program Summary: Ocaliva (obeticholic acid)

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
52750060000330	Ocaliva	Obeticholic Acid Tab 10 MG	10 MG	30	Tablets	30	DAYS				06-01-2020	
52750060000320	Ocaliva	Obeticholic Acid Tab 5 MG	5 MG	30	Tablets	30	DAYS				06-01-2020	

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 primary biliary cholangitis (PBC) and ALL of the following: 1. Diagnosis was confirmed by at least TWO of the following: A. There is biochemical evidence of cholestasis with an alkaline phosphatase (ALP) elevation B. Presence of antimitochondrial antibody (AMA): a titer greater than 1:80 C. If the AMA is negative or present only in low titer (less than or equal to 1:80), presence of other PBC-specific autoantibodies, including sp100 or gp210 D. Histologic evidence of nonsuppurative destruction cholangitis and destruction of interlobular bile ducts **AND** 2. The prescriber has measured the patient's baseline alkaline phosphatase (ALP) level and total bilirubin level (prior to therapy with the requested agent) **AND** 3. ONE of the following: A. The patient does NOT have cirrhosis **OR** B. The patient has compensated cirrhosis with NO evidence of portal hypertension **AND** 4. ONE of the following: A. BOTH of the following: 1. The patient has tried and had an inadequate response after at least 1 year of therapy with ursodeoxycholic acid (UDCA) (inadequate response defined as ALP greater than or equal to 1.67-times the upper limit of normal [ULN], and/or total bilirubin greater than the ULN but less than 2x ULN, after 1 year of treatment with UDCA) **AND** 2. The patient will continue treatment with ursodeoxycholic acid (UDCA) with the requested agent **OR** B. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ursodeoxycholic acid (UDCA) **OR** B. The patient has another FDA approved indication for the requested agent **OR** C. The patient has another indication that is supported in compendia for the requested agent **AND** 2. If the patient has an FDA approved indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**

Module	Clinical Criteria for Approval
	3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** 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 the requested agent through the plan's Prior Authorization process **AND** 2. ONE of the following: A. For primary biliary cholangitis (PBC), ALL of the following: 1. ONE of the following: A. The patient does NOT have cirrhosis **OR** B. The patient has compensated cirrhosis with NO evidence of portal hypertension **AND** 2. ONE of the following: A. The requested agent will be used in combination with ursodeoxycholic acid (UDCA) **OR** B. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ursodeoxycholic acid (UDCA) **AND** 3. The patient has had an alkaline phosphatase (ALP) decrease of greater than or equal to 15% from baseline (prior to therapy with the requested agent) AND ALP is less than 1.67-times the upper limit of normal (ULN) **AND** 4. The patient's total bilirubin is less than or equal to the upper limit of normal (ULN) **OR** B. For another FDA approved indication or another compendia supported indication, 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., gastroenterologist, hepatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** 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. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**

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

• Program Summary: 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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
86720020002040	Cequa	Cyclosporine (Ophth) Soln 0.09% (PF)	0.09 %	60	Vials	30	DAYS				04-01-2019	
86720020001630	Cyclosporine in klarity; Verkazia	Cyclosporine (Ophth) Emulsion 0.1%	0.1 %	120	Vials	30	DAYS					
86720020001620	Restasis; Restasis multidose	Cyclosporine (Ophth) Emulsion; cyclosporine (ophth) emulsion	0.05; 0.05 %	60	Vials	30	DAYS			00023916305; 00023916330; 00023916360; 00378876058; 00378876091; 10702080803; 10702080806; 50090124200; 50090447600; 60505620201; 60505620202; 68180021430; 68180021460	06-01-2018	
86720020001620	Restasis; Restasis multidose	Cyclosporine (Ophth) Emulsion; cyclosporine (ophth) emulsion	0.05; 0.05 %	1	Bottle	30	DAYS			00023530101 ; 00023530105 ; 00023916305 ; 50090447600	04-01-2017	
86734050002020	Xiidra	Lifitegrast Ophth Soln 5%	5 %	60	Vials	30	DAYS				01-01-2017	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Restasis (cyclosporine ophthalmic emulsion)** will be approved when ALL of the following are met: 1. ONE of the following:

