COMMERCIAL PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: August 1, 2023 Notification Posted: June 16, 2023

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

No new policies for August 1, 2023

POLICIES REVISED

• Program Summary: Biologic Immunomodulators

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

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

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
TBD	Abrilada	adalimumab-afzb Injection										

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					
6650007000D5	Actemra actpen	tocilizumab subcutaneous soln auto-injector	162 MG/0.9ML	4	Pens	28	DAYS					
6627001510D520	Amjevita	adalimumab-atto soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS					
6627001510E510	Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.4ML	2	Syringes	28	DAYS					
6627001510E520	Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS					
525050201064	Cimzia	certolizumab pegol for inj kit	200 MG	2	Kits	28	DAYS					
5250502010F840	Cimzia	Certolizumab Pegol Prefilled Syringe Kit	200 MG/ML	2	Kits	28	DAYS					
5250502010F860	Cimzia starter kit	Certolizumab Pegol Prefilled Syringe Kit	200 MG/ML	1	Kit	180	DAYS					
9025057500E530	Cosentyx	Secukinumab Subcutaneous Pref Syr 150 MG/ML (300 MG Dose)	150 MG/ML	2	Syringes	28	DAYS					
9025057500E510	Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe	75 MG/0.5ML	1	Syringe	28	DAYS					
9025057500E520	Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe 150 MG/ML	150 MG/ML	1	Syringe	28	DAYS					
9025057500D530	Cosentyx sensoready pen	Secukinumab Subcutaneous Auto-inj 150 MG/ML (300 MG Dose)	150 MG/ML	2	Pens	28	DAYS					
9025057500D520	Cosentyx sensoready pen	Secukinumab Subcutaneous Soln Auto-injector 150 MG/ML	150 MG/ML	1	Pen	28	DAYS					

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
TBD	Cyltezo	adalimumab-adbm Injection										
662900300021	Enbrel	etanercept for subcutaneous inj	25 MG	8	Vials	28	DAYS					
66290030002015	Enbrel	Etanercept Subcutaneous Inj 25 mg/0.5ml	25 MG/0.5ML	8	Vials	28	DAYS					
6629003000E525	Enbrel	Etanercept Subcutaneous Soln Prefilled Syringe 25 MG/0.5ML	25 MG/0.5ML	4	Syringes	28	DAYS					
6629003000E530	Enbrel	Etanercept Subcutaneous Soln Prefilled Syringe 50 MG/ML	50 MG/ML	4	Syringes	28	DAYS					
6629003000E2	Enbrel mini	etanercept subcutaneous solution cartridge	50 MG/ML	4	Cartridges	28	DAYS					
6629003000D5	Enbrel sureclick	etanercept subcutaneous solution auto-injector	50 MG/ML	4	Pens	28	DAYS					
TBD	Hadlima	adalimumab-bwwd Injection										
TBD	Hulio	adalimumab-fkjp Injection										
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	80 MG/0.8ML	1	Kit	180	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		MG/0.8ML										
6627001500F880	Humira pediatric crohns d	Adalimumab Prefilled Syringe Kit 80 MG/0.8ML & 40 MG/0.4ML	80 MG/0.8ML & 40MG/0.4ML	1	Kit	180	DAYS					
6627001500F440	Humira pen	adalimumab pen-injector kit	80 MG/0.8ML	2	Pens	28	DAYS			00074012402		
6627001500F430	Humira pen	Adalimumab Pen-injector Kit 40 MG/0.4ML	40 MG/0.4ML	2	Pens	28	DAYS					
6627001500F420	Humira pen; Humira pen-cd/uc/hs start	Adalimumab Pen-injector Kit; adalimumab pen-injector kit	40 MG/0.8ML	1	Kit	180	DAYS			00074433906; 50090448700		
6627001500F420	Humira pen; Humira pen-ps/uv starter	Adalimumab Pen-injector Kit; adalimumab pen-injector kit	40 MG/0.8ML	1	Kit	180	DAYS			00074433907; 50090448700		
6627001500F440	Humira pen-cd/uc/hs 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	4	Pens	180	DAYS			00074012404		
6627001500F450	Humira pen-ps/uv starter	Adalimumab Pen-injector Kit 80 MG/0.8ML & 40 MG/0.4ML	80 MG/0.8ML & 40MG/0.4ML	1	Kit	180	DAYS					
TBD	Hyrimoz	adalimumab-adaz Injection										
TBD	Idacio	adalimumab-aacf Injection										
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					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
666030100003	Olumiant	baricitinib tab	1 MG; 2 MG; 4 MG	30	Tablets	30	DAYS					
6640001000E520	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 125 MG/ML	125 MG/ML	4	Syringes	28	DAYS					
6640001000E510	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 50 MG/0.4ML	50 MG/0.4ML	4	Syringes	28	DAYS					
6640001000E515	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 87.5 MG/0.7ML	87.5 MG/0.7ML	4	Syringes	28	DAYS					
6640001000D5	Orencia clickject	abatacept subcutaneous soln auto-injector	125 MG/ML	4	Syringes	28	DAYS					
66603072007530	Rinvoq	Upadacitinib Tab ER	30 MG	30	Tablets	30	DAYS					
66603072007540	Rinvoq	Upadacitinib Tab ER	45 MG	56	Tablets	365	DAYS					
66603072007520	Rinvoq	Upadacitinib Tab ER 24HR 15 MG	15 MG	30	Tablets	30	DAYS					
9025052000E5	Siliq	brodalumab subcutaneous soln prefilled syringe	210 MG/1.5ML	2	Syringes	28	DAYS					
6627004000D540	Simponi	Golimumab Subcutaneous Soln Auto-injector 100 MG/ML	100 MG/ML	1	Syringe	28	DAYS					
6627004000D520	Simponi	Golimumab Subcutaneous Soln Auto-injector 50 MG/0.5ML	50 MG/0.5ML	1	Syringe	28	DAYS					
6627004000E540	Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 100 MG/ML	100 MG/ML	1	Syringe	28	DAYS					
6627004000E520	Simponi	Golimumab Subcutaneous Soln Prefilled	50 MG/0.5ML	1	Syringe	28	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		Syringe 50 MG/0.5ML										
9025057070F8	Skyrizi	risankizumab-rzaa sol prefilled syringe	75 MG/0.83ML	1	Box	84	DAYS					
9025057070E5	Skyrizi	risankizumab-rzaa soln prefilled syringe	150 MG/ML	1	Injection Device	84	DAYS					
5250406070E210	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	180 MG/1.2ML	1	Cartridges	56	DAY					
5250406070E220	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	360 MG/2.4ML	1	Cartridges	56	DAYS					
9025057070D5	Skyrizi pen	risankizumab-rzaa soln auto-injector	150 MG/ML	1	Pen	84	DAYS					
90250524000320	Sotyktu	Deucravacitinib Tab	6 MG	30	Tablets	30	DAYS					
90250585002020	Stelara	Ustekinumab Inj 45 MG/0.5ML	45 MG/0.5ML	1	Vial	84	DAYS					
9025058500E520	Stelara	Ustekinumab Soln Prefilled Syringe 45 MG/0.5ML	45 MG/0.5ML	1	Syringe	84	DAYS					
9025058500E540	Stelara	Ustekinumab Soln Prefilled Syringe 90 MG/ML	90 MG/ML	1	Syringe	56	DAYS					
9025055400D5	Taltz	ixekizumab subcutaneous soln auto-injector	80 MG/ML	1	Syringe	28	DAYS					
9025055400E5	Taltz	ixekizumab subcutaneous soln prefilled syringe	80 MG/ML	1	Syringe	28	DAYS					
9025054200D2	Tremfya	guselkumab soln pen-injector	100 MG/ML	1	Pen	56	DAYS					
9025054200E5	Tremfya	guselkumab soln prefilled syringe	100 MG/ML	1	Syringe	56	DAYS					
66603065102020	Xeljanz	Tofacitinib Citrate Oral Soln	1 MG/ML	240	mLs	30	DAYS					

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
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					
TBD	Yusimry	adalimumab-agvh Injection										

PREFERRED AGENTS

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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

