MHCP PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

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

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

No new policies for June 1, 2024

POLICIES REVISED

• Program Summary: Acute Migraine 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
67604030002020	Elyxyb	Celecoxib Oral Soln	120 MG/4.8 ML	6	Bottles	30	DAYS				
67000030102060	Migranal	Dihydroergotamine Mesylate Nasal Spray 4 MG/ML	4 MG/ML	8	mLs	28	DAYS				
67406540600320	Reyvow	Lasmiditan Succinate Tab 100 MG	100 MG	8	Tablets	30	DAYS				
67406540600310	Reyvow	Lasmiditan Succinate Tab 50 MG	50 MG	8	Tablets	30	DAYS				
67000030113420	Trudhesa	Dihydroergotamine Mesylate HFA Nasal Aerosol	0.725 MG/ACT	12	mLs	28	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Indication	PDL Preferred Agents
Acute treatment of migraine with or without aura	Ubrelvy*
*For Ubrelvy - please see CGRP PAQL program	

Initial Evaluation

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

1. ALL of the following:
   - A. ONE of the following:
     1. The requested agent is being used for acute migraine treatment AND ALL of the following:
        - A. ONE of the following:
          1. The patient's medication history includes ONE triptan agent AND ONE of the following:
             - A. The patient has had an inadequate response to ONE triptan agent **OR**
             - B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over a triptan agent **OR**
          2. The patient has an intolerance or hypersensitivity to triptan therapy **OR**
          3. The patient has an FDA labeled contraindication to ALL triptan agents **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 ALL triptan 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. ONE of the following: 1. The requested agent is NOT REYVOW **OR** 2. The requested agent is REYVOW and the patient will NOT be using the requested agent in combination with another acute migraine therapy (i.e., 5HT-1F, acute use CGRP, ergotamine, triptan) **AND** C. Medication overuse headache has been ruled out **OR** 2. The patient has another FDA labeled indication for the requested agent and route of administration **OR** 3. The patient has another indication that is supported in compendia for the requested agent and route of administration **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 agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) for the requested indication **OR** 2. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) for the requested indication and ONE of the following: A. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** B. The patient 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) for the requested indication as indicated by BOTH of the following: 1. ONE of the following: A. Evidence of a paid claim(s) **OR** B. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND** 2. ONE of the following: A. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR**

Module	Clinical Criteria for Approval
	B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR** C. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) for the requested indication that is not expected to occur with the requested agent **OR** D. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** D. The patient does NOT have any FDA labeled contraindications 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 labeled indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when BOTH of the following are met: 1. The patient has been approved for the requested agent previously 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. BOTH of the following: 1. ONE of the following: A. The requested agent is being used for acute migraine treatment AND ALL of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. ONE of the following: A. The requested agent is NOT REYVOW **OR** B. The requested agent is REYVOW AND the patient will NOT be using the requested agent in combination with another acute migraine therapy (i.e., 5HT-1F, acute use CGRP, ergotamine, triptan) **AND** 3. Medication overuse headache has been ruled out **OR** B. The patient is using the requested agent for an indication other than acute migraine treatment AND has had clinical benefit with the requested agent **AND** 2. The patient does NOT have any FDA labeled contraindications 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 labeled indication **AND** 2. The patient uses an enteral tube for feeding or medication administration **Compendia Allowed:** CMS Approved Compendia **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

	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. The patient has greater than 4 migraine headaches per month AND ONE of the following: 1. The patient is currently being treated with 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 (e.g., Aimovig, AJOVY, Emgality, Nurtec, QULIPTA, Vyepti), onabotulinum toxin A (Botox)] **OR** 2. The patient has an intolerance or hypersensitivity to therapy with 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 (e.g., Aimovig, AJOVY, Emgality, Nurtec, QULIPTA, Vyepti), OR onabotulinum toxin A (Botox)] **OR** 3. The patient has an FDA labeled contraindication to ALL migraine prophylactic medications [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 (e.g., Aimovig, AJOVY, Emgality, Nurtec, QULIPTA, Vyepti), AND onabotulinum toxin A (Botox)] **OR** 4. There is support that the patient's migraines are manageable with acute therapy alone **AND** D. There is support of therapy with a higher dose for the requested indication **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** up to 12 months

● Program Summary: Attention Deficit [Hyperactivity] Disorder (ADHD/ADD) Agents

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

OBJECTIVE

The Quantity Limit (QL) program will apply to all ages.