Module	Clinical Criteria for Approval
	A. ALL of the following: 1. The patient has a diagnosis of dry eye disease (i.e., dry eye syndrome, keratoconjunctivitis sicca [e.g., Sjögren's Syndrome]) **AND** 2. The patient will NOT be using the requested agent in combination with punctal plug(s) **AND** 3. ONE of the following: A. The patient'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 (e.g., artificial tears, gels, ointments [target agents not included]) **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over aqueous enhancements (e.g., artificial tears, gels, ointments [target agents not included]) **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 cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has another FDA approved indication for the requested agent **AND** 2. The patient will NOT be using the requested agent in combination with another ophthalmic immunomodulator agent (e.g., Restasis, Cequa, Xiidra, Verkazia) or Tyrvaya **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Initial Evaluation** **Cequa (cyclosporine), Xiidra (lifitegrast)** will be approved when ALL of the following are met: 1. ONE of the following: A. BOTH of the following: 1. The patient has a diagnosis of dry eye disease (i.e., dry eye syndrome, keratoconjunctivitis sicca [e.g., Sjögren's Syndrome]) **AND** 2. ONE of the following: A. The patient's medication history includes aqueous enhancements (e.g., artificial tears, gels, ointments [target agents not included]) AND ONE of the following:

Module	Clinical Criteria for Approval
	1. The patient has had an inadequate response to aqueous enhancements (e.g., artificial tears, gels, ointments [target agents not included]) **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over aqueous enhancements (e.g., artificial tears, gels, ointments [target agents not included]) **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 cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has another FDA approved indication for the requested agent **AND** 2. The patient will NOT be using the requested agent in combination with another ophthalmic immunomodulator agent (e.g., Restasis, Cequa, Xiidra, Verkazia) or Tyrvaya **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Initial Evaluation** **Verkazia (cyclosporine)** 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**

Module	Clinical Criteria for Approval
	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** 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 **AND** B. The patient has another FDA approved indication for the requested agent **AND** 2. The patient will NOT be using the requested agent in combination with another ophthalmic immunomodulator agent (e.g., Restasis, Cequa, Xiidra, Verkazia) or Tyrvaya **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 4 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

Module	Clinical Criteria for Approval
	Renewal Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient will NOT be using the requested agent in combination with another ophthalmic immunomodulator agent (e.g., Restasis, Cequa, Xiidra, Verkazia) or Tyrvaya **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **Length of Approval**: Initial - Cequa and Xiidra - 3 months, Verkazia - 4 months, Restasis/cyclosporine - 6 months Renewal - 12 months

• Program Summary: Relyvrio (sodium phenylbutyrate/taurursodiol)

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
74509902703020	Relyvrio	Sodium Phenylbutyrate-Taurursodiol Powd Pack	3-1 GM	1	Box	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. The patient has a diagnosis of amyotrophic lateral sclerosis (ALS) [also known as Lou Gehrig's disease] **AND** 2. BOTH of the following: A. The requested agent will be or was started within 18 months of symptom onset **AND**

Module	Clinical Criteria for Approval
	B. The patient has a baseline percent predicted forced vital capacity (FVC) or slow vital capacity (SVC) greater than 60% **AND** 3. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 4. The patient is able to perform most activities of daily living, defined as scores of 2 points or better on each individual item of the ALS Functional Rating Scale-Revised [ALSFRS-R] **AND** 5. ONE of the following: A. The patient is currently being treated with riluzole **OR** B. The patient's medication history includes riluzole AND ONE of the following: 1. The patient has had an inadequate response to riluzole **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over riluzole **OR** C. The patient has an intolerance or hypersensitivity to riluzole **OR** D. The patient has an FDA labeled contraindication to riluzole **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that riluzole cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization criteria **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient is NOT dependent on invasive ventilation or tracheostomy **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantities above the program quantity limit for the Target Agent(s)** will be approved when the following is met: 1. ONE of the following: A. The requested quantity (dose) does NOT exceed the program quantity limit **OR** B. ALL of the following: 1. The requested quantity (dose) is greater than the program quantity limit **AND** 2. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 3. 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:** 6 months for initial; 12 months for renewal

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

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

Sodium-glucose Co-transporter (SGLT) Inhibitors and Combinations Step Therapy – 1-Step Edit