Disease State	Step 1		Step 2 (Directed to ONE step 1 agent)	Step 3a (Directed to TWO step 1 agents)	Step 3b (Directed to TWO agents from step 1 and/or step 2)	Step 3c*** (Directed to THREE step 1 agents)
	Step 1a***	Step 1b (Directed to ONE TNF inhibitor) NOTE: Please see Step 1a for preferred TNF inhibitors				
Rheumatoid Disorders						
Ankylosing Spondylitis (AS)	SQ: Amjevita, Cosentyx, Enbrel, Hadlima, Humira	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Simponi, Taltz	N/A	SQ: Abrilada**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
Nonradiogra	SQ: Cimzia,	Oral: Rinvoq	N/A	SQ: Taltz	N/A	N/A

Module	Clinical Criteria for Approval						
	phic Axial Spondyloarthritis (nr-axSpA)	Cosentyx					
	Polyarticular Juvenile Idiopathic Arthritis (PJIA)	SQ: Amjevita, Enbrel, Hadlima, Humira	Oral: Xeljanz	SQ: Actemra (Amjevita, Hadlima, or Humira are required Step 1 agents)	N/A	SQ: Orencia	SQ: Abrilada**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
	Psoriatic Arthritis (PsA)	SQ: Amjevita, Cosentyx, Enbrel, Hadlima, Humira, Skyrizi, Stelara, Tremfya Oral: Otezla	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Orencia, Simponi, Taltz	N/A	SQ: Abrilada**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
	Rheumatoid Arthritis	SQ: Amjevita, Enbrel, Hadlima, Humira	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Actemra (Amjevita, Hadlima, or Humira are required Step 1 agents)	Oral: Olumiant SQ: Cimzia, Kevzara, Kineret, Orencia, Simponi	N/A	SQ: Abrilada**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
	Dermatological Disorder						
	Hidradenitis Suppurativa (HS)	SQ: Amjevita, Hadlima, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
	Psoriasis (PS)	SQ: Amjevita, Cosentyx, Enbrel, Hadlima, Humira, Skyrizi, Stelara, Tremfya	N/A	N/A	SQ: Cimzia, Ilumya	N/A	SQ: Abrilada**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Siliq, Taltz, Yusimry** Oral:

Module	Clinical Criteria for Approval						
		Oral: Otezla					Sotyktu
	Inflammatory Bowel Disease						
	Crohn's Disease	SQ: Amjevita, Hadlima, Humira, Skyrizi, Stelara	N/A	N/A	SQ: Cimzia (Amjevita, Hadlima, or Humira are require d Step 1 agents)	N/A	SQ: Abrilada**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
	Ulcerative Colitis	SQ: Amjevita, Hadlima, Humira, Stelara	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (A mjevita, Hadlima, or Humira are require d Step 1 agents)	N/A	Zeposia (Amjevita, Hadlima, Humira, Rinvoq, Stelara, OR Xeljanz/Xelj anz XR are required Step agents)	SQ: Abrilada**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
	Other						
	Uveitis	SQ: Amjevita, Hadlima, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
	Indications Without Prerequisite Biologic Immunomodulators Required						
	Alopecia Areata Atopic Dermatitis Deficiency of IL-1 Receptor Antagonist (DIRA) Enthesitis Related Arthritis (ERA) Giant Cell Arteritis	N/A	N/A	N/A	N/A	N/A	N/A

Module	Clinical Criteria for Approval

(GCA) Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Systemic Juvenile Idiopathic Arthritis (SJIA) Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)						

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

**Note: Amjevita, Hadlima, and Humira are required Step 1 agents

***Listed preferred status is effective upon launch

Initial Evaluation

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

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

Agents Eligible for Continuation of Therapy
All target agents EXCEPT the following are eligible for continuation of therapy 1. Abrilada 2. Cyltezo 3. Hulio 4. Hyrimoz 5. Idacio 6. Yusimry

Module	Clinical Criteria for Approval
	1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. ALL of the following: 1. The patient has an FDA labeled indication or an indication supported in compendia for the requested agent and route of administration AND **ONE** of the following: A. The patient has a diagnosis of moderately to severely active rheumatoid arthritis (RA) AND BOTH of the following: 1. ONE of the following: A. The patient has tried and had an inadequate response to maximally tolerated methotrexate (e.g., titrated to 25 mg weekly) for at least 3-months **OR** B. The patient has tried and had an inadequate response to another conventional agent (i.e., hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA for at least 3-months **OR** C. The patient has an intolerance or hypersensitivity to ONE of the following conventional agents (i.e., maximally tolerated methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** D. The patient has an FDA labeled contraindication to ALL of the following conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** E. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of RA **OR** F. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** G. The prescriber has provided documentation that ALL 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

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

Module	Clinical Criteria for Approval
	5. The patient has concomitant severe psoriatic arthritis (PsA) (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR** 6. The patient's medication history indicates use of another biologic immunomodulator agent OR Otezla that is FDA labeled or supported in compendia for the treatment of PS **OR** 7. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 8. The prescriber has provided documentation that ALL conventional agents (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. The patient has a diagnosis of moderately to severely active Crohn's disease (CD) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD for at least 3-months **OR** 2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of CD **OR** 3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of CD **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of CD **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL conventional agents (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse

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

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

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

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

Module	Clinical Criteria for Approval
	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 therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL conventional agents (i.e., methotrexate, leflunomide) used in the treatment of PJIA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** K. The patient has a diagnosis of active systemic juvenile idiopathic arthritis (SJIA) AND ONE of the following: 1. The patient has tried and had an inadequate response to at least ONE NSAID (e.g., ibuprofen, celecoxib) used in the treatment of SJIA for at least 1-month **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 for at least 3-months **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 therapeutics 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 NSAIDs (e.g.,

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

Module	Clinical Criteria for Approval
	total trial **OR** 2. The patient has an intolerance or hypersensitivity to two different NSAIDs used in the treatment of ERA **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of ERA **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of ERA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of ERA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 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 has tried and had an inadequate response to at least a mid- potency topical steroid used in the treatment of AD for a minimum of 4 weeks **AND** a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD for a minimum of 6 weeks **OR** B. The patient has an intolerance or hypersensitivity to at least a mid- potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

Module	Clinical Criteria for Approval
	E. The prescriber has provided documentation that ALL mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. ONE of the following**:** A. The patient has tried and had an inadequate response to a systemic immunosuppressant, including a biologic, used in the treatment of AD for a minimum of 3 months **OR** B. The patient has an intolerance or hypersensitivity to therapy with systemic immunosuppressants, including a biologic, used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL systemic immunosuppressants, including biologics, used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL systemic immunosuppressants, including biologics, used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The prescriber has documented the patient's baseline pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **AND** 5. BOTH of the following: A. The patient is currently treated with topical emollients and practicing good skin care **AND** B. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent **OR** P. BOTH of the following: 1. The patient has a diagnosis of severe alopecia areata (AA) **AND** 2. The patient has at least 50% scalp hair loss that has lasted 6 months or more **OR** Q. The patient has a diagnosis of polymyalgia rheumatica (PMR) AND ONE of the following: 1. The patient has tried and had an inadequate response to systemic

Module	Clinical Criteria for Approval
	corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR for a minimum of 8 weeks **OR** 2. The patient is currently treated with systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone and cannot tolerate a corticosteroid taper **OR** 3. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 4. The prescriber has provided documentation that ALL systemic corticosteroids used in the treatment of PMR cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** R. The patient has a diagnosis not mentioned previously **AND** 2. ONE of the following (reference Step Table): A. The requested indication does NOT require any prerequisite biologic immunomodulator agents **OR** B. The requested agent is a Step 1a agent for the requested indication **OR** C. If the requested agent is a Step 1b agent for the requested indication, then ONE of the following: 1. The patient has tried and had an inadequate response to ONE Tumor Necrosis Factor (TNF) inhibitor for the requested indication for at least 3-months (See Step 1a for preferred TNF inhibitors) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to therapy with a TNF inhibitor for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL TNF inhibitors for the requested indication **OR** 4. BOTH of the following: A. The prescriber has provided information indicating why ALL TNF inhibitors are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

