MHCP PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: July 1, 2024 Notification Posted: June 17, 2024

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

• Program Summary: Fabhalta (iptacopan)

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
85807535200130	Fabhalta	iptacopan 200 mg capsules	200 MG	60	Capsules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) AND ALL of the following: 1. The diagnosis was confirmed by flow cytometry with at least 2 independent flow cytometry reagents on at least 2 cell lineages (e.g., RBCs and WBCs) demonstrating that the patient's peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI) – linked proteins (lab tests required) **AND** 2. The patient's hemoglobin is less than 10 g/dL (lab tests required) **AND** 3. If the patient has NOT been previously treated with complement inhibitor therapy (e.g., Empaveli [pegcetacoplan], Soliris [eculizumab], or Ultomiris [ravulizumab-cwvz]) BOTH of the following (lab tests required): A. The patient has red blood cell clone size greater than or equal to 10% **AND** B. The patient has a lactate dehydrogenase (LDH) level greater than 1.5 times the upper limit of normal (ULN) **AND** 4. ONE of the following: A. The patient's medication history includes Empaveli (pegcetacoplan), Soliris (eculizumab), OR Ultomiris (ravulizumab-cwvz) AND ONE of the following: 1. Empaveli (pegcetacoplan), Soliris (eculizumab), or Ultomiris (ravulizumab-cwvz) 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 Empaveli (pegcetacoplan), Soliris (eculizumab), AND Ultomiris (ravulizumab-cwvz) **OR** B. The patient has an intolerance or hypersensitivity to Empaveli (pegcetacoplan), Soliris (eculizumab) OR Ultomiris (ravulizumab-cwvz) **OR** C. The patient has an FDA labeled contraindication to Empaveli (pegcetacoplan), Soliris (eculizumab), AND Ultomiris (ravulizumab-cwvz) **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. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **OR** E. The prescriber has provided documentation that Empaveli (pegcetacoplan), Soliris (eculizumab), AND Ultomiris (ravulizumab-cwvz) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

Module	Clinical Criteria for Approval
	B. The patient has another FDA labeled indication for the requested agent **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient will NOT be using the requested agent in combination with Empaveli (pegcetacoplan), Soliris (eculizumab), or Ultomiris (ravulizumab-cwvz) for the requested indication **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had improvements or stabilization with the requested agent (e.g., decreased requirement of RBC transfusions, stabilization/improvement of hemoglobin, reduction of lactate dehydrogenase (LDH), stabilization/improvement of symptoms) (medical records required) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient will NOT be using the requested agent in combination with Empaveli (pegcetacoplan), Soliris (eculizumab), or Ultomiris (ravulizumab-cwvz) **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 **Length of Approval**: Initial approval up to 6 months. Renewal approval up to 12 months.

• Program Summary: Xphozah (tenapanor)

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

The BCBS MN Step Therapy Supplement also applies to this program for Medicaid.

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
30903260600325	Xphozah	tenapanor hcl tab	20 MG	60	Tablets	30	DAYS			02-15-2024	
30903260600330	Xphozah	tenapanor hcl tab	30 MG	60	Tablets	30	DAYS			02-15-2024	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Initial Evaluation

PREFERRED PHOSPHATE BINDERS
calcium acetate capsule calcium acetate tablet Renvela powder pack Renvela tablet sevelamer carbonate tablet

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

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

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

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

   B. BOTH of the following:
      1. ONE of the following:
         A. The patient has a diagnosis of chronic kidney disease (CKD) AND ALL of the following:
            1. The patient is on dialysis **AND**
            2. The patient has a phosphorus level of at least 5.5 mg/dL **AND**
            3. ONE of the following:
               A. BOTH of the following:
                  1. The patient's medication history includes a preferred phosphate binder AND ONE of the following:
                     A. The preferred phosphate binder 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

Module	Clinical Criteria for Approval
	supporting the use of the requested agent over preferred phosphate binders **AND** 2. The patient will be using the requested agent in combination with phosphate binder therapy **OR** B. The patient is intolerant or has a hypersensitivity to preferred phosphate binder therapy **OR** C. The patient has an FDA labeled contraindication to ALL preferred phosphate binders **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. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **OR** E. The prescriber has provided documentation that ALL preferred phosphate binders cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has another FDA labeled indication for the requested agent and route of administration **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 2. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [NOTE: Patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. ONE of the following: A. The patient is using the requested agent in combination with phosphate binder therapy **OR** B. The patient is intolerant or has a hypersensitivity to phosphate binder therapy **OR** C. The patient has an FDA labeled contraindication to ALL phosphate binders **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months

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

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	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. There is support for therapy with a higher dose for the requested indication **Length of Approval**: Initial - up to 6 months; Renewal - up to 12 months

POLICIES REVISED

• Program Summary: Agamree (vamorolone), Emflaza (deflazacort) [*f.k.a.* Emflaza deflazacort)

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

The BCBS MN Step Therapy Supplement also applies to this program for Medicaid.

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
22100075001820	Agamree	vamorolone oral susp	40 MG/ML	3	Bottles	30	DAYS				
22100017000350	Emflaza	Deflazacort Tab 18 MG	18 MG	30	Tablets	30	DAYS				
22100017000340	Emflaza	Deflazacort Tab 6 MG	6 MG	60	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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

Module	Clinical Criteria for Approval
	1. The patient has been treated with the requested agent (starting on samples is not approvable) with the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. ALL of the following: 1. ONE of the following: A. The patient has a diagnosis of Duchenne Muscular Dystrophy confirmed by genetic analysis (i.e., dystrophin deletion or duplication mutation) (genetic test required) **OR** B. The patient has another FDA labeled indication for the requested agent and route of administration **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for the use of the requested agent for the patient's age for the requested indication **AND** 3. ONE of the following: A. The patient's medication history includes generic prednisone (or prednisolone) AND ONE of the following: 1. The patient has had an inadequate response generic prednisone (or prednisolone) **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over generic prednisone (or prednisolone) **OR** B. The prescriber has provided information that the patient has an intolerance or hypersensitivity to generic prednisone (or prednisolone) that is NOT expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to generic prednisone (or prednisolone) **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that generic prednisone (or prednisolone) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., pediatric neurologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose based on the patient's weight **Length of Approval:** 6 months for Agamree, 12 months for Emflaza NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria.

Module	Clinical Criteria for Approval
	Renewal Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [NOTE: Patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had improvements or stabilization with the requested agent (e.g., slowed disease progression, improved strength, timed motor function, pulmonary function; reduced need for scoliosis surgery) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., pediatric neurologist), 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 **AND** 5. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose based on the patient's weight **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested agent strength does not have a program quantity limit **OR** 3. The request agent is Emflaza and ONE of the following: A. The requested agent is Emflaza SUSPENSION **OR** B. BOTH of the following: 1. The requested quantity (dose) exceeds the program quantity limit **AND** 2. The requested quantity (dose) cannot be achieved with a lower quantity of any combination of the four Emflaza tablet strengths **OR** 4. 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 **Approval Length:** up to 12 months

• Program Summary: Antidepressant

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
58300040100310		Bupropion HCl Tab 100 MG	100 MG	120	Tablets	30	DAYS				
58300040100305		Bupropion HCl Tab 75 MG	75 MG	60	Tablets	30	DAYS				
58160020100120		Citalopram Hydrobromide Cap	30 MG	30	Capsules	30	DAYS				
581600201020		citalopram hydrobromide oral soln	10 MG/5ML	600	mLs	30	DAYS				
581800200075		desvenlafaxine tab er	100 MG ; 50 MG	30	Tablets	30	DAYS				
58180025106740		Duloxetine HCl Enteric Coated Pellets Cap 40 MG (Base Eq)	40 MG	90	Capsules	30	DAYS				
581600341020		escitalopram oxalate soln	5 MG/5ML	600	mLs	30	DAYS				
58160040006530		Fluoxetine HCl Cap Delayed Release 90 MG	90 MG	4	Capsules	28	DAYS				
58160040002020		Fluoxetine HCl Solution 20 MG/5ML	20 MG/5ML	600	mLs	30	DAYS				
58160040000310		Fluoxetine HCl Tab 10 MG	10 MG	30	Tablets	30	DAYS				
58160040000320		Fluoxetine HCl Tab 20 MG	20 MG	120	Tablets	30	DAYS				
58160040000360		Fluoxetine HCl Tab 60 MG	60 MG	30	Tablets	30	DAYS				
581600451070		fluvoxamine maleate cap er	100 MG ; 150 MG	60	Capsules	30	DAYS				
58160045100330		Fluvoxamine Maleate Tab 100 MG	100 MG	90	Tablets	30	DAYS				
58160045100310		Fluvoxamine Maleate Tab 25 MG	25 MG	30	Tablets	30	DAYS				
58160045100320		Fluvoxamine Maleate Tab 50 MG	50 MG	30	Tablets	30	DAYS				
58160070100130		Sertraline HCl Cap	150 MG	30	Capsules	30	DAYS				
58160070100140		Sertraline HCl Cap	200 MG	30	Capsules	30	DAYS				
58180090057520		Venlafaxine Besylate Tab ER	112.5 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
581800901003		venlafaxine hcl tab	100 MG ; 25 MG ; 37.5 MG ; 50 MG ; 75 MG	90	Tablets	30	DAYS				
58180090107510		Venlafaxine HCl Tab ER ; venlafaxine hcl tab er	37.5 MG	30	Tablets	30	DAYS				
58180090107530		Venlafaxine HCl Tab ER 24HR 150 MG (Base Equivalent)	150 MG	30	Tablets	30	DAYS				
58180090107540		Venlafaxine HCl Tab ER 24HR 225 MG (Base Equivalent)	225 MG	30	Tablets	30	DAYS				
58180090107520		Venlafaxine HCl Tab ER 24HR 75 MG (Base Equivalent)	75 MG	90	Tablets	30	DAYS				
583000402075	Aplenzin	bupropion hbr tab er	174 MG ; 348 MG ; 522 MG	30	Tablets	30	DAYS				
58999902300420	Auvelity	Dextromethorphan HBr-Bupropion HCl Tab ER	45-105 MG	60	Tablets	30	DAYS				
581600201003	Celexa	citalopram hydrobromide tab	10 MG ; 20 ; 20 MG ; 40 MG	30	Tablets	30	DAYS				
58180025106720	Cymbalta	Duloxetine HCl Enteric Coated Pellets Cap 20 MG (Base Eq)	20 MG	60	Capsules	30	DAYS				
58180025106730	Cymbalta	Duloxetine HCl Enteric Coated Pellets Cap 30 MG (Base Eq)	30 MG	60	Capsules	30	DAYS				
58180025106750	Cymbalta	Duloxetine HCl Enteric Coated Pellets Cap 60 MG (Base Eq)	60 ; 60 MG	60	Capsules	30	DAYS				
58180090107050	Effexor xr	Venlafaxine HCl Cap ER ; venlafaxine hcl cap er	150 MG	30	Capsules	30	DAYS				
58180090107020	Effexor xr	Venlafaxine HCl Cap ER 24HR 37.5 MG (Base Equivalent)	37.5 MG	30	Capsules	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
58180090107030	Effexor xr	Venlafaxine HCl Cap ER 24HR 75 MG (Base Equivalent)	75 MG	90	Capsules	30	DAYS				
581800501070	Fetzima	levomilnacipran hcl cap er	120 MG ; 20 MG ; 40 MG ; 80 MG	30	Capsules	30	DAYS				
5818005010B6	Fetzima titration pack	levomilnacipran hcl cap er	20 & 40 MG	28	Capsules	180	DAYS				
583000401075	Forfivo xl ; Wellbutrin xl	bupropion hcl tab er	150 ; 150 MG ; 300 ; 300 MG ; 450 MG	30	Tablets	30	DAYS				
581600341003	Lexapro	escitalopram oxalate tab	10 ; 10 MG ; 20 MG ; 5 MG	30	Tablets	30	DAYS				
581600600018	Paxil	paroxetine hcl oral susp	10 MG/5ML	900	mLs	30	DAYS				
58160060000310	Paxil	Paroxetine HCl Tab 10 MG	10 MG	30	Tablets	30	DAYS				
58160060000320	Paxil	Paroxetine HCl Tab 20 MG	20 MG	30	Tablets	30	DAYS				
58160060000330	Paxil	Paroxetine HCl Tab 30 MG	30 MG	60	Tablets	30	DAYS				
58160060000340	Paxil	Paroxetine HCl Tab 40 MG	40 MG	30	Tablets	30	DAYS				
58160060007520	Paxil cr	Paroxetine HCl Tab ER 24HR 12.5 MG	12.5 MG	30	Tablets	30	DAYS				
58160060007530	Paxil cr	Paroxetine HCl Tab ER 24HR 25 MG	25 MG	60	Tablets	30	DAYS				
58160060007540	Paxil cr	Paroxetine HCl Tab ER 24HR 37.5 MG	37.5 MG	60	Tablets	30	DAYS				
58160060300310	Pexeva	Paroxetine Mesylate Tab 10 MG (Base Equiv)	10 MG	30	Tablets	30	DAYS				
58160060300320	Pexeva	Paroxetine Mesylate Tab 20 MG (Base Equiv)	20 MG	30	Tablets	30	DAYS				
58160060300330	Pexeva	Paroxetine Mesylate Tab 30 MG (Base Equiv)	30 MG	60	Tablets	30	DAYS				
58160060300340	Pexeva	Paroxetine Mesylate Tab 40 MG (Base Equiv)	40 MG	30	Tablets	30	DAYS				
581800202075	Pristiq	desvenlafaxine succinate tab er	100 MG ; 25 MG ; 50 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
58160040000110	Prozac	Fluoxetine HCl Cap 10 MG	10 MG	30	Capsules	30	DAYS				
58160040000120	Prozac	Fluoxetine HCl Cap 20 MG	20 MG	120	Capsules	30	DAYS				
58160040000140	Prozac	Fluoxetine HCl Cap 40 MG	40 MG	60	Capsules	30	DAYS				
580300500003	Remeron	mirtazapine tab	15 MG ; 30 MG ; 45 MG ; 7.5 MG	30	Tablets	30	DAYS				
580300500072	Remeron soltab	mirtazapine orally disintegrating tab	15 MG ; 30 MG ; 45 MG	30	Tablets	30	DAYS				
581200931003	Trintellix	vortioxetine hbr tab	10 MG ; 20 MG ; 5 MG	30	Tablets	30	DAYS				
581200881003	Viibryd	vilazodone hcl tab	10 MG ; 20 MG ; 40 MG	30	Tablets	30	DAYS				
581200881064	Viibryd starter pack	vilazodone hcl tab starter kit	10 & 20 MG	1	Kit	180	DAYS				
58120088106410	Viibryd starter pack	Vilazodone HCl Tab Starter Kit 10 (7) & 20 (23) MG	10 & 20 MG	1	Kit	180	DAYS				
583000401074	Wellbutrin sr	Bupropion HCl Tab ER ; bupropion hcl tab er	100 MG ; 150 MG ; 200 MG	60	Tablets	30	DAYS				
58160070101320	Zoloft	Sertraline HCl Oral Concentrate for Solution 20 MG/ML	20 MG/ML	300	mLs	30	DAYS				
58160070100320	Zoloft	Sertraline HCl Tab 100 MG	100 MG	60	Tablets	30	DAYS				
58160070100305	Zoloft	Sertraline HCl Tab 25 MG	25 MG	30	Tablets	30	DAYS				
58160070100310	Zoloft	Sertraline HCl Tab 50 MG	50 MG	30	Tablets	30	DAYS				
58060090000120	Zurzuvae	zuranolone cap	20 MG	28	Capsules	365	DAYS				
58060090000125	Zurzuvae	zuranolone cap	25 MG	28	Capsules	365	DAYS				
58060090000130	Zurzuvae	zuranolone cap	30 MG	14	Capsules	365	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
58060090000120	Zurzuvae	zuranolone cap	20 MG	*Quantity limit is cumulative for the 20mg and 25 mg strengths.			

