MHCP PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: August 1, 2023 Notification Posted: July 18, 2023

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

No new policies for August 1, 2023

POLICIES REVISED

• Program Summary: Biologic Immunomodulators

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
6650007000E5	Actemra	tocilizumab subcutaneous soln prefilled syringe	162 MG/0.9ML	4	Syringes	28	DAYS					
6650007000D520	Actemra actpen	Tocilizumab Subcutaneous Soln Auto-	162 MG/0.9ML	4	Pens	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
		injector 162 MG/0.9ML										
6627001510D520	Amjevita	adalimumab-atto soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS				02-27-2023	
6627001510E510	Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.4ML	2	Syringes	28	DAYS				02-27-2023	
6627001510E520	Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.8ML	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/0.5ML	1	Syringe	28	DAYS					
9025057500E520	Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe 150 MG/ML	150 MG/ML	1	Syringe	28	DAYS					
9025057500D530	Cosentyx sensoready pen	Secukinumab Subcutaneous Auto-inj 150 MG/ML (300 MG Dose)	150 MG/ML	2	Pens	28	DAYS					
9025057500D520	Cosentyx sensoready pen	Secukinumab Subcutaneous Soln Auto-injector 150 MG/ML	150 MG/ML	1	Pen	28	DAYS					
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/0.5ML	8	Vials	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
6629003000E525	Enbrel	Etanercept Subcutaneous Soln Prefilled Syringe 25 MG/0.5ML	25 MG/0.5ML	4	Syringes	28	DAYS					
6629003000E530	Enbrel	Etanercept Subcutaneous Soln Prefilled Syringe 50 MG/ML	50 MG/ML	4	Syringes	28	DAYS					
6629003000E230	Enbrel mini	Etanercept Subcutaneous Solution Cartridge 50 MG/ML	50 MG/ML	4	Cartridges	28	DAYS					
6629003000D530	Enbrel sureclick	Etanercept Subcutaneous Solution Auto-injector 50 MG/ML	50 MG/ML	4	Syringes	28	DAYS					
6627001500F804	Humira	Adalimumab Prefilled Syringe Kit 10 MG/0.1ML	10 MG/0.1ML	2	Syringes	28	DAYS					
6627001500F809	Humira	Adalimumab Prefilled Syringe Kit 20 MG/0.2ML	20 MG/0.2ML	2	Syringes	28	DAYS					
6627001500F830	Humira	Adalimumab Prefilled Syringe Kit 40 MG/0.4ML	40 MG/0.4ML	2	Syringes	28	DAYS					
6627001500F820	Humira	Adalimumab Prefilled Syringe Kit 40 MG/0.8ML	40 MG/0.8ML	2	Syringes	28	DAYS					
6627001500F840	Humira pediatric crohns d	Adalimumab Prefilled Syringe Kit 80 MG/0.8ML	80 MG/0.8ML	1	Kit	180	DAYS					
6627001500F880	Humira pediatric crohns d	Adalimumab Prefilled Syringe Kit 80 MG/0.8ML & 40 MG/0.4ML	80 MG/0.8ML & 40MG/0.4ML	1	Kit	180	DAYS					
6627001500F440	Humira pen	adalimumab pen-injector kit	80 MG/0.8ML	2	Pens	28	DAYS			00074012402		
6627001500F420	Humira pen	Adalimumab Pen-injector Kit; adalimumab pen-injector kit	40 MG/0.8ML	2	Pens	28	DAYS			00074433902; 50090448700		
6627001500F430	Humira pen	Adalimumab Pen-injector Kit 40 MG/0.4ML	40 MG/0.4ML	2	Pens	28	DAYS					
6627001500F420	Humira pen; Humira pen-	Adalimumab Pen-injector Kit;	40 MG/0.8ML	1	Kit	180	DAYS			00074433906;		

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
	cd/uc/hs start	adalimumab pen-injector kit								50090448700		
6627001500F420	Humira pen; Humira pen-ps/uv starter	Adalimumab Pen-injector Kit; adalimumab pen-injector kit	40 MG/0.8ML	1	Kit	180	DAYS			00074433907; 50090448700		
6627001500F440	Humira pen-cd/uc/hs start	adalimumab pen-injector kit	80 MG/0.8ML	1	Kit	180	DAYS			00074012403		
6627001500F440	Humira pen-pediatric uc s	adalimumab pen-injector kit	80 MG/0.8ML	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/0.8ML & 40MG/0.4ML	1	Kit	180	DAYS					
6650006000E5	Kevzara	sarilumab subcutaneous soln prefilled syringe	150 MG/1.14ML; 200 MG/1.14ML	2	Syringes	28	DAYS					
6650006000D5	Kevzara	sarilumab subcutaneous solution auto-injector	150 MG/1.14ML; 200 MG/1.14ML	2	Pens	28	DAYS					
6626001000E5	Kineret	anakinra subcutaneous soln prefilled syringe	100 MG/0.67ML	28	Syringes	28	DAYS					
666030100003	Olumiant	baricitinib tab	1 MG; 2 MG; 4 MG	30	Tablets	30	DAYS					
6640001000E520	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 125 MG/ML	125 MG/ML	4	Syringes	28	DAYS					
6640001000E510	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 50 MG/0.4ML	50 MG/0.4ML	4	Syringes	28	DAYS					
6640001000E515	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 87.5 MG/0.7ML	87.5 MG/0.7ML	4	Syringes	28	DAYS					
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	56	Tablets	365	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
66603072007520	Rinvoq	Upadacitinib Tab ER 24HR 15 MG	15 MG	30	Tablets	30	DAYS					
9025052000E5	Siliq	brodalumab subcutaneous soln prefilled syringe	210 MG/1.5ML	2	Syringes	28	DAYS					
6627004000D540	Simponi	Golimumab Subcutaneous Soln Auto-injector 100 MG/ML	100 MG/ML	1	Syringe	28	DAYS					
6627004000D520	Simponi	Golimumab Subcutaneous Soln Auto-injector 50 MG/0.5ML	50 MG/0.5ML	1	Syringe	28	DAYS					
6627004000E540	Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 100 MG/ML	100 MG/ML	1	Syringe	28	DAYS					
6627004000E520	Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 50 MG/0.5ML	50 MG/0.5ML	1	Syringe	28	DAYS					
9025057070F820	Skyrizi	Risankizumab-rzaa Sol Prefilled Syringe 2 x 75 MG/0.83ML Kit	75 MG/0.83ML	1	Kit	84	DAYS					
9025057070E540	Skyrizi	Risankizumab-rzaa Soln Prefilled Syringe	150 MG/ML	1	Syringe	84	DAYS					
5250406070E210	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	180 MG/1.2ML	1	Cartridge	56	DAYS					
5250406070E220	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	360 MG/2.4ML	1	Cartridge	56	DAYS					
9025057070D520	Skyrizi pen	Risankizumab-rzaa Soln Auto-injector	150 MG/ML	1	Pen	84	DAYS					
90250524000320	Sotyktu	Deucravacitinib Tab	6 MG	30	Tablets	30	DAYS					
90250585002020	Stelara	Ustekinumab Inj 45 MG/0.5ML	45 MG/0.5ML	1	Vial	84	DAYS					
9025058500E520	Stelara	Ustekinumab Soln Prefilled	45 MG/0.5ML	1	Syringe	84	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		Syringe 45 MG/0.5ML										
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					
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					
66603072007530	Rinvoq	Upadacitinib Tab ER	30 MG	30	Tablets	30	DAYS					

PREFERRED AGENTS

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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
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)	N/A	N/A

Module	Clinical Criteria for Approval

Enthesitis Related Arthritis (ERA) Giant Cell Arteritis (GCA) Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Systemic Juvenile Idiopathic Arthritis (SJIA) Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)		

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

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

Agents Eligible for Continuation of Therapy
All target agents except Amjevita 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. 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**

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

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

Module	Clinical Criteria for Approval
	7. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 8. The prescriber has provided documentation that ALL conventional agents (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. The patient has a diagnosis of moderately to severely active Crohn's disease (CD) AND ONE of the following: 1. The patient's medication history includes ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD AND ONE of the following: A. The patient has had an inadequate response to a conventional agent used in the treatment of CD **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional agents used in the treatment of CD **OR** 2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of CD **OR** 3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of CD **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of CD **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: 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:

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

Module	Clinical Criteria for Approval
	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 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

Module	Clinical Criteria for Approval
	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 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**

Module	Clinical Criteria for Approval
	5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that 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** 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**

Module	Clinical Criteria for Approval
	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: 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**

Module	Clinical Criteria for Approval
	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** 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

Module	Clinical Criteria for Approval
	[females only]; spironolactone [females only]; intralesional corticosteroids [triamcinolone]; clindamycin in combination with rifampin; combination of rifampin, moxifloxacin, and metronidazole; cyclosporine, oral retinoids) used in the treatment of HS AND ONE of the following: A. The patient has had an inadequate response to at a conventional agent used in the treatment of HS **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional agents used in the treatment of HS **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of HS **OR** 3. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of HS **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of HS **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL conventional agents used in the treatment of HS cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 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:

Module	Clinical Criteria for Approval
	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: 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**

Module	Clinical Criteria for Approval
	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** 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:

Module	Clinical Criteria for Approval
	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** 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**

Module	Clinical Criteria for Approval
	C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. The patient has tried and had an inadequate response to two 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 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**

Module	Clinical Criteria for Approval
	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 **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**

Module	Clinical Criteria for Approval
	2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has a diagnosis of polymyalgia rheumatica AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. If the requested agent is Kevzara, the patient does NOT have any of the following: A. Neutropenia (ANC less than 1,000 per mm^3 at the end of the dosing interval) **AND** B. Thrombocytopenia (platelet count is less than 100,000 per mm^3) **AND** C. AST or ALT elevations 3 times the upper limit of normal **OR** C. The patient has a diagnosis other than moderate to severe atopic dermatitis or polymyalgia rheumatica AND the patient has had clinical benefit with the requested agent **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, i.e., clinical trials, phase III studies, guidelines required) **AND** 7. If Cosentyx 300 mg every 4 weeks is requested as maintenance dosing, ONE of the following: A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis **OR** B. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks for at least 3-months **AND** 8. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND** 9. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** 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**

Module	Clinical Criteria for Approval
	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: 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.