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

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

Module	Clinical Criteria for Approval
	1. The patient has tried and had an inadequate response to THREE of the Step 1 agents for the requested indication for at least 3-months (See Step 3c) **OR** 2. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to THREE of the Step 1 agents for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL of the Step 1 agents for the requested indication **OR** 4. BOTH of the following: A. The prescriber has provided information indicating why ALL of the Step 1 agents are not clinically appropriate for the patient **AND** B. The prescriber has provided a complete list of previously tried agents for the requested indication **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL of the Step 1 agents for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. If Cosentyx 300 mg every 4 weeks is requested as maintenance dosing, ONE of the following: A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis **OR** B. The patient has a diagnosis of 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:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **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**

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

Length of Approval: 12 months

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

NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
</td></tr>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td>Option B - Focus Rx</td><td>
Step Table
<table>
<tr><th rowspan="2">Disease State</th><th colspan="2">Step 1</th><th rowspan="2">Step 2 (Directed to ONE step 1 agent)</th><th rowspan="2">Step 3a (Directed to TWO step 1 agents)</th><th rowspan="2">Step 3b (Directed to TWO agents from step 1 and/or step</th><th rowspan="2">Step 3c*** (Directed to THREE step 1 agents)</th></tr>
<tr><th>Step 1a***</th><th>Step 1b (Directed to ONE TNF inhibitor) NOTE:</th></tr>
</table>
</td></tr>
</table>

Module	Clinical Criteria for Approval						
			Please see Step 1a for preferred TNF inhibitors			**2)**	
	Rheumatoid Disorders						
	Ankylosing Spondylitis (AS)	SQ: Amjevita, Cosentyx, Cyltezo, Enbrel, Humira	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Simponi, Taltz	N/A	SQ: Abrilada**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
	Nonradiographic Axial Spondyloarthritis (nr-axSpA)	SQ: Cimzia, Cosentyx	Oral: Rinvoq	N/A	SQ: Taltz	N/A	N/A
	Polyarticular Juvenile Idiopathic Arthritis (PJIA)	SQ: Amjevita, Cyltezo, Enbrel, Humira	Oral: Xeljanz	SQ: Actemra (Amjevita, Cyltezo, or Humira are required Step 1 agents)	N/A	SQ: Orencia	SQ: Abrilada**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
	Psoriatic Arthritis (PsA)	SQ: Amjevita, Cosentyx, Cyltezo, Enbrel, Humira, Skyrizi, Stelara, Tremfya Oral: Otezla	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Orencia, Simponi, Taltz	N/A	SQ: Abrilada**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
	Rheumatoid Arthritis	SQ: Amjevita, Enbrel, Cyltezo, Humira	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Actemra (Amjevita, Cyltezo, or Humira are required Step 1 agents)	Oral: Olumiant SQ: Cimzia, Kevzara, Kineret, Orencia, Simponi	N/A	SQ: Abrilada**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
	Dermatological Disorder						
	Hidradenitis Suppurativa (HS)	SQ: Amjevita, Cyltezo,	N/A	N/A	N/A	N/A	SQ: Abrilada**, Hadlima**,

Module	Clinical Criteria for Approval						
		Humira					Hulio**, Hyrimoz**, Idacio**, Yusimry**
	Psoriasis (PS)	SQ: Amjevita, Cosentyx, Cyltezo, Enbrel, Humira, Skyrizi, Stelara, Tremfya Oral: Otezla	N/A	N/A	SQ: Cimzia, Ilumya	N/A	SQ: Abrilada**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Siliq, Taltz, Yusimry** Oral: Sotyktu
	Inflammatory Bowel Disease						
	Crohn's Disease	SQ: Amjevita, Cyltezo, Humira, Skyrizi, Stelara	N/A	N/A	SQ: Cimzia (Amjevita, Cyltezo, or Humira are required Step 1 agents)	N/A	SQ: Abrilada**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
	Ulcerative Colitis	SQ: Amjevita, Cyltezo, Humira, Stelara	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Amjevita, Cyltezo, or Humira are required Step 1 agents)	N/A	Zeposia (Amjevita, Cyltezo, Humira, Rinvoq, Stelara, OR Xeljanz/Xeljanz XR are required Step agents)	SQ: Abrilada**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
	Other						
	Uveitis	SQ: Amjevita, Cyltezo, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Hadlima**, Hulio**, Hyrimoz**, Idacio**, Yusimry**
	Indications Without Prerequisite Biologic Immunomodulators Required						
	Alopecia Areata Atopic Dermatitis	N/A	N/A	N/A	N/A	N/A	N/A

Module	Clinical Criteria for Approval

Deficiency of IL-1 Receptor Antagonist (DIRA) Enthesitis Related Arthritis (ERA) Giant Cell Arteritis (GCA) Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Systemic Juvenile Idiopathic Arthritis (SJIA) Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)						

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

**Note: Amjevita, Cyltezo, and Humira are required Step 1 agents

***Listed preferred status is effective upon launch

Initial Evaluation

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

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

Module	Clinical Criteria for Approval

the patient's benefit **AND**

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

Agents Eligible for Continuation of Therapy
All target agents EXCEPT the following are eligible for continuation of therapy 1. Abrilada 2. Hadlima 3. Hulio 4. Hyrimoz 5. Idacio 6. Yusimry

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

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

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

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

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

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

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

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

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

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

Module	Clinical Criteria for Approval
	condition or comorbid condition that is likely to cause an 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 has tried and had an inadequate response to two different NSAIDs used in the treatment of ERA for at least a 4-week total trial **OR** 2. The patient has an intolerance or hypersensitivity to two different NSAIDs used in the treatment of ERA **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of ERA **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of ERA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutics outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL NSAIDs used in the treatment of ERA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 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 has tried and had an inadequate response to at least a mid- potency topical steroid used in the treatment of AD for a minimum of 4 weeks **AND** a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD for a minimum of 6 weeks **OR** B. The patient has an intolerance or hypersensitivity to at least a mid- potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus)

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

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

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

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

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

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

Module	Clinical Criteria for Approval
	2. The request is for use in Alopecia Areata and Alopecia Areata is NOT restricted from coverage under the patient's benefit **AND** 3. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (*please note Stelara renewal must be for the same strength as the initial approval) **AND** 4. ONE of the following: A. The patient has a diagnosis of moderate to severe atopic dermatitis AND BOTH of the following: 1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following: A. Affected body surface area **OR** B. Flares **OR** C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **AND** 2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has a diagnosis of polymyalgia rheumatica AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. If the requested agent is Kevzara, the patient does NOT have any of the following: A. Neutropenia (ANC less than 1,000 per mm^3 at the end of the dosing interval) **AND** B. Thrombocytopenia (platelet count is less than 100,000 per mm^3) **AND** C. AST or ALT elevations 3 times the upper limit of normal **OR** C. The patient has a diagnosis other than moderate to severe atopic dermatitis or polymyalgia rheumatica AND the patient has had clinical benefit with the requested agent **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, i.e., clinical trials, phase III studies, guidelines required) **AND** 7. If Cosentyx 300 mg every 4 weeks is requested as maintenance dosing, ONE of the following: A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis **OR** B. The patient has a diagnosis of 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:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months

Module	Clinical Criteria for Approval
	**NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

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

CONTRAINDICATION AGENTS

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

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

• Program Summary: Cannabidiol

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

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	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:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☐ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Module	Clinical Criteria for Approval
	PRIOR AUTHORIZATION 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 has tried and had an inadequate response to hydroxyurea **OR** B. The patient has an intolerance or hypersensitivity to hydroxyurea **OR** C. The patient has an FDA labeled contraindication to hydroxyurea **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that hydroxyurea cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 5. ONE of the following: A. The patient will NOT be using the requested agent in combination with Adakevo (crizanlizumab-tmca) OR Oxbryta (voxelotor) **OR** B. 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 Approval:** 12 months **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved through the plan's Prior Authorization process **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:

Module	Clinical Criteria for Approval
	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 Approval:** 12 months