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Atypical Antipsychotics – Extended Maintenance Agents

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
5925001500E455	Abilify asimtufii	aripiprazole im er susp prefilled syringe	720 MG/2.4ML	1	Syringe	56	DAYS				
5925001500E465	Abilify asimtufii	aripiprazole im er susp prefilled syringe	960 MG/3.2ML	1	Syringe	56	DAYS				
5925001500E4	Abilify asimtufii ; Abilify maintena	aripiprazole im er susp prefilled syringe ; aripiprazole im for er susp prefilled syringe	300 MG ; 400 MG ; 720 MG/2.4ML ; 960 MG/3.2ML	1	Syringe	28	DAYS				
5925001500G2	Abilify maintena	aripiprazole im for extended release susp	300 MG ; 400 MG	1	Vial	28	DAYS				
5925001520E450	Aristada	Aripiprazole Lauroxil IM ER Susp Prefilled Syr 1064 MG/3.9ML	1064 MG/3.9ML	1	Syringe	56	DAYS				
5925001520E420	Aristada	Aripiprazole Lauroxil IM ER Susp Prefilled Syr 441 MG/1.6ML	441 MG/1.6ML	1	Syringe	28	DAYS				
5925001520E430	Aristada	Aripiprazole Lauroxil IM ER Susp Prefilled Syr 662 MG/2.4ML	662 MG/2.4ML	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
5925001520E440	Aristada	Aripiprazole Lauroxil IM ER Susp Prefilled Syr 882 MG/3.2ML	882 MG/3.2ML	1	Syringe	28	DAYS				
5925001520E435	Aristada initio	Aripiprazole Lauroxil IM ER Susp Prefilled Syr 675 MG/2.4ML	675 MG/2.4ML	1	Kit	180	DAYS				
5907005010E670	Invega hafyera	Paliperidone Palmitate ER Susp Pref Syr	1092 MG/3.5ML	1	Syringe	180	DAYS				
5907005010E675	Invega hafyera	Paliperidone Palmitate ER Susp Pref Syr	1560 MG/5ML	1	Syringe	180	DAYS				
5907005010E632	Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 117 MG/0.75ML	117 MG/0.75ML	1	Kit	28	DAYS				
5907005010E635	Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 156 MG/ML	156 MG/ML	1	Kit	28	DAYS				
5907005010E638	Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 234 MG/1.5ML	234 MG/1.5ML	1	Kit	28	DAYS				
5907005010E626	Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 39 MG/0.25ML	39 MG/0.25ML	1	Kit	28	DAYS				
5907005010E629	Invega sustenna	Paliperidone Palmitate ER Susp Pref Syr 78 MG/0.5ML	78 MG/0.5ML	1	Kit	28	DAYS				
5907005010E643	Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 273 MG/0.875ML	273 MG/0.88ML	1	Syringe	84	DAYS				
5907005010E647	Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 410 MG/1.315ML	410 MG/1.32ML	1	Syringe	84	DAYS				
5907005010E651	Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 546 MG/1.75ML	546 MG/1.75ML	1	Syringe	84	DAYS				
5907005010E655	Invega trinza	Paliperidone Palmitate ER Susp Pref Syr 819 MG/2.625ML	819 MG/2.63ML	1	Syringe	84	DAYS				
5907007000E4	Perseris	risperidone subcutaneous for er susp prefilled syr	120 MG ; 90 MG	1	Kit	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
5907007010G2	Risperdal consta	risperidone microspheres for im extended rel susp	12.5 MG ; 25 MG ; 37.5 MG ; 50 MG	2	Vials	28	DAYS				
5907007000G2	Rykindo	risperidone for im extended release suspension	25 MG ; 37.5 MG ; 50 MG	2	Vials	28	DAYS				
5907007000E610	Uzedy	risperidone subcutaneous er susp pref syr	50 MG/0.14ML	1	Syringe	28	DAYS				
5907007000E618	Uzedy	risperidone subcutaneous er susp pref syr	75 MG/0.21ML	1	Syringe	28	DAYS				
5907007000E626	Uzedy	risperidone subcutaneous er susp pref syr	100 MG/0.28ML	1	Syringe	28	DAYS				
5907007000E634	Uzedy	risperidone subcutaneous er susp pref syr	125 MG/0.35ML	1	Syringe	28	DAYS				
5907007000E642	Uzedy	risperidone subcutaneous er susp pref syr	150 MG/0.42ML	1	Syringe	56	DAYS				
5907007000E658	Uzedy	risperidone subcutaneous er susp pref syr	200 MG/0.56ML	1	Syringe	56	DAYS				
5907007000E674	Uzedy	risperidone subcutaneous er susp pref syr	250 MG/0.7ML	1	Syringe	56	DAYS				
59157060101950	Zyprexa relprevv	Olanzapine Pamoate For Extended Rel IM Susp 210 MG (Base Eq)	210 MG	2	Vials	28	DAYS				
59157060101960	Zyprexa relprevv	Olanzapine Pamoate For Extended Rel IM Susp 300 MG (Base Eq)	300 MG	2	Vials	28	DAYS				
59157060101970	Zyprexa relprevv	Olanzapine Pamoate For Extended Rel IM Susp 405 MG (Base Eq)	405 MG	1	Vial	28	DAYS				

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does not have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR**

Module	Clinical Criteria for Approval
	B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. 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) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• Program Summary: Benzodiazepines

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
57100010007205		Alprazolam Orally Disintegrating Tab 0.25 MG	0.25 MG	120	Tablets	30	DAYS				
57100010007210		Alprazolam Orally Disintegrating Tab 0.5 MG	0.5 MG	120	Tablets	30	DAYS				
57100010007215		Alprazolam Orally Disintegrating Tab 1 MG	1 MG	120	Tablets	30	DAYS				
57100010007220		Alprazolam Orally Disintegrating Tab 2 MG	2 MG	90	Tablets	30	DAYS				
57100020100110		Chlordiazepoxide HCl Cap 10 MG	10 MG	120	Capsules	30	DAYS				
57100020100115		Chlordiazepoxide HCl Cap 25 MG	25 MG	120	Capsules	30	DAYS				
57100020100105		Chlordiazepoxide HCl Cap 5 MG	5 MG	120	Capsules	30	DAYS				
62992002200320		Chlordiazepoxide-Amitriptyline Tab 10-25 MG	10-25 MG	180	Tablets	30	DAYS				
62992002200310		Chlordiazepoxide-Amitriptyline Tab 5-12.5 MG	5-12.5 MG	120	Tablets	30	DAYS				
72100010007210		Clonazepam Orally Disintegrating Tab 0.125 MG	0.125 MG	90	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
72100010007215		Clonazepam Orally Disintegrating Tab 0.25 MG	0.25 MG	90	Tablets	30	DAYS				
72100010007220		Clonazepam Orally Disintegrating Tab 0.5 MG	0.5 MG	90	Tablets	30	DAYS				
72100010007230		Clonazepam Orally Disintegrating Tab 1 MG	1 MG	90	Tablets	30	DAYS				
72100010007240		Clonazepam Orally Disintegrating Tab 2 MG	2 MG	60	Tablets	30	DAYS				
57100030100320		Clorazepate Dipotassium Tab 15 MG	15 MG	120	Tablets	30	DAYS				
57100030100305		Clorazepate Dipotassium Tab 3.75 MG	3.75 MG	90	Tablets	30	DAYS				
57100040002001		Diazepam Oral Soln 1 MG/ML	5 MG/5ML	1200	mLs	30	DAYS				
60201005000310		Estazolam Tab 1 MG	1 MG	30	Tablets	30	DAYS				
60201005000320		Estazolam Tab 2 MG	2 MG	30	Tablets	30	DAYS				
60201010100105		Flurazepam HCl Cap 15 MG	15 MG	30	Capsules	30	DAYS				
60201010100110		Flurazepam HCl Cap 30 MG	30 MG	30	Capsules	30	DAYS				
60201025101220		Midazolam HCl Syrup 2 MG/ML (Base Equivalent)	2 MG/ML	10	mLs	30	DAYS				
57100070000105		Oxazepam Cap 10 MG	10 MG	120	Capsules	30	DAYS				
57100070000110		Oxazepam Cap 15 MG	15 MG	120	Capsules	30	DAYS				
57100070000115		Oxazepam Cap 30 MG	30 MG	60	Capsules	30	DAYS				
60201040000305		Triazolam Tab 0.125 MG	0.125 MG	30	Tablets	30	DAYS				
57100010001310	Alprazolam intensol	Alprazolam Conc 1 MG/ML	1 MG/ML	180	mLs	30	DAYS				
57100010007505	Alprazolam xr ; Xanax xr	Alprazolam Tab ER 24HR 0.5 MG	0.5 MG	30	Tablets	30	DAYS				
57100010007510	Alprazolam xr ; Xanax xr	Alprazolam Tab ER 24HR 1 MG	1 MG	30	Tablets	30	DAYS				
57100010007520	Alprazolam xr ; Xanax xr	Alprazolam Tab ER 24HR 2 MG	2 MG	60	Tablets	30	DAYS				
57100010007530	Alprazolam xr ; Xanax xr	Alprazolam Tab ER 24HR 3 MG	3 MG	60	Tablets	30	DAYS				
57100060000305	Ativan	Lorazepam Tab 0.5 MG	0.5 MG	90	Tablets	30	DAYS				
57100060000310	Ativan	Lorazepam Tab 1 MG	1 MG	90	Tablets	30	DAYS				
57100060000315	Ativan	Lorazepam Tab 2 MG	2 MG	150	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
72100030004040	Diastat acudial	Diazepam Rectal Gel Delivery System 10 MG	10 ; 10 MG	2	Twin Pack(s)	30	DAYS				
72100030004060	Diastat acudial	Diazepam Rectal Gel Delivery System 20 MG	20 ; 20 MG	2	Twin Pack(s)	30	DAYS				
72100030004030	Diastat pediatric	Diazepam Rectal Gel Delivery System 2.5 MG	2.5 MG	2	Twin Pack(s)	30	DAYS				
57100040001310	Diazepam intensol	Diazepam Conc 5 MG/ML	5 MG/ML	240	mLs	30	DAYS				
602010280003	Doral	quazepam tab	15 MG	30	Tablets	30	DAYS				
60201040000310	Halcion	Triazolam Tab 0.25 MG	0.25 MG	60	Tablets	30	DAYS				
72100010000305	Klonopin	Clonazepam Tab 0.5 MG	0.5 MG	90	Tablets	30	DAYS				
72100010000310	Klonopin	Clonazepam Tab 1 MG	1 MG	90	Tablets	30	DAYS				
72100010000315	Klonopin	Clonazepam Tab 2 MG	2 MG	60	Tablets	30	DAYS				
57100060001320	Lorazepam intensol	Lorazepam Conc 2 MG/ML	1 MG/0.5ML ; 2 MG/ML	150	mLs	30	DAYS				
5710006000F310	Loreev xr	Lorazepam Cap ER	1 MG	30	Capsules	30	DAYS				
5710006000F315	Loreev xr	Lorazepam Cap ER	1.5 MG	30	Capsules	30	DAYS				
5710006000F320	Loreev xr	Lorazepam Cap ER	2 MG	150	Capsules	30	DAYS				
5710006000F330	Loreev xr	Lorazepam Cap ER	3 MG	90	Capsules	30	DAYS				
72100060002010	Nayzilam	Midazolam Nasal Spray Soln 5 MG/0.1 ML	5 MG/0.1ML	10	Sprays	30	DAYS				
72100007001830	Onfi	Clobazam Suspension 2.5 MG/ML	2.5 MG/ML	480	mLs	30	DAYS				
72100007000310	Onfi	Clobazam Tab 10 MG	10 MG	60	Tablets	30	DAYS				
72100007000320	Onfi	Clobazam Tab 20 MG	20 MG	60	Tablets	30	DAYS				
60201030000105	Restoril	Temazepam Cap 15 MG	15 MG	30	Capsules	30	DAYS				
60201030000108	Restoril	Temazepam Cap 22.5 MG	22.5 MG	30	Capsules	30	DAYS				
60201030000110	Restoril	Temazepam Cap 30 MG	30 ; 30 MG	30	Capsules	30	DAYS				
60201030000103	Restoril	Temazepam Cap 7.5 MG	7.5 MG	30	Capsules	30	DAYS				
72100007008210	Sympazan	Clobazam Oral Film 10 MG	10 MG	60	Films	30	DAYS				
72100007008220	Sympazan	Clobazam Oral Film 20 MG	20 MG	60	Films	30	DAYS				
72100007008205	Sympazan	Clobazam Oral Film 5 MG	5 MG	240	Films	30	DAYS				
57100030100310	Tranxene t	Clorazepate Dipotassium Tab 7.5 MG	7.5 MG	90	Tablets	30	DAYS				
57100040000315	Valium	Diazepam Tab 10 MG	10 MG	120	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
57100040000305	Valium	Diazepam Tab 2 MG	2 MG	120	Tablets	30	DAYS				
57100040000310	Valium	Diazepam Tab 5 MG	5 MG	120	Tablets	30	DAYS				
72100030000930	Valtoco 10 mg dose	Diazepam Nasal Spray 10 MG/0.1 ML	10 MG/0.1ML	5	Boxes	30	DAYS				
7210003000C440	Valtoco 15 mg dose	Diazepam Nasal Spray Ther Pack 2 x 7.5 MG/0.1ML (15 MG Dose)	7.5 MG/0.1ML	5	Boxes	30	DAYS				
7210003000C450	Valtoco 20 mg dose	Diazepam Nasal Spray Ther Pack 2 x 10 MG/0.1ML (20 MG Dose)	10 MG/0.1ML	5	Boxes	30	DAYS				
72100030000920	Valtoco 5 mg dose	Diazepam Nasal Spray 5 MG/0.1 ML	5 MG/0.1ML	5	Boxes	30	DAYS				
57100010000305	Xanax	Alprazolam Tab 0.25 MG	0.25 MG	120	Tablets	30	DAYS				
57100010000310	Xanax	Alprazolam Tab 0.5 MG	0.5 MG	120	Tablets	30	DAYS				
57100010000315	Xanax	Alprazolam Tab 1 MG	1 MG	120	Tablets	30	DAYS				
57100010000320	Xanax	Alprazolam Tab 2 MG	2 MG	90	Tablets	30	DAYS				

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Biologic Immunomodulators

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

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.

The BCBS MN Step Therapy Supplement also applies to this program for Medicaid.

