MHCP PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: March 15, 2024 Notification Posted: March 1, 2024

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

No new policies effective March 15, 2024

POLICIES REVISED

• Program Summary: Biologic Immunomodulators

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6627001502F540		adalimumab-aacf auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS	65219061299			
6627001507F520	Abrilada	adalimumab-afzb auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS				
6627001507F810	Abrilada	adalimumab-afzb prefilled syringe kit	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001507F820	Abrilada	adalimumab-afzb prefilled syringe kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6650007000E5	Actemra	tocilizumab subcutaneous soln prefilled syringe	162 MG/0.9ML	4	Syringes	28	DAYS				
6650007000D520	Actemra actpen	Tocilizumab Subcutaneous Soln Auto-injector 162 MG/0.9ML	162 MG/0.9ML	4	Pens	28	DAYS				
6627001510D517	Amjevita	adalimumab-atto soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				
6627001510D520	Amjevita	adalimumab-atto soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS			02-27-2023	
6627001510D537	Amjevita	adalimumab-atto soln auto-injector	80 MG/0.8ML	2	Pens	28	DAYS				
6627001510E505	Amjevita	adalimumab-atto soln prefilled syringe	10 MG/0.2ML	2	Syringes	28	DAYS				
6627001510E508	Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.2ML	2	Syringes	28	DAYS				
6627001510E510	Amjevita	adalimumab-atto soln prefilled syringe	20 MG/0.4ML	2	Syringes	28	DAYS			02-27-2023	
6627001510E517	Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001510E520	Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS			02-27-2023	
9025051800D520	Bimzelx	bimekizumab-bkzx subcutaneous soln auto-injector	160 MG/ML	2	Pens	56	DAYS				
9025051800E520	Bimzelx	bimekizumab-bkzx subcutaneous soln prefilled syr	160 MG/ML	2	Syringes	56	DAYS				
52505020106420	Cimzia	Certolizumab Pegol For Inj Kit 2 X 200 MG	200 MG	2	Kits	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
5250502010F840	Cimzia	Certolizumab Pegol Prefilled Syringe Kit	200 MG/ML	2	Kits	28	DAYS				
5250502010F860	Cimzia starter kit	Certolizumab Pegol Prefilled Syringe Kit	200 MG/ML	1	Kit	180	DAYS				
9025057500E530	Cosentyx	Secukinumab Subcutaneous Pref Syr 150 MG/ML (300 MG Dose)	150 MG/ML	2	Syringes	28	DAYS				
9025057500E510	Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe	75 MG/0.5ML	1	Syringe	28	DAYS				
9025057500E520	Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe 150 MG/ML	150 MG/ML	1	Syringe	28	DAYS				
9025057500D530	Cosentyx sensoready pen	Secukinumab Subcutaneous Auto-inj 150 MG/ML (300 MG Dose)	150 MG/ML	2	Pens	28	DAYS				
9025057500D520	Cosentyx sensoready pen	Secukinumab Subcutaneous Soln Auto-injector 150 MG/ML	150 MG/ML	1	Pen	28	DAYS				
9025057500D550	Cosentyx unoready	secukinumab subcutaneous soln auto-injector	300 MG/2ML	1	Pen	28	DAYS				
6627001505F520	Cyltezo	adalimumab-adbm auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS	00597037597 00597054522			
6627001505F805	Cyltezo	adalimumab-adbm prefilled syringe kit	10 MG/0.2ML	2	Syringes	28	DAYS				
6627001505F810	Cyltezo	adalimumab-adbm prefilled syringe kit	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001505F820	Cyltezo	adalimumab-adbm prefilled syringe kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001505F520	Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.8ML	6	Pens	180	DAYS	0059703752; 00597054566			
6627001505F520	Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.8ML	4	Pens	180	DAYS	00597037516 00597054544			
66290030002120	Enbrel	Etanercept For Subcutaneous Inj 25 MG	25 MG	8	Vials	28	DAYS				
66290030002015	Enbrel	Etanercept Subcutaneous Inj 25 mg/0.5ml	25 MG/0.5ML	8	Vials	28	DAYS				
6629003000E525	Enbrel	Etanercept Subcutaneous Soln Prefilled Syringe 25 MG/0.5ML	25 MG/0.5ML	4	Syringes	28	DAYS				
6629003000E530	Enbrel	Etanercept Subcutaneous Soln Prefilled Syringe 50 MG/ML	50 MG/ML	4	Syringes	28	DAYS				
6629003000E230	Enbrel mini	Etanercept Subcutaneous Solution Cartridge 50 MG/ML	50 MG/ML	4	Cartridges	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6629003000D530	Enbrel sureclick	Etanercept Subcutaneous Solution Auto-injector 50 MG/ML	50 MG/ML	4	Syringes	28	DAYS				
5250308000D220	Entyvio	vedolizumab soln pen-injector	108 MG/0.68ML	2	Pens	28	DAYS				
6627001520E510	Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001520E520	Hadlima	adalimumab-bwwd soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001520D510	Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				
6627001520D520	Hadlima pushtouch	adalimumab-bwwd soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS				
6627001535F520	Hulio	adalimumab-fkjp auto-injector kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001535F810	Hulio	adalimumab-fkjp prefilled syringe kit	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001535F820	Hulio	adalimumab-fkjp prefilled syringe kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001500F804	Humira	Adalimumab Prefilled Syringe Kit 10 MG/0.1ML	10 MG/0.1ML	2	Syringes	28	DAYS				
6627001500F809	Humira	Adalimumab Prefilled Syringe Kit 20 MG/0.2ML	20 MG/0.2ML	2	Syringes	28	DAYS				
6627001500F830	Humira	Adalimumab Prefilled Syringe Kit 40 MG/0.4ML	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001500F820	Humira	Adalimumab Prefilled Syringe Kit 40 MG/0.8ML	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001500F840	Humira pediatric crohns d	Adalimumab Prefilled Syringe Kit 80 MG/0.8ML	80 MG/0.8ML	1	Kit	180	DAYS				
6627001500F880	Humira pediatric crohns d	Adalimumab Prefilled Syringe Kit 80 MG/0.8ML & 40 MG/0.4ML	80 MG/0.8ML & 40MG/0.4ML	1	Kit	180	DAYS				
6627001500F440	Humira pen	adalimumab pen-injector kit	80 MG/0.8ML	2	Pens	28	DAYS	00074012402			
6627001500F420	Humira pen	Adalimumab Pen-injector Kit; adalimumab pen-injector kit	40 MG/0.8ML	2	Pens	28	DAYS	00074433902 50090448700			
6627001500F430	Humira pen	Adalimumab Pen-injector Kit 40 MG/0.4ML	40 MG/0.4ML	2	Pens	28	DAYS				
6627001500F420	Humira pen; Humira pen-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;	Adalimumab Pen-injector Kit;	40 MG/0.8ML	1	Kit	180	DAYS	00074433907 50090448700			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
	Humira pen-ps/uv starter	adalimumab pen-injector kit									
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 starter	adalimumab pen-injector kit	80 MG/0.8ML	1	Kit	180	DAYS	00074012404			
6627001500F450	Humira pen-ps/uv starter	Adalimumab Pen-injector Kit 80 MG/0.8ML & 40 MG/0.4ML	80 MG/0.8ML & 40MG/0.4ML	1	Kit	180	DAYS				
6627001504D515	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				
6627001504D520	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS				
6627001504E508	Hyrimoz	adalimumab-adaz soln prefilled syringe	10 MG/0.1 ML	2	Syringes	28	DAYS				
6627001504E513	Hyrimoz	adalimumab-adaz soln prefilled syringe	20 MG/0.2ML	2	Syringes	28	DAYS				
6627001504E515	Hyrimoz	adalimumab-adaz soln prefilled syringe	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001504E520	Hyrimoz	adalimumab-adaz soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001504D540	Hyrimoz; Hyrimoz sensoready pens	adalimumab-adaz soln auto-injector	80 MG/0.8ML	2	Pens	28	DAYS	61314045420 83457010701			
6627001504D540	Hyrimoz crohn's disease and UC; Hyrimoz sensoready pens	adalimumab-adaz soln auto-injector	80 MG/0.8ML	1	Starter Kit	180	DAYS	61314045436 83457011301			
6627001504E560	Hyrimoz pediatric crohn's	adalimumab-adaz soln prefilled syr	80 MG/0.8ML & 40MG/0.4ML	2	Syringes	180	DAYS				
6627001504E540	Hyrimoz pediatric crohns	adalimumab-adaz soln prefilled syringe	80 MG/0.8ML	3	Syringes	180	DAYS				
6627001504D560	Hyrimoz plaque psoriasis	adalimumab-adaz soln auto-injector	80 MG/0.8ML & 40MG/0.4ML	1	Starter Kit	180	DAYS				
6627001502F540	Idacio	adalimumab-aacf auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS	65219055408 65219061299			
6627001502F840	Idacio	adalimumab-aacf prefilled syringe kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001502F540	Idacio starter	adalimumab-aacf auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	65219055438			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
	package for CD/UC										
6627001502F540	Idacio starter package for plaque psoriasis	adalimumab-aacf auto-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	65219055428			
6650006000E5	Kevzara	sarilumab subcutaneous soln prefilled syringe	150 MG/1.14ML; 200 MG/1.14ML	2	Syringes	28	DAYS				
6650006000D5	Kevzara	sarilumab subcutaneous solution auto-injector	150 MG/1.14ML; 200 MG/1.14ML	2	Pens	28	DAYS				
6626001000E5	Kineret	anakinra subcutaneous soln prefilled syringe	100 MG/0.67ML	28	Syringes	28	DAYS				
90731060100120	Litfulo	ritlecitinib tosylate cap	50 MG	28	Capsules	28	DAYS				
666030100003	Olumiant	baricitinib tab	1 MG; 2 MG; 4 MG	30	Tablets	30	DAYS				
5250405040D520	Omvoh	mirikizumab-mrkz subcutaneous soln auto-injector	100 MG/ML	2	Pens	28	DAYS				
6640001000E520	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 125 MG/ML	125 MG/ML	4	Syringes	28	DAYS				
6640001000E510	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 50 MG/0.4ML	50 MG/0.4ML	4	Syringes	28	DAYS				
6640001000E515	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 87.5 MG/0.7ML	87.5 MG/0.7ML	4	Syringes	28	DAYS				
6640001000D520	Orencia clickject	Abatacept Subcutaneous Soln Auto-Injector 125 MG/ML	125 MG/ML	4	Syringes	28	DAYS				
66603072007540	Rinvoq	Upadacitinib Tab ER	45 MG	84	Tablets	365	DAYS				
66603072007520	Rinvoq	Upadacitinib Tab ER 24HR 15 MG	15 MG	30	Tablets	30	DAYS				
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	100 MG/ML	1	Syringe	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		Prefilled Syringe 100 MG/ML									
6627004000E520	Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 50 MG/0.5ML	50 MG/0.5ML	1	Syringe	28	DAYS				
9025057070F820	Skyrizi	Risankizumab-rzaa Sol Prefilled Syringe 2 x 75 MG/0.83ML Kit	75 MG/0.83ML	1	Kit	84	DAYS				
9025057070E540	Skyrizi	Risankizumab-rzaa Soln Prefilled Syringe	150 MG/ML	1	Syringe	84	DAYS				
5250406070E210	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	180 MG/1.2ML	1	Cartridge	56	DAYS				
5250406070E220	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	360 MG/2.4ML	1	Cartridge	56	DAYS				
9025057070D520	Skyrizi pen	Risankizumab-rzaa Soln Auto-injector	150 MG/ML	1	Pen	84	DAYS				
90250524000320	Sotyktu	Deucravacitinib Tab	6 MG	30	Tablets	30	DAYS				
90250585002020	Stelara	Ustekinumab Inj 45 MG/0.5ML	45 MG/0.5ML	1	Vial	84	DAYS				
9025058500E520	Stelara	Ustekinumab Soln Prefilled Syringe 45 MG/0.5ML	45 MG/0.5ML	1	Syringe	84	DAYS				
9025058500E540	Stelara	Ustekinumab Soln Prefilled Syringe 90 MG/ML	90 MG/ML	1	Syringe	56	DAYS				
9025055400D520	Taltz	Ixekizumab Subcutaneous Soln Auto-injector 80 MG/ML	80 MG/ML	1	Injection	28	DAYS				
9025055400E520	Taltz	Ixekizumab Subcutaneous Soln Prefilled Syringe 80 MG/ML	80 MG/ML	1	Syringe	28	DAYS				
9025054200D220	Tremfya	Guselkumab Soln Pen-Injector 100 MG/ML	100 MG/ML	1	Pen	56	DAYS				
9025054200E520	Tremfya	Guselkumab Soln Prefilled Syringe 100 MG/ML	100 MG/ML	1	Syringe	56	DAYS				
52504525100350	Velsipity	etrasimod arginine tab	2 MG	30	Tablets	30	DAYS				
66603065102020	Xeljanz	Tofacitinib Citrate Oral Soln	1 MG/ML	240	mLs	30	DAYS				
66603065100330	Xeljanz	Tofacitinib Citrate Tab 10 MG (Base Equivalent)	10 MG	240	Tablets	365	DAYS				
66603065100320	Xeljanz	Tofacitinib Citrate Tab 5 MG (Base Equivalent)	5 MG	60	Tablets	30	DAYS				
66603065107530	Xeljanz xr	Tofacitinib Citrate Tab ER 24HR 11 MG (Base Equivalent)	11 MG	30	Tablets	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
66603065107550	Xeljanz xr	Tofacitinib Citrate Tab ER 24HR 22 MG (Base Equivalent)	22 MG	120	Tablets	365	DAYS				
6627001503F560	Yuflyma	adalimumab-aaty auto-injector kit	80 MG/0.8ML	2	Pens	28	DAYS	72606002304			
6627001503F530	Yuflyma 1-pen kit; Yuflyma 2-pen kit	adalimumab-aaty auto-injector kit	40 MG/0.4ML	2	Pens	28	DAYS				
6627001503F830	Yuflyma 2-syringe kit	adalimumab-aaty prefilled syringe kit	40 MG/0.4ML	1	Kit	28	DAYS				
6627001503F560	Yuflyma cd/uc/hs starter	adalimumab-aaty auto-injector kit	80 MG/0.8ML	1	Kit	180	DAYS	72606002307			
6627001509D240	Yusimry	adalimumab-aqvh soln pen-injector	40 MG/0.8ML	2	Pens	28	DAYS				
66603072007530	Rinvoq	Upadacitinib Tab ER	30 MG	30	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