• Program Summary: Glucagon-like Peptide-1 (GLP-1) Agonists

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
2717005600D230	Adlyxin	Lixisenatide Soln Pen-injector 20 MCG/0.2ML (100 MCG/ML)	20 MCG/0.2ML	2	Pens	28	DAYS	The patient has a diagnosis of type 2 diabetes mellitus				
2717005600F420	Adlyxin starter pack	Lixisenatide Pen-inj Starter Kit 10 MCG/0.2ML & 20 MCG/0.2ML	10 & 20 MCG/0.2ML	2	Pens	180	DAYS	The patient has a diagnosis of type 2 diabetes mellitus				
2717002000D420	Bydureon bcise	Exenatide Extended Release Susp Auto-Injector 2 MG/0.85ML	2 MG/0.85ML	4	Pens	28	DAYS	The patient has a diagnosis of type 2 diabetes mellitus				
2717002000D240	Byetta	Exenatide Soln Pen-injector 10 MCG/0.04ML	10 MCG/0.04ML	1	Pen	30	DAYS	The patient has a diagnosis of type 2 diabetes mellitus				
2717002000D220	Byetta	Exenatide Soln Pen-injector 5 MCG/0.02ML	5 MCG/0.02ML	1	Pen	30	DAYS	The patient has a diagnosis of type 2 diabetes				

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
								mellitus				
2717308000D210	Mounjaro	Tirzepatide Soln Pen-injector	2.5 MG/0.5ML	4	Pens	28	DAYS	The patient has a diagnosis of type 2 diabetes mellitus				
2717308000D215	Mounjaro	Tirzepatide Soln Pen-injector	5 MG/0.5ML	4	Pens	28	DAYS	The patient has a diagnosis of type 2 diabetes mellitus				
2717308000D220	Mounjaro	Tirzepatide Soln Pen-injector	7.5 MG/0.5ML	4	Pens	28	DAYS	The patient has a diagnosis of type 2 diabetes mellitus				
2717308000D225	Mounjaro	Tirzepatide Soln Pen-injector	10 MG/0.5ML	4	Pens	28	DAYS	The patient has a diagnosis of type 2 diabetes mellitus				
2717308000D230	Mounjaro	Tirzepatide Soln Pen-injector	12.5 MG/0.5ML	4	Pens	28	DAYS	The patient has a diagnosis of type 2 diabetes mellitus				
2717308000D235	Mounjaro	Tirzepatide Soln Pen-injector	15 MG/0.5ML	4	Pens	28	DAYS	The patient has a diagnosis of type 2 diabetes mellitus				
2717007000D221	Ozempic	Semaglutide Soln Pen-inj	2 MG/3ML	1	Pen	28	DAYS	The patient has a diagnosis of type 2 diabetes mellitus			04-01-2023	12-31-9999
2717007000D225	Ozempic	Semaglutide Soln	8 MG/3ML	1	Pen	28	DAYS	The				

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
		Pen-inj						patient has a diagnosis of type 2 diabetes mellitus				
2717007000D222	Ozempic	Semaglutide Soln Pen-inj	4 MG/3ML	1	Pen	28	DAYS	The patient has a diagnosis of type 2 diabetes mellitus				
2717007000D210	Ozempic	Semaglutide Soln Pen-inj 0.25 or 0.5 MG/DOSE (2 MG/1.5ML)	2 MG/1.5ML	1	Pen	28	DAYS	The patient has a diagnosis of type 2 diabetes mellitus				
2717007000D220	Ozempic	Semaglutide Soln Pen-inj 1 MG/DOSE (2 MG/1.5ML)	2 MG/1.5ML	2	Pens	28	DAYS	The patient has a diagnosis of type 2 diabetes mellitus				
27170070000330	Rybelsus	Semaglutide Tab 14 MG	14 MG	30	Tablets	30	DAYS	The patient has a diagnosis of type 2 diabetes mellitus				
27170070000310	Rybelsus	Semaglutide Tab 3 MG	3 MG	30	Tablets	180	DAYS	The patient has a diagnosis of type 2 diabetes mellitus				
27170070000320	Rybelsus	Semaglutide Tab 7 MG	7 MG	30	Tablets	30	DAYS	The patient has a diagnosis of type 2 diabetes mellitus				
2717001500D240	Trulicity	Dulaglutide Soln Pen-injector	3 MG/0.5ML	4	Pens	28	DAYS	The patient has a diagnosis				

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
								of type 2 diabetes mellitus				
2717001500D250	Trulicity	Dulaglutide Soln Pen-injector	4.5 MG/0.5ML	4	Pens	28	DAYS	The patient has a diagnosis of type 2 diabetes mellitus				
2717001500D220	Trulicity	Dulaglutide Soln Pen-injector 0.75 MG/0.5ML	0.75 MG/0.5ML	4	Pens	28	DAYS	The patient has a diagnosis of type 2 diabetes mellitus				
2717001500D230	Trulicity	Dulaglutide Soln Pen-injector 1.5 MG/0.5ML	1.5 MG/0.5ML	4	Pens	28	DAYS	The patient has a diagnosis of type 2 diabetes mellitus				
2717005000D220	Victoza	Liraglutide Soln Pen-injector 18 MG/3ML (6 MG/ML)	18 MG/3ML	3	Pens	30	DAYS	The patient has a diagnosis of type 2 diabetes mellitus				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	TARGET AGENT(S) **Adlyxin**® (lixisenatide) **Bydureon**® (exenatide) **Byetta**® (exenatide) **Mounjaro™** (tirzepatide) **Ozempic**® (semaglutide) **Rybelsus**® (semaglutide) **Trulicity**® (dulaglutide) **Victoza**® (liraglutide)

Preferred Agent(s)	Non-Preferred Agent(s)
Bydureon **Mounjaro** **Ozempic** **Rybelsus**	**Adlyxin** **Byetta**

Module	Clinical Criteria for Approval

Trulicity **Victoza**	

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

1. The patient has a diagnosis of type 2 diabetes **AND**
2. ONE of the following:
   - A. If the requested agent is a preferred GLP-1, then ONE of the following:

Agent(s) Eligible for Continuation of Therapy
Ozempic, Rybelsus, Trulicity, Mounjaro, Victoza, Bydureon

      1. Information has been provided that indicates the patient has been treated with a preferred agent (starting on samples is not approvable) within the past 90 days **OR**
      2. The prescriber states the patient has been treated with a preferred agent within the past 90 days (starting on samples is not approvable) AND is at risk if therapy with a preferred agent is discontinued **OR**
   - B. BOTH of the following:
      1. ONE of the following:
         - A. The patient has tried and had an inadequate response to an agent containing metformin or insulin **OR**
         - B. The patient has an intolerance or hypersensitivity to metformin or insulin **OR**
         - C. The patient has an FDA labeled contraindication to BOTH metformin AND insulin **OR**
         - D. The patient has a diagnosis of type 2 diabetes with or at high risk for atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease **OR**
         - E. The patient is currently being treated with the requested agent as indicated by ALL of the following:
            1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
            2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
            3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
         - F. The prescriber has provided documentation that metformin and insulin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
      2. ONE of the following:
         - A. The requested agent is a preferred GLP-1 or GLP-1/GIP **OR**
         - B. The agent is a non-preferred GLP-1 and ONE of the following:
            1. TWO of the following:
               - A. The patient has tried and had an inadequate response, has an intolerance, has a hypersensitivity, or has an FDA labeled contraindication to semaglutide (Ozempic OR Rybelsus) **OR**
               - B. The patient has tried and had an inadequate response, has an intolerance, has a hypersensitivity, or has an FDA labeled contraindication to dulaglutide (Trulicity) **OR**
               - C. The patient has tried and had an inadequate response , has a hypersensitivity, or has an FDA labeled contraindication to tirzepatide (Mounjaro) **OR**

Module	Clinical Criteria for Approval
	2. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 3. The prescriber has provided documentation that semaglutide (Ozempic OR Rybelsus), dulaglutide (Trulicity), AND tirzepatide (Mounjaro) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of approval:** 12 months NOTE: If Quantity Limit program also applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Homozygous Familial Hypercholesterolemia (HoFH) Agents

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	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	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 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 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.,

Module	Clinical Criteria for Approval
	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 has tried with adherence for at least 3 months and had an inadequate response to a PCSK9 inhibitor [e.g., Repatha (evolocumab), Praluent (alirocumab)] **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** 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