Requests for an oral liquid form of a drug must be approved if BOTH of the following apply:

1) the indication is FDA labeled AND
2) the patient is using an enteral tube for feeding or medication administration

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			
6627001507F810	Abrilada	adalimumab-afzb prefilled syringe kit	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001507F820	Abrilada	adalimumab-afzb prefilled syringe kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001507F520	Abrilada 1-pen kit ; Abrilada 2-pen kit	adalimumab-afzb auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS				
6650007000E5	Actemra	tocilizumab subcutaneous soln prefilled syringe	162 MG/0.9ML	4	Syringes	28	DAYS				
6650007000D520	Actemra actpen	Tocilizumab Subcutaneous Soln Auto-injector 162 MG/0.9ML	162 MG/0.9ML	4	Pens	28	DAYS				
6627001510D517	Amjevita	adalimumab-atto soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				
6627001510D520	Amjevita	adalimumab-atto soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS			02-27-2023	
6627001510D537	Amjevita	adalimumab-atto soln auto-injector	80 MG/0.8ML	2	Pens	28	DAYS				
6627001510E505	Amjevita	adalimumab-atto soln prefilled syringe	10 MG/0.2ML	2	Syringes	28	DAYS				
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				

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
6627001510E520	Amjevita	adalimumab-atto soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS			02-27-2023	
9025051800D520	Bimzelx	bimekizumab-bkzx subcutaneous soln auto-injector	160 MG/ML	2	Pens	56	DAYS				
9025051800E520	Bimzelx	bimekizumab-bkzx subcutaneous soln prefilled syr	160 MG/ML	2	Syringes	56	DAYS				
52505020106420	Cimzia	Certolizumab Pegol For Inj Kit 2 X 200 MG	200 MG	2	Kits	28	DAYS				
5250502010F840	Cimzia	Certolizumab Pegol Prefilled Syringe Kit	200 MG/ML	2	Kits	28	DAYS				
5250502010F860	Cimzia starter kit	Certolizumab Pegol Prefilled Syringe Kit	200 MG/ML	1	Kit	180	DAYS				
9025057500E530	Cosentyx	Secukinumab Subcutaneous Pref Syr 150 MG/ML (300 MG Dose)	150 MG/ML	2	Syringes	28	DAYS				
9025057500E510	Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe	75 MG/0.5ML	1	Syringe	28	DAYS				
9025057500E520	Cosentyx	Secukinumab Subcutaneous Soln Prefilled Syringe 150 MG/ML	150 MG/ML	1	Syringe	28	DAYS				
9025057500D530	Cosentyx sensoready pen	Secukinumab Subcutaneous Auto-inj 150 MG/ML (300 MG Dose)	150 MG/ML	2	Pens	28	DAYS				
9025057500D520	Cosentyx sensoready pen	Secukinumab Subcutaneous Soln Auto-injector 150 MG/ML	150 MG/ML	1	Pen	28	DAYS				
9025057500D550	Cosentyx unoready	secukinumab subcutaneous soln auto-injector	300 MG/2ML	1	Pen	28	DAYS				
6627001505F515	Cyltezo	adalimumab-adbm auto-injector kit	40 ; 40 MG/0.4ML	2	Pens	28	DAYS	00597049550 ; 00597057550 ; 82009014422			
6627001505F520	Cyltezo	adalimumab-adbm auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS	00597037597 ; 00597054522 ; 82009014822			

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
6627001505F805	Cyltezo	adalimumab-adbm prefilled syringe kit	10 MG/0.2ML	2	Syringes	28	DAYS				
6627001505F810	Cyltezo	adalimumab-adbm prefilled syringe kit	20 MG/0.4ML	2	Syringes	28	DAYS				
6627001505F815	Cyltezo	adalimumab-adbm prefilled syringe kit	40 ; 40 MG/0.4ML	2	Syringes	28	DAYS				
6627001505F820	Cyltezo	adalimumab-adbm prefilled syringe kit	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001505F515	Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 ; 40 MG/0.4ML	1	Kit	180	DAYS	00597049560 ; 00597057560			
6627001505F515	Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 ; 40 MG/0.4ML	1	Kit	180	DAYS	00597049540 ; 00597057540			
6627001505F520	Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.8ML	4	Pens	180	DAYS	00597037523 ; 00597054544			
6627001505F520	Cyltezo starter package f	adalimumab-adbm auto-injector kit	40 MG/0.8ML	6	Pens	180	DAYS	00597037516 ; 00597054566			
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				
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				

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
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 ; 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/0.4 ML	1	Kit	180	DAYS				
6627001500F440	Humira pen	adalimumab pen-injector kit	80 MG/0.8ML	2	Pens	28	DAYS	00074012402 ; 83457012402			
6627001500F420	Humira pen	Adalimumab Pen-injector Kit ; adalimumab pen-injector kit	40 MG/0.8ML	2	Pens	28	DAYS	00074433902 ; 50090448700			
6627001500F430	Humira pen	Adalimumab Pen-injector Kit 40 MG/0.4ML	40 MG/0.4ML	2	Pens	28	DAYS				
6627001500F440	Humira pen-cd/uc/hs start	adalimumab pen-injector kit	80 MG/0.8ML	1	Kit	180	DAYS	00074012403			
6627001500F420	Humira pen-cd/uc/hs start	Adalimumab Pen-injector Kit ; adalimumab pen-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00074433906			

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
6627001500F440	Humira pen-pediatric uc s	adalimumab pen-injector kit	80 MG/0.8ML	1	Kit	180	DAYS	00074012404			
6627001500F420	Humira pen-ps/uv starter	Adalimumab Pen-injector Kit ; adalimumab pen-injector kit	40 MG/0.8ML	1	Kit	180	DAYS	00074433907			
6627001500F450	Humira pen-ps/uv starter	Adalimumab Pen-injector Kit 80 MG/0.8ML & 40 MG/0.4ML	80 MG/0.8ML & 40MG/0.4 ML	1	Kit	180	DAYS				
6627001504D515	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.4ML	2	Pens	28	DAYS				
6627001504D520	Hyrimoz	adalimumab-adaz soln auto-injector	40 MG/0.8ML	2	Pens	28	DAYS				
6627001504E508	Hyrimoz	adalimumab-adaz soln prefilled syringe	10 MG/0.1 ML	2	Syringes	28	DAYS				
6627001504E513	Hyrimoz	adalimumab-adaz soln prefilled syringe	20 MG/0.2ML	2	Syringes	28	DAYS				
6627001504E515	Hyrimoz	adalimumab-adaz soln prefilled syringe	40 MG/0.4ML	2	Syringes	28	DAYS				
6627001504E520	Hyrimoz	adalimumab-adaz soln prefilled syringe	40 MG/0.8ML	2	Syringes	28	DAYS				
6627001504D540	Hyrimoz ; Hyrimoz sensoready pens	adalimumab-adaz soln auto-injector	80 MG/0.8ML	2	Pens	28	DAYS	61314045420 ; 83457010701			
6627001504D540	Hyrimoz crohn's disease a ; Hyrimoz sensoready pens	adalimumab-adaz soln auto-injector	80 MG/0.8ML	1	Starter Kit	180	DAYS	61314045436 ; 83457011301			
6627001504E560	Hyrimoz pediatric crohn's	adalimumab-adaz soln prefilled syr	80 MG/0.8ML & 40MG/0.4 ML	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/0.4 ML	1	Starter Kit	180	DAYS				
6627001502F540	Idacio (2 pen)	adalimumab-aacf auto-injector kit	40 MG/0.8ML	2	Pens	28	DAYS	65219055408 ; 65219061299			
6627001502F840	Idacio (2 syringe)	adalimumab-aacf prefilled syringe kit	40 MG/0.8ML	1	Kit	28	DAYS				

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	Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8ML	1	Starter Kit	180	DAYS	65219055438			
6627001502F540	Idacio starter package fo	adalimumab-aacf auto-injector kit	40 MG/0.8ML	1	Starter 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				
5250405040E520	Omvoh	mirikizumab-mrkz subcutaneous sol prefill syringe	100 MG/ML	2	Syringes	28	DAYS				
5250405040D520	Omvoh	mirikizumab-mrkz subcutaneous soln auto-injector	100 MG/ML	2	Pens	28	DAYS				
6640001000E520	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 125 MG/ML	125 MG/ML	4	Syringes	28	DAYS				
6640001000E510	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 50 MG/0.4ML	50 MG/0.4ML	4	Syringes	28	DAYS				
6640001000E515	Orencia	Abatacept Subcutaneous Soln Prefilled Syringe 87.5 MG/0.7ML	87.5 MG/0.7ML	4	Syringes	28	DAYS				
6640001000D520	Orencia clickject	Abatacept Subcutaneous Soln Auto-Injector 125 MG/ML	125 MG/ML	4	Syringes	28	DAYS				
66603072007540	Rinvoq	Upadacitinib Tab ER	45 MG	84	Tablets	365	DAYS				
66603072007520	Rinvoq	Upadacitinib Tab ER 24HR 15 MG	15 MG	30	Tablets	30	DAYS				
9025052000E5	Siliq	brodalumab subcutaneous soln prefilled syringe	210 MG/1.5ML	2	Syringes	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6627001540F520	Simlandi 1-pen kit ; Simlandi 2-pen kit	adalimumab-ryvk auto-injector kit	40 MG/0.4ML	2	Pens	28	DAYS				
6627004000D540	Simponi	Golimumab Subcutaneous Soln Auto-injector 100 MG/ML	100 MG/ML	1	Syringe	28	DAYS				
6627004000D520	Simponi	Golimumab Subcutaneous Soln Auto-injector 50 MG/0.5ML	50 MG/0.5ML	1	Syringe	28	DAYS				
6627004000E540	Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 100 MG/ML	100 MG/ML	1	Syringe	28	DAYS				
6627004000E520	Simponi	Golimumab Subcutaneous Soln Prefilled Syringe 50 MG/0.5ML	50 MG/0.5ML	1	Syringe	28	DAYS				
9025057070F820	Skyrizi	Risankizumab-rzaa Sol Prefilled Syringe 2 x 75 MG/0.83ML Kit	75 MG/0.83ML	1	Kit	84	DAYS				
9025057070E540	Skyrizi	Risankizumab-rzaa Soln Prefilled Syringe	150 MG/ML	1	Syringe	84	DAYS				
5250406070E210	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	180 MG/1.2ML	1	Cartridge	56	DAYS				
5250406070E220	Skyrizi	Risankizumab-rzaa Subcutaneous Soln Cartridge	360 MG/2.4ML	1	Cartridge	56	DAYS				
9025057070D520	Skyrizi pen	Risankizumab-rzaa Soln Auto-injector	150 MG/ML	1	Pen	84	DAYS				
90250524000320	Sotyktu	Deucravacitinib Tab	6 MG	30	Tablets	30	DAYS				
90250585002020	Stelara	Ustekinumab Inj 45 MG/0.5ML	45 MG/0.5ML	1	Vial	84	DAYS				
9025058500E520	Stelara	Ustekinumab Soln Prefilled Syringe 45 MG/0.5ML	45 MG/0.5ML	1	Syringe	84	DAYS				
9025058500E540	Stelara	Ustekinumab Soln Prefilled Syringe 90 MG/ML	90 MG/ML	1	Syringe	56	DAYS				
9025055400D520	Taltz	Ixekizumab Subcutaneous Soln Auto-injector 80 MG/ML	80 MG/ML	1	Injection	28	DAYS				
9025055400E520	Taltz	Ixekizumab Subcutaneous Soln Prefilled Syringe 80 MG/ML	80 MG/ML	1	Syringe	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
9025054200D220	Tremfya	Guselkumab Soln Pen-Injector 100 MG/ML	100 MG/ML	1	Pen	56	DAYS				
9025054200E520	Tremfya	Guselkumab Soln Prefilled Syringe 100 MG/ML	100 MG/ML	1	Syringe	56	DAYS				
52504525100350	Velsipity	etrasimod arginine tab	2 MG	30	Tablets	30	DAYS				
66603065102020	Xeljanz	Tofacitinib Citrate Oral Soln	1 MG/ML	240	mLs	30	DAYS				
66603065100330	Xeljanz	Tofacitinib Citrate Tab 10 MG (Base Equivalent)	10 MG	240	Tablets	365	DAYS				
66603065100320	Xeljanz	Tofacitinib Citrate Tab 5 MG (Base Equivalent)	5 MG	60	Tablets	30	DAYS				
66603065107530	Xeljanz xr	Tofacitinib Citrate Tab ER 24HR 11 MG (Base Equivalent)	11 MG	30	Tablets	30	DAYS				
66603065107550	Xeljanz xr	Tofacitinib Citrate Tab ER 24HR 22 MG (Base Equivalent)	22 MG	120	Tablets	365	DAYS				
6627001503F530	Yuflyma 1-pen kit	adalimumab-aaty auto-injector kit	40 MG/0.4ML	2	Pens	28	DAYS	72606002209 ; 72606003009			
6627001503F560	Yuflyma 1-pen kit	adalimumab-aaty auto-injector kit	80 MG/0.8ML	2	Pens	28	DAYS	72606002304 ; 72606004004			
6627001503F530	Yuflyma 2-pen kit	adalimumab-aaty auto-injector kit	40 MG/0.4ML	2	Pens	28	DAYS	72606002210 ; 72606003010			
6627001503F820	Yuflyma 2-syringe kit	adalimumab-aaty prefilled syringe kit	20 MG/0.2ML	2	Syringes	28	DAYS				
6627001503F830	Yuflyma 2-syringe kit	adalimumab-aaty prefilled syringe kit	40 MG/0.4ML	1	Kit	28	DAYS				
6627001503F560	Yuflyma cd/uc/hs starter	adalimumab-aaty auto-injector kit	80 MG/0.8ML	1	Kit	180	DAYS	72606002307			
6627001509D240	Yusimry	adalimumab-aqvh soln pen-injector	40 MG/0.8ML	2	Pens	28	DAYS				
5250504020F530	Zymfentra 1-pen	infliximab-dyyb soln auto-injector kit	120 MG/ML	2	Pens	28	DAYS	72606002501			
5250504020F530	Zymfentra 2-pen	infliximab-dyyb soln auto-injector kit	120 MG/ML	2	Pens	28	DAYS	72606002502			
5250504020F830	Zymfentra 2-syringe	infliximab-dyyb soln prefilled syringe kit	120 MG/ML	2	Syringes	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
66603072007530	Rinvoq	Upadacitinib Tab ER	30 MG	30	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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

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

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	IV: infliximab*	
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	SQ: Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma
Alopecia Areata Atopic Dermatitis Deficiency of IL-1 Receptor Antagonist (DIRA) Enthesitis Related Arthritis (ERA) Giant Cell Arteritis (GCA) Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Systemic Juvenile Idiopathic Arthritis (SJIA) Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)	N/A	N/A

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

** 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**

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	3. ONE of the following: A. If the request is for an oral liquid form of a medication, then BOTH of the following: 1. The patient has an FDA labeled indication **AND** 2. The patient uses an enteral tube for feeding or medication administration **OR** B. ALL of the following: 1. ONE of the following: A. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** B. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** C. ALL of the following: 1. The patient has an FDA labeled indication or an indication supported in compendia for the requested agent and route of administration AND **ONE** of the following: A. The patient has a diagnosis of moderately to severely active rheumatoid arthritis (RA) AND BOTH of the following: 1. ONE of the following: A. The patient's medication history includes ONE conventional agent (i.e., maximally tolerated methotrexate [e.g., titrated to 25 mg weekly], hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA AND ONE of the following: 1. The patient has had an inadequate response to a conventional agent used in the treatment of RA **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional agents used in the treatment of RA **OR** B. The patient has an intolerance or hypersensitivity to ONE of the following conventional agents (i.e., maximally tolerated methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** 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**

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	2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that ALL conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. If the request is for Simponi, ONE of the following: A. The patient will be taking the requested agent in combination with methotrexate **OR** B. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to methotrexate **OR** B. The patient has a diagnosis of active psoriatic arthritis (PsA) AND ONE of the following: 1. The patient's medication history includes ONE conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA AND ONE of the following: A. The patient has had an inadequate response to a conventional agent used in the treatment of PsA **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional agents used in the treatment of PsA **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PsA **OR** 3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PsA **OR** 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**

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

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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: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

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

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

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	5. The prescriber has provided documentation that BOTH oral corticosteroids and periocular/intravitreal corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. ONE of the following: 1. The patient's medication history includes ONE conventional systemic agent (i.e., azathioprine, mycophenolate, methotrexate, cyclosporine, tacrolimus) used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis AND ONE of the following: A. The patient has had an inadequate response to a conventional agent used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional systemic agent used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 3. The patient has an FDA labeled contraindication to ALL conventional systemic agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND**

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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** 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 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:

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	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: A. The patient has had an inadequate response to ONE conventional agent (i.e., methotrexate, leflunomide) used in the treatment of PJIA **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional agents (i.e., methotrexate, leflunomide) used in the treatment of PJIA **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PJIA **OR** 3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PJIA **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of PJIA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following:

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

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

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	C. The patient has an Eczema Area and Severity Index (EASI) score greater than or equal to 16 **OR** D. The patient has an Investigator Global Assessment (IGA) score greater than or equal to 3 **AND** 2. ONE of the following: A. The patient's medication history includes at least a medium-potency topical corticosteroid used in the treatment of AD **AND** a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD AND ONE of the following: 1. The patient has had an inadequate response to at least a medium-potency topical corticosteroid used in the treatment of AD **AND** a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over at least medium-potency topical corticosteroids used in the treatment of AD **AND** topical calcineurin inhibitors (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR** B. The patient has an intolerance or hypersensitivity to at least a medium-potency topical corticosteroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL medium-, high-, and super-potency topical corticosteroids AND topical calcineurin inhibitors used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

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	E. The prescriber has provided documentation ALL medium-, high-, and super-potency topical corticosteroids AND topical calcineurin inhibitors used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The prescriber has documented the patient's baseline (prior to therapy with the requested agent) pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **OR** O. BOTH of the following: 1. The patient has a diagnosis of severe alopecia areata (AA) **AND** 2. The patient has at least 50% scalp hair loss that has lasted 6 months or more **OR** P. The patient has a diagnosis of polymyalgia rheumatica (PMR) AND ONE of the following: 1. The patient's medication history includes ONE systemic corticosteroid at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR AND ONE of the following: A. The patient has had an inadequate response to systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR **OR** 2. The patient is currently treated with systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone and cannot tolerate a corticosteroid taper **OR** 3. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 4. The prescriber has provided documentation that ALL systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR cannot be used due to a documented medical condition or comorbid condition that is likely to cause an

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

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	A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR** B. The request is for Velsipity, Omvoh, or a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following: 1. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following: A. ONE of the following: 1. Evidence of a paid claim **OR** 2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND** B. ONE of the following: 1. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR** 3. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** 4. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 5. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **AND** 3. If Cosentyx 300 mg is requested as maintenance dosing, then ONE of the following: A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis AND the requested dose is 300 mg every 4 weeks **OR** B. The patient has a diagnosis of hidradenitis suppurativa AND ONE of the following:

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	1. The requested dose is 300 mg every 4 weeks **OR** 2. The requested dose is 300 mg every 2 weeks AND the patient has tried and had an inadequate response to Cosentyx 300 mg every 4 weeks after at least a 3-month duration of therapy **OR** C. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND BOTH of the following: 1. The requested dose is 300 mg every 4 weeks **AND** 2. The patient has tried and had an inadequate response to Cosentyx 150 mg every 4 after at least 3-month duration of therapy **AND** 4. If Entyvio is requested for the treatment of ulcerative colitis or Crohn's disease, then ONE of the following: A. The patient has received at least 2 doses of Entyvio intravenous therapy **OR** B. The patient is new to therapy and will receive 2 doses of Entyvio IV therapy **AND** 5. If Omvoh is requested for the treatment of ulcerative colitis, then ONE of the following: A. The patient received Omvoh IV for induction therapy **OR** B. The patient is new to therapy and will receive Omvoh IV for induction therapy **AND** 6. If Skyrizi is requested for the treatment of Crohn's disease, then ONE of the following: A. The patient received Skyrizi IV for induction therapy **OR** B. The patient is new to therapy and will receive Skyrizi IV for induction therapy **AND** 7. If an ustekinumab product is requested for the treatment of Crohn's disease or ulcerative colitis, then ONE of the following: A. The patient received an ustekinumab IV product for induction therapy **OR** B. The patient is new to therapy and will receive an ustekinumab IV product for induction therapy **AND** 8. If Zymfentra is requested for the treatment of Crohn's disease or ulcerative colitis, then ONE of the following: A. The patient received an infliximab IV product for induction therapy **OR** B. The patient is new to therapy and will receive an infliximab IV product for induction therapy **AND** 9. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 2. If an ustekinumab 90 mg product is requested, then ONE of the following: A. The patient has a diagnosis of psoriasis AND weighs >100kg **OR** B. The patient has a dual diagnosis of psoriasis AND psoriatic arthritis AND the patient is >100kg **OR** C. The patient has a diagnosis of Crohn's disease or ulcerative colitis **AND** 3. If Actemra is requested for a diagnosis of systemic sclerosis associated interstitial lung disease, the request is for the Actemra syringe (NOTE: Actemra ACTpen is not approvable for SSc-ILD) **AND** 4. If the patient has moderate-to-severe atopic dermatitis (AD), then 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 **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** 2. There is 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 ustekinumab product renewal must be for the same strength as the initial approval) [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 4. ONE of the following: A. If the request is for an oral liquid form of a medication, then BOTH of the following: 1. The patient has an FDA labeled indication **AND** 2. The patient uses an enteral tube for feeding or medication administration **OR** B. ALL of the following:

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	1. ONE of the following: A. The patient has a diagnosis of moderate to severe atopic dermatitis AND BOTH of the following: 1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following: A. Affected body surface area **OR** B. Flares **OR** C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **OR** D. A decrease in the Eczema Area and Severity Index (EASI) score **OR** E. A decrease in the Investigator Global Assessment (IGA) score **AND** 2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has a diagnosis of polymyalgia rheumatica AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. If the requested agent is Kevzara, the patient does NOT have any of the following: A. Neutropenia (ANC less than 1,000 per mm^3 at the end of the dosing interval) **AND** B. Thrombocytopenia (platelet count is less than 100,000 per mm^3) **AND** C. AST or ALT elevations 3 times the upper limit of normal **OR** C. The patient has a diagnosis other than moderate to severe atopic dermatitis or polymyalgia rheumatica AND the patient has had clinical benefit with the requested agent **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for PS, AD; pulmonologist, radiologist, pathologist, rheumatologist for SSc-ILD; allergist, immunologist for AD) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, guidelines required) **AND** 4. If Cosentyx 300 mg is requested as maintenance dosing, then ONE of the following: A. The patient has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis AND the requested dose is 300 mg every 4 weeks **OR** B. The patient has a diagnosis of hidradenitis suppurativa AND ONE of the following: 1. The requested dose is 300 mg every 4 weeks **OR** 2. The requested dose is 300 mg every 2 weeks AND the patient has tried and had an inadequate response to Cosentyx 300 mg every 4 weeks after at least a 3-month duration of therapy **OR** C. The patient has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis AND BOTH of the following: 1. The requested dose is 300 mg every 4 weeks **AND** 2. The patient has tried and had an inadequate response to Cosentyx 150 mg after at least a 3-month duration of therapy **AND**

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

Module	Clinical Criteria for Approval
	2. The patient has tried and had an inadequate response to at least a 3 month duration of therapy at the maximum FDA labeled dose (medical records required) **AND** 3. ONE of the following: A. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum compendia supported dose for the requested indication **AND** 2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does NOT exceed the program quantity limit **OR** B. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose AND the maximum compendia supported dose for the requested indication **AND** 2. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required) **OR** 2. The patient has a compendia supported indication for the requested agent, AND ONE of the following: A. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum compendia supported dose for the requested indication **AND** 2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does NOT exceed the program quantity limit **OR** B. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum compendia supported dose for the requested indication **AND** 2. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required) **OR** 3. The patient does NOT have an FDA labeled indication NOR a compendia supported indication for the requested agent AND BOTH of the following: A. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit **AND** B. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required) **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** Initial Approval with PA: up to 12 months for all agents EXCEPT adalimumab containing products for ulcerative colitis (UC), Rinvoq for atopic dermatitis (AD), Siliq for plaque psoriasis (PS), Xeljanz and Xeljanz XR for induction therapy for UC, and the agents with indications that require loading doses for new starts. NOTE: For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of the 12 months. Adalimumab containing products for UC may be approved for up to 12 weeks, Rinvoq for AD may be approved for up to 6 months, Siliq for PS may be approved for up to 16 weeks, and Xeljanz and Xeljanz XR for UC may be approved for up to 16 weeks.

Module	Clinical Criteria for Approval
	Renewal Approval with PA: up to 12 months **Standalone QL approval:** up to 12 months or through the remainder of an existing authorization, whichever is shorter **NOTE: Cosentyx for the diagnoses of AS, nr-axSpA, and PSA loading doses are not approvable.

CONTRAINDICATION AGENTS

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

Contraindicated as Concomitant Therapy
Simlandi (adalimumab-ryvk) Simponi (golimumab) Simponi ARIA (golimumab) Skyrizi (risankizumab-rzaa) Sotyktu (deucravacitinib) Spevigo (spesolimab-sbzo) Stelara (ustekinumab) Taltz (ixekizumab) Tezspire (tezepelumab-ekko) Tofidence (tocilizumab-bavi) Tremfya (guselkumab) Truxima (rituximab-abbs) Tyenne (tocilizumab-aazg) Tysabri (natalizumab) Velsipity (etrasimod) Wezlana (ustekinumab-auub) Xeljanz (tofacitinib) Xeljanz XR (tofacitinib extended release) Xolair (omalizumab) Yuflyma (adalimumab-aaty) Yusimry (adalimumab-aqvh) Zeposia (ozanimod) Zymfentra (infliximab-dyyb)

• Program Summary: Combination NSAID

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

The BCBS MN Step Therapy Supplement also applies to this program for Medicaid.

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
349987021003	Consensi	amlodipine besylate-celecoxib tab	10-200 MG ; 2.5-200 MG ; 5-200 MG	30	Tablets	30	DAYS				
661099023203	Duexis	ibuprofen-famotidine tab	800-26.6 MG	90	Tablets	30	DAYS				
661099024406	Vimovo	naproxen-esomeprazole magnesium tab dr	375-20 MG ; 500-20 MG	60	Tablets	30	DAYS				
851599020406	Yosprala	aspirin-omeprazole tab delayed release	325-40 MG ; 81-40 MG	30	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Evaluation

Module	Clinical Criteria for Approval
	Target Agent(s) will be approved when ALL of the following are met: 1. ONE of the following: A. For Consensi, BOTH of the following: 1. The patient has a diagnosis of hypertension **AND** 2. The patient has a diagnosis of osteoarthritis **OR** B. BOTH of the following: 1. ONE of the following: A. For Duexis or ibuprofen/famotidine requests, the patient has a diagnosis of at least ONE of the following: 1. Rheumatoid arthritis **OR** 2. Osteoarthritis **OR** B. For Vimovo or naproxen/esomeprazole requests, the patient has a diagnosis of at least ONE of the following: 1. Osteoarthritis in adults **OR** 2. Rheumatoid arthritis in adults **OR** 3. Ankylosing spondylitis in adults **OR** 4. Juvenile idiopathic arthritis (JIA) in adolescents weighing greater than or equal to 38 kg **AND** 2. The patient has at least ONE of the following risk factors for developing NSAID-induced gastrointestinal (GI) ulcers: A. Age greater than or equal to 65 years B. Prior history of peptic, gastric, or duodenal ulcer C. History of NSAID-related ulcer D. History of clinically significant GI bleeding E. Untreated or active *H. pylori* gastritis F. Concurrent use of oral corticosteroids G. Concurrent use of anticoagulants H. Concurrent use of antiplatelets **OR** C. For Yosprala or aspirin/omeprazole requests, BOTH of the following: 1. The patient has an indication of use of at least ONE of the following: A. Reducing the combined risk of death and nonfatal stroke in patients who have had ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli **OR** B. Reducing the combined risk of death and nonfatal myocardial infarction (MI) in patients with previous MI or unstable angina pectoris **OR** C. Reducing the combined risk of MI and sudden death in patients with chronic stable angina pectoris **OR** D. Use in patients who have undergone revascularization procedures (coronary artery bypass graft [CABG] or percutaneous transluminal coronary angioplasty [PTCA]) when there is a pre-existing condition for which aspirin is already indicated **AND** 2. The patient has at least ONE of the following risk factors for developing NSAID-induced gastrointestinal (GI) ulcers: A. Age greater than or equal to 55 years B. Prior history of peptic, gastric, or duodenal ulcer C. History of NSAID–related ulcer D. History of clinically significant GI bleeding E. Untreated or active *H. pylori* gastritis F. Concurrent use of oral corticosteroids G. Concurrent use of anticoagulants H. Concurrent use of antiplatelets **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. ONE of the following:

Module	Clinical Criteria for Approval
	A. Information has been provided that use of the individual ingredients within the target combination agent, as separate dosage forms, is not clinically appropriate for the patient **OR** B. BOTH of the following: 1. The patient's medication history includes use of the individual ingredients within the target combination agent, as separate dosage forms, as indicated by ONE of the following: A. Evidence of a paid claim(s) **OR** B. The prescriber has stated that the patient has tried the individual ingredients within the target combination agent, as separate dosage forms **AND** 2. ONE of the following: A. The individual ingredients within the target combination agent, as separate dosage forms 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 use of the individual ingredients within the target combination agent, as separate dosage forms **OR** C. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** D. The prescriber has provided documentation that the individual ingredients within the target combination agent, as separate dosage forms, cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The patient 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) 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 maximum FDA labeled dose for the requested indication **AND** C. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• Program Summary: Continuous Glucose Monitor (CGM)

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
97202012026200	Dexcom g6 receiver	*continuous glucose system receiver***		1	Receiver	365	DAYS	08627009111			
97202012046300	Dexcom g6 sensor	*continuous glucose system sensor***		3	Sensors	30	DAYS	08627005303			
97202012066300	Dexcom g6 transmitter	*continuous glucose system transmitter***		1	Transmitter	90	DAYS	08627001601			
97202012026200	Dexcom g7 receiver	*continuous glucose system receiver***		1	Receiver	365	DAYS	08627007801			
97202012046300	Dexcom g7 sensor	*continuous blood glucose system sensor*** ; *continuous glucose system sensor***		3	Sensors	30	DAYS	08627007701			
97202012026200	Freestyle libre 14 day/re	*continuous glucose system receiver***		1	Reader	365	DAYS	57599000200			
97202012046300	Freestyle libre 14 day/se	*continuous blood glucose system sensor*** ; *continuous glucose system sensor***		2	Sensors	28	DAYS	57599000101			
97202012026200	Freestyle libre 2/reader/	*continuous glucose system receiver***		1	Reader	365	DAYS	57599080300			
97202012046300	Freestyle libre 2/sensor/	*continuous glucose system sensor***		2	Sensors	28	DAYS	57599080000			
97202012026200	Freestyle libre 3/reader/	*continuous glucose system receiver***		1	Reader	365	DAYS	57599082000			
97202012046300	Freestyle libre 3/sensor/	*continuous glucose system sensor***		2	Sensors	28	DAYS	57599081800			
97202012026200	Freestyle libre/reader/fl	*continuous glucose system receiver***		1	Reader	365	DAYS	57599000021			

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

• Program Summary: Gabapentin ER (extended-release)

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
62540030000325	Gralise	gabapentin (once-daily) tab	450 MG	30	Tablets	30	DAYS				
62540030000345	Gralise	gabapentin (once-daily) tab	750 MG	30	Tablets	30	DAYS				
62540030000360	Gralise	gabapentin (once-daily) tab	900 MG	60	Tablets	30	DAYS				
62540030000320	Gralise	Gabapentin (Once-Daily) Tab 300 MG	300 MG	30	Tablets	30	DAYS				
62540030000330	Gralise	Gabapentin (Once-Daily) Tab 600 MG	600 MG	90	Tablets	30	DAYS				
62560030200420	Horizant	Gabapentin Enacarbil Tab ER 300 MG	300 MG	60	Tablets	30	DAYS				
62560030200430	Horizant	Gabapentin Enacarbil Tab ER 600 MG	600 MG	60	Tablets	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
62540030000325	Gralise	gabapentin (once-daily) tab	450 MG	Gralise dosage must be titrated up over 15 days			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
62540030000345	Gralise	gabapentin (once-daily) tab	750 MG	Gralise dosage must be titrated up over 15 days			
62540030000360	Gralise	gabapentin (once-daily) tab	900 MG	Gralise dosage must be titrated up over 15 days			
62540030000320	Gralise	Gabapentin (Once-Daily) Tab 300 MG	300 MG	Gralise dosage must be titrated up over 15 days			
62540030000330	Gralise	Gabapentin (Once-Daily) Tab 600 MG	600 MG	Gralise dosage must be titrated up over 15 days			