TARGET AGENT(S)
Farxiga™ (dapagliflozin)
Glyxambi® (empagliflozin/linagliptin)
Inpefa™ (sotagliflozin)
Invokana® (canagliflozin)
Invokamet™ (canagliflozin/metformin)
Invokamet XR™ (canagliflozin/metformin ER)
Jardiance® (empagliflozin)
Qtern® (dapagliflozin/saxagliptin)
Segluromet™ (ertugliflozin/metformin)
Steglatro™ (ertugliflozin)
Steglujan™ (ertugliflozin/sitagliptin)
Synjardy® (empagliflozin/metformin)
Synjardy XR® (empagliflozin/metformin ER)
Trijardy XR™ (empagliflozin/linagliptin/metformin ER)
Xigduo XR™ (dapagliflozin/metformin ER)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Farxiga will be approved when ONE of the following is met:
1. The patient has a diagnosis of heart failure
   OR
2. The patient has a diagnosis of type 2 diabetes with or at high risk for atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease
   OR
3. The patient has a diagnosis of chronic kidney disease (CKD)
   OR
4. The patient's medication history includes use of an agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), I_f channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine in the past
   OR

5. The prescriber has stated that the patient has tried an agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), I_f channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine AND ONE of the following:
    A. An agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), I_f channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine 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 an agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), I_f channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine

OR

6. Information has been provided that indicates the patient is currently being treated with the requested SGLT inhibitor within the past 90 days

OR

7. The prescriber states the patient is currently being treated with the requested SGLT inhibitor within the past 90 days AND is at risk if therapy is changed

OR

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

OR

9. The patient has an intolerance or hypersensitivity to ONE of the following agents: metformin or insulin

OR

10. The patient has an FDA labeled contraindication to ALL of the following agents: metformin and insulins

OR

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

OR

12. The patient has an intolerance or hypersensitivity to ONE of the following agents: ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), I_f channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine

OR

13. The patient has an FDA labeled contraindication to ALL of the following agents: ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), I_f channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate and hydralazine

OR

14. The prescriber has provided documentation that ALL of the following agents: ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), I_f channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate and hydralazine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

Length of Approval: 12 months

Jardiance or Inpefa will be approved when ONE of the following is met:

1. The patient has a diagnosis of heart failure

OR

2. The patient has a diagnosis of type 2 diabetes with or at high risk for atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease

OR

3. The patient's medication history includes use of an agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), I_f channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine in the past
   OR
4. The prescriber has stated that the patient has tried an agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), I_f channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine AND ONE of the following:
   A. An agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), I_f channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine 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 an agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), I_f channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine

   OR
5. Information has been provided that indicates the patient is currently being treated with the requested SGLT inhibitor within the past 90 days
   OR
6. The prescriber states the patient is currently being treated with the requested SGLT inhibitor within the past 90 days AND is at risk if therapy is changed
   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 patient has an intolerance or hypersensitivity to ONE of the following agents: metformin or insulin
   OR
9. The patient has an FDA labeled contraindication to ALL of the following agents: metformin and insulin
   OR
10. The prescriber has provided documentation that metformin AND insulin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm
    OR
11. The patient has an intolerance or hypersensitivity to ONE of the following agents: ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), I_f channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine
    OR
12. The patient has an FDA labeled contraindication to ALL of the following agents: ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), I_f channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate and hydralazine
    OR
13. The prescriber has provided documentation that ALL of the following agents: ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), I_f channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate and hydralazine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

Length of Approval: 12 months

All other target agents will be approved when ONE of the following is met:
1. The patient's medication history includes use of an agent containing metformin or insulin

OR

2. The prescriber has stated that the patient has tried insulin or an agent containing metformin AND ONE of the following:
   A. Insulin or an agent containing metformin 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 insulin or an agent containing metformin

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

   OR
6. The patient has an intolerance or hypersensitivity to one of the following agents: metformin or insulin
   OR
7. The patient has an FDA labeled contraindication to ALL of the following agents: metformin AND insulins
   OR
8. The patient has a diagnosis of type 2 diabetes with or at high risk for atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease
   OR
9. The prescriber has provided documentation that metformin AND insulin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