Module	Clinical Criteria for Approval
	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: Imcivree

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
61253860102020	Imcivree	Setmelanotide Acetate Subcutaneous Soln	10 MG/ML	10	VIALS	30	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient's benefit plan covers the requested agent **AND** 2. ONE of the following: A. ALL of the following: 1. The patient has a diagnosis of monogenic obesity due to pro-opiomelanocortin (POMC) deficiency, proprotein convertase subtilisin/kexin type 1 (PCSK1) deficiency, or leptin receptor (LEPR) deficiency **AND** 2. Genetic testing with an FDA-approved test has confirmed variants in POMC, PCSK1, or LEPR genes (medical records required) **AND** 3. The patient's genetic status is bi-allelic, homozygous, or compound heterozygous (NOT double heterozygous) **AND** 4. The patient's genetic variant is interpreted as pathogenic, likely pathogenic, OR of uncertain significance (VUS) **AND** 5. The patient's genetic variant is NOT classified as benign or likely benign **OR** B. BOTH of the following: 1. The patient has a diagnosis of syndromic obesity due to Bardet-Biedl syndrome (BBS) **AND** 2. The patient's diagnosis has been clinically confirmed by four primary features OR three primary and two secondary features (medical records required) (i.e., primary features [rod-cone dystrophy, polydactyly, obesity, genital anomalies, renal anomalies, learning difficulties]; secondary features [speech delay, developmental delay, diabetes mellitus, dental anomalies, congenital heart disease, bracydactyly/syndactyly, ataxia/poor coordination, anosmia/hyposmia]) **AND** 3. 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** 4. ONE of the following: A. For adult patients, the body mass index (BMI) is greater than or equal to 30 kg/m^2 **OR** B. For pediatric patients, weight is greater than or equal to 95th percentile (for POMC, PCSK1, or LEPR) or 97th percentile (for BBS) using growth chart assessments **AND** 5. ONE of the following: A. The patient is newly starting therapy **OR** B. ONE of the following:

Module	Clinical Criteria for Approval
	1. For patients with obesity due to POMC, PCSK1, or LEPR deficiency, ONE of the following: A. The patient is currently being treated and has received less than 16 weeks (4 months) of therapy **OR** B. The patient has received at least 16 weeks of therapy, and has achieved a weight loss of ONE of the following: 1. Weight loss of greater than or equal to 5% of baseline body weight (prior to the initiation of the requested agent) **OR** 2. For patients with continued growth potential, weight loss of greater than or equal to 5% of baseline BMI (prior to the initiation of the requested agent) **OR** 2. For patients with obesity due to BBS, ONE of the following: A. The patient is currently being treated and has received less than one year of therapy **OR** B. The patient has received at least one year of therapy, and has achieved a weight loss of ONE of the following: 1. Weight loss of greater than or equal to 5% of baseline body weight (prior to the initiation of the requested agent) **OR** 2. For patients aged less than 18 years, weight loss of greater than or equal to 5% of baseline BMI (prior to the initiation of the requested agent) **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist, metabolic disorders) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 4 months for POMC, PCSK1, or LEPR deficiency; 12 months for BBS NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient's benefit plan covers the requested agent **AND** 3. ONE of the following: A. For adult patients, the patient has achieved and maintained weight loss of greater than or equal to 5% of baseline body weight (prior to the initiation of the requested agent) **OR** B. ONE of the following: 1. For patients with POMC, PCSK1, or LEPR deficiency AND continued growth potential, the patient has achieved and maintained weight loss of greater than or equal to 5% of baseline BMI (prior to the initiation of the requested agent) **OR** 2. For patients with BBS AND are aged less than 18 years, the patient has achieved and maintained weight loss of greater than or equal to 5% of baseline BMI (prior to the initiation of the requested agent) **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist, metabolic disorders) 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

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

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of Approval:** Initial - 4 months for POMC, PCSK1, or LEPR deficiency; 12 months for BBS Renewal - 12 months

• Program Summary: Interleukin (IL-1) Inhibitors

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	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 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-

Module	Clinical Criteria for Approval
	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** 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 has tried and had an inadequate response to at least a 6-month trial of colchicine in combination with an NSAID used in the treatment of recurrent pericarditis **AND** B. The patient has tried and had an inadequate response to systemic corticosteroids used in the treatment of recurrent pericarditis **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 has tried and had an inadequate response to an oral immunosuppressant (i.e., azathioprine, methotrexate, mycophenolate) used in the treatment of recurrent pericarditis **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** 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**

Module	Clinical Criteria for Approval
	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:** AHFS or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through 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** 2. BOTH of the following:

Module	Clinical Criteria for Approval
	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 has tried and had an inadequate response to colchicine for at least 6 months **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 has tried and had an inadequate response to TWO of the following drug classes: 1. DMARDs (i.e., methotrexate, leflunomide) for at least a 3-month trial **OR** 2. systemic glucocorticoids (oral or IV) for at least a 3-month trial **OR** 3. NSAIDs for at least a 1-month trial **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**

Module	Clinical Criteria for Approval
	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 has tried and had an inadequate response to at least ONE corticosteroid **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 has tried and had an inadequate response to methotrexate **OR** B. The patient has an intolerance or hypersensitivity to methotrexate **OR** 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**

Module	Clinical Criteria for Approval
	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:** AHFS or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through 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** 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 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)

Contraindicated as Concomitant Therapy
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: Iron Chelation

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
93100025007320	Exjade	Deferasirox Tab For Oral Susp 125 MG	125 MG	30	Tablets	30	DAYS					
93100025007330	Exjade	Deferasirox Tab For Oral Susp 250 MG	250 MG	30	Tablets	30	DAYS					
93100025007340	Exjade	Deferasirox Tab For Oral Susp 500 MG	500 MG	90	Tablets	30	DAYS					
93100028002020	Ferriprox	Deferiprone Oral Soln 100 MG/ML	100 MG/ML	2700	mLs	30	DAYS					
93100028000340	Ferriprox	Deferiprone Tab 1000 MG	1000 MG	270	Tablets	30	DAYS					
93100028000320	Ferriprox	Deferiprone Tab 500 MG	500 MG	540	Tablets	30	DAYS					
93100028000345	Ferriprox twice-a-day	Deferiprone (Twice Daily) Tab 1000 MG	1000 MG	270	Tablets	30	DAYS					
93100025000330	Jadenu	Deferasirox Tab 180 MG	180 MG	30	Tablets	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
93100025000340	Jadenu	Deferasirox Tab 360 MG	360 MG	180	Tablets	30	DAYS					
93100025000320	Jadenu	Deferasirox Tab 90 MG	90 MG	30	Tablets	30	DAYS					
93100025003030	Jadenu sprinkle	Deferasirox Granules Packet 180 MG	180 MG	30	Packets	30	DAYS					
93100025003040	Jadenu sprinkle	Deferasirox Granules Packet 360 MG	360 MG	180	Packets	30	DAYS					
93100025003020	Jadenu sprinkle	Deferasirox Granules Packet 90 MG	90 MG	30	Packets	30	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Exjade, Jadenu	**PRIOR AUTHORIZATION CRITERIA FOR APPROVAL** **Initial Evaluation** **Exjade (deferasirox) or Jadenu (deferasirox)** will be approved when ALL of the following are met: 1. The patient has an FDA labeled indication or compendia supported indication for the requested agent and route of administration AND ONE the following: A. The patient has a diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis) AND BOTH of the following: 1. The patient's baseline (pretreatment) serum ferritin is greater than 1,000 mcg/L **AND** 2. If the patient has been treated with a deferasirox agent within the past 90 days, the patient's current (within the last 30 days) serum ferritin is greater than 500 mcg/L **OR** B. The patient has a diagnosis of chronic iron overload due to a non-transfusion dependent thalassemia syndrome AND BOTH of the following: 1. ONE of the following: A. The patient's baseline (pretreatment) liver iron (FE) concentration (LIC) is at least 5 mg FE/g of dry weight **OR** B. The patient's serum ferritin is greater than 300 mcg/L **OR** C. MRI confirmation of iron deposition **AND** 2. If the patient has been treated with a deferasirox agent within the past 90 days, the LIC is greater than 3 mg FE/g of dry weight **OR** C. The patient has a diagnosis other than chronic iron overload **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: 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