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The patient requires increased quantities of Gralise to accommodate a titration schedule. The increased quantity will be approved for 1 month only **OR** 3. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• Program Summary: Galafold (migalastat)

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
30903650100120	Galafold	Migalastat HCl Cap 123 MG (Base Equivalent)	123 MG	14	Capsules	28	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Initial Evaluation

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

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

Agents Eligible for Continuation of Therapy
Galafold

      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 a diagnosis of Fabry disease AND BOTH of the following:
         A. The diagnosis was confirmed by mutation in the galactosidase alpha (*GLA*) gene **AND**
         B. The patient has a confirmed amenable *GLA* variant based on in vitro assay data (a complete list of amenable variants is available in the Galafold prescribing information, or a specific variant can be verified as amenable at http://www.galafoldamenabilitytable.com/hcp **AND**
      2. If the patient has an FDA labeled indication, then ONE of the following:
         A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
         B. There is support for using the requested agent for the patient's age for the requested indication **AND**
2. The prescriber has assessed current status of ALL of the following: renal function (e.g., proteinuria, glomerular filtration rate [GFR]), cardiac function (e.g., left ventricular hypertrophy, conduction defects, mitral and/or aortic valve abnormalities), ophthalmological signs (e.g., corneal verticillate, subcapsular cataracts, conjunctival and/or retinal vasculopathy), peripheral nerve symptoms (e.g., neuropathic pain, heat and/or cold intolerance, impaired sweat function), and gastrointestinal involvement (e.g., nausea, vomiting, abdominal pain, diarrhea, constipation) **AND**
3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist, nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
4. The patient will NOT be using the requested agent in combination with enzyme replacement therapy (ERT) (e.g., Elfabrio, Fabrazyme) for the requested indication **AND**
5. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 6 months

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

Renewal Evaluation

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

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**

Module	Clinical Criteria for Approval
	2. The patient has had improvements or stabilization with the requested agent as indicated by ONE of the following: A. Renal function (e.g., proteinuria, glomerular filtration rate [GFR]) **OR** B. Cardiac function (e.g., left ventricular hypertrophy, conduction defects, mitral and/or aortic valve abnormalities) **OR** C. Ophthalmological signs (e.g., corneal verticillate, subcapsular cataracts, conjunctival and/or retinal vasculopathy) **OR** D. Peripheral nerve symptoms (e.g., neuropathic pain, heat and/or cold intolerance, impaired sweat function) **OR** E. Gastrointestinal symptoms (e.g., nausea, vomiting, abdominal pain, diarrhea, constipation) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist, nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient will NOT be using the requested agent in combination with enzyme replacement therapy (ERT) (e.g., Elfabrio, Fabrazyme) for the requested indication **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 **Length of Approval:** Initial - up to 6 months; Renewal - 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

Step Therapy only applies to the MN Medicaid Preferred Drug List (PDL) preferred drugs: Byetta, Bydureon pens, Bydureon BCise, Ozempic, and Victoza.

The BCBS MN Step Therapy Supplement applies to this program for Medicaid.

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
2717005600D230	Adlyxin	Lixisenatide Soln Pen-injector 20 MCG/0.2ML (100 MCG/ML)	20 MCG/0.2ML	2	Pens	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
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	Bydureonbcise	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/0.04ML	1	Pen	30	DAYS				
2717002000D220	Byetta	Exenatide Soln Pen-injector 5 MCG/0.02ML	5 MCG/0.02ML	1	Pen	30	DAYS				
2717308000D210	Mounjaro	Tirzepatide Soln Pen-injector	2.5 MG/0.5ML	4	Pens	180	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				
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
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			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
2717002000D420	Bydureon bcise	Exenatide Extended Release Susp Auto-Injector 2 MG/0.85ML	2 MG/0.85ML	The patient must have a diagnosis of type 2 diabetes mellitus			
2717002000D240	Byetta	Exenatide Soln Pen-injector 10 MCG/0.04ML	10 MCG/0.04ML	The patient must have a diagnosis of type 2 diabetes mellitus			
2717002000D220	Byetta	Exenatide Soln Pen-injector 5 MCG/0.02ML	5 MCG/0.02ML	The patient must have a diagnosis of type 2 diabetes mellitus.			
2717007000D225	Ozempic	Semaglutide Soln Pen-inj	8 MG/3ML	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 BCise™** (exenatide extended-release) **Byetta®** (exenatide) **Ozempic®** (semaglutide) **Victoza®** (liraglutide) **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. 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**

Module	Clinical Criteria for Approval
	C. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** D. The 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 **AND** 3. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **Length of Approval:** 12 months NOTE: If Quantity Limit program also applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) 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. There is support for therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months

• Program Summary: Glucose Test Strips and Meters

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
Smart QL											
94100030006100	Glucose Blood Test Strip	Glucose Blood Test Strip		102	Strips	30	DAYS				
94100030006020	Pogo automatic test cartr	Glucose Blood Test Automatic Cartridge		100	Strips	30	DAYS				
97202011006200	Relion all-in-one compact	*Blood Glucose Meter Disposable Device with Test Strips***		2	Systems	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
Smart QL							
94100030006100	Glucose Blood Test Strip	Glucose Blood Test Strip		Quantity limit is without insulin use in the past 90 days			
94100030006020	Pogo automatic test cartr	Glucose Blood Test Automatic Cartridge		Quantity limit is without insulin use in the past 90 days			
97202011006200	Relion all-in-one compact	*Blood Glucose Meter Disposable Device with Test Strips***		Quantity limit is without insulin use in the past 90 days			

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Smart QL	Quantities above the program quantity limit for the **Target Agent(s)** WITHOUT insulin use in the past 90 days will be approved when ONE of the following is met: 1. The patient is currently on insulin therapy **OR** 2. There is support indicating the need for additional blood glucose testing Quantities above the program quantity limit for the **Target Agent(s)** WITH insulin use in the past 90 days will be approved when ONE of the following is met: 1. There is support indicating the need for additional blood glucose testing **Length of Approval:** up to 12 months

• Program Summary: Insomnia Agents

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
602040700001		zaleplon cap	10 MG ; 5 MG	30	Capsules	30	DAYS				
60204080100120		zolpidem tartrate cap	7.5 MG	30	Capsules	30	DAYS				
60204080100708		Zolpidem Tartrate SL Tab 1.75 MG	1.75 MG	30	Tablets	30	DAYS				
60204080100715		Zolpidem Tartrate SL Tab 3.5 MG	3.5 MG	30	Tablets	30	DAYS				
602040801003	Ambien	zolpidem tartrate tab	10 MG ; 5 MG	30	Tablets	30	DAYS				
602040801004	Ambien cr	zolpidem tartrate tab er	12.5 MG ; 6.25 MG	30	Tablets	30	DAYS				
605000700003	Belsomra	suvorexant tab	10 MG ; 15 MG ; 20 MG ; 5 MG	30	Tablets	30	DAYS				
605000400003	Dayvigo	lemborexant tab	10 MG ; 5 MG	30	Tablets	30	DAYS				
60204080100730	Edluar	Zolpidem Tartrate SL Tab 10 MG	10 MG	30	Tablets	30	DAYS				
60204080100720	Edluar	Zolpidem Tartrate SL Tab 5 MG	5 MG	30	Tablets	30	DAYS				
602040350003	Lunesta	eszopiclone tab	1 MG ; 2 MG ; 3 MG	30	Tablets	30	DAYS				
605000201003	Quviviq	daridorexant hcl tab	25 MG ; 50 MG	30	Tablets	30	DAYS				
602500600003	Rozerem	ramelteon tab	8 ; 8 MG	30	Tablets	30	DAYS				
604000301003	Silenor	doxepin hcl (sleep) tab	3 MG ; 6 MG	30	Tablets	30	DAYS				
602040801020	Zolpimist	zolpidem tartrate oral spray	5 MG/ACT	1	Inhaler	30	DAYS				

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR**

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

• Program Summary: Jynarque (tolvaptan)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
30454060000320	Jynarque	tolvaptan tab	15 MG	60	Tablets	30	DAYS	59148008213			
30454060000330	Jynarque	tolvaptan tab	30 MG	30	Tablets	30	DAYS	59148008313			
3045406000B710	Jynarque	Tolvaptan Tab Therapy Pack 15 MG	15 MG	56	Tablets	28	DAYS				
3045406000B720	Jynarque	Tolvaptan Tab Therapy Pack 30 & 15 MG	30 & 15 MG	56	Tablets	28	DAYS				
3045406000B725	Jynarque	Tolvaptan Tab Therapy Pack 45 & 15 MG	45 & 15 MG	56	Tablets	28	DAYS				
3045406000B735	Jynarque	Tolvaptan Tab Therapy Pack 60 & 30 MG	60 & 30 MG	56	Tablets	28	DAYS				
3045406000B745	Jynarque	Tolvaptan Tab Therapy Pack 90 & 30 MG	90 & 30 MG	56	Tablets	28	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of autosomal dominant polycystic kidney disease (ADPKD) and BOTH of the following: A. The patient does not have stage 5 chronic kidney disease (CKD) **AND** B. The patient is not on dialysis **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. The patient will NOT be using the requested agent in combination with another tolvaptan agent **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**

Module	Clinical Criteria for Approval
	5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 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 [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient will NOT be using the requested agent in combination with another tolvaptan agent **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity limit for 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 **Length of Approval:** up to 12 months

• Program Summary: Low Molecular Weight Heparins (LMWH) and Arixtra

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
83101020102020		Enoxaparin Sodium Inj 150 MG/ML		30	Syringes	90	DAYS				
83101020102012		Enoxaparin Sodium Inj 30 MG/0.3ML		30	Syringes	90	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
83101020102014		Enoxaparin Sodium Inj 60 MG/0.6ML		30	Syringes	90	DAYS				
83101020102015		Enoxaparin Sodium Inj 80 MG/0.8ML		30	Syringes	90	DAYS				
83103030102045	Arixtra	Fondaparinux Sodium Subcutaneous Inj 10 MG/0.8ML	10 MG/0.8ML	30	Syringes	90	DAYS				
83103030102020	Arixtra	Fondaparinux Sodium Subcutaneous Inj 2.5 MG/0.5ML	2.5 MG/0.5ML	30	Syringes	90	DAYS				
83103030102035	Arixtra	Fondaparinux Sodium Subcutaneous Inj 5 MG/0.4ML	5 MG/0.4ML	30	Syringes	90	DAYS				
83103030102040	Arixtra	Fondaparinux Sodium Subcutaneous Inj 7.5 MG/0.6ML	7.5 MG/0.6ML	30	Syringes	90	DAYS				
83101010102017	Fragmin	dalteparin sodium inj 2500 unit/ml	10000 UNIT/4ML	30	Vials	90	DAYS				
83101010102080	Fragmin	Dalteparin Sodium Inj 95000 Unit/3.8ML	95000 UNIT/3.8ML	10	Vials	90	DAYS				
8310101010E505	Fragmin	Dalteparin Sodium Soln Prefilled Syr	2500 UNIT/0.2ML	30	Syringes	90	DAYS				
8310101010E515	Fragmin	Dalteparin Sodium Soln Prefilled Syr	5000 UNIT/0.2ML	30	Syringes	90	DAYS				
8310101010E520	Fragmin	Dalteparin Sodium Soln Prefilled Syr	7500 UNIT/0.3ML	30	Syringes	90	DAYS				
8310101010E530	Fragmin	Dalteparin Sodium Soln Prefilled Syr	10000 UNIT/ML	30	Syringes	90	DAYS				
8310101010E535	Fragmin	Dalteparin Sodium Soln Prefilled Syr	12500 UNIT/0.5ML	30	Syringes	90	DAYS				
8310101010E540	Fragmin	Dalteparin Sodium Soln Prefilled Syr	15000 UNIT/0.6ML	30	Syringes	90	DAYS				
8310101010E550	Fragmin	Dalteparin Sodium Soln Prefilled Syr	18000 UNT/0.72ML	30	Syringes	90	DAYS				
83101020102050	Lovenox	Enoxaparin Sodium Inj 300 MG/3ML	300 MG/3ML	10	Vials	90	DAYS				
8310102010E520	Lovenox	Enoxaparin Sodium Inj Soln Pref Syr	30 MG/0.3ML	30	Syringes	90	DAYS				
8310102010E525	Lovenox	Enoxaparin Sodium Inj Soln Pref Syr	40 MG/0.4ML	30	Syringes	90	DAYS				
8310102010E530	Lovenox	Enoxaparin Sodium Inj Soln Pref Syr	60 MG/0.6ML	30	Syringes	90	DAYS				
8310102010E535	Lovenox	Enoxaparin Sodium Inj Soln Pref Syr	80 MG/0.8ML	30	Syringes	90	DAYS				
8310102010E540	Lovenox	Enoxaparin Sodium Inj Soln Pref Syr	100 MG/ML	30	Syringes	90	DAYS				
8310102010E560	Lovenox	Enoxaparin Sodium Inj Soln Pref Syr	120 MG/0.8ML	30	Syringes	90	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
8310102010E565	Lovenox	Enoxaparin Sodium Inj Soln Pref Syr	150 MG/ML	30	Syringes	90	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
83103030102020	Arixtra	Fondaparinux Sodium Subcutaneous Inj 2.5 MG/0.5ML	2.5 MG/0.5ML	a single course of therapy			

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The patient requires extended treatment for primary or secondary prophylaxis of thromboembolism during pregnancy and/or puerperium **OR** 3. The patient requires extended prophylaxis and/or treatment of symptomatic VTE (DVT and/or PE) **AND** the patient has cancer **OR** 4. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does not have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• Program Summary: Lyrica and Savella

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
72600057000125	Lyrica	Pregabalin Cap 100 MG	100 MG	90	Capsules	30	DAYS				
72600057000135	Lyrica	Pregabalin Cap 150 MG	150 MG	90	Capsules	30	DAYS				
72600057000145	Lyrica	Pregabalin Cap 200 MG	200 MG	90	Capsules	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
72600057000150	Lyrica	Pregabalin Cap 225 MG	225 ; 225 MG	60	Capsules	30	DAYS				
72600057000110	Lyrica	Pregabalin Cap 25 MG	25 MG	90	Capsules	30	DAYS				
72600057000160	Lyrica	Pregabalin Cap 300 MG	300 ; 300 MG	60	Capsules	30	DAYS				
72600057000115	Lyrica	Pregabalin Cap 50 MG	50 MG	90	Capsules	30	DAYS				
72600057000120	Lyrica	Pregabalin Cap 75 MG	75 ; 75 MG	90	Capsules	30	DAYS				
72600057002020	Lyrica	Pregabalin Soln 20 MG/ML	20 MG/ML	900	mLs	30	DAYS				
62540060007530	Lyrica cr	Pregabalin Tab ER 24HR 165 MG	165 MG	30	Tablets	30	DAYS				
62540060007540	Lyrica cr	Pregabalin Tab ER 24HR 330 MG	330 MG	60	Tablets	30	DAYS				
62540060007520	Lyrica cr	Pregabalin Tab ER 24HR 82.5 MG	82.5 MG	30	Tablets	30	DAYS				
625040501003	Savella	milnacipran hcl tab	100 MG ; 12.5 MG ; 25 MG ; 50 MG	60	Tablets	30	DAYS				
62504050106320	Savella titration pack	Milnacipran HCl Tab 12.5 MG (5) & 25 MG (8) & 50 MG (42) Pak	12.5 & 25 & 50 MG	1	Pack	180	DAYS				

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Radicava (edaravone)

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
74509030001820	Radicava ors ; Radicava ors starter kit	Edaravone Oral Susp	105 MG/5ML	50	mLs	28	DAYS				
74509030001820	Radicava ors starter kit	edaravone oral susp	105 MG/5ML	70	mLs	180	DAYS	70510232101 ; 70510232102			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Initial Evaluation

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

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

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

      1. The patient has been treated with the requested agent within the past 90 days **OR**
      2. 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**

   B. ALL of the following:
      1. The patient has a diagnosis of amyotrophic lateral sclerosis (ALS) **AND**
      2. The patient has had the diagnosis of ALS for a duration of 2 years or less **AND**
      3. The patient has a baseline percent forced vital capacity (FVC%) or slow vital capacity (SVC) of 80% or greater **AND**
      4. The patient is able to perform most activities of daily living, defined as scores of 2 points or better on each individual item of the ALS Functional Rating Scale – Revised [ALSFRS-R] **AND**
      5. ONE of the following:
         A. BOTH of the following:
            1. The patient is currently being treated with riluzole **AND**
            2. The patient will continue riluzole in combination with the requested agent **OR**
         B. The patient's medication history includes riluzole AND ONE of the following:
            1. The patient has had an inadequate response to riluzole **OR**
            2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over riluzole **OR**
         C. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to riluzole **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**

Module	Clinical Criteria for Approval
	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 riluzole cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months **NOTE:** For patients initiating therapy, approval will include 28 bags per 28 days (initial dose) for the first month and 20 bags per 28 days for the remainder of the 6 months. For patients initiating therapy with oral suspension, approval will include 70 mL starter kit per 180 days (initial dose) and 50 mL per 28 days for the remainder of the 6 months. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient is NOT dependent on invasive ventilation or tracheostomy **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	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 **Length of Approval:** Initial: up to 6 months; Renewal: up to 12 months

• Program Summary: Selective Serotonin Inverse Agonist (SSIA)

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
59400028200120	Nuplazid	Pimavanserin Tartrate Cap 34 MG (Base Equivalent)	34 MG	30	Capsules	30	DAYS				
59400028200310	Nuplazid	Pimavanserin Tartrate Tab 10 MG (Base Equivalent)	10 MG	30	Tablets	30	DAYS				

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

• Program Summary: Self-Administered Oncology Agents

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

The BCBS MN Step Therapy Supplement also applies to this program for Medicaid.