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

Disease State	PDL Preferred Agents	PDL Non-Preferred Agents
Ankylosing Spondylitis (AS)	SQ: Enbrel, Humira Oral: Xeljanz IV: infliximab*	SQ: Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cimzia, Cosentyx, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simponi, Taltz, Yuflyma Oral: Rinvoq, Xeljanz XR
Nonradiographic Axial Spondyloarthritis (nr-axSpA)	N/A	SQ: Cimzia, Cosentyx, Taltz Oral: Rinvoq
Polyarticular Juvenile Idiopathic Arthritis (PJIA)	SQ: Enbrel, Humira Oral: Xeljanz	SQ: Abrilada, Actemra, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Orencia, Yuflyma Oral: Xeljanz solution
Psoriatic Arthritis (PsA)	SQ: Enbrel, Humira Oral: Otezla, Xeljanz IV: infliximab*	SQ: Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cimzia, Cosentyx, Cyltezo, Hadlima, Hulio, Hyrimoz,

Module	Clinical Criteria for Approval		
			Idacio, Orencia, Simponi, Skyrizi, Stelara, Taltz, Tremfya, Yuflyma Oral: Rinvoq, Xeljanz XR
	Rheumatoid Arthritis	SQ: Enbrel, Humira Oral: Xeljanz IV: infliximab*	SQ: Abrilada, Actemra, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cimzia, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Kevzara, Kineret, Orencia, Simponi, Yuflyma Oral: Olumiant, Rinvoq, Xeljanz XR
	Hidradenitis Suppurativa (HS)	SQ: Humira	SQ: Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma
	Psoriasis (PS)	SQ: Enbrel, Humira Oral: Otezla IV: infliximab*	SQ: Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Bimzelx, Cimzia, Cosentyx, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Siliq, Skyrizi, Sotyktu, Stelara, Taltz, Tremfya, Yuflyma
	Crohn's Disease	SQ: Humira IV: infliximab*	SQ: Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cimzia, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Skyrizi, Stelara, Yuflyma
	Ulcerative Colitis	SQ: Humira Oral: Xeljanz IV: infliximab*	SQ: Abrilada syringe/pen, adalimumab-adaz syringe/pen, adalimumab-adbm syringe/pen, adalimumab-fkjp syringe/pen, Amjevita syringe/autoinjector, Cyltezo syringe/pen, Entyvio, Hadlima, Hulio, Hyrimoz, Idacio, Simponi, Stelara, Yuflyma Oral: Rinvoq, Xeljanz XR
	Uveitis	SQ: Humira	N/A

Module	Clinical Criteria for Approval

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

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

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

Initial Evaluation

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

1. The request is NOT for use of Olumiant or Actemra in the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) *NOTE: This indication is not covered under the pharmacy benefit **AND**
2. If the request is for use in Alopecia Areata and Alopecia Areata is NOT restricted from coverage under the patient's benefit **AND**
3. ONE of the following:
    A. If the request is for an oral liquid form of a medication, then BOTH of the following:
        1. The patient has an FDA approved indication **AND**
        2. The patient uses an enteral tube for feeding or medication administration **OR**
    B. ALL of the following:
        1. ONE of the following:
            A. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**
            B. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR**
            C. ALL of the following:
                1. The patient has an FDA labeled indication or an indication supported in compendia for the requested agent and route of administration AND ONE of the following:
                    A. The patient has a diagnosis of moderately to severely active rheumatoid arthritis (RA) AND BOTH of the following:
                        1. ONE of the following:
                            A. The patient's medication history includes ONE conventional agent (i.e., maximally tolerated methotrexate [e.g., titrated to

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

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	decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. If the request is for Simponi, ONE of the following: A. The patient will be taking the requested agent in combination with methotrexate **OR** B. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to methotrexate **OR** B. The patient has a diagnosis of active psoriatic arthritis (PsA) AND ONE of the following: 1. The patient's medication history includes ONE conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA AND ONE of the following: A. The patient has had an inadequate response to a conventional agent used in the treatment of PsA **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional agents used in the treatment of PsA **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PsA **OR** 3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PsA **OR** 4. The patient has severe active PsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR** 5. The patient has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** 6. The patient's medication history indicates use of another biologic immunomodulator agent OR Otezla that is FDA labeled or supported in compendia for the treatment of PsA **OR** 7. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive

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

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

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

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	therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 7. The prescriber has provided documentation that ALL of the conventional agents used in the treatment of UC cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** F. The patient has a diagnosis of non-infectious intermediate uveitis, posterior uveitis, or panuveitis AND ONE of the following: 1. BOTH of the following: A. ONE of the following: 1. The patient's medication history includes oral corticosteroids OR periocular or intravitreal corticosteroid injections used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis AND ONE of the following: A. The patient has had an inadequate response to oral corticosteroids OR periocular or intravitreal corticosteroid injections used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over oral corticosteroids OR periocular or intravitreal corticosteroid injections used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR**

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

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	uveitis, or panuveitis AND ONE of the following: A. The patient has had an inadequate response to a conventional agent used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional systemic agent used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 3. The patient has an FDA labeled contraindication to ALL conventional systemic agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be

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	ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL conventional systemic agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 2. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** G. The patient has a diagnosis of giant cell arteritis (GCA) AND ONE of the following: 1. The patient's medication history includes systemic corticosteroids (e.g., prednisone, methylprednisolone) used in the treatment of GCA AND ONE of the following: A. The patient has had an inadequate response to systemic corticosteroids (e.g., prednisone, methylprednisolone) used in the treatment of GCA **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over systemic corticosteroids (e.g., prednisone, methylprednisolone) used in the treatment of GCA **OR** 2. The patient has an intolerance or hypersensitivity to systemic corticosteroids used in the treatment of GCA **OR** 3. The patient has an FDA labeled contraindication to ALL systemic corticosteroids **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of GCA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND**

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

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

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

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	A. The patient has had an inadequate response to at a conventional agent used in the treatment of HS **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional agents used in the treatment of HS **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of HS **OR** 3. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of HS **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of HS **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL conventional agents used in the treatment of HS cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** L. BOTH of the following: 1. The patient has a diagnosis of systemic sclerosis associated interstitial lung disease (SSc-ILD) **AND** 2. The patient's diagnosis has been confirmed on high-resolution computed tomography (HRCT) or chest radiography scans **OR** M. The patient has a diagnosis of active enthesitis related arthritis (ERA) and ONE of the following: 1. The patient's medication history includes two different NSAIDs used in the treatment of ERA AND ONE of the following: A. The patient has had an inadequate response to two different NSAIDs used in the treatment of ERA **OR**

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	B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over NSAIDs used in the treatment of ERA **OR** 2. The patient has an intolerance or hypersensitivity to two different NSAIDs used in the treatment of ERA **OR** 3. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of ERA **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation ALL NSAIDs used in the treatment of ERA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 6. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of ERA **OR** N. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following: 1. ONE of the following: A. The patient has at least 10% body surface area involvement **OR** B. The patient has involvement of the palms and/or soles of the feet **AND** 2. ONE of the following: A. The patient's medication history includes at least a mid- potency topical steroid used in the treatment of AD AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD AND ONE of the following: 1. The patient has had an inadequate response to at least a mid- potency topical steroid used in the treatment of AD AND a topical

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

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	biologic, used in the treatment of AD AND ONE of the following: 1. The patient has had an inadequate response to a systemic immunosuppressant, including a biologic, used in the treatment of AD **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over a systemic immunosuppressant, including a biologic, used in the treatment of AD **OR** B. The patient has an intolerance or hypersensitivity to therapy with systemic immunosuppressants, including a biologic, used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL systemic immunosuppressants, including biologics, used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation ALL systemic immunosuppressants, including biologics, used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The prescriber has documented the patient's baseline pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **AND** 5. BOTH of the following:

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	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** O. BOTH of the following: 1. The patient has a diagnosis of severe alopecia areata (AA) **AND** 2. The patient has at least 50% scalp hair loss that has lasted 6 months or more **OR** P. The patient has a diagnosis of polymyalgia rheumatica (PMR) AND ONE of the following: 1. The patient's medication history includes ONE systemic corticosteroid at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR AND ONE of the following: A. The patient has had an inadequate response tosystemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR **OR** 2. The patient is currently treated with systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone and cannot tolerate a corticosteroid taper **OR** 3. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 4. The prescriber has provided documentation that ALL systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or

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	maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** Q. The patient has a diagnosis not mentioned previously **AND** 2. ONE of the following: A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR** B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following: 1. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following: A. ONE of the following: 1. Evidence of a paid claim **OR** 2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND** B. ONE of the following: 1. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR** 3. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** 4. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse

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	reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 5. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **AND** 3. If Cosentyx 300 mg every 4 weeks is requested as maintenance dosing, ONE of the following: A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis **OR** B. The patient has a diagnosis of hidradenitis suppurativa **OR** C. 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 Entyvio is requested for the treatment of ulcerative colitis, the patient has received at least 2 doses of Entyvio intravenous therapy **AND** 5. If Omvoh is requested for the treatment of ulcerative colitis, the patient received Omvoh IV for induction therapy **AND** 6. If Skyrizi is requested for the treatment of Crohn's disease, the patient received Skyrizi IV for induction therapy **AND** 7. If Stelara is requested for the treatment of Crohn's disease or ulcerative colitis, the patient received Stelara IV for induction therapy **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. 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** 4. 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** 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 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**

Module	Clinical Criteria for Approval
	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. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 8. The patient has been tested for latent tuberculosis (TB) when required by the prescribing information for the requested agent AND if positive the patient has begun therapy for latent TB **Length of Approval:** 12 months for all agents EXCEPT adalimumab containing products for ulcerative colitis (UC), Rinvoq for atopic dermatitis (AD), Siliq for plaque psoriasis (PS), Xeljanz and Xeljanz XR for induction therapy for UC, and the agents with indications that require loading doses for new starts. NOTE: For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of the 12 months. Adalimumab containing products for UC may be approved for 12 weeks, Rinvoq for AD may be approved for 6 months, Siliq for PS may be approved for 16 weeks, and Xeljanz and Xeljanz XR for UC may be approved for 16 weeks. **Compendia Allowed:** CMS Approved Compendia **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
	Renewal Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The request is NOT for use of Olumiant or Actemra in the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) *NOTE: This indication is not covered under the pharmacy benefit **AND** 2. The request is for use in Alopecia Areata and Alopecia Areata is NOT restricted from coverage under the patient's benefit **AND** 3. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (*please note Stelara renewal must be for the same strength as the initial approval) **AND** 4. ONE of the following: A. If the request is for an oral liquid form of a medication, then BOTH of the following: 1. The patient has an FDA approved indication **AND** 2. The patient uses an enteral tube for feeding or medication administration **OR** B. ALL of the following: 1. ONE of the following: A. The patient has a diagnosis of moderate to severe atopic dermatitis AND BOTH of the following: 1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following: A. Affected body surface area **OR** B. Flares **OR** C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **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:

Module	Clinical Criteria for Approval
	1. The patient has had clinical benefit with the requested agent **AND** 2. If the requested agent is Kevzara, the patient does NOT have any of the following: A. Neutropenia (ANC less than 1,000 per mm^3 at the end of the dosing interval) **AND** B. Thrombocytopenia (platelet count is less than 100,000 per mm^3) **AND** C. AST or ALT elevations 3 times the upper limit of normal **OR** C. The patient has a diagnosis other than moderate to severe atopic dermatitis or polymyalgia rheumatica AND the patient has had clinical benefit with the requested agent **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, i.e., clinical trials, phase III studies, guidelines required) **AND** 4. 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 hidradenitis suppurativa **OR** C. 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** 5. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 12 months **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL All Program Type	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. The requested agent is Xeljanz/Xeljanz XR for a diagnosis of ulcerative colitis, AND BOTH of the following: 1. 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** 2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit **OR** B. The requested agent is Xeljanz oral solution for a diagnosis of polyarticular course juvenile idiopathic arthritis, AND ONE of the following: 1. BOTH of the following: A. The requested quantity (dose) does not exceed the maximum FDA labeled dose (i.e., 5 mg twice daily) NOR the maximum compendia supported dose **AND** B. The prescriber has provided information stating why the patient cannot take Xeljanz 5 mg tablets **OR** 2. The requested quantity (dose) exceeds the maximum FDA labeled dose but does NOT exceed the maximum compendia supported dose for the requested indication **OR** 3. BOTH of the following: A. The requested quantity (dose) exceeds the maximum FDA labeled dose AND the maximum compendia supported dose for the requested indication **AND** B. The prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required) **OR** 4. The requested agent is NOT Xeljanz/Xeljanz XR for a diagnosis of ulcerative colitis or polyarticular course juvenile idiopathic arthritis, AND ONE of the following: A. The patient has an FDA labeled indication for the requested agent, AND ONE of the following: 1. BOTH of the following: A. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose **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. ALL of the following: A. The requested quantity (dose) exceeds the FDA maximum labeled dose **AND** B. 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. ONE of the following: A. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum compendia

Module	Clinical Criteria for Approval
	supported dose for the requested indication **AND** 2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does NOT exceed the program quantity limit **OR** B. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose AND the maximum compendia supported dose for the requested indication **AND** 2. The prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required) **OR** C. The patient has a compendia supported indication for the requested agent, AND ONE of the following: 1. BOTH of the following: A. The requested quantity (dose) does NOT exceed the maximum compendia supported dose for the requested indication **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. BOTH of the following: A. The requested quantity (dose) exceeds the maximum compendia supported dose for the requested indication **AND** B. The prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required) **OR** 3. The patient does NOT have an FDA labeled indication NOR a compendia supported indication for the requested agent AND BOTH of the following:

Module	Clinical Criteria for Approval
	A. The requested quantity (dose) cannot be achieved with a lower quanityt of a higher strength and/or package size that does not exceepd the program quantity limit **AND** B. The prescriber has provided information in support of therapy with a higher dose or shortened dosing internal for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required) **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** **Initial Approval with PA:** 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 **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit AND The prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly
Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)

Contraindicated as Concomitant Therapy
Cibinqo (abrocitinib)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Litfulo (ritlecitinib)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tysabri (natalizumab)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)

Contraindicated as Concomitant Therapy
Yusimry (adalimumab-aqvh) Zeposia (ozanimod) Zymfentra (infliximab-dyyb)

• Program Summary: DPP-4 Inhibitors and Combinations

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
27992502700340	Janumet	Sitagliptin-Metformin HCl Tab 50-1000 MG	50-1000 MG	60	Tablets	30	DAYS				
27992502700320	Janumet	Sitagliptin-Metformin HCl Tab 50-500 MG	50-500 MG	60	Tablets	30	DAYS				
27992502707540	Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 100-1000 MG	100-1000 MG	30	Tablets	30	DAYS				
27992502707530	Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 50-1000 MG	50-1000 MG	60	Tablets	30	DAYS				
27992502707520	Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 50-500 MG	50-500 MG	30	Tablets	30	DAYS				
27550070100340	Januvia	Sitagliptin Phosphate Tab 100 MG (Base Equiv)	100 MG	30	Tablets	30	DAYS				
27550070100320	Januvia	Sitagliptin Phosphate Tab 25 MG (Base Equiv)	25 MG	30	Tablets	30	DAYS				
27550070100330	Januvia	Sitagliptin Phosphate Tab 50 MG (Base Equiv)	50 MG	30	Tablets	30	DAYS				
27992502400340	Jentadueto	Linagliptin-Metformin HCl Tab 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS				
27992502400320	Jentadueto	Linagliptin-Metformin HCl Tab 2.5-500 MG	2.5-500 MG	60	Tablets	30	DAYS				
27992502400330	Jentadueto	Linagliptin-Metformin HCl Tab 2.5-850 MG	2.5-850 MG	60	Tablets	30	DAYS				
27992502407520	Jentadueto xr	Linagliptin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS				
27992502407530	Jentadueto xr	Linagliptin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	30	Tablets	30	DAYS				
27992502100330	Kazano	Alogliptin-Metformin HCl Tab 12.5-1000 MG	12.5-1000 MG	60	Tablets	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
27992502100320	Kazano	Alogliptin-Metformin HCl Tab 12.5-500 MG	12.5-500 MG	60	Tablets	30	DAYS				
27992502607520	Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS				
27992502607540	Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	30	Tablets	30	DAYS				
27992502607530	Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 5-500 MG	5-500 MG	30	Tablets	30	DAYS				
27550010100320	Nesina	Alogliptin Benzoate Tab 12.5 MG (Base Equiv)	12.5 MG	30	Tablets	30	DAYS				
27550010100330	Nesina	Alogliptin Benzoate Tab 25 MG (Base Equiv)	25 MG	30	Tablets	30	DAYS				
27550010100310	Nesina	Alogliptin Benzoate Tab 6.25 MG (Base Equiv)	6.25 MG	30	Tablets	30	DAYS				
27550065100320	Onglyza	Saxagliptin HCl Tab 2.5 MG (Base Equiv)	2.5 MG	30	Tablets	30	DAYS				
27550065100330	Onglyza	Saxagliptin HCl Tab 5 MG (Base Equiv)	5 MG	30	Tablets	30	DAYS				
27994002100320	Oseni	Alogliptin-Pioglitazone Tab 12.5-15 MG	12.5-15 MG	30	Tablets	30	DAYS				
27994002100325	Oseni	Alogliptin-Pioglitazone Tab 12.5-30 MG	12.5-30 MG	30	Tablets	30	DAYS				
27994002100330	Oseni	Alogliptin-Pioglitazone Tab 12.5-45 MG	12.5-45 MG	30	Tablets	30	DAYS				
27994002100340	Oseni	Alogliptin-Pioglitazone Tab 25-15 MG	25-15 MG	30	Tablets	30	DAYS				
27994002100345	Oseni	Alogliptin-Pioglitazone Tab 25-30 MG	25-30 MG	30	Tablets	30	DAYS				
27994002100350	Oseni	Alogliptin-Pioglitazone Tab 25-45 MG	25-45 MG	30	Tablets	30	DAYS				
27550050000320	Tradjenta	Linagliptin Tab 5 MG	5 MG	30	Tablets	30	DAYS				
27550070000320	Zituvio	sitagliptin tab	25 MG	30	Tablets	30	DAYS				
27550070000330	Zituvio	sitagliptin tab	50 MG	30	Tablets	30	DAYS				
27550070000340	Zituvio	sitagliptin tab	100 MG	30	Tablets	30	DAYS				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	TARGET AGENT(S) **Januvia** (sitagliptin) **Janumet** (sitagliptin/metformin)