Module	Clinical Criteria for Approval

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

C. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**

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

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

Brand	Generic Equivalent
Exjade (deferasirox) Jadenu (deferasirox)	Generic deferasirox

4. The patient does NOT have severe hepatic impairment (Child-Pugh-Turcotte C) **AND**
5. 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**
6. The patient will NOT be using the requested agent in combination with another iron chelating agent targeted in this program **AND**
7. 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 see Quantity Limit Criteria

Renewal Evaluation

Exjade (deferasirox) or Jadenu (deferasirox) 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 an FDA labeled indication or compendia supported indication for the requested agent and route of administration AND ONE of the following:
   A. The patient has a diagnosis of chronic iron overload due to blood transfusions, AND BOTH of the following:
      1. The patient has had a decrease in serum ferritin from baseline (pretreatment) **AND**
      2. The patient's current serum ferritin is greater than 500 mcg/L **OR**
   B. The patient has a diagnosis of non-transfusional chronic iron overload due to thalassemia syndromes AND the patient's current serum ferritin is greater than 300 mcg/L **OR**
   C. The patient has a diagnosis other than chronic iron overload and has had clinical benefit with

Module	Clinical Criteria for Approval
	the requested agent **AND** 3. The patient does NOT have severe hepatic impairment (Child-Pugh-Turcotte C) **AND** 4. 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** 5. The patient will NOT be using the requested agent in combination with another iron chelating agent targeted in this program **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please see Quantity Limit Criteria
Ferriprox	**Iron Chelation PAQL** **Initial Evaluation** **Ferriprox** (deferiprone) will be approved when ALL of the following are met: 1. The patient has an FDA labeled indication or compendia supported indication for the requested agent and route of administration AND ONE of the following: A. The patient has a diagnosis of transfusional iron overload with thalassemia syndromes **OR** B. The patient has a diagnosis of transfusional iron overload with sickle cell disease or other anemias AND BOTH of the following: 1. The patient does NOT have myelodysplastic syndrome **AND** 2. The patient does NOT have Diamond Blackfan anemia **OR** C. The patient has a diagnosis other than transfusional iron overload **AND** 2. The patient has an absolute neutrophil count (ANC) greater than or equal to 1.5 X 10^9/L **AND** 3. If the patient has an FDA approved indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 4. If the request is for a brand agent, then ONE of the following: A. The patient has tried and had an inadequate response to a generic deferiprone **OR** B. The patient has an intolerance or hypersensitivity to a generic deferiprone that is not expected to occur with the brand agent **OR** C. The patient has an FDA labeled contraindication to a generic deferiprone that is not expected to occur with the brand agent **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that generic deferiprone cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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 prescriber has provided information to support the use of the requested brand agent over

Module	Clinical Criteria for Approval
	a generic deferiprone (NOTE: patient compliance will only be accepted after a trial of a generic) **AND** 5. ONE of the following: A. The patient has tried and had an inadequate response to Exjade (deferasirox) or Jadenu (deferasirox) **OR** B. The patient has an intolerance or hypersensitivity to Exjade (deferasirox) or Jadenu (deferasirox) **OR** C. The patient has an FDA labeled contraindication to BOTH Exjade (deferasirox) AND Jadenu (deferasirox) **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 BOTH Exjade (deferasirox) AND Jadenu (deferasirox) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 7. The patient will NOT be using the requested agent in combination with another iron chelating agent targeted in this program **AND** 8. 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 see Quantity Limit Criteria **Renewal Evaluation** **Ferriprox** (deferiprone) 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 has an absolute neutrophil count (ANC) greater than or equal to 1.5 X 10^9/L **AND** 4. 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** 5. The patient will NOT be using the requested agent in combination with another iron chelating agent targeted in this program **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please see 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 are met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication Length of approval: 12 months

• Program Summary: Lupus

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
9942201500D5	Benlysta	belimumab subcutaneous solution auto-injector	200 MG/ML	4	SYRNGS	28	DAYS					
9942201500E5	Benlysta	belimumab subcutaneous solution prefilled syringe	200 MG/ML	4	SYRNGS	28	DAYS					
994020800001	Lupkynis	voclosporin cap	7.9 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 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**

Module	Clinical Criteria for Approval
	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 systemic lupus erythematosus (SLE) disease WITHOUT active Lupus Nephritis AND BOTH of the following: 1. The requested agent is FDA approved for SLE **AND** 2. BOTH of the following: A. ONE of the following: 1. The patient has tried and had an inadequate response to hydroxychloroquine **OR** 2. The patient has an intolerance or hypersensitivity to hydroxychloroquine **OR** 3. The patient has an FDA labeled contraindication to hydroxychloroquine **OR** 4. The patient is currently being treated with the reqeusted 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 hydroxychloroquine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. ONE of the following: 1. The patient has tried and had an inadequate response to corticosteroids OR immunosuppressives (i.e., azathioprine, methotrexate, oral cyclophosphamide, mycophenolate) **OR** 2. The patient has an intolerance or hypersensitivity to therapy with corticosteroids OR immunosuppressives (i.e., azathioprine, methotrexate, oral cyclophosphamide, mycophenolate) **OR** 3. The patient has an FDA labeled contraindication to ALL corticosteroids AND immunosuppressives (i.e., azathioprine, methotrexate, oral cyclophosphamide, mycophenolate) **OR** 4. The patient is currently being treated with the reqeusted 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 corticosteroids AND immunosuppressives (i.e., azathioprine, methotrexate, oral cyclophosphamide, mycophenolate) cannot be used due to a documented medical condition or comorbid condition that is likely

Module	Clinical Criteria for Approval
	to cause an 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 active lupus nephritis (LN) AND BOTH of the following: 1. The requested agent is FDA approved for lupus nephritis **AND** 2. The patient has Class III, IV, or V lupus nephritis confirmed via kidney biopsy **OR** D. The patient has another FDA approved indication for the requested agent **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent and route of administration **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication and route of administration **AND** 3. ONE of the following: A. The patient has a diagnosis of active systemic lupus erythematosus (SLE) disease WITHOUT active Lupus Nephritis AND BOTH of the following: 1. The patient is currently treated with standard SLE therapy (i.e., corticosteroids, hydroxychloroquine, azathioprine, methotrexate, oral cyclophosphamide, mycophenolate) **AND** 2. The patient will continue standard SLE therapy (i.e., corticosteroids, hydroxychloroquine, azathioprine, methotrexate, oral cyclophosphamide, mycophenolate) in combination with the requested agent **OR** B. The patient has a diagnosis of active lupus nephritis AND BOTH of the following: 1. The patient is currently treated with standard lupus nephritis therapy (i.e., azathioprine, mycophenolate, IV cyclophosphamide may also be accepted for Benlysta) **AND** 2. The patient will continue standard lupus nephritis therapy (i.e., azathioprine, mycophenolate, IV cyclophosphamide may also be accepted for Benlysta) in combination with the requested agent **OR** C. The patient has another FDA approved indication for the requested agent **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist, nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have severe active central nervous system lupus **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 agents **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 7. If the requested agent is Lupkynis, the patient will NOT be using the requested agent in combination with cyclophosphamide **AND** 8. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months ***NOTE:** Approve Benlysta subcutaneous loading dose for 1 month, then maintenance dose can be approved for the remainder of 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

Module	Clinical Criteria for Approval
	Renewal Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. ONE of the following: A. The patient has a diagnosis of active systemic lupus erythematosus (SLE) disease WITHOUT active Lupus Nephritis AND ALL of the following: 1. The requested agent is FDA approved for SLE **AND** 2. The patient will continue standard SLE therapy (i.e., corticosteroids, hydroxychloroquine, azathioprine, methotrexate, oral cyclophosphamide, mycophenolate) **AND** 3. The patient has had clinical benefit with the requested agent **OR** B. The patient has a diagnosis of active lupus nephritis (LN) AND ALL of the following: 1. The requested agent is FDA approved for lupus nephritis **AND** 2. The patient will continue standard lupus nephritis therapy (i.e., azathioprine, mycophenolate) **AND** 3. The patient has had clinical benefit with the requested agent **OR** C. The patient has another FDA approved indication for the requested agent AND has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist, nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have severe active central nervous system lupus **AND** 5. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agents **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 6. If the requested agent is Lupkynis, the patient will NOT be using the requested agent in combination with cyclophosphamide **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	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