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
61400020100530		Methylphenidate HCl Chew Tab 10 MG	10 MG	180	Tablets	30	DAYS				
61400020100510		Methylphenidate HCl Chew Tab 2.5 MG	2.5 MG	90	Tablets	30	DAYS				
61400020100520		Methylphenidate HCl Chew Tab 5 MG	5 MG	90	Tablets	30	DAYS				
61400020100403		Methylphenidate HCl Tab ER 10 MG	10 MG	90	Tablets	30	DAYS				
61400020100405		Methylphenidate HCl Tab ER 20 MG	20 MG	90	Tablets	30	DAYS				
61400020107518		Methylphenidate HCl Tab ER 24HR 18 MG	18 MG	30	Tablets	30	DAYS				
61400020107527		Methylphenidate HCl Tab ER 24HR 27 MG	27 MG	30	Tablets	30	DAYS				
61400020107536		Methylphenidate HCl Tab ER 24HR 36 MG	36 MG	60	Tablets	30	DAYS				
61400020107554		Methylphenidate HCl Tab ER 24HR 54 MG	54 MG	30	Tablets	30	DAYS				
61109902100310	Adderall	Amphetamine-Dextroamphetamine Tab 10 MG	10 MG	60	Tablets	30	DAYS				
61109902100312	Adderall	Amphetamine-Dextroamphetamine Tab 12.5 MG	12.5 MG	60	Tablets	30	DAYS				
61109902100315	Adderall	Amphetamine-Dextroamphetamine Tab 15 MG	15 MG	60	Tablets	30	DAYS				
61109902100320	Adderall	Amphetamine-Dextroamphetamine Tab 20 MG	20 MG	90	Tablets	30	DAYS				
61109902100330	Adderall	Amphetamine-Dextroamphetamine Tab 30 MG	30 MG	60	Tablets	30	DAYS				
61109902100305	Adderall	Amphetamine-Dextroamphetamine Tab 5 MG	5 MG	60	Tablets	30	DAYS				
61109902100307	Adderall	Amphetamine-Dextroamphetamine Tab 7.5 MG	7.5 MG	60	Tablets	30	DAYS				
611099021070	Adderall xr; Mydayis	amphetamine-dextroamphetamine; amphetamine-dextroamphetamine cap er	10 MG; 12.5 MG; 15 MG; 20 MG; 25 MG; 30 MG; 37.5 MG; 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
			50 MG								
614000201070	Adhansia xr; Aptensio xr; Jornay pm; Ritalin la	methylphenidate hcl cap delayed er; methylphenidate hcl cap er	10 MG; 100 MG; 15 MG; 20 MG; 25 MG; 30 MG; 35 MG; 40 MG; 45 MG; 50 MG; 55 MG; 60 MG; 70 MG; 80 MG; 85 MG	30	Capsules	30	DAYS				
6110001000H440	Adzenys xr-odt	Amphetamine Tab Extended Release Disintegrating 12.5 MG	12.5 MG	30	Tablets	30	DAYS				
6110001000H450	Adzenys xr-odt	Amphetamine Tab Extended Release Disintegrating 15.7 MG	15.7 MG	30	Tablets	30	DAYS				
6110001000H460	Adzenys xr-odt	Amphetamine Tab Extended Release Disintegrating 18.8 MG	18.8 MG	30	Tablets	30	DAYS				
6110001000H410	Adzenys xr-odt	Amphetamine Tab Extended Release Disintegrating 3.1 MG	3.1 MG	60	Tablets	30	DAYS				
6110001000H420	Adzenys xr-odt	Amphetamine Tab Extended Release Disintegrating 6.3 MG	6.3 MG	60	Tablets	30	DAYS				
6110001000H430	Adzenys xr-odt	Amphetamine Tab Extended Release Disintegrating 9.4 MG	9.4 MG	30	Tablets	30	DAYS				
61409802800120	Azstarys	Serdexmethylphenidate-Dexmethylphenidate Cap	26.1-5.2 MG	30	Capsules	30	DAYS				
61409802800130	Azstarys	Serdexmethylphenidate-Dexmethylphenidate Cap	39.2-7.8 MG	30	Capsules	30	DAYS				
61409802800140	Azstarys	Serdexmethylphenidate-Dexmethylphenidate Cap	52.3-10.4 MG	30	Capsules	30	DAYS				