Module	Clinical Criteria for Approval
	Janumet XR (sitagliptin/metformin ER) **Jentadueto** (linagliptin/metformin) **Jentadueto XR** (linagliptin/metformin ER) **Kombiglyze XR** (saxagliptin/metformin ER) **Nesina** (alogliptin) **Onglyza** (saxagliptin) **Tradjenta** (linagliptin) **Target Agent(s)** will be approved when ONE of the following is met: 1. Information has been provided that indicates the patient is currently being treated with the requested agent within the past 90 days **OR** 2. The prescriber states the patient is currently being treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR** 3. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 4. The patient's medication history includes use of an agent containing metformin or insulin **OR** 5. The prescriber has stated that the patient has tried insulin or an agent containing metformin AND ONE of the following: A. Insulin or an agent containing metformin was discontinued due to lack of effectiveness or an adverse event **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over insulin or an agent containing metformin **OR** 6. The patient has an intolerance or hypersensitivity to ONE of the following: metformin or insulin **OR** 7. The patient has an FDA labeled contraindication to ALL of the following: metformin and insulins **OR** 8. The prescriber has provided documentation that metformin AND insulins cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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 Standalone	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. ONE of the following: A. The requested quantity (dose) does NOT exceed the program quantity limit **OR** B. Information has been provided that fulfills the criteria listed under the "Allowed exception cases/diagnoses" (if applicable) **OR** C. The requested quantity (dose) is greater than the program quantity limit AND ONE of the following: 1. BOTH of the following: A. The requested agent does not have a maximum FDA labeled dose for the requested indication **AND** B. Information has been provided to support therapy with a higher dose for the requested indication **OR** 2. BOTH of the following:

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

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

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
2717002000D120		Exenatide Extended Release for Susp Pen-injector 2 MG		4	Pens	28	DAYS				
2717002000G220		Exenatide For Inj Extended Release Susp 2 MG		4	Vials	28	DAYS				
2717007000D220		Semaglutide Soln Pen-inj 1 MG/DOSE (2 MG/1.5ML)		2	Pens	28	DAYS				
2717005600D230	Adlyxin	Lixisenatide Soln Pen-injector 20 MCG/0.2ML (100 MCG/ML)	20 MCG/0.2ML	2	Pens	28	DAYS				
2717005600F420	Adlyxin starter pack	Lixisenatide Pen-inj Starter Kit 10 MCG/0.2ML & 20 MCG/0.2ML	10 & 20 MCG/0.2ML	2	Pens	180	DAYS				
2717002000D420	Bydureon bcise	Exenatide Extended Release Susp Auto-Injector 2 MG/0.85ML	2 MG/0.85ML	4	Injection Devices	28	DAYS				
2717002000D240	Byetta	Exenatide Soln Pen-injector 10 MCG/0.04ML	10 MCG/0.04 ML	1	Pen	30	DAYS				
2717002000D220	Byetta	Exenatide Soln Pen-injector 5 MCG/0.02ML	5 MCG/0.02 ML	1	Pen	30	DAYS				
2717308000D210	Mounjaro	Tirzepatide Soln Pen-injector	2.5 MG/0.5ML	4	Pens	28	DAYS				
2717308000D215	Mounjaro	Tirzepatide Soln Pen-injector	5 MG/0.5ML	4	Pens	28	DAYS				
2717308000D220	Mounjaro	Tirzepatide Soln Pen-injector	7.5 MG/0.5ML	4	Pens	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
2717308000D225	Mounjaro	Tirzepatide Soln Pen-injector	10 MG/0.5ML	4	Pens	28	DAYS				
2717308000D230	Mounjaro	Tirzepatide Soln Pen-injector	12.5 MG/0.5ML	4	Pens	28	DAYS				
2717308000D235	Mounjaro	Tirzepatide Soln Pen-injector	15 MG/0.5ML	4	Pens	28	DAYS				
2717007000D225	Ozempic	Semaglutide Soln Pen-inj	8 MG/3ML	1	Pen	28	DAYS				
2717007000D222	Ozempic	Semaglutide Soln Pen-inj	4 MG/3ML	1	Pen	28	DAYS				
2717007000D210	Ozempic	Semaglutide Soln Pen-inj 0.25 or 0.5 MG/DOSE (2 MG/1.5ML)	2 MG/1.5ML	1	Pen	28	DAYS				
27170070000330	Rybelsus	Semaglutide Tab 14 MG	14 MG	30	Tablets	30	DAYS				
27170070000310	Rybelsus	Semaglutide Tab 3 MG	3 MG	30	Tablets	180	DAYS				
27170070000320	Rybelsus	Semaglutide Tab 7 MG	7 MG	30	Tablets	30	DAYS				
2717001500D2	Trulicity	dulaglutide soln pen-injector	0.75 MG/0.5ML; 1.5 MG/0.5ML; 3 MG/0.5ML; 4.5 MG/0.5ML	4	Pens	28	DAYS				
27170050	Victoza	liraglutide soln pen-injector	18 MG/3ML	3	Pens	30	DAYS				

ADDITIONAL QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
2717002000D120		Exenatide Extended Release for Susp Pen-injector 2 MG		The patient must have a diagnosis of type 2 diabetes mellitus			
2717007000D220		Semaglutide Soln Pen-inj 1 MG/DOSE (2 MG/1.5ML)		The patient must have a diagnosis of type 2 diabetes mellitus			
2717005600D230	Adlyxin	Lixisenatide Soln Pen-injector 20 MCG/0.2ML (100 MCG/ML)	20 MCG/0.2ML	The patient must have a diagnosis of type 2 diabetes mellitus			
2717005600F420	Adlyxin starter pack	Lixisenatide Pen-inj Starter Kit 10 MCG/0.2ML & 20 MCG/0.2ML	10 & 20 MCG/0.2ML	The patient must have a diagnosis of type 2 diabetes mellitus			
2717002000D420	Bydureon bcise	Exenatide Extended Release	2 MG/0.85ML	The patient must have a diagnosis of type 2 diabetes mellitus			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		Susp Auto-Injector 2 MG/0.85ML					
2717002000D240	Byetta	Exenatide Soln Pen-injector 10 MCG/0.04ML	10 MCG/0.04 ML	The patient must have a diagnosis of type 2 diabetes mellitus			
2717002000D220	Byetta	Exenatide Soln Pen-injector 5 MCG/0.02ML	5 MCG/0.02 ML	The patient must have a diagnosis of type 2 diabetes mellitus.			
2717007000D222	Ozempic	Semaglutide Soln Pen-inj	4 MG/3ML	The patient must have a diagnosis of type 2 diabetes mellitus			
2717007000D210	Ozempic	Semaglutide Soln Pen-inj 0.25 or 0.5 MG/DOSE (2 MG/1.5ML)	2 MG/1.5ML	The patient must have a diagnosis of type 2 diabetes mellitus			
27170070000330	Rybelsus	Semaglutide Tab 14 MG	14 MG	The patient must have a diagnosis of type 2 diabetes mellitus.			
27170070000310	Rybelsus	Semaglutide Tab 3 MG	3 MG	The patient must have a diagnosis of type 2 diabetes mellitus			
27170070000320	Rybelsus	Semaglutide Tab 7 MG	7 MG	The patient must have a diagnosis of type 2 diabetes mellitus.			
2717001500D2	Trulicity	dulaglutide soln pen-injector	0.75 MG/0.5ML; 1.5 MG/0.5ML; 3 MG/0.5ML; 4.5 MG/0.5ML	The patient must have a diagnosis of type 2 diabetes mellitus			
27170050	Victoza	liraglutide soln pen-injector	18 MG/3ML	The patient must have a diagnosis of type 2 diabetes mellitus.			

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	TARGET AGENT(S) **Bydureon™** (exenatide extended-release) **Bydureon BCise™** (exenatide extended-release) **Byetta®** (exenatide) **Ozempic®** (semaglutide) **Victoza®** (liraglutide) **PRIOR AUTHORIZATION CRITERIA FOR APPROVAL** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of type 2 diabetes mellitus **AND** 2. ONE of the following: A. Information has been provided that indicates the patient is currently being treated with the requested GLP-1 within the past 90 days **OR** B. The prescriber states the patient is currently being treated with the requested GLP-1 within the past 90 days AND is at risk if therapy is changed **OR** C. The patient is currently being treated with the requested agent as indicated by ALL of the following:

Module	Clinical Criteria for Approval
	1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** D. The patient's medication history includes use of one or more of the following: an agent containing metformin or insulin **OR** E. The prescriber has stated that the patient has tried insulin or an agent containing metformin AND ONE of the following: 1. Insulin or an agent containing metformin was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over insulin or an agent containing metformin **OR** F. The patient has an intolerance or hypersensitivity to ONE of the following agents: metformin or insulin **OR** G. The patient has an FDA labeled contraindication to ALL of the following agents: metformin AND insulin **OR** H. 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** I. The prescriber has provided documentation that ALL of the following agents: metformin and insulin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval:** 12 months NOTE: If Quantity Limit program also applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. Information has been provided that fulfills the criteria listed under the "Allowed exception cases/diagnoses" (if applicable) **OR** 3. The requested quantity (dose) is greater than the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does not have a maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• Program Summary: Hereditary Angioedema (HAE)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
85802022006420	Berinert	C1 Esterase Inhibitor (Human) For IV Inj Kit 500 Unit	500 UNIT	10	Vials	30	DAYS				
85802022002120	Cinryze	C1 Esterase Inhibitor (Human) For IV Inj 500 Unit	500 UNIT	20	Vials	30	DAYS				
8582004010E520	Firazyr; Sajazir	icatibant acetate inj 30 mg/3ml (base equivalent)	30 MG/3ML	6	Syringes	30	DAYS				
85802022002130	Haegarda	C1 Esterase Inhibitor (Human) For Subcutaneous Inj 2000 Unit	2000 UNIT	27	Vials	28	DAYS				
85802022002140	Haegarda	C1 Esterase Inhibitor (Human) For Subcutaneous Inj 3000 Unit	3000 UNIT	18	Vials	28	DAYS				
85840010200120	Orladeyo	Berotralstat HCl Cap	110 MG	30	Capsules	30	DAYS				
85840010200130	Orladeyo	Berotralstat HCl Cap	150 MG	30	Capsules	30	DAYS				
85802022102130	Ruconest	C1 Esterase Inhibitor (Recombinant) For IV Inj 2100 Unit	2100 UNIT	8	Vials	30	DAYS				
85842040202020	Takhzyro	Lanadelumab-flyo Inj 300 MG/2ML (150 MG/ML)	300 MG/2ML	2	Vials	28	DAYS				
8584204020E520	Takhzyro	Lanadelumab-flyo Soln Pref Syringe	300 MG/2ML	2	Syringes	28	DAYS				