Length of Approval: 12 months

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

• Program Summary: Tavneos (avacopan)

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
85805510000120	Tavneos	Avacopan Cap	10 MG	180	Capsules	30	DAYS				03-01-2022	

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:

Module	Clinical Criteria for Approval
	A. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** B. The prescriber states the patient has been treated with the requested agent within the past 90 days (starting on samples is not approvable) AND is at risk if therapy is changed **OR** C. ALL of the following: 1. The patient has a diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and/or microscopic polyangiitis [MPA]) **AND** 2. The patient has a positive ANCA-test **AND** 3. The patient has been screened for prior or current hepatitis B infection AND if positive a prescriber specializing in hepatitis B treatment has been consulted **OR** D. BOTH of the following: 1. The patient has another FDA approved indication for the requested agent **AND** 2. The patient has been screened for prior or current hepatitis B infection AND if positive a prescriber specializing in hepatitis B treatment has been consulted **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient does NOT have severe hepatic impairment (Child-Pugh C) **AND** 4. If the patient has a diagnosis of ANCA-associated vasculitis, then BOTH of the following: A. The patient is currently treated with standard therapy (e.g., cyclophosphamide, rituximab, azathioprine, mycophenolate mofetil) for the requested indication **AND** B. The patient will continue standard therapy (e.g., cyclophosphamide, rituximab, azathioprine, mycophenolate mofetil) in combination with the requested agent for the requested indication **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approva**l: 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient does NOT have severe hepatic impairment (Child-Pugh C) **AND** 4. ONE of the following: A. The patient has a diagnosis of ANCA associated vasculitis AND **BOTH** of the following: 1. The patient is currently treated with standard therapy (e.g., azathioprine, mycophenolate mofetil) for the requested indication **AND** 2. The patient will continue standard therapy (e.g., azathioprine, mycophenolate mofetil) in combination with the requested agent for the requested indication **OR** B. The patient has another FDA approved indication for the requested agent **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent

Module	Clinical Criteria for Approval
	Length of Approval: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Tyrvaya (varenicline)

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
86280080202020	Tyrvaya	Varenicline Tartrate Nasal Soln	0.03 MG/ACT	2	Bottles	30	DAYS				03-01-2022	

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. BOTH of the following: 1. The patient has a diagnosis of dry eye disease (i.e., dry eye syndrome, keratoconjunctivitis sicca [e.g., Sjögren's Syndrome]) **AND** 2. ONE of the following: A. The patient's medication history includes aqueous enhancements (e.g., artificial tears, gels, ointments [target agents not included]) AND ONE of the following:

Module	Clinical Criteria for Approval
	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 approved indication for the requested agent **AND** 2. The patient will NOT be using the requested agent in combination with an ophthalmic immunomodulator agent (e.g., Restasis, Cequa, Xiidra, Verkazia) **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 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 **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 an ophthalmic immunomodulator agent (e.g., Restasis, Cequa, Xiidra, Verkazia) **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. ALL of the following:

Module	Clinical Criteria for Approval
	A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **Length of approval**: Initial requests - 2 months; Renewal requests - 12 months

• Program Summary: Vascepa

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
39500035100110	Vascepa	Icosapent Ethyl Cap 0.5 GM	0.5 GM	240	Capsules	30	DAYS				07-01-2019	
39500035100120	Vascepa	Icosapent Ethyl Cap 1 GM	1 GM	120	Capsules	30	DAYS				07-01-2019	

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 pre-treatment triglyceride (TG) level of greater than or equal to 500 mg/dL **OR** B. The patient is using the requested agent to reduce the risk of myocardial infarction, stroke, coronary revascularization, or unstable angina requiring hospitalization AND ALL of the following: 1. ONE of the following: A. The patient is on maximally tolerated statin therapy **OR** B. The patient has an intolerance or hypersensitivity to statin therapy **OR** C. The patient has an FDA labeled contraindication to ALL statins **AND** 2. The patient's triglyceride (TG) level is greater than or equal to 150 mg/dL **AND** 3. ONE of the following: A. The patient has established cardiovascular disease **OR** B. The patient has diabetes mellitus AND 2 or more additional risk factors for cardiovascular disease (e.g., hypertension, premature family history, chronic kidney disease) **OR** C. The patient has another FDA approved indication for the requested agent and route of administration **OR** D. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA approved indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent

Module	Clinical Criteria for Approval
	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 the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

● Program Summary: Verquvo

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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
40900085000321	Verquvo	Vericiguat Tab	2.5 MG	30	Tablets	30	DAYS				06-01-2021	

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
40900085000330	Verquvo	Vericiguat Tab	5 MG	30	Tablets	30	DAYS				06-01-2021	
40900085000340	Verquvo	Vericiguat Tab	10 MG	30	Tablets	30	DAYS				06-01-2021	

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:

Agent(s) Eligible for Continuation of Therapy
All target agents are eligible for continuation of therapy

     1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**
     2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR**
   - B. The patient has a diagnosis of symptomatic chronic heart failure (NYHA class II-IV) and ALL of the following:
     1. The patient has a baseline prior to therapy with the requested agent OR current left ventricular ejection fraction of 45% or less **AND**
     2. The patient has had a worsening heart failure event, defined as a heart failure hospitalization within 6 months of agent request, or use of outpatient intravenous diuretics for heart failure within 3 months of agent request **AND**
     3. ONE of the following:
        - A. The patient will be using standard CHF therapy (e.g., beta blockers, ACE inhibitors) in combination with the requested agent **OR**
        - B. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to ALL standard CHF therapy (e.g., beta blockers, ACE inhibitors) that is not expected to occur with the requested agent **OR**
        - C. The patient is currently being treated with the requested agent as indicated by ALL of the following:
          1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
          2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
          3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
        - D. BOTH of the following:
          1. The patient's medication history includes standard CHF therapy (e.g., beta blockers, ACE inhibitors) as indicated by ONE of the following:
             - A. Evidence of a paid claim(s) **OR**
             - B. The prescriber has stated that the patient has tried using standard CHF therapy (e.g., beta blockers, ACE inhibitors) **AND**
          2. ONE of the following:

Module	Clinical Criteria for Approval
	A. Standard CHF therapy 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 standard CHF therapy **OR** E. The prescriber has provided documentation ALL standard CHF therapy (e.g., beta blockers, ACE inhibitors) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has another FDA approved indication for the requested agent and route of administration **OR** D. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS approved compendia NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Length of Approval:** 12 months **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. If the requested agent is being used for heart failure, ONE of the following: A. The patient will be using standard CHF therapy (e.g., beta blockers, ACE inhibitors) in combination with the requested agent **OR** B. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to ALL standard CHF therapy (e.g., beta blockers, ACE inhibitors) that is not expected to occur with the requested agent **OR** C. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** D. BOTH of the following: 1. The patient's medication history includes standard CHF therapy (e.g., beta blockers, ACE inhibitors) as indicated by ONE of the following: A. Evidence of a paid claim(s) **OR**

Module	Clinical Criteria for Approval
	B. The prescriber has stated that the patient has tried using standard CHF therapy (e.g., beta blockers, ACE inhibitors) **AND** 2. ONE of the following: A. Standard CHF therapy 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 standard CHF therapy **OR** E. The prescriber has provided documentation ALL standard CHF therapy (e.g., beta blockers, ACE inhibitors) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Length of Approval:** 12 months