61400020100460	Concerta; Relexxii	Methylphenidate HCl Tab ER Osmotic Release (OSM) 18 MG	18 MG	30	Tablets	30	DAYS				
61400020100465	Concerta; Relexxii	Methylphenidate HCl Tab ER Osmotic Release (OSM) 27 MG	27 MG	30	Tablets	30	DAYS				
61400020100470	Concerta; Relexxii	Methylphenidate HCl Tab ER Osmotic Release (OSM) 36 MG	36 MG	60	Tablets	30	DAYS				
61400020100480	Concerta; Relexxii	Methylphenidate HCl Tab ER Osmotic Release (OSM) 54 MG	54 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
6140002000H420	Cotempla xr-odt	Methylphenidate Tab Extended Release Disintegrating 17.3 MG	17.3 MG	60	Tablets	30	DAYS				
6140002000H430	Cotempla xr-odt	Methylphenidate Tab Extended Release Disintegrating 25.9 MG	25.9 MG	60	Tablets	30	DAYS				
6140002000H410	Cotempla xr-odt	Methylphenidate Tab Extended Release Disintegrating 8.6 MG	8.6 MG	30	Tablets	30	DAYS				
614000200059	Daytrana	methylphenidate td patch	10 MG/9HR; 15 MG/9HR; 20 MG/9HR; 30 MG/9HR	30	Patches	30	DAYS				
61100030100305	Desoxyn	Methamphetamine HCl Tab 5 MG	5 MG	150	Tablets	30	DAYS				
61100020107010	Dexedrine	Dextroamphetamine Sulfate Cap ER 24HR 10 MG	10 MG	120	Capsules	30	DAYS				
61100020107015	Dexedrine	Dextroamphetamine Sulfate Cap ER 24HR 15 MG	15 MG	120	Capsules	30	DAYS				
61100020107005	Dexedrine	Dextroamphetamine Sulfate Cap ER 24HR 5 MG	5 MG	90	Capsules	30	DAYS				
6110001000H2	Dyanavel xr	amphetamine chew tab extended release	10 MG; 15 MG; 20 MG; 5 MG	30	Tablet	30	DAYS				
6110001000G120	Dyanavel xr	Amphetamine Extended Release Susp 2.5 MG/ML	2.5 MG/ML	240	mLs	30	DAYS				
6110001000G120	Dyanavel xr	Amphetamine Extended Release Susp 2.5 MG/ML	2.5 MG/ML	240	mLs	30	DAYS				
61100010100320	Evekeo	Amphetamine Sulfate Tab 10 MG	10 MG	180	Tablets	30	DAYS				
61100010100310	Evekeo	Amphetamine Sulfate Tab 5 MG	5 MG	90	Tablets	30	DAYS				
611000101072	Evekeo odt	amphetamine sulfate orally disintegrating tab	10 MG; 15 MG; 20 MG; 5 MG	60	Tablets	30	DAYS				
614000161003	Focalin	dexmethylphenidate hcl tab	10 MG; 2.5 MG; 5 MG	60	Tablets	30	DAYS				
614000161070	Focalin xr	dexmethylphenidate hcl cap er	10 MG; 15 MG; 20 MG; 25 MG; 30 MG; 35 MG; 40 MG; 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
613530301075	Intuniv	guanfacine hcl tab er	1 MG; 2 MG; 3 MG; 4 MG	30	Tablets	30	DAYS				
61353020107420	Kapvay	Clonidine HCl Tab ER 12HR 0.1 MG	0.1 MG	120	Tablets	30	DAYS				
614000201002	Metadate cd	methylphenidate hcl cap er	10 MG; 20 MG; 30 MG; 40 MG; 50 MG; 60 MG	30	Capsules	30	DAYS				
61400020102030	Methylin	Methylphenidate HCl Soln 10 MG/5ML	10 ; 10 MG/5ML	900	mLs	30	DAYS				
61400020102020	Methylin	Methylphenidate HCl Soln 5 MG/5ML	5 MG/5ML	450	mLs	30	DAYS				
61100020102020	Procentra	Dextroamphetamine Sulfate Oral Solution 5 MG/5ML	5 MG/5ML	1800	mLs	30	DAYS				
61354080207020	Qelbree	Viloxazine HCl Cap ER	100 MG	30	Capsules	30	DAYS				