Requests for an oral liquid form of a drug must be approved if BOTH of the following apply:
1) the indication is FDA approved AND
2) the patient is using an enteral tube for feeding or medication administration

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
21406010200310		Abiraterone Acetate Tab 125 MG		120	Tablets	30	DAYS				
2156006000B730		Selinexor Tab Therapy Pack 20 MG (100 MG Once Weekly)		20	Tablets	28	DAYS				
2156006000B712		Selinexor Tab Therapy Pack 20 MG (40 MG Once Weekly)		8	Tablets	28	DAYS				
2156006000B715		Selinexor Tab Therapy Pack 20 MG (40 MG Twice Weekly)		16	Tablets	28	DAYS				
2156006000B750		Selinexor Tab Therapy Pack 20 MG (60 MG Once Weekly)		12	Tablets	28	DAYS				
2156006000B740		Selinexor Tab Therapy Pack 20 MG (80 MG Once Weekly)		16	Tablets	28	DAYS				
215325300003	Afinitor	Everolimus Tab	10 MG ; 2.5 MG ; 5 MG ; 7.5 MG	30	Tablets	30	DAYS				
21532530007310	Afinitor disperz	Everolimus Tab for Oral Susp 2 MG	2 MG	60	Tablets	30	DAYS				
21532530007320	Afinitor disperz	Everolimus Tab for Oral Susp 3 MG	3 MG	90	Tablets	30	DAYS				
21532530007340	Afinitor disperz	Everolimus Tab for Oral Susp 5 MG	5 MG	60	Tablets	30	DAYS				
21409902120320	Akeega	niraparib tosylate-abiraterone acetate tab	50-500 MG	60	Tablets	30	DAYS				
21409902120330	Akeega	niraparib tosylate-abiraterone acetate tab	100-500 MG	60	Tablets	30	DAYS				
215305071001	Alecensa	alectinib hcl cap	150 MG	240	Capsules	30	DAYS				
21530510000330	Alunbrig	Brigatinib Tab	30 MG	120	Tablets	30	DAYS				
21530510000350	Alunbrig	Brigatinib Tab	90 MG	30	Tablets	30	DAYS				
21530510000365	Alunbrig	Brigatinib Tab	180 MG	30	Tablets	30	DAYS				
2153051000B720	Alunbrig	Brigatinib Tab Initiation Therapy Pack	90 & 180 MG	30	Tablets	180	DAYS				
21533865000120	Augtyro	repotrectinib cap	40 MG	240	Capsules	30	DAYS				
214900090003	Ayvakit	avapritinib tab	100 MG ; 200 MG ; 25 MG ; 300 MG ; 50 MG	30	Tablets	30	DAYS				
21532225000320	Balversa	Erdafitinib Tab 3 MG	3 MG	90	Tablets	30	DAYS				
21532225000325	Balversa	Erdafitinib Tab 4 MG	4 MG	60	Tablets	30	DAYS				
21532225000330	Balversa	Erdafitinib Tab 5 MG	5 MG	30	Tablets	30	DAYS				
2170007750E520	Besremi	Ropeginterferon alfa-	500 MCG/ML	2	Syringes	28	DAYS				
21531812000120	Bosulif	bosutinib cap	50 MG	30	Capsules	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
21531812000130	Bosulif	bosutinib cap	100 MG	150	Capsules	30	DAYS				
21531812000320	Bosulif	Bosutinib Tab	100 MG	90	Tablets	30	DAYS				
21531812000327	Bosulif	Bosutinib Tab	400 MG	30	Tablets	30	DAYS				
21531812000340	Bosulif	Bosutinib Tab	500 MG	30	Tablets	30	DAYS				
215320400001	Braftovi	encorafenib cap	75 MG	180	Capsules	30	DAYS				
21532195000120	Brukinsa	Zanubrutinib Cap	80 MG	120	Capsules	30	DAYS				
21533010100320	Cabometyx	Cabozantinib S-Malate Tab	20 MG	30	Tablets	30	DAYS				
21533010100330	Cabometyx	Cabozantinib S-Malate Tab	40 MG	30	Tablets	30	DAYS				
21533010100340	Cabometyx	Cabozantinib S-Malate Tab	60 MG	30	Tablets	30	DAYS				
215321030001	Calquence	acalabrutinib cap	100 MG	60	Capsules	30	DAYS				
215321035003	Calquence	acalabrutinib maleate tab	100 MG	60	Tablets	30	DAYS				
21533085000320	Caprelsa	Vandetanib Tab	100 MG	60	Tablets	30	DAYS				
21533085000340	Caprelsa	Vandetanib Tab	300 MG	30	Tablets	30	DAYS				
21533010106470	Cometriq	Cabozantinib S-Mal Cap	80 & 20 MG	1	Carton	28	DAYS				
21533010106480	Cometriq	Cabozantinib S-Mal Cap	3 x 20 MG & 80 MG	1	Carton	28	DAYS				
21533010106460	Cometriq	Cabozantinib S-Malate Cap	20 MG	1	Carton	28	DAYS				
215380300001	Copiktra	duvelisib cap	15 MG ; 25 MG	56	Capsules	28	DAYS				
215335302003	Cotellic	cobimetinib fumarate tab	20 MG	63	Tablets	28	DAYS				
21370030300335	Daurismo	Glasdegib Maleate Tab 100 MG (Base Equivalent)	100 MG	30	Tablets	30	DAYS				
21370030300320	Daurismo	Glasdegib Maleate Tab 25 MG (Base Equivalent)	25 MG	60	Tablets	30	DAYS				
21370070000120	Erivedge	Vismodegib Cap 150 MG	150 MG	30	Capsules	30	DAYS				
21402410000360	Erleada	apalutamide tab	240 MG	30	Tablets	30	DAYS				
21402410000320	Erleada	Apalutamide Tab 60 MG	60 MG	120	Tablets	30	DAYS				
215315501001	Farydak	panobinostat lactate cap	10 MG ; 15 MG ; 20 MG	6	Capsules	21	DAYS				
21533076250120	Fotivda	Tivozanib HCl Cap	0.89 MG	21	Capsules	28	DAYS				
21533076250130	Fotivda	Tivozanib HCl Cap	1.34 MG	21	Capsules	28	DAYS				
21335035000120	Fruzaqla	fruquintinib cap	1 MG	84	Capsules	28	DAYS				
21335035000140	Fruzaqla	fruquintinib cap	5 MG	21	Capsules	28	DAYS				
215357500001	Gavreto	pralsetinib cap	100 MG	120	Capsules	30	DAYS				
213600061003	Gilotrif	afatinib dimaleate tab	20 MG ; 30 MG ; 40 MG	30	Tablets	30	DAYS				
21531835100320	Gleevec	Imatinib Mesylate Tab	100 MG	90	Tablets	30	DAYS				
21531835100340	Gleevec	Imatinib Mesylate Tab	400 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
215310600001	Ibrance	palbociclib cap	100 MG ; 125 MG ; 75 MG	21	Capsules	28	DAYS				
215310600003	Ibrance	palbociclib tab	100 MG ; 125 MG ; 75 MG	21	Tablets	28	DAYS				
21531875100315	Iclusig	Ponatinib HCl Tab	10 MG	30	Tablets	30	DAYS				
21531875100320	Iclusig	Ponatinib HCl Tab	15 MG	30	Tablets	30	DAYS				
21531875100330	Iclusig	Ponatinib HCl Tab	30 MG	30	Tablets	30	DAYS				
21531875100340	Iclusig	Ponatinib HCl Tab	45 MG	30	Tablets	30	DAYS				
21535030200340	Idhifa	Enasidenib Mesylate Tab 100 MG (Base Equivalent)	100 MG	30	Tablets	30	DAYS				
21535030200320	Idhifa	Enasidenib Mesylate Tab 50 MG (Base Equivalent)	50 MG	30	Tablets	30	DAYS				
21532133000110	Imbruvica	Ibrutinib Cap	70 MG	30	Capsules	30	DAYS				
21532133000120	Imbruvica	Ibrutinib Cap	140 MG	90	Capsules	30	DAYS				
21532133001820	Imbruvica	Ibrutinib Oral Susp	70 MG/ML	2	Bottles	30	DAYS				
215321330003	Imbruvica	ibrutinib tab	140 MG ; 280 MG ; 420 MG ; 560 MG	30	Tablets	30	DAYS				
21335013000320	Inlyta	Axitinib Tab	1 MG	180	Tablets	30	DAYS				
21335013000340	Inlyta	Axitinib Tab	5 MG	120	Tablets	30	DAYS				
219900022503	Inqovi	decitabine-cedazuridine tab	35-100 MG	5	Tablets	28	DAYS				
21537520200120	Inrebic	Fedratinib HCl Cap 100 MG	100 MG	120	Capsules	30	DAYS				
213600300003	Iressa	gefitinib tab	250 MG	30	Tablets	30	DAYS				
21757220300320	Iwilfin	eflornithine hcl tab	192 MG	240	Tablets	30	DAYS				
215375602003	Jakafi	ruxolitinib phosphate tab	10 MG ; 15 MG ; 20 MG ; 25 MG ; 5 MG	60	Tablets	30	DAYS				
21532165000320	Jaypirca	pirtobrutinib tab	50 MG	30	Tablets	30	DAYS				
21532165000330	Jaypirca	pirtobrutinib tab	100 MG	60	Tablets	30	DAYS				
2153107050B720	Kisqali	Ribociclib Succinate Tab Pack 200 MG Daily Dose	200 MG	21	Tablets	28	DAYS				
2153107050B740	Kisqali	Ribociclib Succinate Tab Pack 400 MG Daily Dose (200 MG Tab)	200 MG	42	Tablets	28	DAYS				
2153107050B760	Kisqali	Ribociclib Succinate Tab Pack 600 MG Daily Dose (200 MG Tab)	200 MG	63	Tablets	28	DAYS				
2199000260B730	Kisqali femara 200 dose	Ribociclib 200 MG Dose (200 MG Tab) & Letrozole 2.5 MG TBPK	200 & 2.5 MG	49	Tablets	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
2199000260B740	Kisqali femara 400 dose	Ribociclib 400 MG Dose (200 MG Tab) & Letrozole 2.5 MG TBPK	200 & 2.5 MG	70	Tablets	28	DAYS				
2199000260B760	Kisqali femara 600 dose	Ribociclib 600 MG Dose (200 MG Tab) & Letrozole 2.5 MG TBPK	200 & 2.5 MG	91	Tablets	28	DAYS				
21533565500110	Koselugo	Selumetinib Sulfate Cap 10 MG	10 MG	240	Capsules	30	DAYS				
21533565500125	Koselugo	Selumetinib Sulfate Cap 25 MG	25 MG	120	Capsules	30	DAYS				
21532410000320	Krazati	Adagrasib Tab	200 MG	180	Tablets	30	DAYS				
2133505420B220	Lenvima 10 mg daily dose	Lenvatinib Cap Therapy Pack	10 MG	30	Capsules	30	DAYS				
2133505420B223	Lenvima 12mg daily dose	Lenvatinib Cap Therapy Pack	4 MG	90	Capsules	30	DAYS				
2133505420B240	Lenvima 14 mg daily dose	Lenvatinib Cap Therapy Pack	10 & 4 MG	60	Capsules	30	DAYS				
2133505420B244	Lenvima 18 mg daily dose	Lenvatinib Cap Ther Pack	10 MG & 2 x 4 MG	90	Capsules	30	DAYS				
2133505420B230	Lenvima 20 mg daily dose	Lenvatinib Cap Therapy Pack	10 MG	60	Capsules	30	DAYS				
2133505420B250	Lenvima 24 mg daily dose	Lenvatinib Cap Ther Pack	2 x 10 MG & 4 MG	90	Capsules	30	DAYS				
2133505420B210	Lenvima 4 mg daily dose	Lenvatinib Cap Therapy Pack	4 MG	30	Capsules	30	DAYS				
2133505420B215	Lenvima 8 mg daily dose	Lenvatinib Cap Therapy Pack	4 MG	60	Capsules	30	DAYS				
21990002750320	Lonsurf	Trifluridine-Tipiracil Tab 15-6.14 MG	15-6.14 MG	60	Tablets	28	DAYS				
21990002750330	Lonsurf	Trifluridine-Tipiracil Tab 20-8.19 MG	20-8.19 MG	80	Tablets	28	DAYS				
21530556000320	Lorbrena	Lorlatinib Tab	25 MG	90	Tablets	30	DAYS				
21530556000330	Lorbrena	Lorlatinib Tab	100 MG	30	Tablets	30	DAYS				
21532480000340	Lumakras	sotorasib tab	320 MG	90	Tablets	30	DAYS				
21532480000320	Lumakras	Sotorasib Tab	120 MG	240	Tablets	30	DAYS				
215355600003	Lynparza	olaparib tab	100 MG ; 150 MG	120	Tablets	30	DAYS				
2153222800B720	Lytgobi	Futibatinib Tab Therapy Pack	4 MG	84	Tablets	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
2153222800B725	Lytgobi	Futibatinib Tab Therapy Pack	4 MG	112	Tablets	28	DAYS				
2153222800B730	Lytgobi	Futibatinib Tab Therapy Pack	4 MG	140	Tablets	28	DAYS				
21533570102120	Mekinist	trametinib dimethyl sulfoxide for soln	0.05 MG/ML	1170	mLs	28	DAYS				
21533570100310	Mekinist	Trametinib Dimethyl Sulfoxide Tab 0.5 MG (Base Equivalent)	0.5 MG	90	Tablets	30	DAYS				
21533570100330	Mekinist	Trametinib Dimethyl Sulfoxide Tab 2 MG (Base Equivalent)	2 MG	30	Tablets	30	DAYS				
215335200003	Mektovi	binimetinib tab	15 MG	180	Tablets	30	DAYS				
21533035100320	Nerlynx	Neratinib Maleate Tab	40 MG	180	Tablets	30	DAYS				
21533060400320	Nexavar	Sorafenib Tosylate Tab 200 MG (Base Equivalent)	200 MG	120	Tablets	30	DAYS				
215360451001	Ninlaro	ixazomib citrate cap	2.3 MG ; 3 MG ; 4 MG	3	Capsules	28	DAYS				
21402425000320	Nubeqa	Darolutamide Tab 300 MG	300 MG	120	Tablets	30	DAYS				
213700602001	Odomzo	sonidegib phosphate cap	200 MG	30	Capsules	30	DAYS				
21532350200320	Ogsiveo	nirogacestat hydrobromide tab	50 MG	180	Tablets	30	DAYS				
21537540300320	Ojjaara	momelotinib dihydrochloride tab	100 MG	30	Tablets	30	DAYS				
21537540300330	Ojjaara	momelotinib dihydrochloride tab	150 MG	30	Tablets	30	DAYS				
21537540300340	Ojjaara	momelotinib dihydrochloride tab	200 MG	30	Tablets	30	DAYS				
213000030003	Onureg	azacitidine tab	200 MG ; 300 MG	14	Tablets	28	DAYS				