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: 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	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
61200010100305		Benzphetamine HCl Tab 25 MG		90	Tablets	30	DAYS					
61200010100310		Benzphetamine HCl Tab 50 MG	50 MG	90	Tablets	30	DAYS					
61200020100305		Diethylpropion HCl Tab 25 MG	25 MG	90	Tablet	30	DAYS					
61200020107510		Diethylpropion HCl Tab ER 24HR 75 MG	75 MG	30	Tablets	30	DAYS					
61200050107010		Phendimetrazine Tartrate Cap ER 24HR 105 MG	105 MG	30	Capsules	30	DAYS					
61200050100305		Phendimetrazine Tartrate Tab 35 MG	35 MG	180	Tablets	30	DAYS					
61200070100110		Phentermine HCl Cap 15 MG	15 MG	30	Capsules	30	DAYS					
61200070100115		Phentermine HCl Cap 30 MG	30 MG	30	Capsules	30	DAYS					
61200070100120	Adipex-p	Phentermine HCl Cap 37.5 MG	37.5 MG	30	Capsules	30	DAYS					
61200070100310	Adipex-p	Phentermine HCl Tab 37.5 MG	37.5 MG	30	Tablets	30	DAYS					
61259902507420	Contrave	Naltrexone HCl-Bupropion HCl Tab ER 12HR 8-90 MG	8-90 MG	120	Tablets	30	DAYS					
61200070100305	Lomaira	Phentermine HCl Tab 8 MG	8 MG	90	Tablets	30	DAYS					
61209902307040	Qsymia	Phentermine HCl-Topiramate Cap ER 24HR 11.25-69 MG	11.25-69 MG	30	Capsules	30	DAYS					
61209902307050	Qsymia	Phentermine HCl-Topiramate Cap ER 24HR 15-92 MG	15-92 MG	30	Capsules	30	DAYS					
61209902307020	Qsymia	Phentermine HCl-Topiramate Cap ER 24HR 3.75-23 MG	3.75-23 MG	30	Capsules	30	DAYS					
61209902307030	Qsymia	Phentermine HCl-Topiramate Cap ER 24HR 7.5-46 MG	7.5-46 MG	30	Capsules	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
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 ; 0.25 MG/0.5ML	8	Pens	180	DAYS	* - This strength is not approvable for maintenance dosing				
6125207000D525	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	0.5 MG/0.5ML	8	Pens	180	DAYS	* - This strength is not approvable for maintenance dosing				
6125207000D530	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	1 MG/0.5ML	8	Pens	180	DAYS	* - This strength is not approvable for maintenance dosing				
6125207000D535	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	1.7 MG/0.75 ML	4	Pens	28	DAYS	1.7mg formulation is allowed as maintenance for pediatric patients				
6125207000D540	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	2.4 MG/0.75 ML	4	Pens	28	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
Contrave	orlistat Xenical

Module	Clinical Criteria for Approval

Saxenda Wegovy	

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 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**
     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 did not achieve a weight loss of 1 pound or more per week while on the weight loss regimen prior to initiating therapy with the requested agent **AND**
     4. The patient is currently on and will continue a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **AND**
2. If the patient has an FDA approved indication, ONE of the following:
   - A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
   - B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**
3. 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**

Module	Clinical Criteria for Approval
	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 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** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication **AND** 6. ONE of the following: A. The patient has not tried a targeted weight loss agent in the past 12 months **OR** B. The patient has tried a targeted weight loss agent for a previous course of therapy in the past 12 months AND the prescriber anticipates success with repeating therapy **AND** 7. 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. The prescriber has provided information in support of 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 the initiation of requested agent) **OR**

Module	Clinical Criteria for Approval
	D. The requested agent is Xenical (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 the 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 the initiation of requested agent) **OR** E. The requested agent is Saxenda and ALL of the following: 1. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND** 2. ONE of the following: A. The patient is 18 years of age or over and ONE of the following: 1. The patient is newly starting therapy **OR** 2. The patient is currently being treated and has received less than 16 weeks (4 months) of therapy **OR** 3. The patient has achieved and maintained a weight loss of greater than or equal to 4% from baseline (prior to the initiation of requested agent) **OR** B. The patient is pediatric (12 to less than 18 years of age) and BOTH of the following: 1. The requested agent is NOT being used to treat type 2 diabetes **AND** 2. ONE of the following: A. The patient is newly starting therapy **OR** B. The patient is currently being treated and has received less than 20 weeks (5 months) of therapy **OR** C. The patient has achieved and maintained a reduction in BMI of greater than or equal to 1% from baseline (prior to the initiation of requested agent) **OR** F. The requested agent is Wegovy and ALL of the following: 1. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND** 2. The patient does NOT have a history of pancreatitis **AND** 3. ONE of the following: A. The patient is newly starting therapy **OR** B. The patient is currently being treated and has received less than 52 weeks (1 year) of therapy **OR** C. ONE of the following: 1. 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 the requested agent) **OR** 2. The patient is pediatric (12 to less than 18 years of age) AND has achieved and maintained a reduction in BMI of atleast 5% from baseline (prior to initiation of the requested agent)