Module	Clinical Criteria for Approval
	strength that does not exceed the program quantity limit **Length of Approval**: 12 months

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents not allowed 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) 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)

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

• Program Summary: Northera (droxidopa)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	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: 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**

Module	Clinical Criteria for Approval
	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's medication history includes the required generic equivalent as indicated by: 1. Evidence of a paid claim(s) **OR** 2. The prescriber has stated that the patient has tried the generic equivalent AND the generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR** B. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR** C. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR** D. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that the generic equivalent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 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

Module	Clinical Criteria for Approval

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's medication history includes the required generic equivalent as indicated by:
     1. Evidence of a paid claim(s) **OR**
     2. The prescriber has stated that the patient has tried the generic equivalent AND the generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**
   - B. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**
   - C. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR**
   - D. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent **OR**
   - E. The patient is currently being treated with the requested agent as indicated by ALL of the following:
     1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
     2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
     3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
   - F. The prescriber has provided documentation that the generic equivalent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
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**

Module	Clinical Criteria for Approval
	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: Opioids Immediate Release (IR) New to Therapy (NTT) with Daily Quantity Limit

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

OBJECTIVE

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

TARGET AGENT(S) FOR NEW TO THERAPY[b]

SINGLE INGREDIENT AGENT(S)				
Brand (generic)	**GPI**	**Daily Quantity Limit**	**Quantity Equaling <50 MME/day**	**Age Limit**
butorphanol[a]				
10 mg/mL nasal spray	65200020102050	0.25 mL	See note*	NA
Codeine				
15 mg tablet	65100020200305	6 tablets	22 tablets	≥18 years
30 mg tablet[a]	65100020200310	6 tablets	11 tablets	≥18 years
60 mg tablet	65100020200315	6 tablets	5 tablets	≥18 years
Dilaudid (hydromorphone)[a]				

2 mg tablet	65100035100310	6 tablets	5 tablets	NA
4 mg tablet	65100035100320	6 tablets	3 tablets	NA
8 mg tablet	65100035100330	6 tablets	1 tablet	NA
1 mg/mL liquid	65100035100920	48 mL	10 mL	NA
Levorphanol[a]				
2 mg tablet	65100040100305	4 tablets	2 tablets	NA
3 mg tablet	65100040100310	4 tablets	1 tablet	NA
Meperidine				
50 mg tablet	65100045100305	12 tablets	10 tablets	NA
50 mg/5 mL solution	65100045102060	60 mL	50 mL	NA
Dolophine (methadone)[a]				
5 mg tablet	65100050100305	3 tablets	3 tablets	NA
10 mg tablet	65100050100310	3 tablets	1 tablet	NA
Methadose, Methadone[a]				
40 mg soluble tablet	65100050107320	3 tablets	see note*	NA
5 mg/5 mL solution	65100050102010	30 mL	11 mL	NA
10 mg/5 mL solution	65100050102015	15 mL	6 mL	NA
10 mg/mL concentrate	65100050101310	3 mL	1 mL	NA
Morphine sulfate[a]				
15 mg tablet	65100055100310	12 tablets	3 tablets	NA
30 mg tablet	65100055100315	6 tablets	1 tablet	NA
10 mg/5 mL solution	65100055102065	90 mL	25 mL	NA
20 mg/5 mL solution	65100055102070	45 mL	12 mL	NA
20 mg/mL concentrate	65100055102090	9 mL	2 mL	NA
Oxaydo, Roxybond, Roxicodone (oxycodone)				
5 mg capsule[a]	65100075100110	12 capsules	6 capsules	NA
5 mg tablet[a]	65100075100310	12 tablets	6 tablets	NA
5 mg tablet	6510007510A530	12 tablets	6 tablets	NA
7.5 mg tablet	65100075100315	6 tablets	4 tablets	NA
10 mg tablet[a]	65100075100320	6 tablets	3 tablets	NA
15 mg tablet[a]	65100075100325	6 tablets	2 tablets	NA
15 mg tablet	6510007510A540	6 tablets	2 tablets	NA
20 mg tablet[a]	65100075100330	6 tablets	1 tablet	NA
30 mg tablet[a]	65100075100340	6 tablets	1 tablet	NA
30 mg tablet	6510007510A560	6 tablets	1 tablet	NA
5 mg/5 mL solution[a]	65100075102005	180 mL	33 mL	NA
20 mg/mL concentrate[a]	65100075101320	9 mL	1 mL	NA
Opana (oxymorphone)[a]				
5 mg tablet	65100080100305	6 tablets	3 tablets	NA
10 mg tablet	65100080100310	6 tablets	1 tablet	NA
Nucynta (tapentadol)				
50 mg tablet	65100091100320	6 tablets	2 tablets	NA
75 mg tablet	65100091100330	6 tablets	1 tablet	NA
100 mg tablet	65100091100340	6 tablets	1 tablet	NA
Qdolo, Ultram, Tramadol				
50 mg tablet[a]	65100095100320	8 tablets	5 tablets	≥18 years
100 mg tablet	65100095100340	4 tablets	3 tablets	≥18 years
5 mg/mL solution	65100095102005	80 mL	50 mL	≥18 years
COMBINATION INGREDIENT AGENT(S)				
Apadaz, Benzhydrocodone/acetaminophen				
4.08/325 mg tablet	65990002020310	12 tablets	11 tablets[‡]	NA

6.12/325 mg tablet	65990002020320	12 tablets	7 tablets‡	NA
8.16/325 mg tablet	65990002020330	12 tablets	6 tablets‡	NA
Tylenol w/Codeine (acetaminophen/codeine)[a]				
120 mg/12 mg/5 mL solution	65991002052020	90 mL	138 mL‡	≥18 years
300 mg/15 mg tablet	65991002050310	12 tablets	22 tablets‡	≥18 years
300 mg/30 mg tablet	65991002050315	12 tablets	11 tablets‡	≥18 years
300 mg/60 mg tablet	65991002050320	6 tablets	5 tablets‡	≥18 years
Fioricet w/Codeine (butalbital/acetaminophen/caffeine/codeine)[a]				
50 mg/300 mg/40 mg/30 mg capsule	65991004100113	6 capsules	11 capsules‡	≥18 years
50 mg/325 mg/40 mg/30 mg capsule	65991004100115	6 capsules	11 capsules‡	≥18 years
Fiorinal w/Codeine (butalbital/aspirin/caffeine/codeine)[a]				
50 mg/325 mg/40 mg/30 mg capsule	65991004300115	6 capsules	11 capsules‡	≥18 years
Trezix, Acetaminophen/caffeine/dihydrocodeine				
320.5 mg/30 mg/16 mg capsule	65991303050115	10 capsules	12 capsules‡	≥18 years
325 mg/30 mg/16 mg tablet	65991303050320	10 tablets	12 tablets‡	≥18 years
Lortab, Norco, Hydrocodone/acetaminophen				
5 mg/300 mg tablet[a]	65991702100309	8 tablets	10 tablets‡	NA
5 mg/325 mg tablet[a]	65991702100356	8 tablets	10 tablets‡	NA
7.5 mg/300 mg tablet[a]	65991702100322	6 tablets	6 tablets‡	NA
7.5 mg/325 mg tablet[a]	65991702100358	6 tablets	6 tablets‡	NA
10 mg/300 mg tablet[a]	65991702100375	6 tablets	5 tablets‡	NA
10 mg/325 mg tablet[a]	65991702100305	6 tablets	5 tablets‡	NA
7.5 mg/325 mg/15 mL solution[a]	65991702102015	90 mL	100 mL‡	NA
10 mg/300 mg/15 mL solution	65991702102024	67.5 mL	74 mL‡	NA
10 mg/325 mg/15 mL solution	65991702102025	90 mL	74 mL‡	NA
Hydrocodone/Ibuprofen				
5 mg/200 mg tablet	65991702500315	5 tablets	10 tablets‡	NA
7.5 mg/200 mg tablet[a]	65991702500320	5 tablets	6 tablets‡	NA
10 mg/200 mg tablet[a]	65991702500330	5 tablets	5 tablets‡	NA
Percocet, Prolate, Oxycodone/acetaminophen, Nalocet, Primlev				
2.5 mg/300 mg tablet	65990002200303	12 tablets	13 tablets‡	NA
2.5 mg/325 mg tablet[a]	65990002200305	12 tablets	13 tablets‡	NA
5 mg/300 mg tablet	65990002200308	12 tablets	6 tablets‡	NA
5 mg/325 mg tablet[a]	65990002200310	12 tablets	6 tablets‡	NA
7.5 mg/300 mg tablet	65990002200325	8 tablets	4 tablets‡	NA
7.5 mg/325 mg tablet[a]	65990002200327	8 tablets	4 tablets‡	NA
10 mg/300 mg tablet	65990002200333	6 tablets	3 tablets‡	NA
10 mg/325 mg tablet[a]	65990002200335	6 tablets	3 tablets‡	NA
10 mg/300 mg/5 mL solution	65990002202020	30 mL	15 mL‡	NA
5 mg/325 mg/5 mL solution	65990002202005	60 mL	30 mL‡	NA
Oxycodone/Aspirin				