214055700003	Orgovyx	relugolix tab	120 MG	30	Tablets	30	DAYS				
21403720100320	Orserdu	elacestrant hydrochloride tab	86 MG	90	Tablets	30	DAYS				
21403720100340	Orserdu	elacestrant hydrochloride tab	345 MG	30	Tablets	30	DAYS				
21532260000340	Pemazyre	Pemigatinib Tab 13.5 MG	13.5 MG	14	Tablets	21	DAYS				
21532260000320	Pemazyre	Pemigatinib Tab 4.5 MG	4.5 MG	14	Tablets	21	DAYS				
21532260000330	Pemazyre	Pemigatinib Tab 9 MG	9 MG	14	Tablets	21	DAYS				
2153801000B720	Piqray 200mg daily dose	Alpelisib Tab Therapy Pack 200 MG Daily Dose	200 MG	28	Tablets	28	DAYS				
2153801000B725	Piqray 250mg daily dose	Alpelisib Tab Pack 250 MG Daily Dose (200 MG & 50 MG Tabs)	200 & 50 MG	56	Tablets	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
2153801000B730	Piqray 300mg daily dose	Alpelisib Tab Pack 300 MG Daily Dose (2x150 MG Tab)	150 MG	56	Tablets	28	DAYS				
214500800001	Pomalyst	pomalidomide cap	1 MG ; 2 MG ; 3 MG ; 4 MG	21	Capsules	28	DAYS				
21533053000320	Qinlock	Ripretinib Tab	50 MG	90	Tablets	30	DAYS				
21535779000120	Retevmo	Selpercatinib Cap	40 MG	180	Capsules	30	DAYS				
21535779000140	Retevmo	Selpercatinib Cap	80 MG	120	Capsules	30	DAYS				
99394050000130	Revlimid	Lenalidomide Cap 10 MG	10 MG	30	Capsules	30	DAYS				
99394050000140	Revlimid	Lenalidomide Cap 15 MG	15 MG	21	Capsules	28	DAYS				
99394050000145	Revlimid	Lenalidomide Cap 20 MG	20 MG	21	Capsules	28	DAYS				
99394050000150	Revlimid	Lenalidomide Cap 25 MG	25 MG	21	Capsules	28	DAYS				
99394050000120	Revlimid	Lenalidomide Cap 5 MG	5 MG	30	Capsules	30	DAYS				
99394050000110	Revlimid	Lenalidomide Caps 2.5 MG	2.5 MG	30	Capsules	30	DAYS				
21534960000120	Rezlidhia	Olutasidenib Cap	150 MG	60	Capsules	30	DAYS				
21533820000120	Rozlytrek	Entrectinib Cap 100 MG	100 MG	30	Capsules	30	DAYS				
21533820000130	Rozlytrek	Entrectinib Cap 200 MG	200 MG	90	Capsules	30	DAYS				
21533820003020	Rozlytrek	entrectinib pellet pack	50 MG	336	Packets	28	DAYS				
21535570200320	Rubraca	Rucaparib Camsylate Tab 200 MG (Base Equivalent)	200 MG	120	Tablets	30	DAYS				
21535570200325	Rubraca	Rucaparib Camsylate Tab 250 MG (Base Equivalent)	250 MG	120	Tablets	30	DAYS				
21535570200330	Rubraca	Rucaparib Camsylate Tab 300 MG (Base Equivalent)	300 MG	120	Tablets	30	DAYS				
21533030000130	Rydapt	Midostaurin Cap 25 MG	25 MG	240	Capsules	30	DAYS				
21531806100320	Scemblix	Asciminib HCl Tab	20 MG	60	Tablets	30	DAYS				
21531806100340	Scemblix	Asciminib HCl Tab	40 MG	300	Tablets	30	DAYS				
21531820000320	Sprycel	Dasatinib Tab	20 MG	90	Tablets	30	DAYS				
21531820000340	Sprycel	Dasatinib Tab	50 MG	30	Tablets	30	DAYS				
21531820000350	Sprycel	Dasatinib Tab	70 MG	30	Tablets	30	DAYS				
21531820000354	Sprycel	Dasatinib Tab	80 MG	30	Tablets	30	DAYS				
21531820000360	Sprycel	Dasatinib Tab	100 MG	30	Tablets	30	DAYS				
21531820000380	Sprycel	Dasatinib Tab	140 MG	30	Tablets	30	DAYS				
215330500003	Stivarga	regorafenib tab	40 MG	84	Tablets	28	DAYS				
21533070300120	Sutent	Sunitinib Malate Cap 12.5 MG (Base Equivalent)	12.5 MG	90	Capsules	30	DAYS				
21533070300130	Sutent	Sunitinib Malate Cap 25 MG (Base Equivalent)	25 MG	30	Capsules	30	DAYS				
21533070300135	Sutent	Sunitinib Malate Cap 37.5 MG (Base Equivalent)	37.5 MG	30	Capsules	30	DAYS				
21533070300140	Sutent	Sunitinib Malate Cap 50 MG (Base Equivalent)	50 MG	30	Capsules	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
215337162003	Tabrecta	capmatinib hcl tab	150 MG ; 200 MG	120	Tablets	30	DAYS				
215320251001	Tafinlar	dabrafenib mesylate cap	50 MG ; 75 MG	120	Capsules	30	DAYS				
21532025107320	Tafinlar	dabrafenib mesylate tab for oral susp	10 MG	840	Tablets	28	DAYS				
213600682003	Tagrisso	osimertinib mesylate tab	40 MG ; 80 MG	30	Tablets	30	DAYS				
21535580400105	Talzenna	talazoparib tosylate cap	0.1 MG	30	Capsules	30	DAYS				
21535580400112	Talzenna	talazoparib tosylate cap	0.35 MG	30	Capsule	30	DAYS				
21535580400114	Talzenna	Talazoparib Tosylate Cap	0.5 MG	30	Capsules	30	DAYS				
21535580400118	Talzenna	Talazoparib Tosylate Cap	0.75 MG	30	Capsules	30	DAYS				
21535580400110	Talzenna	Talazoparib Tosylate Cap 0.25 MG (Base Equivalent)	0.25 MG	90	Capsules	30	DAYS				
21535580400120	Talzenna	Talazoparib Tosylate Cap 1 MG (Base Equivalent)	1 MG	30	Capsules	30	DAYS				
21360025100320	Tarceva	Erlotinib HCl Tab	25 MG	60	Tablets	30	DAYS				
21360025100330	Tarceva	Erlotinib HCl Tab	100 MG	30	Tablets	30	DAYS				
21360025100360	Tarceva	Erlotinib HCl Tab	150 MG	30	Tablets	30	DAYS				
215318602001	Tasigna	nilotinib hcl cap	150 MG ; 200 MG ; 50 MG	120	Capsules	30	DAYS				
215336752003	Tazverik	tazemetostat hbr tab	200 MG	240	Tablets	30	DAYS				
21533773100320	Tepmetko	Tepotinib HCl Tab	225 MG	60	Tablets	30	DAYS				
99392070000130	Thalomid	Thalidomide Cap 100 MG	100 MG	120	Capsules	30	DAYS				
99392070000135	Thalomid	Thalidomide Cap 150 MG	150 MG	60	Capsules	30	DAYS				
99392070000140	Thalomid	Thalidomide Cap 200 MG	200 MG	60	Capsules	30	DAYS				
99392070000120	Thalomid	Thalidomide Cap 50 MG	50 MG	90	Capsules	30	DAYS				
21534940000320	Tibsovo	Ivosidenib Tab 250 MG	250 MG	60	Tablets	30	DAYS				
21530320000320	Truqap	capivasertib tab	160 MG	64	Tablets	28	DAYS				
21530320000325	Truqap	capivasertib tab	200 MG	64	Tablets	28	DAYS				
2153223540B235	Truseltiq	Infigratinib Phos Cap Pack	100 & 25 MG	42	Capsules	28	DAYS				
2153223540B220	Truseltiq	Infigratinib Phos Cap Ther Pack	25 MG	42	Capsules	28	DAYS				
2153223540B225	Truseltiq	Infigratinib Phos Cap Ther Pack	25 MG	63	Capsules	28	DAYS				
2153223540B230	Truseltiq	Infigratinib Phos Cap Ther Pack	100 MG	21	Capsules	28	DAYS				
21170080000320	Tukysa	Tucatinib Tab	50 MG	300	Tablets	30	DAYS				
21170080000340	Tukysa	Tucatinib Tab	150 MG	120	Tablets	30	DAYS				
21533045010110	Turalio	Pexidartinib HCl Cap	125 MG	120	Capsules	30	DAYS				
21533045010120	Turalio	Pexidartinib HCl Cap	200 MG	120	Capsules	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
21533026100320	Tykerb	Lapatinib Ditosylate Tab	250 MG	180	Tablets	30	DAYS				
21533047100320	Vanflyta	quizartinib dihydrochloride tab	17.7 MG	28	Tablets	28	DAYS				
21533047100325	Vanflyta	quizartinib dihydrochloride tab	26.5 MG	56	Tablets	28	DAYS				
21470080000320	Venclexta	Venetoclax Tab 10 MG	10 MG	60	Tablets	30	DAYS				
21470080000360	Venclexta	Venetoclax Tab 100 MG	100 MG	180	Tablets	30	DAYS				
21470080000340	Venclexta	Venetoclax Tab 50 MG	50 MG	30	Tablets	30	DAYS				
2147008000B720	Venclexta starting pack	Venetoclax Tab Therapy Starter Pack 10 & 50 & 100 MG	10 & 50 & 100 MG	1	Pack	180	DAYS				
215310100003	Verzenio	abemaciclib tab	100 MG ; 150 MG ; 200 MG ; 50 MG	60	Tablets	30	DAYS				
21533835200150	Vitrakvi	Larotrectinib Sulfate Cap 100 MG (Base Equivalent)	100 MG	60	Capsules	30	DAYS				
21533835200120	Vitrakvi	Larotrectinib Sulfate Cap 25 MG (Base Equivalent)	25 MG	180	Capsules	30	DAYS				
21533835202020	Vitrakvi	Larotrectinib Sulfate Oral Soln 20 MG/ML (Base Equivalent)	20 MG/ML	300	mLs	30	DAYS				
213600190003	Vizimpro	dacomitinib tab	15 MG ; 30 MG ; 45 MG	30	Tablets	30	DAYS				
215375501001	Vonjo	pacritinib citrate cap	100 MG	120	Capsules	30	DAYS				
21533042100320	Votrient	Pazopanib HCl Tab	200 MG	120	Tablets	30	DAYS				
21421020000320	Welireg	Belzutifan Tab	40 MG	90	Tablets	30	DAYS				
215305170001	Xalkori	crizotinib cap	200 MG ; 250 MG	120	Capsules	30	DAYS				
21530517006820	Xalkori	crizotinib cap sprinkle	20 MG	120	Capsules	30	DAYS				
21530517006830	Xalkori	crizotinib cap sprinkle	50 MG	120	Capsules	30	DAYS				
21530517006850	Xalkori	crizotinib cap sprinkle	150 MG	180	Capsules	30	DAYS				
21533020200320	Xospata	Gilteritinib Fumarate Tablet	40 MG	90	Tablets	30	DAYS				
2156006000B760	Xpovio	Selinexor Tab Therapy Pack	40 MG	4	Tablets	28	DAYS				
2156006000B765	Xpovio	Selinexor Tab Therapy Pack	40 MG	8	Tablets	28	DAYS				
2156006000B770	Xpovio	Selinexor Tab Therapy Pack	40 MG	8	Tablets	28	DAYS				
2156006000B775	Xpovio	Selinexor Tab Therapy Pack	50 MG	8	Tablets	28	DAYS				
2156006000B780	Xpovio	Selinexor Tab Therapy Pack	60 MG	4	Tablets	28	DAYS				
2156006000B755	Xpovio 60 mg twice weekly	Selinexor Tab Therapy Pack 20 MG (60 MG Twice Weekly)	20 MG	24	Tablets	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
2156006000B720	Xpovio 80 mg twice weekly	Selinexor Tab Therapy Pack 20 MG (80 MG Twice Weekly)	20 MG	32	Tablets	28	DAYS				
214024300001	Xtandi	enzalutamide cap	40 MG	120	Capsules	30	DAYS				
21402430000320	Xtandi	Enzalutamide Tab	40 MG	120	Tablets	30	DAYS				
21402430000340	Xtandi	Enzalutamide Tab	80 MG	60	Tablets	30	DAYS				
21406010250310	Yonsa	abiraterone acetate tab 125 mg	125 MG	120	Tablets	30	DAYS				
215355502001	Zejula	niraparib tosylate cap	100 MG	90	Capsules	30	DAYS				
21535550200320	Zejula	niraparib tosylate tab	100 MG	30	Tablets	30	DAYS				
21535550200330	Zejula	niraparib tosylate tab	200 MG	30	Tablets	30	DAYS				
21535550200340	Zejula	niraparib tosylate tab	300 MG	30	Tablets	30	DAYS				
21532080000320	Zelboraf	Vemurafenib Tab 240 MG	240 MG	240	Tablets	30	DAYS				
21531575000120	Zolinza	Vorinostat Cap 100 MG	100 MG	120	Capsules	30	DAYS				
215380400003	Zydelig	idelalisib tab	100 MG ; 150 MG	60	Tablets	30	DAYS				
215305140003	Zykadia	ceritinib tab	150 MG	90	Tablets	30	DAYS				
21406010200320	Zytiga	Abiraterone Acetate Tab 250 MG	250 MG	120	Tablets	30	DAYS				
21406010200330	Zytiga	Abiraterone Acetate Tab 500 MG	500 MG	60	Tablets	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
21532530007310	Afinitor disperz	Everolimus Tab for Oral Susp 2 MG	2 MG	Calculation is based on 4.5 mg/m2 with a standard BSA of 2.0 and rounding up to nearest full dose			
21532530007320	Afinitor disperz	Everolimus Tab for Oral Susp 3 MG	3 MG	Calculation is based on 4.5 mg/m2 with a standard BSA of 2.0 and rounding up to nearest full dose			
21532530007340	Afinitor disperz	Everolimus Tab for Oral Susp 5 MG	5 MG	Calculation is based on 4.5 mg/m2 with a standard BSA of 2.0 and rounding up to nearest full dose			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA QL	**Initial Evaluation** **Target Agent(s)** will be approved when ONE of the following are met: 1. ALL of the following: A. ONE of the following: 1. The patient has been treated with the requested agent within the past 180 days **OR** 2. The prescriber states the patient is being treated with the requested agent within the past 180 days AND is at risk if therapy is changed **OR**