61354080207030	Qelbree	Viloxazine HCl Cap ER	150 MG	60	Capsules	30	DAYS				
61354080207040	Qelbree	Viloxazine HCl Cap ER	200 MG	90	Capsules	30	DAYS				
6140002010H220	Quillichewer	Methylphenidate HCl Chew Tab Extended Release 20 MG	20 MG	30	Tablets	30	DAYS				
6140002010H230	Quillichewer	Methylphenidate HCl Chew Tab Extended Release 30 MG	30 MG	60	Tablets	30	DAYS				
6140002010H240	Quillichewer	Methylphenidate HCl Chew Tab Extended Release 40 MG	40 MG	30	Tablets	30	DAYS				
6140002010G2	Quillivant xr	methylphenidate hcl for er susp	25 MG/5ML	360	mLs	30	DAYS				
61400020100475	Relexxii	Methylphenidate HCl Tab ER Osmotic Release (OSM)	45 MG	30	Tablets	30	DAYS				
61400020100485	Relexxii	Methylphenidate HCl Tab ER Osmotic Release (OSM)	63 MG	30	Tablets	30	DAYS				
61400020100490	Relexxii	Methylphenidate HCl Tab ER Osmotic Release (OSM) 72 MG	72 MG	30	Tablets	30	DAYS				
614000201003	Ritalin	methylphenidate hcl tab	10 MG; 20 MG; 5 ; 5 MG	90	Tablets	30	DAYS				
61354015100110	Strattera	Atomoxetine HCl Cap 10 MG (Base Equiv)	10 MG	60	Capsules	30	DAYS				
61354015100180	Strattera	Atomoxetine HCl Cap 100 MG (Base Equiv)	100 MG	30	Capsules	30	DAYS				
61354015100118	Strattera	Atomoxetine HCl Cap 18 MG (Base Equiv)	18 MG	60	Capsules	30	DAYS				
61354015100125	Strattera	Atomoxetine HCl Cap 25 MG (Base Equiv)	25 MG	60	Capsules	30	DAYS				
61354015100140	Strattera	Atomoxetine HCl Cap 40 MG (Base Equiv)	40 MG	60	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
61354015100160	Strattera	Atomoxetine HCl Cap 60 MG (Base Equiv)	60 MG	30	Capsules	30	DAYS				
61354015100170	Strattera	Atomoxetine HCl Cap 80 MG (Base Equiv)	80 MG	30	Capsules	30	DAYS				
611000251001	Vyvanse	lisdexamfetamine dimesylate cap	10 MG; 20 MG; 30 MG; 40 MG; 50 MG; 60 MG; 70 MG	30	Capsules	30	DAYS				
611000251005	Vyvanse	lisdexamfetamine dimesylate chew tab	10 MG; 20 MG; 30 MG; 40 MG; 50 MG; 60 MG	30	Tablets	30	DAYS				
61100020005910	Xelstrym	Dextroamphetamine TD Patch	4.5 MG/9HR	30	Patches	30	DAYS				
61100020005920	Xelstrym	Dextroamphetamine TD Patch	9 MG/9HR	30	Patches	30	DAYS				
61100020005930	Xelstrym	Dextroamphetamine TD Patch	13.5 MG/9HR	30	Patches	30	DAYS				
61100020005940	Xelstrym	Dextroamphetamine TD Patch	18 MG/9HR	30	Patches	30	DAYS				
61100020100310	Zenzedi	Dextroamphetamine Sulfate Tab 10 MG	10 MG	180	Tablets	30	DAYS				
61100020100315	Zenzedi	Dextroamphetamine Sulfate Tab 15 MG	15 MG	90	Tablets	30	DAYS				
61100020100303	Zenzedi	Dextroamphetamine Sulfate Tab 2.5 MG	2.5 MG	90	Tablets	30	DAYS				
61100020100330	Zenzedi	Dextroamphetamine Sulfate Tab 20 MG	20 MG	90	Tablets	30	DAYS				
61100020100350	Zenzedi	Dextroamphetamine Sulfate Tab 30 MG	30 MG	60	Tablets	30	DAYS				
61100020100305	Zenzedi	Dextroamphetamine Sulfate Tab 5 MG	5 MG	90	Tablets	30	DAYS				
61100020100308	Zenzedi	Dextroamphetamine Sulfate Tab 7.5 MG	7.5 MG	90	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**