Module	Clinical Criteria for Approval
	• 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.

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)

Contraindicated as Concomitant Therapy
Tysabri (natalizumab) Xeljanz (tofacitinib) Xeljanz XR (tofacitinib extended release) Xolair (omalizumab) Zeposia (ozanimod)

• Program Summary: Cannabidiol

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
	726000170020	Epidiolex	cannabidiol soln	100 MG/ML	M; N; O; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of seizures associated with ONE of the following: A. Lennox-Gastaut syndrome (LGS) **OR** B. Dravet syndrome (DS) **OR** C. Tuberous sclerosis complex (TSC) **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 requested agent will NOT be used as monotherapy for seizure management **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 **AND** 6. The requested quantity (dose) is within FDA labeled dosing for the requested indication **Length of Approval:** 12 months **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The requested agent will NOT be used as monotherapy for seizure management **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 **AND** 6. The requested quantity (dose) is within FDA labeled dosing for the requested indication **Length of Approval:** 12 months

● Program Summary: Endari

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
	828010200030	Endari	glutamine (sickle cell) powd pack	5 GM	M; N; O; Y				04-01-2018

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 sickle cell disease **AND** 2. The patient is using the requested agent to reduce the acute complications of sickle cell disease **AND** 3. If the patient has an FDA 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 **AND** 4. ONE of the following A. The patient's medication history includes hydroxyurea AND ONE of the following: 1. The patient has had an inadequate response to hydroxyurea **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over hydroxyurea **OR** B. The patient has an intolerance or hypersensitivity to hydroxyurea **OR** C. The patient has an FDA labeled contraindication to hydroxyurea **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that hydroxyurea cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 5. ONE of the following: A. The patient will NOT be using the requested agent in combination with Adakevo (crizanlizumab-tmca) OR Oxbryta (voxelotor) **OR** B. Information has been provided supporting the use of the requested agent in combination with Adakveo (crizanlizumab-tmca) or Oxbryta (voxelotor) **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 7. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **Length of Initial Approval:** 12 months

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 through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent (i.e., reduction in acute complications of sickle cell disease since initiating therapy with the requested agent) **AND** 3. ONE of the following: A. The patient will NOT be using the requested agent in combination with Adakevo (crizanlizumab-tmca) OR Oxbryta (voxelotor) **OR** B. Information has been provided supporting the use of the requested agent in combination with Adakevo (crizanlizumab-tmca) or Oxbryta (voxelotor) **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **Length of Renewal Approval:** 12 months

• Program Summary: Homozygous Familial Hypercholesterolemia Agents (HoFH)

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
3948005020	Juxtapid	lomitapide mesylate cap	10 MG; 20 MG; 30 MG; 5 MG	30	Capsules	30	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has the diagnosis of homozygous familial hypercholesterolemia (HoFH) and ALL of the following: 1. The patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) confirmed by ONE of the following: A. Genetic confirmation of two mutant alleles at the *LDLR, Apo-B, PCSK9, ARH* adaptor protein 1/*LDLRAP1* gene locus **OR** B. History of untreated LDL-C greater than 500 mg/dL (greater than 13 mmol/L) or treated LDL-C greater than or equal to 300 mg/dL (greater than or equal to 7.76 mmol/L) with ONE of the following: 1. The patient had cutaneous or tendon xanthoma before age 10 years **OR** 2. Untreated elevated cholesterol levels consistent with heterozygous FH in both parents [untreated LDL-C greater than 190 mg/dL (greater

Module	Clinical Criteria for Approval
	than 4.9 mmol/L) or untreated total cholesterol greater than 290 mg/dL (greater than 7.5 mmol/L)] **AND** 2. ONE of the following: A. The patient is currently being treated with a maximally tolerated statin containing lipid-lowering regimen (i.e., rosuvastatin in combination with ezetimibe OR atorvastatin in combination with ezetimibe) **OR** B. The patient has an intolerance, or hypersensitivity to ALL of these therapies (i.e., rosuvastatin in combination with ezetimibe AND atorvastatin in combination with ezetimibe) **OR** C. The patient has an FDA labeled contraindication to ALL of these therapies (i.e., rosuvastatin in combination with ezetimibe AND atorvastatin in combination with ezetimibe) **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 a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL therapies (i.e., rosuvastatin in combination with ezetimibe AND atorvastatin in combination with ezetimibe) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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 PCSK9 inhibitor (e.g., Repatha (evolocumab), Praluent (alirocumab)) AND ONE of the following: 1. The prescriber has determined that the patient failed to be sufficiently controlled on a PCSK9 inhibitor (e.g., Repatha, Praluent) **OR** 2. The prescriber has submitted an evidence-based and peer reviewed clinical practice guideline supporting the use of the requested agent over a PCSK9 inhibitor (e.g., Repatha, Praluent) **OR** B. The patient has an intolerance or hypersensitivity to ALL PCSK9 inhibitors **OR** C. The patient has an FDA labeled contraindication to ALL PCSK9 inhibitors **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 a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL PCSK9 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 patient is taking daily vitamin E, linoleic acid, alpha-linolenic acid (ALA), eicosapentaenoic acid (EPA), and docosahexaenoic acid (DHA) supplements **OR** B. The patient has another FDA approved indication for the requested agent and route of administration **OR**

Module	Clinical Criteria for Approval
	C. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, endocrinologist, lipid specialist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved 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 **AND** 3. If the patient's diagnosis is homozygous familial hypercholesterolemia, BOTH of the following: A. ONE of the following: 1. The patient is currently being treated with a maximally tolerated statin containing lipid-lowering regimen (i.e., rosuvastatin in combination with ezetimibe OR atorvastatin in combination with ezetimibe) **OR** 2. The patient has an intolerance or hypersensitivity to ALL of these therapies (i.e., rosuvastatin in combination with ezetimibe AND atorvastatin in combination with ezetimibe) **OR** 3. The patient has an FDA labeled contraindication to ALL of these therapies (i.e., rosuvastatin in combination with ezetimibe AND atorvastatin in combination with ezetimibe) **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 a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL therapies (i.e., rosuvastatin in combination with ezetimibe AND atorvastatin in combination with ezetimibe) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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 is taking daily vitamin E, linoleic acid, alpha-linolenic acid (ALA), eicosapentaenoic acid (EPA), and docosahexaenoic acid (DHA) supplements **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, endocrinologist, lipid specialist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **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	**Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **Length of Approval:** 12 months

• Program Summary: Interleukin (IL)-1 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
664500600021	Arcalyst	rilonacept for inj	220 MG	8	Vials	28	DAYS					
664600200020	Ilaris	canakinumab subcutaneous inj	150 MG/ML	2	Vials	28	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Arcalyst	**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 indications: A. Cryopyrin Associated Periodic Syndrome (CAPS) **OR** B. Familial Cold Auto-Inflammatory Syndrome (FCAS) **OR** C. Muckle-Wells Syndrome (MWS) **AND** 2. BOTH of the following: A. The patient has elevated pretreatment serum inflammatory markers (C-reactive protein/serum amyloid A) **AND** B. The patient has at least TWO of the following symptoms typical for CAPS: 1. Urticaria-like rash 2. Cold/stress triggered episodes 3. Sensorineural hearing loss 4. Musculoskeletal symptoms of arthralgia/arthritis/myalgia 5. Chronic aseptic meningitis 6. Skeletal abnormalities of epiphyseal overgrowth/frontal bossing **OR** B. BOTH of the following: 1. The patient has a diagnosis of deficiency of interleukin-1 receptor antagonist **AND**

Module	Clinical Criteria for Approval
	2. The requested agent is being used for maintenance of remission **OR** C. The patient has a diagnosis of recurrent pericarditis AND ONE of the following 1. BOTH of the following: A. The patient's medication history includes colchicine in combination with an NSAID AND ONE of the following: 1. The patient had an inadequate response to colchicine in combination with an NSAID **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over colchicine in combination with an NSAID **AND** B. The patient's medication history includes systemic corticosteroids AND ONE of the following: 1. The patient had an inadequate response to systemic corticosteroids **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over systemic corticosteroids **OR** 2. The patient has an intolerance or hypersensitivity to colchicine in combination with NSAIDs AND systemic corticosteroids used in the treatment of recurrent pericarditis **OR** 3. The patient's medication history includes an oral immunosuppressant (i.e., azathioprine, methotrexate, mycophenolate) AND ONE of the following: A. The patient had an inadequate response to an oral immunosuppressant (i.e., azathioprine, methotrexate, mycophenolate) **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over an oral immunosuppressant **OR** 4. The patient has an intolerance or hypersensitivity to oral immunosuppressants used in the treatment of recurrent pericarditis **OR** 5. The patient has an FDA labeled contraindication to colchicine in combination with an NSAID, systemic corticosteroids, AND oral immunosuppressants used in the treatment of recurrent pericarditis **OR** 6. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 7. The prescriber has provided documentation that colchicine in combination with NSAIDs, systemic corticosteroids, AND 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** D. The patient has another FDA approved indication for the requested agent **OR** E. The patient has another indication that is supported in compendia for the requested agent **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**

Module	Clinical Criteria for Approval
	3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, pediatrician, cardiologist) 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. **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 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 area of the patient's diagnosis (e.g., allergist, immunologist, pediatrician, cardiologist) 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 **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Ilaris	**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 indications: A. Cryopyrin Associated Periodic Syndrome (CAPS) **OR** B. Familial Cold Auto-Inflammatory Syndrome (FCAS) **OR** C. Muckle-Wells Syndrome (MWS) **AND**