Module	Clinical Criteria for Approval
	3. ALL of the following: A. ONE of the following: 1. The patient has an FDA labeled indication for the requested agent **OR** 2. The patient has an indication that is supported by NCCN 1, 2A, or 2B recommended use, AHFS, DrugDex level of evidence of 1, IIa, or IIb, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) [i.e., this indication must be supported by ALL requirements in the compendia (e.g., performance status, disease severity, previous failures, monotherapy vs combination therapy, etc.)] for the requested agent **AND** B. If the patient has an FDA labeled indication, then ONE of the following: 1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** 2. There is support for using the requested agent for the patient's age for the requested indication **AND** C. ONE of the following: 1. The requested indication does NOT require genetic/specific diagnostic testing per FDA labeling or compendia (NCCN 1, 2A, or 2B recommended use, AHFS, DrugDex level of evidence of 1, IIa, or IIb, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested agent **OR** 2. The requested indication requires genetic/specific diagnostic testing per FDA labeling or compendia (NCCN 1, 2A, or 2B recommended use, AHFS, DrugDex level of evidence of 1, IIa, or IIb, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested agent AND BOTH of the following: A. Genetic/specific diagnostic testing has been completed **AND** B. The results of the genetic/specific diagnostic testing indicate therapy with the requested agent is appropriate **AND** D. ONE of the following: 1. The requested agent is being used as monotherapy and is approved for use as monotherapy in the FDA labeling or compendia (NCCN 1, 2A, or 2B recommended use, AHFS, DrugDex level of evidence of 1, IIa, or IIb, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested indication **OR** 2. The requested agent will be used as combination therapy with all agent(s) and/or treatments (e.g., radiation) listed for concomitant use in the FDA labeling or compendia (NCCN 1, 2A, or 2B recommended use, AHFS, DrugDex level of evidence of 1, IIa, or IIb, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested indication **AND** E. ONE of the following: 1. The requested agent will be used as a first-line agent and is FDA labeled or compendia (NCCN 1, 2A, or 2B recommended use, AHFS, DrugDex level of evidence of 1, IIa, or IIb, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) as a first-line agent for the requested indication **OR** 2. The patient has tried and had an inadequate response to the appropriate number and type(s) of prerequisite agent(s) listed in the FDA labeling or compendia (NCCN 1, 2A, or 2B recommended use, AHFS, DrugDex level of evidence of 1, IIa, or IIb, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested indication **OR** 3. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to the appropriate number and type(s) of prerequisite agent(s) listed in the FDA labeling or compendia (NCCN 1, 2A, or 2B recommended use, AHFS, DrugDex level of evidence of 1, IIa, or IIb, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested indication **OR**

Module	Clinical Criteria for Approval
	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 the appropriate prerequisite agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. The patient does not have any FDA labeled contraindications to the requested agent **AND** C. The patient does not have any FDA labeled limitation(s) of use that is otherwise not supported in NCCN to the requested agent **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Length of Approval:** Up to 3 months for dose titration requests over the program quantity limit and Vitrakvi; Up to 12 months for all other requests, approve starter packs and loading doses where appropriate and maintenance dose for the remainder of the authorization NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when BOTH of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. ONE of the following: A. ALL of the following: 1. ONE of the following: A. The requested agent is Vitrakvi AND the patient has experienced clinical benefit (i.e., partial response, complete response, or stable disease) with the requested agent **OR** B. The requested agent is NOT Vitrakvi **AND** 2. The patient does not have any FDA labeled contraindications to the requested agent **AND** 3. The patient does not have any FDA labeled limitation(s) of use that is otherwise not supported in NCCN to the requested agent **OR** B. 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 **Length of Approval:** Up to 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

Module	Clinical Criteria for Approval
	FDA Companion Diagnostics: https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools

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) 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. There is support for therapy with a higher dose for the requested indication **Length of Approval**: Up to 3 months for dose titration requests over the program quantity limit and Vitrakvi; Up to 12 months for all other requests, approve starter packs/loading doses where appropriate and maintenance doses for the remainder of the authorization

• Program Summary: Substrate Reduction Therapy

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

The BCBS MN Step Therapy Supplement also applies to this program for Medicaid.

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
82700040600120	Cerdelga	Eliglustat Tartrate Cap 84 MG (Base Equivalent)	84 MG	60	Capsules	30	DAYS				
30907760000120	Opfolda	miglustat (gaa deficiency) cap	65 MG	8	Capsules	28	DAYS				
82700070000120	Yargesa ; Zavesca	Miglustat Cap 100 MG	100 MG	90	Capsules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Cerdelga, Zavesca	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met:

Module	Clinical Criteria for Approval
	1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND BOTH of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. ONE of the following: A. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** B. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **AND** 2. The prescriber has assessed current status of the following: spleen volume, hemoglobin level, liver volume, platelet count, growth, bone pain or crisis **OR** B. ALL of the following: 1. The patient has a diagnosis of Gaucher disease type 1 (GD1) **AND** 2. ONE of the following: A. The patient has baseline (prior to therapy for the requested indication) glucocerebrosidase enzyme activity of less than or equal to 15% of mean normal in fibroblasts, leukocytes, or other nucleated cells **OR** B. Genetic analysis confirmed two (2) pathogenic alleles in the glucocerebrosidase (*GBA*) gene **AND** 3. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 4. The patient does NOT have any neuronopathic symptoms indicative of Gaucher disease type 2 or type 3 [e.g., bulbar signs (e.g., stridor, strabismus, swallowing difficulty), pyramidal signs (e.g., opisthotonos, head retroflexion, spasticity, trismus), oculomotor apraxia, tonic-clonic seizures, myoclonic epilepsy, dementia, ataxia] **AND** 5. The prescriber has assessed baseline (prior to therapy for the requested indication) status of hemoglobin level, platelet count, liver volume, and spleen volume **AND** 6. The patient has at least ONE of the following clinical presentations at baseline (prior to therapy for the requested indication): A. Anemia defined as mean hemoglobin (Hb) level below the testing laboratory's lower limit of the normal range based on age and gender **OR** B. Thrombocytopenia (platelet count less than 100,000/microliter on at least 2 measurements) **OR** C. Hepatomegaly **OR** D. Splenomegaly **OR** E. Growth failure (i.e., growth velocity is below the standard mean for age) **OR** F. Evidence of bone disease with other causes ruled out **AND** 7. If the requested agent is Zavesca or miglustat, enzyme replacement therapy (ERT) is NOT a therapeutic option (e.g., due to allergy, hypersensitivity, poor venous access, previous ERT failure) **AND** 2. If the requested agent is Cerdelga or eliglustat, the patient is a CYP2D6 extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM), as detected by an FDA-cleared test for determining CYP2D6 genotype **AND** 3. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following: A. The patient's medication history includes use of the generic equivalent **OR**

Module	Clinical Criteria for Approval

B. BOTH of the following:
   1. The prescriber has stated that the patient has tried the generic equivalent **AND**
   2. The generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**

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

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

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

Brand	Generic Equivalent
Zavesca	miglustat

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

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

4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
5. The patient will NOT be using the requested agent in combination with another substrate reduction therapy agent (e.g., Cerdelga, Opfolda, Zavesca) for the requested indication **AND**
6. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 12 months

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

Renewal Evaluation

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

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**
2. The patient has had improvements or stabilization with the requested agent as indicated by ONE of the following:
   A. Spleen volume **OR**
   B. Hemoglobin level **OR**
   C. Liver volume **OR**
   D. Platelet count (sufficient to decrease the risk of bleeding) **OR**
   E. Growth **OR**
   F. Bone pain or crisis **AND**
3. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following:
   A. The patient's medication history includes use of the generic equivalent **OR**
   B. BOTH of the following:
      1. The prescriber has stated that the patient has tried the generic equivalent **AND**

Module	Clinical Criteria for Approval
	2. The generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR** C. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR** D. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR** E. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent **OR** **Brand** / **Generic Equivalent** Zavesca / miglustat F. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** G. The prescriber has provided documentation that the generic equivalent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist) or the prescriber has consulted with a specialist in the area of patient's diagnosis **AND** 5. The patient will NOT be using the requested agent in combination with another substrate reduction therapy agent (e.g., Cerdelga, Opfolda, Zavesca) for the requested indication **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval**: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Opfolda	**Initial Evaluation** **Opfolda** 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** Opfolda 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. ALL of the following: 1. The patient has a diagnosis of late-onset Pompe disease (acid maltase deficiency [AMD]; glycogen storage disease type II [GSDII]) confirmed by at least ONE of the following: A. Genetic analysis confirms biallelic mutation (two pathogenic variants) in the *GAA* gene **OR** B. The patient has deficient acid alpha-glucosidase glycogen enzyme activity in dried blood spots, leukocytes, skin fibroblasts, and/or skeletal muscle tissue **AND** 2. The patient is not improving on their current enzyme replacement therapy (ERT) **AND**

Module	Clinical Criteria for Approval
	3. The requested agent will be taken in combination with Pombiliti **AND** 4. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 2. The prescriber has assessed current status of the following: gross motor function (e.g., walking distance), pulmonary function (e.g., forced vital capacity [FVC]) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist) 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. **Renewal Evaluation** **Opfolda** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had improvements or stabilization with the requested agent as indicated by ONE of the following: A. Gross motor function (e.g., walking distance) **OR** B. Pulmonary function (e.g., forced vital capacity [FVC]) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist) 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.

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**

Module	Clinical Criteria for Approval
	C. There is support of therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• Program Summary: Symlin

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
2715005010D240	Symlinpen 120	Pramlintide Acetate Pen-inj 2700 MCG/2.7ML (1000 MCG/ML)	2700 MCG/2.7 ML	4	Pens	30	DAYS				
2715005010D220	Symlinpen 60	Pramlintide Acetate Pen-inj 1500 MCG/1.5ML (1000 MCG/ML)	1500 MCG/1.5 ML	4	Pens	30	DAYS				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Target Agents will be approved when ONE of the following is met: 1. The patient has been 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 in 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 insulin **OR** 5. The prescriber has stated that the patient has tried insulin therapy AND ONE of the following: A. Insulin therapy was discontinued due to lack of effectiveness or an adverse event **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over insulin therapy **OR** 6. The patient has an intolerance or hypersensitivity to insulin therapy **OR** 7. The patient has an FDA labeled contraindication to ALL insulin therapy **OR** 8. The prescriber has provided documentation that ALL insulin therapy 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. 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. There is support for therapy with a higher dose for the requested indication **Length of approval:** up to 12 months

• Program Summary: Triptan

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

The BCBS MN Step Therapy Supplement applies to this program for Medicaid.

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
674060101003		almotriptan malate tab	12.5 MG ; 6.25 MG	12	Tablets	30	DAYS				
67406070102010		Sumatriptan Succinate Inj 6 MG/0.5ML	6 MG/0.5ML	10	Vials	30	DAYS				
674060800072		zolmitriptan orally disintegrating tab	2.5 MG ; 5 MG	12	Tablets	30	DAYS				
674060501003	Amerge	naratriptan hcl tab	1 MG ; 2.5 MG	18	Tablets	30	DAYS				
674060301003	Frova	frovatriptan succinate tab	2.5 MG	18	Tablets	30	DAYS				
67406070002040	Imitrex	sumatriptan nasal spray	20 MG/ACT	12	Units	30	DAYS				
67406070002010	Imitrex	Sumatriptan Nasal Spray 5 MG/ACT	5 MG/ACT	12	Units	30	DAYS				
674060701003	Imitrex	sumatriptan succinate tab	100 MG ; 25 MG ; 50 MG	18	Tablets	30	DAYS				
6740607010E210	Imitrex statdose refill	Sumatriptan Succinate Solution Cartridge 4 MG/0.5ML	4 MG/0.5ML	12	Doses	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
6740607010E220	Imitrex statdose refill	Sumatriptan Succinate Solution Cartridge 6 MG/0.5ML	6 MG/0.5ML	12	Doses	30	DAYS				
6740607010D520	Imitrex statdose system	sumatriptan succinate solution auto-injector	6 MG/0.5ML	12	Doses	30	DAYS				
6740607010D510	Imitrex statdose system	Sumatriptan Succinate Solution Auto-injector 4 MG/0.5ML	4 MG/0.5ML	12	Doses	30	DAYS				
674060601003	Maxalt	rizatriptan benzoate tab	10 MG ; 5 MG	18	Tablets	30	DAYS				
674060601072	Maxalt-mlt	rizatriptan benzoate oral disintegrating tab	10 MG ; 5 MG	18	Tablets	30	DAYS				
6740607010G420	Onzetra xsail	Sumatriptan Succinate Exhaler Powder 11 MG/NOSEPIECE	11 MG/NOSEPC	2	Kits	30	DAYS				
674060251003	Relpax	eletriptan hydrobromide tab	20 MG ; 40 MG	12	Tablets	30	DAYS				
67406070002020	Tosymra	Sumatriptan Nasal Spray 10 MG/ACT	10 MG/ACT	18	Sprays	30	DAYS				
679920026003	Treximet	sumatriptan-naproxen sodium tab	85-500 MG	18	Tablets	30	DAYS				
6740607010D505	Zembrace symtouch	sumatriptan succinate solution auto-injector	3 MG/0.5ML	24	Pens	30	DAYS				
674060800020	Zomig	zolmitriptan nasal spray	2.5 MG ; 5 MG	2	Boxes	30	DAYS				
674060800003	Zomig	zolmitriptan tab	2.5 MG ; 5 MG	12	Tablets	30	DAYS				

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. ALL of the following: A. The patient has a diagnosis of migraine headache **AND** B. ONE of the following: 1. The patient is currently using migraine prophylactic medication (i.e., anticonvulsants [i.e., divalproex, valproate, topiramate], beta blockers [i.e., atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [i.e., amitriptyline, venlafaxine], candesartan, prophylactic use CGRP [i.e., Aimovig, AJOVY, Emgality, Nurtec, QULIPTA, Vyepti], onabotulinum toxin A (Botox]) **OR** 2. The patient has an intolerance or hypersensitivity to an anticonvulsant, a beta blocker, an antidepressant, candesartan, prophylactic use CGRP, or onabotulinum toxin A listed above **OR** 3. The patient has an FDA labeled contraindication to ALL anticonvulsants, beta blockers, antidepressants, candesartan, prophylactic use CGRP, or onabotulinum toxin A listed above **OR**

Module	Clinical Criteria for Approval
	4. BOTH of the following: A. The patient's medication history includes a migraine prophylactic medication (i.e., anticonvulsants [i.e., divalproex, valproate, topiramate], beta blockers [i.e., atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [i.e., amitriptyline, venlafaxine], candesartan, prophylactic use CGRP [i.e., Aimovig, AJOVY, Emgality, Nurtec, QULIPTA, Vyepti], onabotulinum toxin A (Botox]), or a drug in the same pharmacological class with the same mechanism of action as indicated by ONE of the following: 1. Evidence of a paid claim(s) **OR** 2. The prescriber has stated that the patient has tried a migraine prophylactic medication (i.e., anticonvulsants [i.e., divalproex, valproate, topiramate], beta blockers [i.e., atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [i.e., amitriptyline, venlafaxine], candesartan, prophylactic use CGRP [i.e., Aimovig, AJOVY, Emgality, Nurtec, QULIPTA, Vyepti], onabotulinum toxin A (Botox]), or a drug in the same pharmacological class with the same mechanism of action **AND** B. ONE of the following: 1. Migraine prophylactic medication 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 migraine prophylactic medication **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 migraine prophylactic medication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** C. Medication overuse headache has been ruled out **AND** D. The patient will NOT be using the requested agent in combination with another acute migraine therapy (e.g., triptan, 5HT-1F [REYVOW], ergotamine, acute use CGRP [e.g., Nurtec, UBRELVY, Zavzpret]) **AND** E. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **OR** 2. BOTH of the following: A. The patient has a diagnosis of cluster headache **AND** B. The requested agent is an injection or nasal spray **Length of Approval:** up to 12 months [For a diagnosis of migraine, the quantity requested up to the FDA labeled maximum dose allowed per 24 hours will be approved.]