Module	Clinical Criteria for Approval
	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

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
59250015002020		Aripiprazole Oral Solution 1 MG/ML	1 MG/ML	900	mLs	30	DAYS				
592500150072		aripiprazole orally disintegrating tab	10 MG; 15 MG	60	Tablets	30	DAYS				
59152020007230		Clozapine Orally Disintegrating Tab 100 MG	100 MG	90	Tablets	30	DAYS				
59152020007210		Clozapine Orally Disintegrating Tab 12.5 MG	12.5 MG	90	Tablets	30	DAYS				
59152020007240		Clozapine Orally Disintegrating Tab 150 MG	150 MG	180	Tablets	30	DAYS				
59152020007250		Clozapine Orally Disintegrating Tab 200 MG	200 MG	120	Tablets	30	DAYS				
59152020007220		Clozapine Orally Disintegrating Tab 25 MG	25 MG	270	Tablets	30	DAYS				
59153070100325		Quetiapine Fumarate Tab	150 MG	30	Tablets	30	DAYS				
59070070007210		Risperidone Orally Disintegrating Tab 0.25 MG	0.25 MG	60	Tablets	30	DAYS				
59070070007220		Risperidone Orally Disintegrating Tab 0.5 MG	0.5 MG	60	Tablets	30	DAYS				
59070070007230		Risperidone Orally Disintegrating Tab 1 MG	1 MG	60	Tablets	30	DAYS				
59070070007240		Risperidone Orally Disintegrating Tab 2 MG	2 MG	60	Tablets	30	DAYS				
59070070007250		Risperidone Orally Disintegrating Tab 3 MG	3 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
59070070007260		Risperidone Orally Disintegrating Tab 4 MG	4 MG	120	Tablets	30	DAYS				
59070070000303		Risperidone Tab 0.25 MG	0.25 MG	60	Tablets	30	DAYS				
592500150003	Abilify	aripiprazole tab	10 MG; 15 MG; 2 MG; 20 MG; 30 MG; 5 MG	30	Tablets	30	DAYS				
5925001503B706	Abilify mycite maintenanc	Aripiprazole Tab	2 MG	30	Tablets	30	DAYS				
5925001503B711	Abilify mycite maintenanc	Aripiprazole Tab	5 MG	30	Tablets	30	DAYS				
5925001503B721	Abilify mycite maintenanc	Aripiprazole Tab	10 MG	30	Tablets	30	DAYS				
5925001503B731	Abilify mycite maintenanc	Aripiprazole Tab	15 MG	30	Tablets	30	DAYS				
5925001503B741	Abilify mycite maintenanc	Aripiprazole Tab	20 MG	30	Tablets	30	DAYS				
5925001503B751	Abilify mycite maintenanc	Aripiprazole Tab	30 MG	30	Tablets	30	DAYS				
5925001503B705	Abilify mycite starter ki	Aripiprazole Tab	2 MG	30	Tablets	30	DAYS				
5925001503B710	Abilify mycite starter ki	Aripiprazole Tab	5 MG	30	Tablets	30	DAYS				
5925001503B720	Abilify mycite starter ki	Aripiprazole Tab	10 MG	30	Tablets	30	DAYS				
5925001503B730	Abilify mycite starter ki	Aripiprazole Tab	15 MG	30	Tablets	30	DAYS				
5925001503B740	Abilify mycite starter ki	Aripiprazole Tab	20 MG	30	Tablets	30	DAYS				
5925001503B750	Abilify mycite starter ki	Aripiprazole Tab	30 MG	30	Tablets	30	DAYS				
594000224001	Caplyta	lumateperone tosylate cap	10.5 MG; 21 MG; 42 MG	30	Capsules	30	DAYS				
59152020000330	Clozaril	Clozapine Tab 100 MG	100 MG	270	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
59152020000340	Clozaril	Clozapine Tab 200 MG	200 MG	120	Tablets	30	DAYS				
59152020000320	Clozaril	Clozapine Tab 25 MG	25 MG	90	Tablets	30	DAYS				
59152020000325	Clozaril	Clozapine Tab 50 MG	50 MG	90	Tablets	30	DAYS				
590700350003	Fanapt	iloperidone tab	1 MG; 10 MG; 12 MG; 2 MG; 4 MG; 6 MG; 8 MG	60	Tablets	30	DAYS				
59070035006320	Fanapt titration pack	Iloperidone Tab 1 MG & 2 MG & 4 MG & 6 MG Titration Pak	1 & 2 & 4 & 6 MG	1	Pack	180	DAYS				
594000851001	Geodon	ziprasidone hcl cap	20 MG; 40 MG; 60 MG; 80 MG	60	Capsules	30	DAYS				
59400085202120	Geodon	Ziprasidone Mesylate For Inj 20 MG (Base Equivalent)	20 MG	60	Vials	30	DAYS				