Module	Clinical Criteria for Approval
	2. BOTH of the following: A. The patient has elevated pretreatment serum inflammatory markers (C-reactive protein/serum amyloid A) **AND** B. The patient has at least TWO of the following symptoms typical for CAPS: 1. Urticaria-like rash 2. Cold/stress triggered episodes 3. Sensorineural hearing loss 4. Musculoskeletal symptoms of arthralgia/arthritis/myalgia 5. Chronic aseptic meningitis 6. Skeletal abnormalities of epiphyseal overgrowth/frontal bossing **OR** B. The patient has a diagnosis of Familial Mediterranean Fever (FMF) AND ONE of the following: 1. The patient's medication history includes colchicine AND ONE of the following: A. The patient had an inadequate response to colchicine **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over colchicine **OR** 2. The patient has an intolerance or hypersensitivity to colchicine **OR** 3. The patient has an FDA labeled contraindication to colchicine **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 colchicine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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. BOTH of the following: 1. The patient has a diagnosis of Hyperimmunoglobulin D Syndrome (HIDS) or Mevalonate Kinase Deficiency (MKD) **AND** 2. The patient's diagnosis was confirmed via genetic testing for mutations in the mevalonate kinase (MVK) gene **OR** D. BOTH of the following: 1. The patient has a diagnosis of Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) **AND** 2. The patient's diagnosis was confirmed via genetic testing for mutations in the TNFR1 gene **OR** E. The patient has a diagnosis of Active systemic juvenile idiopathic arthritis (SJIA) AND BOTH of the following: 1. The patient has documented active systemic features (e.g., ongoing fever for at least 2 weeks, evanescent erythematous rash, generalized lymphadenopathy, greater than or equal to 1 joint with active arthritis, hepatomegaly, splenomegaly, serositis) **AND** 2. ONE of the following: A. The patient's medication history includes TWO of the following drug classes: DMARDS (i.e., methotrexate, leflunomide), systemic glucocorticoids (oral or IV), or NSAIDS AND ONE of the following: 1. The patient had an inadequate response to TWO of the following drug classes: DMARDS (i.e., methotrexate, leflunomide), systemic glucocorticoids (oral or IV), or NSAIDS **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent

Module	Clinical Criteria for Approval
	over DMARDS (i.e., methotrexate, leflunomide), systemic glucocorticoids (oral or IV), and NSAIDS **OR** B. The patient has an intolerance or hypersensitivity to TWO of the prerequisite drug classes **OR** C. The patient has an FDA labeled contraindication to ALL prerequisite agents **OR** D. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of SJIA **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 prerequisite agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** F. The patient has a diagnosis of Adult-onset Still's disease and BOTH of the following: 1. ONE of the following: A. The patient's medication history includes at least one corticosteroid AND ONE of the following: 1. The patient had an inadequate response to at least one corticosteroid **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over corticosteroids **OR** B. The patient has an intolerance or hypersensitivity to ONE corticosteroid **OR** C. The patient has an FDA labeled contraindication to ALL 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 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** 2. ONE of the following: A. The patient's medication history includes methotrexate AND ONE of the following: 1. The patient had an inadequate response to methotrexate **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over methotrexate **OR** B. The patient has an intolerance or hypersensitivity to methotrexate **OR**

Module	Clinical Criteria for Approval
	C. The patient has an FDA labeled contraindication to methotrexate **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 methotrexate cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** G. The patient has another FDA approved indication for the requested agent **OR** H. The patient has another indication that is supported in compendia for the requested agent **AND** 2. If the patient has an FDA approve 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, pediatrician, rheumatologist) 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. **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 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 area of the patient's diagnosis (e.g., allergist, immunologist, pediatrician, rheumatologist) 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**

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** 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 **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

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents Contraindicated as Concomitant Therapy
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)

Contraindicated as Concomitant Therapy
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: Morphine Equivalent Dose (MED) Override

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

Calculating Morphine Equivalent Dose[9-12]

The Morphine Equivalent Dose (MED) per day is used to translate the dose and route of each of the opioids the patient has received over the last 24 hours to a morphine equivalent using a standard conversion table.

For patients taking more than one opioid, the MED of the different opioids must be added together to determine the cumulative dose (see Table 1). For example, if a patient takes six hydrocodone 5mg/acetaminophen 500mg and two 20mg oxycodone extended release tablets per day, the cumulative dose may be calculated as follows:

1) Hydrocodone 5mg x 6 tablets per day = 30mg per day
2) 30mg Hydrocodone = 30mg Morphine equivalents
3) Oxycodone 20mg x 2 tablets per day = 40mg per day
4) 40mg Oxycodone = 60mg Morphine equivalents
5) Cumulative dose is 30mg + 60mg = 90mg Morphine equivalents per day

Table 1. MED Conversion Factor

Target Drug	MED conversion factor*	Number of target drug mg/day to equal 90 MED	Number of target drug mg/day to equal 120 MED
Codeine	0.15	600 mg	800 mg
Hydrocodone	1	90 mg	120 mg
Hydromorphone	5	22.5 mg	30 mg
Morphine	1	90 mg	120 mg
Oxycodone	1.5	60 mg	80 mg
Oxymorphone	3	30 mg	40 mg
Tapentadol	0.4	225 mg	300 mg
Tramadol	0.2	900 mg	1200 mg
Fentanyl immediate release (e.g., transmucosal)	100-125	900 mcg	1200 mcg

*approximate oral conversion factor
MED = morphine equivalent dose

Table 2. Transdermal Fentanyl Conversion Factor

Fentanyl transdermal (patch)	Mg/day morphine*
25 mcg/hour	60-134
50 mcg/hour	135-224
75 mcg/hour	225-314
100 mcg/hour	315 to 404

*approximate oral conversion factor

Online conversion tables
http://www.agencymeddirectors.wa.gov/Calculator/DoseCalculator

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Doses greater than 90 MED per day will be approved when ONE of the following are met:

1. ONE of the following:
   A. The patient has a diagnosis of chronic cancer pain due to an active malignancy
      OR
   B. The patient is currently enrolled in a hospice program
      OR
   C. The patient is eligible for hospice (life expectancy of six months or less) or palliative care
      OR
   D. The patient has a diagnosis of sickle cell disease

   OR
2. Patient is undergoing treatment of chronic non-cancer pain and ALL of the following are met:
   A. The prescriber has provided information that a formal, consultative evaluation which includes ALL of the following, was conducted for the primary pain state:
      i. Diagnosis
         AND
      ii. The nature of pain
         AND
      iii. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy
         AND
      iv. A patient-specific pain management plan is on file for the patient

      AND
   B. The prescriber has reviewed the patient's records in the state's prescription drug monitoring program (PDMP)
      AND

C. Patient has been assessed for opioid induced hyperalgesia and if present, provider has provided information that the patient has an active treatment plan for his/her opiate therapy, such as a plan for ongoing treatment, a plan for opioid discontinuation, or a plan for switching to another product (opiate or non-opiate)
AND
D. Patient is routinely (at least every 3 months) being assessed for function, pain status and opioid dose

OR

3. Patient qualifies for an emergency override when ALL of the following are met:
   A. Prescriber has attested that the inability for his/her patient to get requested drug will precipitate severe pain or opioid withdrawal
   AND
   B. Prescriber understands that this patient is using opioids (combined from all opioid drugs) that is at or above 90 MED
   AND
   C. Prescriber understands that opioid dose at or above 90 MED is associated with substantially higher risk of overdose
   AND
   D. Patient has not received another emergency override within the last 6 months

Length of Approval: 12 months for cancer/hospice diagnoses
6 months for all other diagnoses

Emergency Override: 1 fill up to 1 month supply

• Program Summary: Northera (droxidopa)

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
38700030000130	Northera	Droxidopa Cap 100 MG	100 MG	450	CAPS	30	DAYS					
38700030000140	Northera	Droxidopa Cap 200 MG	200 MG	180	CAPS	30	DAYS					
38700030000150	Northera	Droxidopa Cap 300 MG	300 MG	180	CAPS	30	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of neurogenic orthostatic hypotension (nOH) AND ALL of the following: 1. The prescriber has performed baseline (prior to therapy with the requested agent) blood pressure readings while the patient is sitting or supine (laying face up) AND also within 3 minutes of standing from a supine position **AND** 2. The patient has a decrease of at least 20 mmHg in systolic blood pressure or 10 mmHg diastolic blood pressure within three minutes after standing **AND** 3. The patient has persistent and consistent symptoms of neurogenic orthostatic hypotension (nOH) caused by ONE of the following:

Module	Clinical Criteria for Approval

A. Primary autonomic failure (Parkinson's disease [PD], multiple system atrophy, or pure autonomic failure) **OR**
B. Dopamine beta-hydroxylase deficiency **OR**
C. Non-diabetic autonomic neuropathy **AND**

4. The prescriber has assessed the severity of the patient's baseline (prior to therapy with the requested agent) symptoms of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out **AND**
5. The prescriber has assessed and adjusted, if applicable, any medications known to exacerbate orthostatic hypotension (e.g., diuretics, vasodilators, beta-blockers) **AND**
6. ONE of the following:
   A. The patient has tried and had an inadequate response to midodrine **OR**
   B. The patient has an intolerance or hypersensitivity to therapy with midodrine **OR**
   C. The patient has an FDA labeled contraindication to midodrine **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 midodrine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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. If the patient has an FDA approved indication, ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
   B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**
3. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following:

Brand	Generic Equivalent
Northera	droxidopa

   A. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**
   B. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR**
   C. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent **OR**
   D. BOTH of the following
      1. The prescriber has stated that the patient has tried the generic equivalent **AND**
      2. ONE of the following:
         A. The generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**
         B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the generic equivalent **OR**
   E. The patient is currently being treated with the requested agent as indicated by ALL of the following:

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 the generic equivalent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, 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:** 1 month 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 neurogenic orthostatic hypotension (nOH) **AND** BOTH of the following: 1. The patient has had improvement in severity from baseline symptoms (prior to therapy with the requested agent) of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out **AND** 2. The patient had an increase in systolic blood pressure from baseline (prior to therapy with the requested agent) of at least 10 mmHg upon standing from a supine (laying face up) position **OR** B. BOTH of the following: 1. The patient has another FDA approved indication for the requested agent **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following: **Brand** / **Generic Equivalent** Northera / droxidopa A. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR** B. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR** C. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent **OR** D. BOTH of the following 1. The prescriber has stated that the patient has tried the generic equivalent **AND** 2. ONE of the following: A. The generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**

Module	Clinical Criteria for Approval
	B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the generic equivalent **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that the generic equivalent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, 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:** 3 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 - 1 month; Renewal - 3 months

• Program Summary: Otezla (apremilast)

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
6670001500	Otezla	apremilast tab; apremilast tab starter therapy pack	10 & 20 & 30 MG; 30 MG	60	TABS	30	DAYS					
66700015000330	Otezla	Apremilast Tab 30 MG	30 MG	60	TABS	30	DAYS					
6670001500B720	Otezla	Apremilast Tab Starter Therapy Pack 10 MG & 20 MG & 30 MG	10 & 20 & 30 MG	1	KIT	180	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when the 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** B. The patient has a diagnosis of active psoriatic arthritis (PsA) 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 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 (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) 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 a

Module	Clinical Criteria for Approval
	conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA **OR** 3. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of PsA **OR** 4. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PsA **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 PsA **OR** 6. The prescriber has provided documentation that ALL conventional agents (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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 plaque psoriasis (PS) 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 use of 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 (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) 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 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 **OR** 3. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PS **OR** 4. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of PS **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 PS **OR** 6. 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) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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 Behcet's disease (BD) AND ALL of the following: 1. The patient has active oral ulcers associated with BD **AND** 2. The patient has had at least 3 occurrences of oral ulcers in the last 12-months **AND** 3. ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** B. The patient's medication history includes ONE conventional agent (i.e., topical oral corticosteroids [i.e., triamcinolone dental paste], colchicine, azathioprine) used in the treatment of BD AND ONE OF the following: 1. The patient has had an inadequate response to a conventional agent (i.e., topical oral corticosteroids [i.e., triamcinolone dental paste], colchicine, azathioprine) used in the treatment of BD **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional agent (i.e., topical oral corticosteroids [i.e., triamcinolone dental paste], colchicine, azathioprine) used in the treatment of BD **OR** C. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of BD **OR** D. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of BD **OR** E. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of BD **OR** F. The prescriber has provided documentation that ALL conventional agents (i.e., topical oral corticosteroids [i.e., triamcinolone dental paste], colchicine, azathioprine) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** E. The patient has another FDA labeled indication for the requested agent not mentioned previously **OR** F. The patient has another indication that is supported in compendia for the requested agent not mentioned previously **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. 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** 4. ONE of the following: A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR** B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following:

Module	Clinical Criteria for Approval
	1. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following: A. ONE of the following: 1. Evidence of a paid claim(s) **OR** 2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND** B. ONE of the following: 1. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR** 3. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** 4. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 5. 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, 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 **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. 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** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) 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 (e.g., clinical trials, phase III studies, guidelines required) **Length of Approval**: 12 months

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Contraindicated as Concomitant Therapy
Adbry (tralokinumab-ldrm)
Actemra (tocilizumab) Arcalyst (rilonacept) Avsola (infliximab-axxq) Benlysta (belimumab) Cibinqo (abrocitinib) Cimzia (certolizumab) Cinqair (reslizumab) Cosentyx (secukinumab) Dupixent (dupilumab) Enbrel (etanercept) Entyvio (vedolizumab) Fasenra (benralizumab) Humira (adalimumab) Ilaris (canakinumab) Ilumya (tildrakizumab-asmn)

Contraindicated as Concomitant Therapy
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: Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
3935001000	Praluent	Alirocumab Subcutaneous Soln Prefilled Syringe; alirocumab subcutaneous solution auto-injector	150 MG/ML; 75; 75 MG/ML	2	SYRNGS	28	DAYS					
3935002000E5	Repatha	evolocumab subcutaneous soln prefilled syringe	140 MG/ML	2	SYRNGS	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
3935002000E2	Repatha pushtronex system	evolocumab subcutaneous soln cartridge/infusor	420 MG/3.5ML	2	CARTS	28	DAYS					
3935002000D5	Repatha sureclick	evolocumab subcutaneous soln auto-injector	140 MG/ML	2	PENS	28	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. BOTH of the following: 1. ONE of the following: A. The patient has a diagnosis of heterozygous familial hypercholesterolemia (HeFH) AND ONE of the following: 1. Genetic confirmation of <u>one</u> mutant allele at the *LDLR, Apo-B, PCSK9*, or *1/LDLRAP1* gene **OR** 2. History of LDL-C greater than 190 mg/dL (greater than 4.9 mmol/L) (pretreatment) **OR** 3. The patient has clinical manifestations of HeFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthoma, or xanthelasma) **OR** 4. The patient has "definite" or "possible" familial hypercholesterolemia as defined by the Simon Broome criteria **OR** 5. The Patient has a Dutch Lipid Clinic Network Criteria score of greater than 5 **OR** 6. The patient has a treated low-density lipoprotein cholesterol (LDL-C) level greater than or equal to 100 mg/dL after treatment with antihyperlipidemic agents but prior to PCSK9 inhibitor therapy **OR** B. The patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) AND ONE of the following: 1. Genetic confirmation of TWO mutant alleles at the *LDLR, Apo-B, PCSK9*, or *LDLRAP1* gene **OR** 2. History of untreated LDL-C greater than 500 mg/dL (greater than 13 mmol/L) or treated LDL-C greater than or equal to 300 mg/dL (greater than or equal to 7.76 mmol/L) **OR** 3. The patient has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas, or xanthelasma) **OR** C. The patient has a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) AND has ONE of the following: 1. Acute coronary syndrome 2. History of myocardial infarction 3. Stable or unstable angina 4. Coronary or other arterial revascularization 5. History of stroke 6. History of transient ischemic attack 7. Peripheral arterial disease, including aortic aneurysm, presumed to be of atherosclerotic origin **OR**

Module	Clinical Criteria for Approval
	D. The patient has a diagnosis of primary hyperlipidemia AND ONE of the following: 1. The patient has a coronary artery calcium or calcification (CAC) score greater than or equal to 300 Agatston units **OR** 2. The patient has an LDL-C level greater than or equal to 220 mg/dL (greater than or equal to 5.7 mmol/L) while receiving maximally tolerated statin and ezetimibe therapy **OR** E. The patient has greater than or equal to 20% 10-year ASCVD risk AND ONE of the following: 1. The patient has greater than or equal to 40% 10-year ASCVD risk AND BOTH of the following: A. LDL-C greater than or equal to 70 mg/dL while on maximally tolerated statin therapy **AND** B. ONE of the following: 1. The patient has extensive or active burden of ASCVD (i.e., polyvascular ASCVD, which affects all 3 vascular beds—coronary, cerebrovascular, and peripheral arterial; clinical peripheral arterial disease in addition to coronary and/or cerebrovascular disease; a clinical ASCVD event with multivessel coronary artery disease defined as greater than or equal to 40% stenosis in greater than or equal to 2 large vessels; or recurrent myocardial infarction within 2 years of the initial event) in the presence of adverse or poorly controlled cardiometabolic risk factors **OR** 2. Extremely high-risk elevations in cardiometabolic factors with less-extensive ASCVD (i.e., diabetes, LDL-C greater than or equal to 100 mg/dL, less than high–intensity statin therapy, chronic kidney disease, poorly controlled hypertension, high-sensitivity C-reactive protein greater than 3 mg/L, or metabolic syndrome, usually occurring with other extremely high–risk or very-high-risk characteristics), usually with other adverse or poorly controlled cardiometabolic risk factors present. **OR** 3. Patients with ASCVD and LDL-C greater than or equal to 220 mg/dL with greater than or equal to 45% 10- year ASCVD risk despite statin therapy **OR** 2. The patient has 30-39% 10-year ASCVD risk AND ALL of the following: A. LDL-C greater than or equal to 100 mg/dL while on maximally tolerated statin therapy **AND** B. Less-extensive clinical ASCVD (i.e., no polyvascular ASCVD, no clinical peripheral arterial disease, a prior ASCVD event greater than or equal to 2 years prior, and no coronary artery bypass grafting) **AND** C. Adverse or poorly controlled cardiometabolic risk factor(s) including age 65 years or older, current smoking, chronic kidney disease, lipoprotein(a) greater than or equal to 37 nmol/L, high-sensitivity C-reactive protein 1–3 mg/L, metabolic syndrome with a history of myocardial infarction, ischemic stroke, or symptomatic peripheral arterial disease,