Module	Clinical Criteria for Approval
	Length of Approval: • For Wegovy: 12 months • For Saxenda pediatric patients (age 12 to less than 18): 5 months. • For Saxenda (adults) and Contrave: 4 months. • For all other agents: 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** (Patient continuing a current weight loss course of therapy) **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. 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** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. For Saxenda only, BOTH of the following: A. The requested agent is NOT being used to treat type 2 diabetes in pediatric patients (12 to less than 18 years of age) **AND** B. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND** 5. For Wegovy only, ALL of the following: A. The requested dose is 1.7 mg or 2.4 mg **AND** B. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND** C. The patient does NOT have a history of pancreatitis **AND** 6. 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. For Saxenda only, ONE of the following: 1. If the patient is 18 years of age or over, the patient has achieved and maintained a weight loss greater than or equal to 4% from baseline (prior to initiation of requested agent) **OR** 2. If the patient is pediatric (12 to less than 18 years of age), the patient has achieved and maintained a reduction in BMI of greater than or equal to 1% from baseline (prior to initiation of requested agent) **OR** C. For Qsymia only, ONE of the following: 1. For pediatric patients aged 12 years and older, the patient has achieved and maintained a reduction of at least 5% of baseline (prior to initiation of the requested agent) BMI **OR** 2. The patient has achieved and maintained a weight loss less than 5% from baseline (prior to initiation of requested agent) for adults, or a reduction in BMI less than 5% from baseline (prior to initiation of the requested agent) for pediatric patients aged 12 years or older, AND BOTH of the following: A. The patient's dose is being titrated upward (for the 3.75 mg/23 mg, 7.5 mg/46 mg or 11.25 mg/69 mg strengths only) **AND** B. The patient has received less than 12 weeks of therapy on the 15mg/92mg strength **OR** D. For Xenical (orlistat) only, 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**

Module	Clinical Criteria for Approval
	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) **OR** E. For Wegovy only, ONE of the following: 1. The patient is an adult AND has received less than 52 weeks of therapy on the 2.4 mg dose **OR** 2. The patient is pediatric (12 to less than 18 years of age) AND one of the following: A. The patient has received less than 52 weeks of therapy on the maximum-tolerated dose (2.4mg or 1.7mg) **OR** B. The patient has achieved and maintained a reduction in BMI of at least 5% from baseline (prior to initiation of the requested agent) **AND** 7. 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** 8. The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication **Length of Approval:** • Qsymia: greater than or equal to 5% weight loss from baseline (adults); greater than or equal to 5% reduction in BMI from baseline (pediatrics): 12 months • Qsymia less than 5% weight loss from baseline (adults); less than 5% reduction in BMI from baseline (pediatrics): 3 months • All other agents: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: • Initial Approval: o For Wegovy: 12 months o For Saxenda pediatric patients (age 12 to less than 18): 5 months. o For Saxenda (adults) and Contrave: 4 months. o For all other agents: 3 months • Renewal Approval: o 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

Module	Clinical Criteria for Approval
	○ Qsymia. less than 5% weight loss from baseline (adults); less than 5% reduction in BMI from baseline (pediatrics): 3 months ○ All other agents: 12 months

● Program Summary: Xolair (omalizumab)