59070050007505	Invega	Paliperidone Tab ER 24HR 1.5 MG	1.5 MG	30	Tablets	30	DAYS				
59070050007510	Invega	Paliperidone Tab ER 24HR 3 MG	3 MG	30	Tablets	30	DAYS				
59070050007520	Invega	Paliperidone Tab ER 24HR 6 MG	6 MG	60	Tablets	30	DAYS				
59070050007530	Invega	Paliperidone Tab ER 24HR 9 MG	9 MG	30	Tablets	30	DAYS				
59400023100350	Latuda	Lurasidone HCl Tab 120 MG	120 MG	30	Tablets	30	DAYS				
59400023100310	Latuda	Lurasidone HCl Tab 20 MG	20 MG	30	Tablets	30	DAYS				
59400023100320	Latuda	Lurasidone HCl Tab 40 MG	40 MG	30	Tablets	30	DAYS				
59400023100330	Latuda	Lurasidone HCl Tab 60 MG	60 MG	30	Tablets	30	DAYS				
59400023100340	Latuda	Lurasidone HCl Tab 80 MG	80 MG	60	Tablets	30	DAYS				
62994802500310	Lybalvi	Olanzapine-Samidorphan L-Malate Tab	5-10 MG	30	Tablets	30	DAYS				
62994802500320	Lybalvi	Olanzapine-Samidorphan L-Malate Tab	10-10 MG	30	Tablets	30	DAYS				
62994802500330	Lybalvi	Olanzapine-Samidorphan L-Malate Tab	15-10 MG	30	Tablets	30	DAYS				
62994802500340	Lybalvi	Olanzapine-Samidorphan L-Malate Tab	20-10 MG	30	Tablets	30	DAYS				
592500200003	Rexulti	brexpiprazole tab	0.25 MG; 0.5 MG; 1 MG; 2 MG; 3 MG; 4 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
59070070002010	Risperdal	Risperidone Soln 1 MG/ML	1 MG/ML	480	mLs	30	DAYS				
59070070000306	Risperdal	Risperidone Tab 0.5 MG	0.5 MG	60	Tablets	30	DAYS				
59070070000310	Risperdal	Risperidone Tab 1 MG	1 MG	60	Tablets	30	DAYS				
59070070000320	Risperdal	Risperidone Tab 2 MG	2 MG	60	Tablets	30	DAYS				
59070070000330	Risperdal	Risperidone Tab 3 MG	3 MG	60	Tablets	30	DAYS				
59070070000340	Risperdal	Risperidone Tab 4 MG	4 MG	120	Tablets	30	DAYS				
591550151007	Saphris	asenapine maleate sl tab	10 MG; 2.5 MG; 5 MG	60	Tablets	30	DAYS				
591550150085	Secuado	asenapine td patch	3.8 MG/24HR; 5.7 MG/24HR; 7.6 MG/24HR	30	Patches	30	DAYS				
59153070100320	Seroquel	Quetiapine Fumarate Tab 100 MG	100 MG	90	Tablets	30	DAYS				
59153070100330	Seroquel	Quetiapine Fumarate Tab 200 MG	200 MG	90	Tablets	30	DAYS				
59153070100310	Seroquel	Quetiapine Fumarate Tab 25 MG	25 MG	90	Tablets	30	DAYS				
59153070100340	Seroquel	Quetiapine Fumarate Tab 300 MG	300 MG	60	Tablets	30	DAYS				
59153070100350	Seroquel	Quetiapine Fumarate Tab 400 MG	400 MG	60	Tablets	30	DAYS				
59153070100314	Seroquel	Quetiapine Fumarate Tab 50 MG	50 MG	90	Tablets	30	DAYS				
59153070107515	Seroquel xr	Quetiapine Fumarate Tab ER 24HR 150 MG	150 MG	30	Tablets	30	DAYS				
59153070107520	Seroquel xr	Quetiapine Fumarate Tab ER 24HR 200 MG	200 MG	30	Tablets	30	DAYS				
59153070107530	Seroquel xr	Quetiapine Fumarate Tab ER 24HR 300 MG	300 MG	60	Tablets	30	DAYS				
59153070107540	Seroquel xr	Quetiapine Fumarate Tab ER 24HR 400 MG	400 MG	60	Tablets	30	DAYS				
59153070107505	Seroquel xr	Quetiapine Fumarate Tab ER 24HR 50 MG	50 MG	60	Tablets	30	DAYS				
591520200018	Versacloz	clozapine susp	50 MG/ML	540	mLs	30	DAYS				
594000181001	Vraylar	cariprazine hcl cap	1.5 MG; 3 MG; 4.5 MG; 6 MG	30	Capsules	30	DAYS				
5940001810B220	Vraylar	Cariprazine HCl Cap Therapy Pack 1.5 MG (1) & 3 MG (6)	1.5 & 3 MG	1	Pack	180	DAYS				
59157060002120	Zyprexa	Olanzapine For IM Inj 10 MG	10 MG	60	Vials	30	DAYS				
591570600003	Zyprexa	olanzapine tab	10 MG; 15 MG; 2.5 MG; 20 MG; 5 MG; 7.5 MG	30	Tablets	30	DAYS				
591570600072	Zyprexa zydis	olanzapine orally disintegrating tab	10 MG; 15 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
			20 MG; 5 MG								