Module	Clinical Criteria for Approval
	usually in the presence of other adverse or poorly controlled cardiometabolic risk factors **OR** 3. The patient has 20-29% 10-year ASCVD risk AND BOTH of the following: A. LDL-C greater than or equal to 130 mg/dL while on maximally tolerated statins **AND** B. ONE of the following: 1. The patient has less extensive ASCVD and well-controlled cardiometabolic risk factors (i.e., no diabetes, nonsmoker, on high-intensity statin with LDL-C less than 100 mg/dL, blood pressure less than 140/90 mm Hg, and C-reactive protein less than 1 mg/dL) **OR** 2. The use is for primary prevention with LDL-C greater than or equal to 220 mg/dL AND BOTH of the following: A. No clinical ASCVD or CAC less than 100 Agatston units **AND** B. Poorly controlled cardiometabolic risk factor **AND** 2. ONE of the following: A. The patient has been adherent to high-intensity statin therapy (i.e., rosuvastatin greater than or equal to 20 mg daily, atorvastatin greater than or equal to 40 mg daily) for greater than or equal to 8 continuous weeks AND ONE of the following: 1. The patient's LDL-C level after this treatment regimen remains greater than or equal to 70 mg/dL **OR** 2. The patient has not achieved a 50% reduction in LDL-C from baseline after this treatment regimen **OR** 3. If the patient has ASCVD, the patient's non HDL-C level after this treatment regimen remains greater than or equal to 100 mg/dL **OR** B. The patient has been determined to be statin intolerant by meeting one of the following criteria: 1. The patient experienced statin-related rhabdomyolysis **OR** 2. The patient experienced skeletal-related muscle symptoms (e.g., myopathy [muscle weakness] or myalgia [muscle aches, soreness, stiffness, or tenderness]) and BOTH of the following: A. The skeletal-related muscle symptoms (e.g., myopathy or myalgia) occurred while receiving separate trials of both atorvastatin AND rosuvastatin (as single-entity or as combination products) **AND** B. When receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) the skeletal-related muscle symptoms (e.g., myopathy, myalgia) resolved upon discontinuation of each respective statin therapy (atorvastatin AND rosuvastatin) **OR** 3. The patient experienced elevations in hepatic transaminase while receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) **OR** C. The patient has a hypersensitivity to atorvastatin AND rosuvastatin **OR** D. The patient has an FDA labeled contraindication to atorvastatin AND rosuvastatin **OR**

Module	Clinical Criteria for Approval
	E. The patient's medication history includes use of high intensity atorvastatin or rosuvastatin therapy, or a drug in the same pharmacological class with the same mechanism of action, AND ONE of the following: 1. High intensity atorvastatin or rosuvastatin or a drug in the same pharmacological class with the same mechanism of action was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over high-intensity rosuvastatin or atorvastatin therapy **OR** F. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** G. The prescriber has provided documentation that atorvastatin AND rosuvastatin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 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, 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 agent was prescribed by, or in consultation with, a cardiologist, an endocrinologist, and/or a physician who focuses in the treatment of cardiovascular (CV) risk management and/or lipid disorders **AND** 4. The patient will NOT be using the requested agent in combination with another PCSK9 agent 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 request is for a preferred agent **OR** B. The patient's medication history includes a preferred agent AND ONE of the following: 1. The patient has had an inadequate response a preferred agent **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL preferred agents **OR** C. The patient has an intolerance or hypersensitivity to the preferred agent **OR** D. The patient has an FDA labeled contraindication to ALL preferred agents **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 preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse

Module	Clinical Criteria for Approval
	reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for therapy for PCSK9 inhibitors through the plan's prior authorization process **AND** 2. ONE of the following: A. The request is for a preferred agent **OR** B. The patient's medication history includes a preferred agent AND ONE of the following: 1. The patient has had an inadequate response a preferred agent **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL preferred agents **OR** C. The patient has an intolerance or hypersensitivity to the preferred agent **OR** D. The patient has an FDA labeled contraindication to ALL preferred agents **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 preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The patient has shown clinical benefit with a PCSK9 inhibitor **AND** 4. The patient is currently adherent to therapy with a PCSK9 inhibitor **AND** 5. If the patient has cardiovascular disease OR hyperlipidemia, then ONE of the following: A. The patient is currently adherent to high-intensity statin therapy (i.e., rosuvastatin greater than or equal to 20 mg daily, atorvastatin greater than or equal to 40 mg daily) **OR** B. The patient has been determined to be statin intolerant by meeting one of the following criteria: 1. The patient experienced statin-related rhabdomyolysis **OR** 2. The patient experienced skeletal-related muscle symptoms (e.g., myopathy [muscle weakness] or myalgia [muscle aches, soreness, stiffness, or tenderness]) and BOTH of the following: A. The skeletal-related muscle symptoms (e.g., myopathy or myalgia) occurred while receiving separate trials of both atorvastatin AND rosuvastatin (as single-entity or as combination products) **AND** B. When receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) the skeletal-related muscle symptoms (e.g., myopathy, myalgia) resolved upon discontinuation of each respective statin therapy (atorvastatin AND rosuvastatin) **OR**

Module	Clinical Criteria for Approval
	3. The patient experienced elevations in hepatic transaminase while receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) **OR** C. The patient has a hypersensitivity to atorvastatin AND rosuvastatin **OR** D. The patient has an FDA labeled contraindication to atorvastatin AND rosuvastatin **OR** E. The patient's medication history includes use of high-intensity rosuvastatin or atorvastatin therapy or a drug in the same pharmacological class with the same mechanism of action AND ONE of the following: 1. High-intensity rosuvastatin or atorvastatin, or a drug in the same pharmacological class with the same mechanism of action, was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over high-intensity rosuvastatin or atorvastatin therapy **OR** F. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** G. The prescriber has provided documentation that atorvastatin and rosuvastatin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 6. The agent was prescribed by, or in consultation with, a cardiologist, an endocrinologist, and/or a physician who focuses in the treatment of cardiovascular (CV) risk management and/or lipid disorders **AND** 7. The patient will NOT be using the requested agent in combination with another PCSK9 agent for the requested indication **AND** 8. 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	**Evaluation** **Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of approval:** 12 months

• Program Summary: Proton Pump Inhibitors (PPI's)

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
49270025 3065		esomeprazole strontium cap delayed release	49.3 MG	30	Capsules	30	DAYS	120 days/365 days	Hypersecretory disease (i.e., Zollinger-Ellison Syndrome) Esophageal Stricture Barrett's Esophagus H. Pylori treatment Erosive Esophagitis Peptic Ulcer Disease Active Gastrointestinal Bleed GERD associated with G-Tube Infants with esophagitis or GERD GERD associated with obesity-related gastric surgeries (e.g. sleeve gastrectomy) Eosinophilic Esophagitis **Length of Approval:** One time only for H. Pylori treatment *12 months for quantity and/or duration limit approvals for allowed exception cases/diagnoses Up to 120 days for all other quantity limit approvals			
49270060 006510		Omeprazole Cap Delayed Release 10 MG	10 MG	30	Capsules	30	DAYS	120 days/365 days	Hypersecretory disease (i.e., Zollinger-Ellison Syndrome) Esophageal Stricture Barrett's Esophagus H. Pylori treatment Erosive Esophagitis Peptic Ulcer Disease Active Gastrointestinal Bleed GERD associated with G-Tube Infants with esophagitis or GERD GERD associated with obesity-related gastric			

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
									surgeries (e.g. sleeve gastrectomy) Eosinophilic Esophagitis **Length of Approval:** One time only for H. Pylori treatment *12 months for quantity and/or duration limit approvals for allowed exception cases/diagnoses Up to 120 days for all other quantity limit approvals			
49270060006520		Omeprazole Cap Delayed Release 20 MG	20 MG	30	Capsules	30	DAYS	120 days/365 days	Hypersecretory disease (i.e., Zollinger-Ellison Syndrome) Esophageal Stricture Barrett's Esophagus H. Pylori treatment Erosive Esophagitis Peptic Ulcer Disease Active Gastrointestinal Bleed GERD associated with G-Tube Infants with esophagitis or GERD GERD associated with obesity-related gastric surgeries (e.g. sleeve gastrectomy) Eosinophilic Esophagitis **Length of Approval:** One time only for H. Pylori treatment *12 months for quantity and/or duration limit approvals for allowed exception cases/diagnoses Up to 120 days for all other quantity limit approvals			
49270060006530		Omeprazole Cap Delayed Release 40 MG	40 MG	30	Capsules	30	DAYS	120 days/365 days	Hypersecretory disease (i.e., Zollinger-Ellison Syndrome) Esophageal Stricture Barrett's Esophagus H. Pylori treatment Erosive Esophagitis			

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
									Peptic Ulcer Disease Active Gastrointestinal Bleed GERD associated with G-Tube Infants with esophagitis or GERD GERD associated with obesity-related gastric surgeries (e.g. sleeve gastrectomy) Eosinophilic Esophagitis **Length of Approval:** One time only for H. Pylori treatment *12 months for quantity and/or duration limit approvals for allowed exception cases/diagnoses Up to 120 days for all other quantity limit approvals			
49270076 1006	Aciphex	rabeprazole sodium ec tab	20 MG	30	Tablets	30	DAYS	120 days/365 days	Hypersecretory disease (i.e., Zollinger-Ellison Syndrome) Esophageal Stricture Barrett's Esophagus H. Pylori treatment Erosive Esophagitis Peptic Ulcer Disease Active Gastrointestinal Bleed GERD associated with G-Tube Infants with esophagitis or GERD GERD associated with obesity-related gastric surgeries (e.g. sleeve gastrectomy) Eosinophilic Esophagitis **Length of Approval:** One time only for H. Pylori treatment *12 months for quantity and/or duration limit approvals for allowed exception cases/diagnoses			

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
									Up to 120 days for all other quantity limit approvals			
492700761068	Aciphex sprinkle	rabeprazole sodium capsule sprinkle dr	10 MG; 5 MG	30	Capsules	30	DAYS	120 days/365 days	Hypersecretory disease (i.e., Zollinger-Ellison Syndrome) Esophageal Stricture Barrett's Esophagus H. Pylori treatment Erosive Esophagitis Peptic Ulcer Disease Active Gastrointestinal Bleed GERD associated with G-Tube Infants with esophagitis or GERD GERD associated with obesity-related gastric surgeries (e.g. sleeve gastrectomy) Eosinophilic Esophagitis **Length of Approval:** One time only for H. Pylori treatment *12 months for quantity and/or duration limit approvals for allowed exception cases/diagnoses Up to 120 days for all other quantity limit approvals			
492700251065	CVS esomeprazole magnesiu; Eq esomeprazole magnesium; GNP esomeprazole magnesiu; Goodsense esomeprazole ma; HM esomeprazole magnesium; Kls esomeprazole magnesiu; Nexium; Nexium 24hr; Nexium 24hr clear minis;	esomeprazole magnesium cap delayed release	20 MG; 40 MG	30	Capsules	30	DAYS	120 days/365 days	Hypersecretory disease (i.e., Zollinger-Ellison Syndrome) Esophageal Stricture Barrett's Esophagus H. Pylori treatment Erosive Esophagitis Peptic Ulcer Disease Active Gastrointestinal Bleed GERD associated with G-Tube Infants with esophagitis or GERD GERD associated with obesity-related gastric surgeries (e.g. sleeve gastrectomy) Eosinophilic Esophagitis			