ADDITIONAL QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
85802022006420	Berinert	C1 Esterase Inhibitor (Human) For IV Inj Kit 500 Unit	500 UNIT	based on CDC 90th percentile for men and women averaged to 247.5 lbs or 112.5 kg (112.5 kg * 20 IU/kg=2,250 IU/500 IU/bottle=4.5 or 5 bottles or 2500 units/attack x 2 attacks/month = 10 vials/28 days			
85802022002120	Cinryze	C1 Esterase Inhibitor (Human) For IV Inj 500 Unit	500 UNIT	10,000 Units (20 vials)/30 days Maximum 25,000 Units (50 vials)/30 days if inadequate response to initial dosing			
85802022002130	Haegarda	C1 Esterase Inhibitor (Human) For Subcutaneous Inj 2000 Unit	2000 UNIT	*QL calculation based on CDC 90 percentile for weight in adults, averaged for men and women, and rounded to the nearest even dose to reduce waste (112.5 kg individual). See Special Clinical			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
				Criteria Table ** Do not wildcard PA- detail to GPI 14			
85802022002140	Haegarda	C1 Esterase Inhibitor (Human) For Subcutaneous Inj 3000 Unit	3000 UNIT	*QL calculation based on CDC 90 percentile for weight in adults, averaged for men and women, and rounded to the nearest even dose to reduce waste (112.5 kg individual). See Special Clinical Criteria Table ** Do not wildcard PA- detail to GPI 14			

ALLOWED EXCEPTIONS QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
85802022002130	Haegarda	C1 Esterase Inhibitor (Human) For Subcutaneous Inj 2000 Unit	2000 UNIT	See Haegarda weight-based quantity limit table located in section titled 'Quantity Limit Clinical Criteria for Approval'.			
85802022002140	Haegarda	C1 Esterase Inhibitor (Human) For Subcutaneous Inj 3000 Unit	3000 UNIT	See Haegarda weight-based quantity limit table located in section titled 'Quantity Limit Clinical Criteria for Approval'.			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Berinert, Firazyr, icatibant, or Ruconest	

Indication	PDL Preferred Agents
Treatment of acute attacks of hereditary angioedema (HAE)	Berinert, icatibant
Routine prophylaxis to prevent hereditary angioedema (HAE) attacks	Cinryze

Initial Evaluation

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

1. The patient has a diagnosis of hereditary angioedema (HAE) evidenced by ONE of the following:
    A. For patients with HAE with C1 inhibitor deficiency/dysfunction (HAE type 1 or 2), BOTH of the following: (medical records/lab results required)
        1. C4 level below the lower limit of normal as defined by the laboratory performing the test **AND**
        2. ONE of the following:
            A. C1 inhibitor protein level below the lower limit of normal as defined by the laboratory performing the test **OR**
            B. C1 inhibitor function level below the lower limit of normal as defined by the laboratory performing the test **OR**
    B. For patients with HAE with normal C1 inhibitor (HAE-nI-C1INH, previously HAE type 3), ONE of the following: (medical records/lab results required)
        1. Mutation in ONE of the following genes associated with HAE
            A. Coagulation factor XII;

Module	Clinical Criteria for Approval
	B. Plasminogen; C. Angiopoietin-1; D. Kininogen 1; E. Heparan sulfate 3-O-sulfotransferase 6; F. Myoferlin **OR** 2. Family history or personal history of angioedema AND failure to respond to chronic, high-dose antihistamine therapy **AND** 2. The requested agent will be used for treatment of acute HAE attacks **AND** 3. ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 4. The requested agent will NOT be used in combination with other treatments for acute HAE attacks (e.g., Berinert, Firazyr, Sajazir, icatibant, Kalbitor, Ruconest) **AND** 5. Medications known to cause angioedema (i.e., ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate **AND** 6. ONE of the following: A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR** B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following: 1. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. The patient's medication history includes two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) AND ONE of the following: A. The patient had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) **OR** B. The prescriber has submitted an evidence-based and peer reviewed clinical practice guideline supporting the use of the requested agent over the preferred agent(s) **OR** 3. The patient has a documented intolerance or hypersensitivity to two preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** 4. The patient has an FDA labeled contraindication to ALL preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** C. The prescriber has provided documentation that the required preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **AND** 7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td></td><td>
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.

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 requested agent is being used for treatment of acute HAE attacks AND
3. The patient continues to have acute HAE attacks (documentation required) AND
4. The requested agent will NOT be used in combination with other treatments for acute HAE attacks (e.g., Berinert, Firazyr, Sajazir, icatibant, Kalbitor, Ruconest) AND
5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, allergist, immunologist) 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.
</td></tr>
<tr><td>Cinryze</td><td>
<table>
<tr><th>Indication</th><th>PDL Preferred Agents</th></tr>
<tr><td>Treatment of acute attacks of hereditary angioedema (HAE)</td><td>Berinert, icatibant</td></tr>
<tr><td>Routine prophylaxis to prevent hereditary angioedema (HAE) attacks</td><td>Cinryze</td></tr>
</table>
Initial Evaluation

Target Agent(s) will be approved when ALL of the following are met:
1. The patient has a diagnosis of hereditary angioedema (HAE) evidenced by ONE of the following:
A. For patients with HAE with C1 inhibitor deficiency/dysfunction (HAE type I or II), BOTH of the following: (medical records/lab results required)
1. C4 level below the lower limit of normal as defined by the laboratory performing the test AND
2. ONE of the following:
A. C1 inhibitor protein level below the lower limit of normal as defined by the laboratory performing the test OR
B. C1 inhibitor function level below the lower limit of normal as defined by the laboratory performing the test OR
B. For patients with HAE with normal C1 inhibitor (HAE-nI-C1INH, previously HAE type 3), ONE of the following: (medical records/lab results required)
1. Mutation in ONE of the following genes associated with HAE
A. Coagulation factor XII;
B. Plasminogen;
C. Angiopoietin-1
D. Kininogen 1
E. Heparan sulfate 3-O-sulfotransferase 6;
F. Myoferlin OR
</td></tr>
</table>

Module	Clinical Criteria for Approval
	2. Family history or personal history of angioedema AND failure to respond to chronic, high-dose antihistamine therapy **AND** 2. ONE of the following: A. ALL of the following: 1. The requested agent will be used for treatment of acute HAE attacks **AND** 2. The requested agent will NOT be used in combination with other treatments for acute HAE attacks (e.g., Berinert, Firazyr, Sajazir, icatibant, Kalbitor, Ruconest) **OR** B. The requested agent will be used for prophylaxis against HAE attacks AND ALL of the following: 1. The requested agent will NOT be used in combination with other agents for prophylaxis against HAE attacks (e.g., Haegarda, Orladeyo, Takhzyro) **AND** 2. The patient has a history of at least two severe acute HAE attacks per month (e.g., swelling of the throat, incapacitating gastrointestinal or cutaneous swelling) **AND** 3. 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. Medications known to cause angioedema (i.e., ACE-Inhibitors, estrogens, angiotensin receptor blockers) have been evaluated and discontinued when appropriate **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, allergist, immunologist) 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. **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 requested agent was initially approved for acute HAE attacks and ALL of the following: 1. The patient continues to have acute HAE attacks (documentation required) **AND** 2. The requested agent will NOT be used in combination with other treatments for acute HAE attacks (e.g., Berinert, Firazyr, Sajazir, icatibant, Kalbitor, Ruconest) **OR** B. The requested agent was initially approved for prophylaxis of HAE attacks and ALL of the following: 1. Information has been provided that indicates the patient has had a decrease in the frequency of acute HAE attacks from baseline (prior to treatment) (documentation required) **AND** 2. The requested agent will NOT be used in combination with other agents for prophylaxis against HAE attacks (e.g., Haegarda, Orladeyo, Takhzyro) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

Module	Clinical Criteria for Approval
Haegarda, Orladeyo, Takhzyro	

Indication	PDL Preferred Agents
Treatment of acute attacks of hereditary angioedema (HAE)	Berinert, icatibant
Routine prophylaxis to prevent hereditary angioedema (HAE) attacks	Cinryze

Initial Evaluation

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

1. The patient has a diagnosis of hereditary angioedema (HAE) evidenced by ONE of the following:
    A. For patients with HAE with C1 inhibitor deficiency/dysfunction (HAE type I or II), BOTH of the following: (medical records/lab results required)
        1. C4 level below the lower limit of normal as defined by the laboratory performing the test **AND**
        2. ONE of the following:
            A. C1 inhibitor protein level below the lower limit of normal as defined by the laboratory performing the test **OR**
            B. C1 inhibitor function level below the lower limit of normal as defined by the laboratory performing the test **OR**
    B. For patients with HAE with normal C1 inhibitor (HAE-nI-C1INH, previously HAE type III), ONE of the following: (medical records/lab results required)
        1. Mutation in ONE of the following genes associated with HAE
            1. Coagulation factor XII;
            2. Plasminogen;
            3. Angiopoietin-1;
            4. Kininogen 1;
            5. Heparan sulfate 3-O-sulfotransferase 6;
            6. Mypferlin **OR**
        2. Family history or personal history of angioedema AND failure to respond to chronic, high-dose antihistamine therapy **AND**
2. The requested agent will be used for prophylaxis against HAE attacks **AND**
3. ONE of the following:
    A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
    B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**
4. The requested agent will NOT be used in combination with other agents for prophylaxis against HAE attacks (e.g., Cinryze, Haegarda, Orladeyo, Takhzyro) **AND**
5. The patient has a history of at least two severe acute HAE attacks per month (e.g., swelling of the throat, incapacitating gastrointestinal or cutaneous swelling) **AND**
6. ONE of the following:
    A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR**
    B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following:
        1. The patient is currently being treated with the requested agent as indicated by ALL of the following:
            A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
            B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
            C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
        2. The patient's medication history includes two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) AND ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) **OR** B. The prescriber has submitted an evidence-based and peer reviewed clinical practice guideline supporting the use of the requested agent over the preferred agent(s) **OR** 3. The patient has a documented intolerance or hypersensitivity to two preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** 4. The patient has an FDA labeled contraindication to ALL preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** 5. The prescriber has provided documentation that the required preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 6. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **AND** 7. If Takhzyro is requested, ONE of the following: A. The patient is initiating therapy with the requested agent **OR** B. The patient has been treated with the requested agent for less than 6 consecutive months **OR** C. The patient has been treated with the requested agent for at least 6 consecutive months **AND** ONE of the following: 1. The patient has been free of acute HAE attacks for at least 6 consecutive months and ONE of the following: A. The patient's dose will be reduced to 300 mg every 4 weeks **OR** B. The prescriber has provided information in support of therapy using 300 mg every 2 weeks **OR** 2. The patient has NOT been free of acute HAE attacks for at least 6 consecutive months **AND** 8. Medications known to cause angioedema (i.e., ACE-Inhibitors, estrogens, angiotensin receptor blockers) have been evaluated and discontinued when appropriate **AND** 9. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 10. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The requested agent is being used for prophylaxis against HAE attacks **AND** 3. Information has been provided that indicates the patient has had a decrease in the frequency of acute HAE attacks from baseline (prior to treatment) (documentation required) **AND** 4. The requested agent will NOT be used in combination with other agents for prophylaxis against HAE attacks (e.g., Cinryze, Haegarda, Orladeyo, Takhzyro) **AND** 5. If Takhzyro is requested, ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient has been free of acute HAE attacks for at least 6 consecutive months and ONE of the following: 1. The patient's dose will be reduced to 300 mg every 4 weeks **OR** 2. The prescriber has provided information in support of therapy using 300 mg every 2 weeks **OR** B. The patient has NOT been free of acute HAE attacks for at least 6 consecutive months **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, allergist, immunologist) 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:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Berinert, Firazyr, icatibant, or Ruconest	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) is within the program quantity limit (allows for 2 acute HAE attacks per month) **OR** 2. The requested quantity (dose) exceeds the program quantity limit and prescriber has provided information (e.g., frequency of attacks within the past 3 months has been greater than 2 attacks per month) in support of therapy with a higher dose or quantity **Length of Approval:** 12 months
Cinryze	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) is within the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND prescriber has provided information in support of therapy with a higher dose or quantity **Length of Approval:** 12 months
Haegarda, Orladeyo, Takhzyro	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) is within the program quantity limit (If Haegarda, prescriber must provide patient weight; refer to Haegarda weight-based quantity limit table and, if needed, extended dosing table) **OR** 2. The requested quantity (dose) exceeds the program quantity limit and prescriber has provided information in support of therapy with a higher dose or quantity **Length of Approval**: 12 months **HAEGARDA WEIGHT-BASED QUANTITY LIMITS: EXTENDED DOSING TABLE**