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 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: Cablivi (caplacizumab-yhdp)

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
85151020806420	Cablivi	Caplacizumab-yhdp for Inj Kit 11 MG	11 MG	58	Vials	365	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. BOTH of the following A. The patient had at least one occurrence of acquired thrombotic thrombocytopenic purpura (aTTP) during the current course of therapy **AND** B. The patient has NOT had more than 2 occurrences of aTTP while using the requested agent during the current course of therapy **OR**

Module	Clinical Criteria for Approval
	2. The patient had a relapse/recurrence of aTTP after completion of a course of therapy and requires an additional course of therapy **Length of Approval:** Occurrence of aTTP on current course of therapy - requested number of vials up to 58 vials/365 days; Relapse of aTTP - 58 vials/365 days

• Program Summary: Calcitonin Gene-Related Peptide (CGRP)

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
67701010000310	Qulipta	Atogepant Tab	10 MG	30	Tablets	30	DAYS				
67701010000320	Qulipta	Atogepant Tab	30 MG	30	Tablets	30	DAYS				
67701010000330	Qulipta	Atogepant Tab	60 MG	30	Tablets	30	DAYS				
67701080000340	Ubrelvy	Ubrogepant Tab 100 MG	100 MG	16	Tablets	30	DAYS				
67701080000320	Ubrelvy	Ubrogepant Tab 50 MG	50 MG	16	Tablets	30	DAYS				
67701090202020	Zavzpret	zavegepant hcl nasal spray	10 MG/ACT	8	Devices	30	DAYS				
6770202010D540	Aimovig	Erenumab-aooe Subcutaneous Soln Auto-Injector 140 MG/ML	140 MG/ML	1	Injection Device	28	DAYS				
6770202010D520	Aimovig	Erenumab-aooe Subcutaneous Soln Auto-Injector 70 MG/ML	70 MG/ML	1	Injection Device	28	DAYS				
6770203530D520	Emgality	Galcanezumab-gnlm Subcutaneous Soln Auto-Injector 120 MG/ML	120 MG/ML	1	Injection Device	28	DAYS				
6770203530E515	Emgality	Galcanezumab-gnlm Subcutaneous Soln Prefilled Syr 100 MG/ML	100 MG/ML	9	Syringes	180	DAYS				
6770203530E520	Emgality	Galcanezumab-gnlm Subcutaneous Soln Prefilled Syr 120 MG/ML	120 MG/ML	1	Syringe	28	DAYS				
67701060707220	Nurtec	Rimegepant Sulfate Tab Disint 75 MG	75 MG	16	Tablets	30	DAYS			05-19-2022	
6770203020D520	Ajovy	Fremanezumab-vfrm Subcutaneous Soln Auto-inj 225 MG/1.5ML	225 MG/1.5 ML	3	Injection Devices	84	DAYS				
6770203020E520	Ajovy	Fremanezumab-vfrm Subcutaneous Soln Pref Syr 225 MG/1.5ML	225 MG/1.5 ML	3	Syringes	84	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Indication	PDL Preferred Agents
Acute treatment of migraine with or without aura	Ubrelvy
Preventative treatment of migraine	Ajovy, Emgality
Treatment of episodic cluster headache	Emgality