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
	QC esomeprazole magnesium; RA esomeprazole magnesium; SM esomeprazole magnesium								**Length of Approval:** One time only for H. Pylori treatment *12 months for quantity and/or duration limit approvals for allowed exception cases/diagnoses Up to 120 days for all other quantity limit approvals			
492700400065	CVS lansoprazole; EQ lansoprazole; EQL lansoprazole; GNP lansoprazole; Goodsense lansoprazole; HM lansoprazole; Kls lansoprazole; Prevacid; Prevacid 24hr; QC lansoprazole; SM lansoprazole	lansoprazole cap delayed release	15 MG; 30 MG	30	Capsules	30	DAYS	120 days/365 days	Hypersecretory disease (i.e., Zollinger-Ellison Syndrome) Esophageal Stricture Barrett's Esophagus H. Pylori treatment Erosive Esophagitis Peptic Ulcer Disease Active Gastrointestinal Bleed GERD associated with G-Tube Infants with esophagitis or GERD GERD associated with obesity-related gastric surgeries (e.g. sleeve gastrectomy) Eosinophilic Esophagitis **Length of Approval:** One time only for H. Pylori treatment *12 months for quantity and/or duration limit approvals for allowed exception cases/diagnoses Up to 120 days for all other quantity limit approvals			
4927004000H3	CVS lansoprazole; Prevacid solutab	lansoprazole tab delayed release orally disintegrating	15 MG; 30 MG	30	Tablets	30	DAYS	120 days/365 days	Hypersecretory disease (i.e., Zollinger-Ellison Syndrome) Esophageal Stricture Barrett's Esophagus H. Pylori treatment Erosive Esophagitis Peptic Ulcer Disease Active Gastrointestinal Bleed			

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
									GERD associated with G-Tube Infants with esophagitis or GERD GERD associated with obesity-related gastric surgeries (e.g. sleeve gastrectomy) Eosinophilic Esophagitis **Length of Approval:** One time only for H. Pylori treatment *12 months for quantity and/or duration limit approvals for allowed exception cases/diagnoses Up to 120 days for all other quantity limit approvals			
49996002 6001	CVS omeprazole/sodium bic; Zegerid	omeprazole-sodium bicarbonate cap	20-1100 MG; 40-1100 MG	30	Capsules	30	DAYS	120 days/365 days	Hypersecretory disease (i.e., Zollinger-Ellison Syndrome) Esophageal Stricture Barrett's Esophagus H. Pylori treatment Erosive Esophagitis Peptic Ulcer Disease Active Gastrointestinal Bleed GERD associated with G-Tube Infants with esophagitis or GERD GERD associated with obesity-related gastric surgeries (e.g. sleeve gastrectomy) Eosinophilic Esophagitis **Length of Approval:** One time only for H. Pylori treatment *12 months for quantity and/or duration limit approvals for allowed exception cases/diagnoses Up to 120 days for all other quantity limit approvals			

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
49270020 0065	Dexilant	dexlansoprazol e cap delayed release	30 MG; 60 MG	30	Capsules	30	DAYS	120 days/365 days	Hypersecretory disease (i.e., Zollinger-Ellison Syndrome) Esophageal Stricture Barrett's Esophagus H. Pylori treatment Erosive Esophagitis Peptic Ulcer Disease Active Gastrointestinal Bleed GERD associated with G-Tube Infants with esophagitis or GERD GERD associated with obesity-related gastric surgeries (e.g. sleeve gastrectomy) Eosinophilic Esophagitis **Length of Approval:** One time only for H. Pylori treatment *12 months for quantity and/or duration limit approvals for allowed exception cases/diagnoses Up to 120 days for all other quantity limit approvals			
49996002 601920	Konvomep	omeprazole-sodium bicarbonate for oral susp	2-84 MG/ML	600	mLs	30	DAYS	120 days / 365 days	Hypersecretory disease (i.e., Zollinger-Ellison Syndrome) Esophageal Stricture Barrett's Esophagus H. Pylori treatment Erosive Esophagitis Peptic Ulcer Disease Active Gastrointestinal Bleed GERD associated with G-Tube Infants with esophagitis or GERD GERD associated with obesity-related gastric surgeries (e.g. sleeve gastrectomy) Eosinophilic Esophagitis **Length of Approval:** One time only for H. Pylori treatment			

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
									*12 months for quantity and/or duration limit approvals for allowed exception cases/diagnoses Up to 120 days for all other quantity limit approvals			
49270025 1030	Nexium	esomeprazole magnesium for delayed release susp pack; esomeprazole magnesium for delayed release susp packet	10 MG; 2.5 MG; 20 MG; 40 MG; 5 MG	30	Packets	30	DAYS	120 days/365 days	Hypersecretory disease (i.e., Zollinger-Ellison Syndrome) Esophageal Stricture Barrett's Esophagus H. Pylori treatment Erosive Esophagitis Peptic Ulcer Disease Active Gastrointestinal Bleed GERD associated with G-Tube Infants with esophagitis or GERD GERD associated with obesity-related gastric surgeries (e.g. sleeve gastrectomy) Eosinophilic Esophagitis **Length of Approval:** One time only for H. Pylori treatment *12 months for quantity and/or duration limit approvals for allowed exception cases/diagnoses Up to 120 days for all other quantity limit approvals			
49270060 103030	Prilosec	Omeprazole Magnesium For Delayed Release Susp Packet 10 MG	10 MG	30	Packets	30	DAYS	120 days/365 days	Hypersecretory disease (i.e., Zollinger-Ellison Syndrome) Esophageal Stricture Barrett's Esophagus H. Pylori treatment Erosive Esophagitis Peptic Ulcer Disease Active Gastrointestinal Bleed GERD associated with G-Tube Infants with esophagitis or GERD			

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
									GERD associated with obesity-related gastric surgeries (e.g. sleeve gastrectomy) Eosinophilic Esophagitis **Length of Approval:** One time only for H. Pylori treatment *12 months for quantity and/or duration limit approvals for allowed exception cases/diagnoses Up to 120 days for all other quantity limit approvals			
49270060103020	Prilosec	Omeprazole Magnesium For Delayed Release Susp Packet 2.5 MG	2.5 MG	60	Packets	30	DAYS	120 days/365 days	Hypersecretory disease (i.e., Zollinger-Ellison Syndrome) Esophageal Stricture Barrett's Esophagus H. Pylori treatment Erosive Esophagitis Peptic Ulcer Disease Active Gastrointestinal Bleed GERD associated with G-Tube Infants with esophagitis or GERD GERD associated with obesity-related gastric surgeries (e.g. sleeve gastrectomy) Eosinophilic Esophagitis **Length of Approval:** One time only for H. Pylori treatment *12 months for quantity and/or duration limit approvals for allowed exception cases/diagnoses Up to 120 days for all other quantity limit approvals			
49270070 1006	Protonix	pantoprazole sodium ec tab	20 MG; 40 MG	30	Tablets	30	DAYS	120 days/365 days	Hypersecretory disease (i.e., Zollinger-Ellison Syndrome) Esophageal Stricture Barrett's Esophagus			

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
									H. Pylori treatment Erosive Esophagitis Peptic Ulcer Disease Active Gastrointestinal Bleed GERD associated with G-Tube Infants with esophagitis or GERD GERD associated with obesity-related gastric surgeries (e.g. sleeve gastrectomy) Eosinophilic Esophagitis **Length of Approval:** One time only for H. Pylori treatment *12 months for quantity and/or duration limit approvals for allowed exception cases/diagnoses Up to 120 days for all other quantity limit approvals			
49270070 1030	Protonix	pantoprazole sodium for delayed release susp packet	40 MG	30	Packets	30	DAYS	120 days/365 days	Hypersecretory disease (i.e., Zollinger-Ellison Syndrome) Esophageal Stricture Barrett's Esophagus H. Pylori treatment Erosive Esophagitis Peptic Ulcer Disease Active Gastrointestinal Bleed GERD associated with G-Tube Infants with esophagitis or GERD GERD associated with obesity-related gastric surgeries (e.g. sleeve gastrectomy) Eosinophilic Esophagitis **Length of Approval:** One time only for H. Pylori treatment *12 months for quantity and/or duration limit approvals for allowed exception cases/diagnoses			

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
									Up to 120 days for all other quantity limit approvals			
499960026030	Zegerid	omeprazole-sodium bicarbonate powd pack for susp	20-1680 MG; 40-1680 MG	30	Packets	30	DAYS	120 days/365 days	Hypersecretory disease (i.e., Zollinger-Ellison Syndrome) Esophageal Stricture Barrett's Esophagus H. Pylori treatment Erosive Esophagitis Peptic Ulcer Disease Active Gastrointestinal Bleed GERD associated with G-Tube Infants with esophagitis or GERD GERD associated with obesity-related gastric surgeries (e.g. sleeve gastrectomy) Eosinophilic Esophagitis **Length of Approval:** One time only for H. Pylori treatment *12 months for quantity and/or duration limit approvals for allowed exception cases/diagnoses Up to 120 days for all other quantity limit approvals			

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Increased quantities and/or extended duration of target PPIs (formulary and non-formulary) will be approved when ONE of the following are met: 1. ONE of the following: A. The quantity (dose) requested is greater than the program daily quantity limit, then BOTH of the following: 1. The quantity (dose) requested cannot be achieved using a lesser quantity of a higher strength **AND** 2. ONE of the following: A. BOTH of the following: 1. The quantity (dose) requested is less than or equal to the maximum dose recommended in FDA approved labeling **AND** 2. The dosage increase requested is appropriate based on recommended dosage titrations in FDA labeling or compendia (i.e., dosage increase is not excessive, or patient has been on