Weight (lb)	Weight (kg)	Quantity Limit of 3000 IU vials per 28 days	Quantity Limit of 2000 IU vials per 28 days	Number of 3000 IU vials used per dose	Number of 2000 IU vials used per dose

Module	Clinical Criteria for Approval					
	greater than 330-365	greater than 150-166	16	16	2	2
	greater than 293-330	greater than 133-150	24	0	3	0
	greater than 255-293	greater than 116-133	0	32	0	4
	greater than 220-255	greater than 100-116	8	16	1	2
	greater than 182.6-220	greater than 83-100	16	0	2	0
	greater than 145-182.6	greater than 66-83	8	8	1	1
	greater than 110-145	greater than 50-66	0	16	0	2
	greater than or equal to 75-110	greater than or equal to 34-50	8	0	1	0
	less than 75	less than 34	0	8	0	1

• Program Summary: Interleukin (IL)-1 Inhibitors

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
664500600021	Arcalyst	rilonacept for inj	220 MG	8	Vials	28	DAYS				
664600200020	Ilaris	canakinumab subcutaneous inj	150 MG/ML	2	Vials	28	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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

Module	Clinical Criteria for Approval
	No target agents are eligible for continuation of therapy 1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. BOTH of the following: 1. The patient has ONE of the following indications: A. Cryopyrin Associated Periodic Syndrome (CAPS) **OR** B. Familial Cold Auto-Inflammatory Syndrome (FCAS) **OR** C. Muckle-Wells Syndrome (MWS) **AND** 2. BOTH of the following: A. The patient has elevated pretreatment serum inflammatory markers (C-reactive protein/serum amyloid A) **AND** B. The patient has at least TWO symptoms typical for CAPS (i.e., urticaria-like rash, cold/stress triggered episodes, sensorineural hearing loss, musculoskeletal symptoms of arthralgia/arthritis/myalgia, chronic aseptic meningitis, skeletal abnormalities of epiphyseal overgrowth/frontal bossing) **OR** C. 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** D. The patient has a diagnosis of recurrent pericarditis AND ONE of the following 1. BOTH of the following: A. The patient's medication history includes colchicine AND ONE of the following: 1. The patient had an inadequate response to colchicine **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over colchicine **AND** B. ONE of the following: 1. Colchicine was used concomitantly with at least a 1 week trial of a non-steroidal anti-inflammatory drug (NSAID) AND a corticosteroid **OR** 2. The patient's medication history includes at least a 1 week trial of a non-steroidal anti-inflammatory (NSAID) AND a corticosteroid AND ONE of the following: A. The patient had an inadequate response to a non-steroidal anti-inflammatory (NSAID) AND a corticosteroid **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over a non-steroidal anti-inflammatory (NSAID) AND a corticosteroid **OR** 3. The patient has an intolerance or hypersensitivity to BOTH an NSAID AND a corticosteroid **OR** 4. The patient has an FDA labeled contraindication to ALL NSAIDs AND ALL corticosteroids **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's medication history includes an oral immunosuppressant (i.e., azathioprine, methotrexate, mycophenolate) AND ONE of the following: A. The patient had an inadequate response to an oral immunosuppressant (i.e., azathioprine, methotrexate, mycophenolate) **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over an oral immunosuppressant **OR**

Module	Clinical Criteria for Approval
	5. The patient has an intolerance or hypersensitivity to oral immunosuppressants used in the treatment of recurrent pericarditis **OR** 6. The patient has an FDA labeled contraindication to oral immunosuppressants used in the treatment of recurrent pericarditis **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 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** E. The patient has another FDA approved indication for the requested agent **OR** F. 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** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS approved compendia **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in area of the patient's diagnosis (e.g., allergist, immunologist, pediatrician, cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):

Module	Clinical Criteria for Approval
	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. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** No target agents are eligible for continuation of therapy 1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. BOTH of the following: 1. The patient has ONE of the following indications: A. Cryopyrin Associated Periodic Syndrome (CAPS) **OR** B. Familial Cold Auto-Inflammatory Syndrome (FCAS) **OR** C. Muckle-Wells Syndrome (MWS) **AND** 2. BOTH of the following: A. The patient has elevated pretreatment serum inflammatory markers (C-reactive protein/serum amyloid A) **AND** B. The patient has at least TWO of the following symptoms typical for CAPS (i.e., urticaria-like rash, cold/stress triggered episodes, sensorineural hearing loss, musculoskeletal symptoms of arthralgia/arthritis/myalgia, chronic aseptic meningitis, skeletal abnormalities of epiphyseal overgrowth/frontal bossing) **OR** C. The patient has a diagnosis of Familial Mediterranean Fever (FMF) AND ONE of the following: 1. The patient's medication history includes colchicine AND ONE of the following: A. The patient had an inadequate response to colchicine **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over colchicine **OR** 2. The patient has an intolerance or hypersensitivity to colchicine **OR** 3. The patient has an FDA labeled contraindication to colchicine **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

Module	Clinical Criteria for Approval
	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** D. 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** E. 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** F. The patient has a diagnosis of active systemic juvenile idiopathic arthritis (SJIA) AND ALL of the following: 1. The patient has ongoing fever for at least 2 weeks **AND** 2. The patient has arthritis in greater than or equal to 1 joint **AND** 3. The patient has ONE or more of the following: A. Evanescent erythematous rash B. Generalized lymphadenopathy C. Hepatomegaly or splenomegaly D. Pericarditis, pleuritis and/or peritonitis **OR** G. The patient has a diagnosis of adult-onset Still's disease (AOSD) and BOTH of the following: 1. ONE of the following: A. The patient's medication history includes ONE corticosteroid or ONE non-steroidal anti-inflammatory drug (NSAID) and ONE of the following: 1. The patient had an inadequate response to at least ONE corticosteroid or ONE non-steroidal anti-inflammatory drug (NSAID) **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over corticosteroids and non-steroidal anti-inflammatory drugs (NSAIDs) **OR** B. The patient has an intolerance or hypersensitivity to ONE corticosteroid or ONE non-steroidal anti-inflammatory drug (NSAID) **OR** C. The patient has an FDA labeled contraindication to ALL corticosteroids AND ALL non-steroidal anti-inflammatory drugs (NSAIDs) **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 and ALL non-steroidal anti-inflammatory drugs (NSAIDs) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an 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:

Module	Clinical Criteria for Approval
	A. The patient's medication history includes ONE immunosuppressant used in treatment of AOSD (i.e., methotrexate, cyclosporine, azathioprine) AND ONE of the following: 1. The patient had an inadequate response to ONE immunosuppressant used in treatment of AOSD (i.e., methotrexate, cyclosporine, azathioprine) **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over immunosuppressants used in treatment of AOSD (i.e., methotrexate, cyclosporine, azathioprine) **OR** B. The patient has an intolerance or hypersensitivity to ONE immunosuppressant used in treatment of AOSD (i.e., methotrexate, cyclosporine, azathioprine) **OR** C. The patient has an FDA labeled contraindication to ALL immunosuppressants used in treatment of AOSD (i.e., methotrexate, cyclosporine, azathioprine) **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that immunosuppressants used in treatment of AOSD (i.e., methotrexate, cyclosporine, 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** H. The patient has a diagnosis of gout flares AND ALL of the following: 1. The patient has experienced greater than or equal to 3 flares in the past 12 months **AND** 2. ONE of the following: A. The patient's medication history includes ONE non-steroidal anti-inflammatory drug (NSAID) AND ONE of the following: 1. The patient had an inadequate response to ONE non-steroidal anti-inflammatory drug (NSAID) **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over non-steroidal anti-inflammatory drugs (NSAIDs) **OR** B. The patient has an intolerance or hypersensitivity to ONE non-steroidal anti-inflammatory drug (NSAID) **OR** C. The patient has an FDA labeled contraindication to ALL non-steroidal anti-inflammatory drugs (NSAIDs) **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that non-steroidal anti-inflammatory drugs (NSAIDs) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction,

Module	Clinical Criteria for Approval
	decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. ONE of the following: A. The patient's medication history includes colchicine AND ONE of the following: 1. The patient had an inadequate response to colchicine **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over colchicine **OR** B. The patient has an intolerance or hypersensitivity to colchicine **OR** C. The patient has an FDA labeled contraindication to colchicine **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 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 **AND** 4. Repeated courses of corticosteroids are not appropriate for the patient **OR** I. The patient has another FDA approved indication for the requested agent **OR** J. The patient has another indication that is supported in compendia for the requested agent **AND** 2. If the patient has an FDA approve indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, pediatrician, rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 12 weeks for gout flares; 12 months for all other diagnoses 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:

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

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly
Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)

Contraindicated as Concomitant Therapy
Bimzelx (bimekizumab-bkzx)
Cibinqo (abrocitinib)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Litfulo (ritlecitinib)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tysabri (natalizumab)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)

Contraindicated as Concomitant Therapy
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)
Zymfentra (infliximab-dyyb)