4.8355 mg/325 mg tablet	65990002220340	12 tablets	6 tablets‡	NA
Oxycodone/Ibuprofen				
5 mg/400 mg tablet	65990002260320	4 tablets	6 tablets‡	NA
pentazocine/naloxone[a]				
50 mg/0.5 mg tablet	65200040300310	12 tablets	2 tablets‡	NA
Seglentis (celecoxib/tramadol)				
56 mg/44 mg tablet	65995002100320	4 tablets	13 tablets‡	≥18 years
Ultracet (tramadol/acetaminophen)[a]				
37.5 mg/325 mg tablet	65995002200320	8 tablets	7 tablets	≥18 years

a - generic available

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

* - product minimum dosage strength surpasses 50 MME

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

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

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

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

duration (>7 days) and/or greater than a 50 morphine milligram equivalents (MME) per day

AND

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

a. Diagnosis

AND

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

AND

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

AND

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

AND

2. ONE of the following:

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

OR

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

OR

ii. The requested quantity (dose) is greater than the program daily quantity limit AND ALL of the following:

a. ONE of the following:

1. There is information that the patient is NOT new to opioid therapy in the past 120 days

OR

2. The prescriber states the patient is NOT new to opioid therapy AND is at risk if therapy is changed

OR

3. The patient has a claim for an oncology agent in the past 120 days

OR

4. The prescriber has provided information in support of use of immediate-release single or combination opioids for an extended duration (>7 days) and/or greater than a 50 morphine milligram equivalents (MME) per day

AND

b. ONE of the following:

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

OR

2. The patient is eligible for hospice OR palliative care

OR

3. The patient has a diagnosis of sickle cell disease

OR

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

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

i. Diagnosis

AND

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

AND

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

AND

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

AND

c. ONE of the following:

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

OR

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

AND

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

AND

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

OR

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

A. ONE of the following:

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

OR

ii. The patient is eligible for hospice OR palliative care

OR

iii. The patient has a diagnosis of sickle cell disease

OR

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

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

1. Diagnosis

AND

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

AND

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

AND

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

AND

B. ONE of the following:

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

OR

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

AND

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

AND

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

AND

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

OR

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

Length of Approval: 6 months

• Program Summary: Otezla (apremilast)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	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 has tried and had an inadequate response to ONE conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA for at least 3-months **OR** 2. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of PsA **OR** 3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PsA **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of PsA **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 (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 has tried and had an inadequate response to ONE conventional agent (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS for at least 3-months **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PS **OR** 3. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of PS **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of PS **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

Module	Clinical Criteria for Approval
	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 (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: A. The patient has tried and had an inadequate response to ONE conventional agent (i.e., topical oral corticosteroids [i.e., triamcinolone dental paste], colchicine, azathioprine) used in the treatment of BD **OR** B. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of BD **OR** C. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of BD **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 BD **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., 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

Module	Clinical Criteria for Approval
	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. 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 **Compendia Allowed:** AHFS or DrugDex 1 or 2a level of evidence **Length of approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **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: 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:

Module	Clinical Criteria for Approval
	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
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)
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)

Contraindicated as Concomitant Therapy
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:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	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					
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**

Module	Clinical Criteria for Approval
	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** 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

Module	Clinical Criteria for Approval
	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, 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**

Module	Clinical Criteria for Approval
	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** E. The patient's medication history includes use of high intensity atorvastatin or rosuvastatin therapy in the past 999 days **OR** F. BOTH of the following: 1. The prescriber has stated that the patient has tried high intensity atorvastatin or rosuvastatin therapy **AND** 2. High intensity atorvastatin or rosuvastatin was discontinued due to lack of effectiveness or an adverse event **OR** G. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** H. 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**

Module	Clinical Criteria for Approval
	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 has tried and had an inadequate response to the preferred agent **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 the preferred agent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse 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:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for 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 has tried and had an inadequate response to the preferred agent **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

Module	Clinical Criteria for Approval
	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** 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 atorvastatin or rosuvastatin **OR** F. BOTH of the following: 1. The prescriber has stated that the patient has tried high intensity atorvastatin or rosuvastatin **AND** 2. High intensity atorvastatin or rosuvastatin was discontinued due to lack of effectiveness or an adverse event **OR** G. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** H. 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

Module	Clinical Criteria for Approval
	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: Pyrukynd (mitapivat)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	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				10-01-2022	
85870050700325	Pyrukynd	Mitapivat Sulfate Tab	20 MG	56	Tablets	28	DAYS				10-01-2022	
85870050700340	Pyrukynd	Mitapivat Sulfate Tab	50 MG	56	Tablets	28	DAYS				10-01-2022	
8587005070B710	Pyrukynd taper pack	Mitapivat Sulfate Tab Therapy Pack	5 MG	7	Tablets	365	DAYS				10-01-2022	
8587005070B720	Pyrukynd taper pack	Mitapivat Sulfate Tab Therapy Pack	7 x 20 MG & 7 x 5 MG	14	Tablets	365	DAYS				10-01-2022	
8587005070B735	Pyrukynd taper pack	Mitapivat Sulfate Tab Therapy Pack	7 x 50 MG & 7 x 20 MG	14	Tablets	365	DAYS				10-01-2022	

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. 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 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
	Quantity Limit for the requested agent 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

Module	Clinical Criteria for Approval
	strength that does not exceed the program quantity limit **Length of Approval:** Initial - 6 months Renewal - 12 months

• Program Summary: Samsca (tolvaptan)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	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; 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**

Module	Clinical Criteria for Approval
	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** 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:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
85805510000120	Tavneos	Avacopan Cap	10 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. 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**

Module	Clinical Criteria for Approval
	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** 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:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	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	50 MG	60	Tablets	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		Olamine Tab 50 MG (Base Equiv)										
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: 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 has tried and had an inadequate response to ONE 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

Module	Clinical Criteria for Approval
	cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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** 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 has tried and had an inadequate response to ONE 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**

Module	Clinical Criteria for Approval
	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** 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 has tried and had an inadequate response to BOTH antithymocyte globulin (ATG) AND cyclosporine therapy **OR** B. The patient has an intolerance or hypersensitivity to BOTH

Module	Clinical Criteria for Approval
	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** 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 has tried and had an inadequate response to ONE 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**

Module	Clinical Criteria for Approval
	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** 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 has tried and had an inadequate response to ONE 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 a 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** B. The patient will use the requested agent in combination with another agent included in this

Module	Clinical Criteria for Approval
	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:** AHFS, or DrugDex 1 or 2a level of evidence NCCN 1 or 2a recommended use **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:

Module	Clinical Criteria for Approval
	1. ONE of the following: 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

Module	Clinical Criteria for Approval
	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 **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