Module	Clinical Criteria for Approval

current dose a sufficient length of time to determine efficacy/adverse effects) **OR**

B. The prescriber has submitted information that the patient has a diagnosis listed under "Allowed exception cases/diagnoses" **OR**

C. The prescriber has submitted information in support of therapy with a higher dose for an accepted diagnosis for exception **OR**

B. The duration of therapy requested exceeds the set duration limit, then ONE of the following:

1. The prescriber has submitted information in support of therapy for a longer duration for an accepted diagnosis for exception **OR**
2. The prescriber has submitted information that the patient has a diagnosis listed under "Allowed exception cases/diagnoses" **OR**

2. BOTH of the following:

A. The quantity (dose) requested is greater than the program daily quantity limit, then BOTH of the following:

1. The quantity (dose) requested cannot be achieved using a lesser quantity of a higher strength **AND**
2. ONE of the following:

A. BOTH of the following:

1. The quantity (dose) requested is less than or equal to the maximum dose recommended in FDA approved labeling **AND**
2. The dosage increase requested is appropriate based on recommended dosage titrations in FDA labeling or compendia (i.e., dosage increase is not excessive, or patient has been on current dose a sufficient length of time to determine efficacy/adverse effects) **OR**

B. The prescriber has submitted information that the patient has a diagnosis listed under "Allowed exception cases/diagnoses" **AND**

B. The duration of therapy requested exceeds the set duration limit AND the prescriber has submitted information that the patient has a diagnosis listed under "Allowed exception cases/diagnoses"

Allowed exception cases/diagnoses
Hypersecretory disease (i.e., Zollinger-Ellison Syndrome)
Esophageal Stricture
Barrett's Esophagus
H. Pylori treatment
Erosive Esophagitis
Peptic Ulcer Disease
Active Gastrointestinal Bleed
GERD associated with G-Tube
Infants with esophagitis or GERD
GERD associated with obesity-related gastric surgeries (e.g. sleeve gastrectomy)
Eosinophilic Esophagitis

Length of Approval:
One time only for H. Pylori treatment
*12 months for quantity and/or duration limit approvals for allowed exception cases/diagnoses
Up to 120 days for all other quantity limit approvals

Module	Clinical Criteria for Approval
	*When a request is for BOTH a quantity override AND a duration override, both overrides will be approved ONLY when being used to treat an allowed exception case/diagnosis.

• Program Summary: Pyrukynd (mitapivat)

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
85870050700310	Pyrukynd	Mitapivat Sulfate Tab	5 MG	56	Tablets	28	DAYS				09-01-2022	
85870050700325	Pyrukynd	Mitapivat Sulfate Tab	20 MG	56	Tablets	28	DAYS				09-01-2022	
85870050700340	Pyrukynd	Mitapivat Sulfate Tab	50 MG	56	Tablets	28	DAYS				09-01-2022	
8587005070B710	Pyrukynd taper pack	Mitapivat Sulfate Tab Therapy Pack	5 MG	7	Tablets	365	DAYS				09-01-2022	
8587005070B720	Pyrukynd taper pack	Mitapivat Sulfate Tab Therapy Pack	20 MG; 5MG	14	Tablets	365	DAYS				09-01-2022	
8587005070B735	Pyrukynd taper pack	Mitapivat Sulfate Tab Therapy Pack	50 MG; 20MG	14	Tablets	365	DAYS				09-10-2022	

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. The patient has a diagnosis of hemolytic anemia with pyruvate kinase deficiency (PKD) as confirmed by genetic testing showing a pathogenic PKLR gene mutation **AND** 2. The patient is NOT homozygous for the c.1436G > A (p.R479H) variant **AND** 3. The patient has at least 2 variant alleles in the PKLR gene, of which at least 1 is a missense variant **AND** 4. ONE of the following: A. The patient has a hemoglobin of less than or equal to 10g/dL **OR** B. The patient has had more than 4 red blood cell (RBC) transfusions in the past year **AND** 5. 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** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months

Module	Clinical Criteria for Approval
	NOTE: If Quantity Limit applies, please 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. The patient has had clinical benefit with the requested agent (e.g., hemoglobin has increased or is within normal range, decrease in red blood cell transfusion burden) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please see Quantity Limit criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Target Agent(s) will be met 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 request 6 months Renewal request 12 months

● Program Summary: Samsca (tolvaptan)

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
30454060000320	Samsca	tolvaptan tab	15 MG	30	Tablets	365	DAYS			31722086803; 31722086831; 49884076852; 49884076854; 59148002050; 60505431700; 60505470400; 60505470402; 67877063502; 67877063533		
30454060000330	Samsca	tolvaptan tab	30 MG	60	Tablets	365	DAYS			31722086903; 49884077052; 49884077054;		

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
										59148002150; 60505431800; 60505470500; 60505470501; 67877063602; 67877063633		

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The requested agent was initiated (or re-initiated) in the hospital **AND** 2. Prior to initiating the requested agent, the patient has/had a diagnosis of clinically significant hypervolemic or euvolemic hyponatremia defined by one of the following: A. serum sodium less than 125 mEq/L **OR** B. serum sodium greater than or equal to 125 mEq/L and has symptomatic hyponatremia that has resisted correction with fluid restriction **AND** 3. The patient does NOT have underlying liver disease, including cirrhosis **AND** 4. Medications known to cause hyponatremia (e.g., antidepressants [SSRIs, tricyclics, MAOIs, venlafaxine], anticonvulsants [carbamazepine, oxcarbazepine, sodium valproate, lamotrigine], antipsychotics [phenothiazines, butyrophenones], anticancer [vinca alkaloids, platinum compounds, ifosfamide, melphalan, cyclophosphamide, methotrexate, pentostatin], antidiabetic [chlorpropamide, tolbutamide], vasopressin analogues [desmopressin, oxytocin, terlipressin, vasopressin], miscellaneous [amiodarone, clofibrate, interferon, NSAIDs, levamisole, linezolid, monoclonal antibodies, nicotine, opiates, PPIs]) have been evaluated and discontinued when appropriate **AND** 5. The patient will NOT be using the requested agent in combination with another tolvaptan agent for the requested indication **AND** 6. The patient does not have any FDA labeled contraindications to the requested agent **AND** 7. The patient has not already received 30 days of therapy with the requested agent for the current hospitalization **Length of Approval:** 30 tablets/365 days of the 15 mg tablets 60 tablets/365 days of the 30 mg tablets NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Evaluation** **Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose and/or duration of therapy) does NOT exceed the program quantity limit **OR** 2. BOTH of the following: A. The requested quantity (dose and/or duration of therapy) is greater than the program quantity limit **AND**

Module	Clinical Criteria for Approval
	B. The patient has had an additional hospitalization for hyponatremia for initiation of the requested agent **Length of Approval:** 30 tablets/365 days of the 15 mg tablets 60 tablets/365 days of the 30 mg tablets

• 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	CAPS	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: 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. 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**

Module	Clinical Criteria for Approval
	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 **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: Thrombopoietin Receptor Agonists and Tavalisse

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
82405010200320	Doptelet	Avatrombopag Maleate Tab 20 MG (Base Equiv)	20 MG	60	Tablets	30	DAYS					
82405045000320	Mulpleta	Lusutrombopag Tab 3 MG	3 MG	7	Tablets	7	DAYS					
82405030103030	Promacta	Eltrombopag Olamine Powder Pack for Susp 12.5 MG (Base Eq)	12.5 MG	30	Packets	30	DAYS					
82405030103020	Promacta	Eltrombopag Olamine Powder Pack for Susp 25 MG (Base Equiv)	25 MG	30	Packets	30	DAYS					
82405030100310	Promacta	Eltrombopag Olamine Tab 12.5 MG (Base Equiv)	12.5 MG	30	Tablets	30	DAYS					
82405030100320	Promacta	Eltrombopag Olamine Tab 25 MG (Base Equiv)	25 MG	30	Tablets	30	DAYS					
82405030100330	Promacta	Eltrombopag Olamine Tab 50 MG (Base Equiv)	50 MG	60	Tablets	30	DAYS					
82405030100340	Promacta	Eltrombopag Olamine Tab 75 MG (Base Equiv)	75 MG	60	Tablets	30	DAYS					
857560401003	Tavalisse	fostamatinib disodium tab	100 MG; 150 MG	60	Tablets	30	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when the ALL of the following are met: 1. ONE of the following: A. The requested agent is Doptelet AND ONE of the following: 1. The patient has a diagnosis of chronic (defined as lasting for at least 12 months) immune (idiopathic) thrombocytopenia (ITP) AND BOTH of the following: A. ONE of the following:

Module	Clinical Criteria for Approval
	1. The patient has a platelet count less than or equal to 30 X 10^9/L **OR** 2. The patient has a platelet count greater than 30 X 10^9/L but less than 50 X 10^9/L AND has symptomatic bleeding and/or an increased risk for bleeding **AND** B. ONE of the following: 1. The patient's medication history includes ONE corticosteroid used for the treatment of ITP AND ONE of the following: A. The patient has had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over corticosteroid used for the treatment of ITP **OR** 2. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR** 3. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR** 4. The patient has tried and had an inadequate response to another thrombopoietin receptor agonist (e.g., Nplate, Promacta) or Tavalisse **OR** 5. The patient has tried and had an inadequate response to immunoglobulins (IVIg or Anti-D) **OR** 6. The patient has had an inadequate response to a splenectomy **OR** 7. The patient has tried and had an inadequate response to rituximab **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 corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 2. The patient has a diagnosis of thrombocytopenia and has chronic liver disease AND ALL of the following: A. The patient has a platelet count less than 50 X 10^9/L **AND** B. The patient is scheduled to undergo a procedure with an associated risk of bleeding (e.g., gastrointestinal endoscopy, liver biopsy, bronchoscopy, dental procedure) **AND** C. The patient would require a platelet transfusion unless platelet counts are clinically increased from baseline (prior to therapy with the requested agent) **OR** 3. The patient has another FDA approved indication for the requested agent **OR** 4. The patient has another indication supported in compendia for the requested agent **OR** B. The requested agent is Mulpleta (lusutrombopag) AND ONE of the following: 1. BOTH of the following: A. The patient has a platelet count less than 50 X 10^9/L **AND**