• Program Summary: Multiple Sclerosis

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
624040700003	Aubagio	teriflunomide tab	14 MG; 7 MG	30	Tablets	30	DAYS				
6240306045F8	Avonex	interferon beta-	30 MCG/0.5 ML	4	Syringes	28	DAYS				
6240306045F5	Avonex pen	interferon beta-	30 MCG/0.5 ML	4	Pens	28	DAYS				
62405550006520	Bafiertam	Monomethyl Fumarate Capsule Delayed Release	95 MG	120	Capsules	30	DAYS				
624030605064	Betaseron	Interferon Beta- ; interferon beta-	0.3 MG	14	Vials	28	DAYS	50419052401; 50419052435			
6240003010E520	Copaxone ; Glatopa	Glatiramer Acetate Soln Prefilled Syringe 20 MG/ML	20 MG/ML	30	Syringes	30	DAYS				
6240003010E540	Copaxone ; Glatopa	Glatiramer Acetate Soln Prefilled Syringe 40 MG/ML	40 MG/ML	12	Syringes	28	DAYS				
624030605064	Extavia	Interferon Beta- ; interferon beta-	0.3 MG	15	Vials	30	DAYS	00078056912; 00078056961; 00078056999			
624070251001	Gilenya	fingolimod hcl cap	0.25 MG; 0.5 MG	30	Capsules	30	DAYS				
6240506500D520	Kesimpta	Ofatumumab Soln Auto-Injector	20 MG/0.4 ML	1	Syringe	28	DAYS				
6240101500B744	Mavenclad	Cladribine Tab Therapy Pack 10 MG (10 Tabs)	10 MG	20	Tablets	301	DAYS				
6240101500B718	Mavenclad	Cladribine Tab Therapy Pack 10 MG (4 Tabs)	10 MG	8	Tablets	301	DAYS				
6240101500B722	Mavenclad	Cladribine Tab Therapy Pack 10 MG (5 Tabs)	10 MG	10	Tablets	301	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6240101500B726	Mavenclad	Cladribine Tab Therapy Pack 10 MG (6 Tabs)	10 MG	12	Tablets	301	DAYS				
6240101500B732	Mavenclad	Cladribine Tab Therapy Pack 10 MG (7 Tabs)	10 MG	14	Tablets	301	DAYS				
6240101500B736	Mavenclad	Cladribine Tab Therapy Pack 10 MG (8 Tabs)	10 MG	8	Tablets	301	DAYS				
6240101500B740	Mavenclad	Cladribine Tab Therapy Pack 10 MG (9 Tabs)	10 MG	9	Tablets	301	DAYS				
62407070200330	Mayzent	Siponimod Fumarate Tab	1 MG	30	Tablets	30	DAYS				
62407070200320	Mayzent	Siponimod Fumarate Tab 0.25 MG (Base Equiv)	0.25 MG	120	Tablets	30	DAYS				
62407070200340	Mayzent	Siponimod Fumarate Tab 2 MG (Base Equiv)	2 MG	30	Tablets	30	DAYS				
6240707020B710	Mayzent starter pack	Siponimod Fumarate Tab	0.25 MG	7	Tablets	180	DAYS				
6240707020B720	Mayzent starter pack	Siponimod Fumarate Tab 0.25 MG (12) Starter Pack	0.25 MG	12	Tablets	180	DAYS				
6240307530E521	Plegridy	Peginterferon Beta-	125 MCG/0.5 ML	2	Syringes	28	DAYS				
6240307530D220	Plegridy	Peginterferon Beta-1a Soln Pen-injector 125 MCG/0.5ML	125 MCG/0.5 ML	2	Pens	28	DAYS				
6240307530E520	Plegridy	Peginterferon Beta-1a Soln Prefilled Syringe 125 MCG/0.5ML	125 MCG/0.5 ML	2	Syringes	28	DAYS				
6240307530D250	Plegridy starter pack	Peginterferon Beta-1a Soln Pen-inj 63 & 94 MCG/0.5ML Pack	63 & 94 MCG/0.5 ML	1	Kit	180	DAYS				
6240307530E550	Plegridy starter pack	Peginterferon Beta-1a Soln Pref Syr 63 & 94 MCG/0.5ML Pack	63 & 94 MCG/0.5 ML	1	Kit	180	DAYS				
62407060000320	Ponvory	Ponesimod Tab	20 MG	30	Tablets	30	DAYS				
6240706000B720	Ponvory 14-day starter pa	Ponesimod Tab Starter Pack	2-3-4-5-6-7-8-9 & 10 MG	14	Tablets	180	DAYS				
6240306045E520	Rebif	Interferon Beta-1a Soln Pref Syr 22 MCG/0.5ML (12MU/ML)	22 MCG/0.5 ML	12	Syringes	28	DAYS				
6240306045E540	Rebif	Interferon Beta-1a Soln Pref Syr 44 MCG/0.5ML (24MU/ML)	44 MCG/0.5 ML	12	Syringes	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6240306045D520	Rebif rebidose	Interferon Beta-1a Soln Auto-Inj 22 MCG/0.5ML (12MU/ML)	22 MCG/0.5 ML	12	Syringes	28	DAYS				
6240306045D540	Rebif rebidose	Interferon Beta-1a Soln Auto-inj 44 MCG/0.5ML (24MU/ML)	44 MCG/0.5 ML	12	Syringes	28	DAYS				
6240306045E560	Rebif titration pack	Interferon Beta-1a Pref Syr 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6X8.8 & 6X22 MCG	1	Kit	180	DAYS				
6240306045E560	Rebif titration pack	Interferon Beta-1a Pref Syr 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6X8.8 & 6X22 MCG	1	Kit	180	DAYS				
624070252072	Tascenso odt	fingolimod lauryl sulfate tablet disintegrating	0.25 MG; 0.5 MG	30	Tablets	30	DAYS				
62405525006520	Tecfidera	Dimethyl Fumarate Capsule Delayed Release 120 MG	120 MG	56	Capsules	180	DAYS				
62405525006540	Tecfidera	Dimethyl Fumarate Capsule Delayed Release 240 MG	240 MG	60	Capsules	30	DAYS				
6240552500B320	Tecfidera starter pack	dimethyl fumarate capsule dr starter pack	120 & 240 MG	1	Kit	180	DAYS				
62405530006540	Vumerity	Diroximel Fumarate Capsule Delayed Release 231 MG	231 MG	120	Capsules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Mavenclad	**TARGET AGENT(S) - Preferred agents are the MN Medicaid Preferred Drug List (PDL) preferred drugs** **Preferred Agents** **Avonex®** (interferon beta-1a) **Betaseron®** (interferon beta-1b) **Copaxone®** 20 mg/mL (glatiramer) -a **dimethyl fumarate** **fingolimod** **Rebif®** (interferon beta-1a) **teriflunomide** **Nonpreferred Agents** **Aubagio®** (teriflunomide) **Bafiertam™** (monomethyl fumarate) **Copaxone®** 40 mg/mL (glatiramer) -a **dimethyl fumarate Starter Pack** **Extavia®** (interferon beta-1b)Glatiramer 20 mg/mL **Gilenya®** (fingolimod) -a **Glatiramer 40 mg/mL**

Module	Clinical Criteria for Approval
	Glatopa® (glatiramer) -a **Kesimpta®** (ofatumumab) **Mavenclad®** (cladribine) **Mayzent®** (siponimod) **Plegridy®** (peginterferon beta-1a) **Ponvory™** (ponesimod) **Tecfidera®** (dimethyl fumarate) -a **Tascenso ODT™** (fingolimod) **Vumerity®** (diroximel fumarate) a -generic available

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

Initial Evaluation

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

1. ONE of the following:
    - A. Information has been provided that the patient has been treated with the requested agent within the past 90 days **OR**
    - B. The prescriber states the patient has been treated with the requested agent within the past 90 days AND the patient is at risk if therapy is changed **OR**
    - C. The patient has ONE of the following relapsing forms of multiple sclerosis (MS):
        1. Relapsing-remitting disease (RRMS)
        2. Active secondary progressive disease (SPMS) **AND**
2. ONE of the following:
    - A. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following:
        1. The patient is currently being treated with the requested agent as indicated by ALL of the following:
            - A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
            - B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
            - C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
        2. The patient's medication history includes two preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) AND ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient had an inadequate response to two preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) **OR** B. The prescriber has submitted an evidence-based and peer reviewed clinical practice guideline supporting the use of the requested agent over the preferred agent(s) **OR** 3. The patient has an intolerance or hypersensitivity to two preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** 4. The patient has an FDA labeled contraindication to ALL preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** 5. The prescriber has provided information that the required preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 6. The prescriber has provided information supporting the use of the non-preferred agent over the preferred agent(s) **OR** B. The patient has been previously treated with the requested agent AND BOTH of the following: 1. The prescriber has provided the number of courses the patient has completed (one course consists of 2 cycles of 4-5 days each) **AND** 2. The patient has NOT completed 2 courses of the requested agent (one course consists of 2 cycles of 4-5 days each) **AND** 3. A complete CBC with differential including lymphocyte count has been performed **AND** 4. The lymphocyte count is within normal limits **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (i.e., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. ONE of the following: A. The patient will NOT be using the requested agent with an additional disease modifying agent (DMA) for the requested indication **OR** B. BOTH of the following: 1. The patient is currently using the requested agent **AND** 2. Information has been provided supporting the use of the additional DMA (e.g., relapse between cycles) **AND** 7. ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 8. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 36 weeks for new starts OR if patient is currently taking the requested agent, approve for remainder of the annual course (1 course consists of 2 cycles of 4-5 days) NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria **Renewal Evaluation** **Mavenclad (cladribine)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND**

Module	Clinical Criteria for Approval
	2. The patient has had clinical benefit with the requested agent **AND** 3. A complete CBC with differential including lymphocyte count has been performed **AND** 4. The patient has a lymphocyte count of at least 800 cells/µL **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (i.e., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. ONE of the following: A. The patient will NOT be using the requested agent in combination with an additional disease modifying agent (DMA) for the requested indication **OR** B. Information has been provided supporting the use of the additional DMA (e.g., relapse between cycles) **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 8. It has been at least 35 weeks but not more than 67 weeks since the last dose of the requested agent **AND** 9. BOTH of the following: A. The prescriber has provided the number of courses the patient has completed (one course consists of 2 cycles of 4-5 days each) **AND** B. The patient has NOT completed 2 courses with the requested agent (one course consists of 2 cycles of 4-5 days) **Length of Approval:** 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria
MS Agents other than Mavenclad	**TARGET AGENT(S) - Preferred agents are the MN Medicaid Preferred Drug List (PDL) preferred drugs** **Preferred Agents** **Avonex®** (interferon beta-1a) **Betaseron®** (interferon beta-1b) **Copaxone®** 20 mg/mL (glatiramer) -a **dimethyl fumarate** **fingolimod** **Rebif®** (interferon beta-1a) **teriflunomide** **Nonpreferred Agents** **Aubagio®** (teriflunomide) **Bafiertam™** (monomethyl fumarate) **Copaxone®** 40 mg/mL (glatiramer) -a **dimethyl fumarate Starter Pack** **Extavia®** (interferon beta-1b) **Glatiramer 20 mg/mL** **Gilenya®** (fingolimod) -a **Glatiramer 40 mg/mL** **Glatopa®** (glatiramer) -a **Kesimpta®** (ofatumumab) **Mavenclad®** (cladribine) **Mayzent®** (siponimod) **Plegridy®** (peginterferon beta-1a) **Ponvory™** (ponesimod) **Tecfidera®** (dimethyl fumarate) -a **Tascenso ODT™** (fingolimod)

Module	Clinical Criteria for Approval

Vumerity® (diroximel fumarate)
a -generic available

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

Initial Evaluation

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

1. ONE of the following:
    - A. Information has been provided that the patient has been treated with the requested agent within the past 90 days **OR**
    - B. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR**
    - C. The patient has a diagnosis of a relapsing form of MS AND ALL of the following:
        1. The patient has an FDA labeled indication for the requested agent **AND**
        2. ONE of the following:
            - A. The patient has a diagnosis of clinically isolated syndrome (CIS) AND ALL of the following:
                1. The patient had a single event that lasted at least 24 hours **AND**
                2. The event was not due to fever or infection **AND**
                3. The patient has MS-like brain lesion(s) confirmed by magnetic resonance imaging (MRI) **OR**
            - B. The patient has a diagnosis of relapsing remitting multiple sclerosis (RRMS) or secondary progressive multiple sclerosis (SPMS) **AND**
        3. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following:
            - A. The patient is currently being treated with the requested agent as indicated by ALL of the following:
                1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
                2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
                3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
            - B. The patient's medication history includes two preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) AND ONE of the following:

Module	Clinical Criteria for Approval
	1. The patient had an inadequate response to two preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) **OR** 2. The prescriber has submitted an evidence-based and peer reviewed clinical practice guideline supporting the use of the requested agent over the preferred agent(s) **OR** C. The patient has an intolerance or hypersensitivity to two preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** D. The patient has an FDA labeled contraindication to ALL preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** E. The prescriber has provided information that the required preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** F. The prescriber has provided information supporting the use of the non-preferred agent over the preferred agent(s) **AND** 4. If the requested agent is Aubagio (teriflunomide), the prescriber has obtained transaminase and bilirubin levels within 6 months prior to initiating treatment **AND** 5. If the requested agent is Gilenya (fingolimod) or Tascenso ODT (fingolimod) the prescriber has performed an electrocardiogram within 6 months prior to initiating treatment **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (i.e., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. ONE of the following: A. The patient will NOT be using the requested agent in combination with an additional disease modifying agent (DMA) for the requested indication **OR** B. The patient will be using the requested agent in combination with another DMA used for the treatment of the requested indication AND BOTH of the following: 1. The requested agent will be used in combination with Mavenclad (cladribine) **AND** 2. Information has been provided supporting the use of the requested agent in combination with Mavenclad (e.g., relapse between cycles of Mavenclad) **Length of Approval:** 12 months. **NOTE:** For agents requiring a starter dose for initial use, the starter dose can be approved for the FDA labeled starting dose and the maintenance dose can be approved for the remainder of 12 months. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria **Renewal Evaluation** **Target agent(s) (excluding Mavenclad [cladribine])** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (i.e., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following: A. The patient will NOT be using the requested agent in combination with an additional disease modifying agent (DMA) for the requested indication **OR**

Module	Clinical Criteria for Approval
	B. The patient will be using the requested agent in combination with another DMA used for the requested indication AND BOTH of the following: 1. The requested agent will be used in combination with Mavenclad cladribine) **AND** 2. Information has been provided supporting the use of the requested agent in combination with Mavenclad (e.g., relapse between cycles of Mavenclad) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **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 - All agents excluding Mavenclad	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: 12 months. **NOTE**: For agents requiring a starter dose for initial use, the starter dose can be approved for the FDA labeled starting dose and the maintenance dose can be approved for the remainder of 12 months.
QL with PA Mavenclad	**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. BOTH of the following A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) cannot be achieved with a lower quantity of packs and a higher pack size (e.g., two 10 tablet packs instead of four 5 tablet packs) that does not exceed the program quantity limit **Length of Approval:** Initial: 36 weeks for new starts OR if patient is currently taking the requested agent, approve for remainder of the annual course (1 course consists of 2 cycles of 4-5 days); Renewal: 3 months

CLASS AGENTS

Class	Class Drug Agents
Class Ia antiarrhythmics	
Class Ia antiarrhythmics	NORPACE*Disopyramide Phosphate Cap
Class Ia antiarrhythmics	Pronestyl (procainamide)
Class Ia antiarrhythmics	quinidine

Class	Class Drug Agents
Class III antiarrhythmics	
Class III antiarrhythmics	BETAPACE*Sotalol HCl Tab
Class III antiarrhythmics	Cordarone, Pacerone (amiodarone)
Class III antiarrhythmics	CORVERT*Ibutilide Fumarate Inj
Class III antiarrhythmics	MULTAQ*Dronedarone HCl Tab
Class III antiarrhythmics	TIKOSYN*Dofetilide Cap
MS Disease Modifying Agents drug class: CD20 monoclonal antibody	
MS Disease Modifying Agents drug class: CD20 monoclonal antibody	BRIUMVI*ublituximab-xiiy soln for iv infusion
MS Disease Modifying Agents drug class: CD20 monoclonal antibody	KESIMPTA*Ofatumumab Soln Auto-Injector
MS Disease Modifying Agents drug class: CD20 monoclonal antibody	OCREVUS*Ocrelizumab Soln For IV Infusion
MS Disease Modifying Agents drug class: CD52 monoclonal antibody	
MS Disease Modifying Agents drug class: CD52 monoclonal antibody	LEMTRADA*Alemtuzumab IV Inj
MS Disease Modifying Agents drug class: Fumarates	
MS Disease Modifying Agents drug class: Fumarates	BAFIERTAM*Monomethyl Fumarate Capsule Delayed Release
MS Disease Modifying Agents drug class: Fumarates	TECFIDERA*Dimethyl Fumarate Capsule Delayed Release
MS Disease Modifying Agents drug class: Fumarates	VUMERITY*Diroximel Fumarate Capsule Delayed Release
MS Disease Modifying Agents drug class: Glatiramer	
MS Disease Modifying Agents drug class: Glatiramer	COPAXONE*Glatiramer Acetate Soln Prefilled Syringe
MS Disease Modifying Agents drug class: Glatiramer	GLATOPA*Glatiramer Acetate Soln Prefilled Syringe
MS Disease Modifying Agents drug class: IgG4k monoclonal antibody	
MS Disease Modifying Agents drug class: IgG4k monoclonal antibody	TYSABRI*Natalizumab for IV Inj Conc
MS Disease Modifying Agents drug class: Interferons	
MS Disease Modifying Agents drug class: Interferons	AVONEX*Interferon beta-1a injection
MS Disease Modifying Agents drug class: Interferons	BETASERON*Interferon beta-1b injection
MS Disease Modifying Agents drug class: Interferons	EXTAVIA*Interferon beta-1b injection
MS Disease Modifying Agents drug class: Interferons	PLEGRIDY*Peginterferon beta-1a injection
MS Disease Modifying Agents drug class: Interferons	REBIF*Interferon Beta-
MS Disease Modifying Agents drug class: Purine antimetabolite	
MS Disease Modifying Agents drug class: Purine antimetabolite	MAVENCLAD*Cladribine Tab Therapy Pack
MS Disease Modifying Agents drug class: Pyrimidine synthesis inhibitor	
MS Disease Modifying Agents drug class: Pyrimidine synthesis inhibitor	AUBAGIO*Teriflunomide Tab

Class	Class Drug Agents
MS Disease Modifying Agents drug class: Sphingosine 1-phosphate (SIP) receptor modulator	
MS Disease Modifying Agents drug class: Sphingosine 1-phosphate (SIP) receptor modulator	GILENYA*Fingolimod HCl Cap
MS Disease Modifying Agents drug class: Sphingosine 1-phosphate (SIP) receptor modulator	MAYZENT*Siponimod Fumarate Tab
MS Disease Modifying Agents drug class: Sphingosine 1-phosphate (SIP) receptor modulator	PONVORY*Ponesimod Tab
MS Disease Modifying Agents Drug Class: Sphingosine 1-phosphate (SIP) receptor modulator	
MS Disease Modifying Agents Drug Class: Sphingosine 1-phosphate (SIP) receptor modulator	TASCENSO*fingolimod lauryl sulfate tablet disintegrating
MS Disease Modifying Agents drug class: Sphingosine 1-phosphate (SIP) receptor modulator	
MS Disease Modifying Agents drug class: Sphingosine 1-phosphate (SIP) receptor modulator	ZEPOSIA*Ozanimod capsule

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Examples of Contraindicated Concomitant Disease Modifying Agents (DMAs) **Aubagio** (teriflunomide)* **Avonex** (interferon β-1a) **Bafiertam** (monomethyl fumarate) **Betaseron** (interferon β-1b) **Briumvi** (ublituximab-xiiy) **Copaxone** (glatiramer)* dimethyl fumarate **Extavia** (interferon β-1b) fingolimod **Gilenya** (fingolimod)* **Glatopa** (glatiramer) glatiramer **Kesimpta** (ofatumumab) **Lemtrada** (alemtuzumab) **Mavenclad** (cladribine) **Mayzent** (siponimod) **Ocrevus** (ocrelizumab) **Plegridy** (peginterferon β-1a) **Ponvory** (ponesimod) **Rebif** (interferon β-1a) **Tascenso ODT** (fingolimod) **Tecfidera** (dimethyl fumarate)* teriflunomide **Tysabri** (natalizumab) **Vumerity** (diroximel fumarate) **Zeposia** (ozanimod) * -generic available

● Program Summary: Ophthalmic Immunomodulator

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
86720020002040	Cequa	Cyclosporine (Ophth) Soln 0.09% (PF)	0.09 %	60	Vials	30	DAYS			04-01-2019	
86720020001630	Cyclosporine in klarity; Verkazia	Cyclosporine (Ophth) Emulsion 0.1%	0.1 %	120	Vials	30	DAYS				
86720020001620	Restasis	cyclosporine (ophth) emulsion	0.05 %	60	Vials	30	DAYS	00023916330; 00023916360; 00378876058; 00378876091; 10702080803; 10702080806; 50090124200; 50090447600; 60505620201; 60505620202; 68180021430; 68180021460		06-01-2018	
86720020001620	Restasis; Restasis multidose	cyclosporine (ophth) emulsion	0.05 %	1	Bottle	30	DAYS	00023530105; 50090447600		04-01-2017	
86720020002043	Vevye	cyclosporine (ophth) soln	0.1 %	1	Bottle	30	DAYS				
86734050002020	Xiidra	Lifitegrast Ophth Soln 5%	5 %	60	Vials	30	DAYS			01-01-2017	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Verkazia (cyclosporine)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of vernal keratoconjunctivitis (VKC) AND BOTH of the following: 1. ONE of the following: A. The patient's medication history includes combination of a topical ophthalmic mast cell stabilizer AND an antihistamine used in the treatment of VKC AND ONE of the following: 1. The patient has had an inadequate response to the combination of a topical ophthalmic mast cell stabilizer AND an antihistamine used in the treatment of VKC **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the combination of a topical ophthalmic mast cell stabilizer AND an antihistamine used in the treatment of VKC **OR** B. The patient has an intolerance or hypersensitivity to combination of a topical ophthalmic mast cell stabilizer AND an antihistamine used in the treatment of VKC **OR** C. The patient has an FDA labeled contraindication to ALL topical ophthalmic mast cell stabilizers AND antihistamines **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 ALL topical ophthalmic mast cell stabilizers AND antihistamines cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. ONE of the following: A. The patient's medication history includes a topical ophthalmic corticosteroid used in the treatment of VKC AND ONE of the following: 1. The patient has had an inadequate response to a topical ophthalmic corticosteroid used in the treatment of VKC **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over a topical ophthalmic corticosteroid used in the treatment of VKC **OR** B. The patient has an intolerance or hypersensitivity to topical ophthalmic corticosteroid therapy **OR** C. The patient has an FDA labeled contraindication to ALL topical ophthalmic corticosteroids **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL topical ophthalmic corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has another FDA approved indication for the requested agent **AND** 2. The patient will NOT be using the requested agent in combination with another ophthalmic immunomodulator agent (e.g., Restasis, Cequa, Xiidra) or Tyrvaya **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 4 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met:

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

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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