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

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 moderate to severe persistent asthma AND ALL of the following: 1. ONE of the following: A. The patient is 6 to less than 12 years of age AND BOTH of the following: 1. The pretreatment IgE level is 30 IU/mL to 1300 IU/mL **AND** 2. The patient's weight is 20 kg to 150 kg **OR** B. The patient is 12 years of age or over AND BOTH of the following: 1. The pretreatment IgE level is 30 IU/mL to 700 IU/mL **AND** 2. The patient's weight is 30 kg to 150 kg **AND** 2. Allergic asthma has been confirmed by a positive skin test or in vitro reactivity test (RAST) 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 **AND** 4. ONE of the following: A. The patient is NOT currently being treated with the requested agent AND is currently treated with a maximally tolerated inhaled corticosteroid **OR** B. The patient is currently being treated with the requested agent AND ONE of the following: 1. Is currently treated with an inhaled corticosteroid that is adequately dosed to control symptoms **OR** 2. Is currently treated with a maximally tolerated inhaled corticosteroid **OR** C. The patient has an intolerance or hypersensitivity to inhaled corticosteroid therapy **OR** D. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids **OR** E. 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** F. The prescriber has provided documentation that ALL inhaled corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 5. ONE of the following: A. The patient is currently being treated with ONE of the following: 1. A long-acting beta-2 agonist (LABA) **OR** 2. A leukotriene receptor antagonist (LTRA) **OR** 3. Long-acting muscarinic antagonist (LAMA) **OR** 4. Theophylline **OR** B. The patient has an intolerance or hypersensitivity to therapy with long-acting beta-2 agonists (LABA), leukotriene receptor antagonists (LTRA), long-acting muscarinic antagonists (LAMA), or theophylline **OR** C. The patient has an FDA labeled contraindication to ALL long-acting beta-2 agonists (LABA), leukotriene receptor antagonists (LTRA), long-acting muscarinic antagonists (LAMA), AND theophylline **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 long-acting beta-2 agonists (LABA), leukotriene receptor antagonists (LTRA), long-acting muscarinic antagonists (LAMA), AND theophylline cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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 continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **AND** 7. 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 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. The prescriber has provided information indicating that a reduced dose or discontinuation of any medications known to cause or worsen urticaria is not appropriate **AND** 3. ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient's medication history includes use of a second-generation H-1 antihistamine (e.g., cetirizine, levocetirizine, fexofenadine, loratadine, desloratadine) **AND** B. ONE of the following: 1. 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** A. 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 prescriber has provided information indicating the patient cannot be treated with a dose above the FDA labeled maximum dose of a second-generation H-1 antihistamine **OR** 2. 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** 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 **AND** 4. 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 polyposis (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. 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:

Module	Clinical Criteria for Approval
	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 **AND** 5. 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** 6. 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 another FDA approved indication for the requested agent AND the requested dose is within FDA labeled dosing for the requested indication **OR** E. The patient has another indication that is supported in compendia for the requested agent AND the requested dose is supported in compendia for the requested indication **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The 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. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., 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:** 6 months for asthma, chronic idiopathic urticaria, and nasal polyps 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 **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**

Module	Clinical Criteria for Approval
	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 idiopathic urticaria 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 polyposis (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 **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 another FDA approved 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** E. The patient has another indication that is supported in compendia for the requested agent AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The requested dose is supported in compendia for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, otolaryngologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., 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

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly
Abrilada (adalimumab-afzb) Actemra (tocilizumab) Adbry (tralokinumab-ldrm) Amjevita (adalimumab-atto) Arcalyst (rilonacept) Avsola (infliximab-axxq) Benlysta (belimumab) Cibinqo (abrocitinib) Cimzia (certolizumab) Cinqair (reslizumab) Cosentyx (secukinumab) Cyltezo (adalimumab-adbm) Dupixent (dupilumab) Enbrel (etanercept) Entyvio (vedolizumab) Fasenra (benralizumab) Hadlima (adalimumab-bwwd) Hulio (adalimumab-fkjp) Humira (adalimumab) Hyrimoz (adalimumab-adaz) Idacio (adalimumab-aacf) Ilaris (canakinumab) Ilumya (tildrakizumab-asmn) Inflectra (infliximab-dyyb) Infliximab Kevzara (sarilumab) Kineret (anakinra) Nucala (mepolizumab) Olumiant (baricitinib) Opzelura (ruxolitinib) Orencia (abatacept) Otezla (apremilast) Remicade (infliximab) Renflexis (infliximab-abda) Riabni (rituximab-arrx) Rinvoq (upadacitinib) Rituxan (rituximab) Rituxan Hycela (rituximab/hyaluronidase human) Ruxience (rituximab-pvvr) Siliq (brodalumab) Simponi (golimumab) Simponi ARIA (golimumab) Skyrizi (risankizumab-rzaa) Sotyktu (deucravacitinib) Stelara (ustekinumab) Taltz (ixekizumab) Tezspire (tezepelumab-ekko) Tremfya (guselkumab) Truxima (rituximab-abbs) Tysabri (natalizumab) Xeljanz (tofacitinib) Xeljanz XR (tofacitinib extended release)

Contraindicated as Concomitant Therapy
Xolair (omalizumab) Yusimry (adalimumab-aqvh) Zeposia (ozanimod)