Module	Clinical Criteria for Approval
	B. The patient has a diagnosis of thrombocytopenia and has chronic liver disease AND BOTH of the following: 1. The patient is scheduled to undergo a procedure with an associated risk of bleeding (e.g., gastrointestinal endoscopy, liver biopsy, bronchoscopy, dental procedure) **AND** 2. The patient would require a platelet transfusion unless platelet counts are clinically increased from baseline (prior to therapy with the requested agent) **OR** 2. The patient has another FDA approved indication for the requested agent **OR** 3. The patient has another indication supported in compendia for the requested agent **OR** C. The requested agent is Nplate (romiplostim) AND ONE of the following: 1. The patient has a diagnosis of hematopoietic syndrome of acute radiation syndrome (HS-ARS) **OR** 2. The patient has a diagnosis of immune (idiopathic) thrombocytopenia (ITP) AND ALL of the following: A. ONE of the following: 1. The patient is between the ages of 1 and 17 years old AND the diagnosis has lasted for at least 6 months **OR** 2. The patient is 18 years old or over **AND** B. ONE of the following: 1. The patient has a platelet count less than or equal to 30 X 10^9/L **OR** 2. The patient has a platelet count greater than 30 X 10^9/L but less than 50 x 10^9/L AND has symptomatic bleeding and/or an increased risk for bleeding **AND** C. ONE of the following: 1. The patient's medication history includes ONE corticosteroid used for the treatment of ITP AND ONE of the following: A. The patient has had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over corticosteroid used for the treatment of ITP **OR** 2. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR** 3. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR** 4. The patient has tried and had an inadequate response to immunoglobulins (IVIg or anti-D) **OR** 5. The patient has had an inadequate response to a splenectomy **OR** 6. The patient has tried and had an inadequate response to rituximab **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**

Module	Clinical Criteria for Approval
	8. The prescriber has provided documentation that 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** 3. The patient has another FDA approved indication for the requested agent **OR** 4. The patient has another indication supported in compendia for the requested agent **OR** D. The requested agent is Promacta (eltrombopag) AND ONE of the following: 1. The patient has a diagnosis of hepatitis C associated thrombocytopenia AND ONE of the following: A. The intent of therapy with the requested agent is to increase platelet counts sufficiently to initiate pegylated interferon therapy AND the patient's platelet count is less than 75 x 10^9/L **OR** B. The patient is on concurrent therapy with a pegylated interferon and ribavirin AND is at risk for discontinuing hepatitis C therapy due to thrombocytopenia **OR** 2. The patient has a diagnosis of severe aplastic anemia AND ALL of the following: A. The patient has at least 2 of the following blood criteria: 1. Neutrophils less than 0.5 X 10^9/L 2. Platelets less than 30 X 10^9/L 3. Reticulocyte count less than 60 X 10^9/L **AND** B. The patient has 1 of the following marrow criteria: 1. Severe hypocellularity: less than 25% **OR** 2. Moderate hypocellularity, 25-50% with hematopoietic cells representing less than 30% of residual cells **AND** C. ONE of the following: 1. BOTH of the following: A. The patient will use the requested agent as first-line treatment **AND** B. The patient will use the requested agent in combination with standard immunosuppressive therapy (i.e., antithymocyte globulin [ATG] AND cyclosporine) **OR** 2. ONE of the following: A. The patient's medication history includes BOTH antithymocyte globulin (ATG) AND cyclosporine therapy AND ONE of the following: 1. The patient has had an inadequate response to BOTH antithymocyte globulin (ATG) AND cyclosporine therapy **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over BOTH antithymocyte globulin (ATG) AND cyclosporine therapy **OR** B. The patient has an intolerance or hypersensitivity to BOTH ATG AND cyclosporine **OR** C. The patient has an FDA labeled contraindication to BOTH ATG AND cyclosporine **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**

Module	Clinical Criteria for Approval
	2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that BOTH antithymocyte globulin (ATG) AND cyclosporine therapy cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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** 3. The patient has a diagnosis of persistent or chronic (defined as lasting for at least 3 months) immune (idiopathic) thrombocytopenia (ITP) AND BOTH of the following: A. ONE of the following: 1. The patient has a platelet count less than or equal to 30 x 10^9/L **OR** 2. The patient has a platelet count greater than 30 x 10^9/L but less than 50 x 10^9/L AND has symptomatic bleeding and/or an increased risk for bleeding **AND** B. ONE of the following: 1. The patient's medication history includes ONE corticosteroid used for the treatment of ITP AND ONE of the following: A. The patient has had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over corticosteroid used for the treatment of ITP **OR** 2. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR** 3. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR** 4. The patient has tried and had an inadequate response to immunoglobulins (IVIg or anti-D) **OR** 5. The patient has had an inadequate response to a splenectomy **OR** 6. The patient has tried and had an inadequate response to rituximab **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 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** 4. The patient has another FDA approved indication for the requested agent **OR** 5. The patient has another indication supported in compendia for the requested agent **OR**

Module	Clinical Criteria for Approval
	E. The requested agent is Tavalisse (fostamatinib disodium hexahydrate) AND ONE of the following: 1. The patient has a diagnosis of chronic (defined as lasting for at least 12 months) immune (idiopathic) thrombocytopenia (ITP) AND BOTH of the following: A. ONE of the following; 1. The patient has a platelet count less than or equal to 30 X 10^9/L **OR** 2. The patient has a platelet count greater than 30 X 10^9/L but less than 50 x 10^9/L AND has symptomatic bleeding and/or an increased risk for bleeding **AND** B. ONE of the following: 1. The patient's medication history includes ONE corticosteroid used for the treatment of ITP AND ONE of the following: A. The patient has had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over corticosteroid used for the treatment of ITP **OR** 2. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR** 3. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR** 4. The patient has tried and had an inadequate response to another thrombopoietin receptor agonist (e.g., Doptelet, Nplate, Promacta) **OR** 5. The patient has tried and had an inadequate response to immunoglobulins (IVIg or Anti-D) **OR** 6. The patient has had an inadequate response to a splenectomy **OR** 7. The patient has tried and had an inadequate response to rituximab **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 corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 2. The patient has another FDA approved indication for the requested agent **OR** 3. The patient has another indication 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** 3. ONE of the following: A. The patient will NOT use the requested agent in combination with another agent included in this program **OR**

Module	Clinical Criteria for Approval
	B. The patient will use the requested agent in combination with another agent included in this program AND BOTH of the following: 1. The requested agent is Nplate **AND** 2. The patient has a diagnosis of hematopoietic syndrome of acute radiation syndrome (HS-ARS) **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Initial Lengths of Approval:** **Doptelet:** **ITP:** 6 months **Thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure:** 1 month **All other indications:** 6 months **Mulpleta** **Thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure:** 1 month **All other indications:** 6 months **Nplate** **HS-ARS:** 1 time **ITP:** 4 months **All other indications:** 6 months **Promacta** **ITP:** 2 months **Thrombocytopenia in Hep C:** 3 months **First-Line therapy in severe aplastic anemia:** 6 months **All other severe aplastic anemia:** 4 months **All other indications:** 6 months **Tavalisse** **All indications:** 6 months NOTE If Quantity Limit applies, please see Quantity Limit criteira **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process. Note: Doptelet and Mulpleta for thrombocytopenia with chronic liver disease AND Nplate for hematopoietic syndrome of acute radiation syndrome (HS-ARS) should always be reviewed under initial criteria **AND** 2. ONE of the following: A. The patient has a diagnosis of immune (idiopathic) thrombocytopenia (ITP) AND ONE of the following: 1. The patient's platelet count is greater than or equal to 50 x 10^9/L **OR** 2. The patient's platelet count has increased sufficiently to avoid clinically significant bleeding **OR** B. The patient has the diagnosis of hepatitis C associated thrombocytopenia AND BOTH of the following: 1. ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient will be initiating hepatitis C therapy with pegylated interferon and ribavirin **OR** B. The patient will be maintaining hepatitis C therapy with pegylated interferon and ribavirin **AND** 2. ONE of the following: A. The patient's platelet count is greater than or equal to 90 x 10^9/L **OR** B. The patient's platelet count has increased sufficiently to initiate or maintain pegylated interferon based therapy for the treatment of hepatitis C **OR** C. The patient has another indication for the requested agent AND has shown clinical improvement (i.e., decreased symptom severity and/or frequency) **AND** 3. The patient will NOT use the requested agent in combination with another agent included in this program **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Renewal Lengths of approval:** **ITP**:12 months **Thrombocytopenia in hepatitis C:** 6 months **All other indications for the requested agent:** 12 months NOTE If Quantity Limit Applies, please see 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 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 I**nitial Lengths of Approval:** **Doptelet:** **ITP:** 6 months **Thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure:** 1 month **All other indications:** 6 months **Mulpleta:** **Thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure:** 1 month **All other indications:** 6 months

Module	Clinical Criteria for Approval
	Nplate **HS-ARS:** 1 time **ITP:** 4 months **All other indications:** 6 months **Promacta** **ITP:** 2 months **Thrombocytopenia in Hep C:** 3 months **First-Line therapy in severe aplastic anemia:** 6 months **All other severe aplastic anemia:** 4 months **All other indications:** 6 months **Tavalisse** **All indications:** 6 months **Renewal Lengths of approval:** **ITP:** 12 months **Severe aplastic anemia:** 12 months **All other indications for the requested agent:** 12 months **Thrombocytopenia in hepatitis C:** 6 months