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 being used for migraine prophylaxis AND ALL of the following:
        1. ONE of the following:
            A. The patient has at least 15 headache days per month of migraine-like or tension-like headache for a minimum of 3 months (chronic migraine) AND ALL of the following:
                1. The patient has at least 8 migraine headache days per month for a minimum of 3 months **AND**
                2. The patient will NOT be using the requested agent in combination with another prophylactic use CGRP **AND**
                3. The requested agent and strength are FDA labeled for chronic migraine prophylaxis **OR**
            B. The patient has less than 15 headache days per month (episodic migraine) AND ALL of the following:
                1. ONE of the following:
                    A. The patient has greater than 4 migraine headache days per month **OR**
                    B. The patient's migraine headaches last greater than 12 hours **OR**
                    C. The patient's migraine attacks cause significant disability or diminished quality of life despite appropriate therapy with acute agents only **OR**
                    D. The patient's medication history includes acute therapies AND ONE of the following:
                        1. The patient has had an inadequate response to acute therapy **OR**
                        2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over acute therapies **OR**
                    E. The patient has contraindications to acute therapies **OR**
                    F. The patient has serious side effects to acute therapies **OR**
                    G. The patient is at risk of medication overuse headache without preventative therapy **OR**
                    H. 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**

I. The prescriber has provided documentation that acute therapies 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 patient will NOT be using the requested agent in combination with another prophylactic use CGRP agent **AND**
3. The requested agent and strength are FDA labeled for episodic migraine prophylaxis **AND**

2. ONE of the following:
   A. The patient's medication history includes at least one migraine prophylaxis class [i.e., anticonvulsants (i.e., divalproex, valproate, topiramate), beta blockers (i.e., atenolol, metoprolol, nadolol, propranolol, timolol), antidepressants (i.e., amitriptyline, venlafaxine), candesartan] AND ONE of the following:
      1. The patient has had an inadequate response to at least one migraine prophylaxis class [i.e., anticonvulsants (i.e., divalproex, valproate, topiramate), beta blockers (i.e., atenolol, metoprolol, nadolol, propranolol, timolol), antidepressants (i.e., amitriptyline, venlafaxine), candesartan] **OR**
      2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL migraine prophylaxis class [i.e., anticonvulsants (i.e., divalproex, valproate, topiramate), beta blockers (i.e., atenolol, metoprolol, nadolol, propranolol, timolol), antidepressants (i.e., amitriptyline, venlafaxine), candesartan] **OR**
   B. The patient has an intolerance or hypersensitivity to therapy with at least one migraine prophylaxis class listed above **OR**
   C. The patient has an FDA labeled contraindication to ALL migraine prophylaxis agents listed above **OR**
   D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
      2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
      3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
   E. The prescriber has provided documentation that ALL migraine prophylaxis classed [i.e., anticonvulsants (i.e., divalproex, valproate, topiramate), beta blockers (i.e., atenolol, metoprolol, nadolol, propranolol, timolol), antidepressants (i.e., amitriptyline, venlafaxine), candesartan] 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. Medication overuse headache has been ruled out **AND**
4. ONE of the following:
   A. The requested agent is a preferred agent **OR**
   B. The requested agent is a nonpreferred agent OR a covered drug AND ONE of the following:
      1. The patient's medication history includes TWO preferred agents AND ONE of the following:

A. The patient has had an inadequate response TWO preferred agents **OR**
B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL preferred agents **OR**

2. The patient has an intolerance or hypersensitivity to TWO preferred agents that is not expected to occur with the requested agent **OR**
3. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested agent **OR**
4. The patient is currently being treated with the requested agent as indicated by ALL of the following:
   A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
   B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
   C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
5. The prescriber has provided documentation that ALL preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

B. The requested agent is being used for the treatment of episodic cluster headache AND ALL of the following:
1. The patient has had at least 5 cluster headache attacks **AND**
2. The patient has at least two cluster period lasting 7-365 days **AND**
3. The patient's cluster periods are separated by a pain-free remission period of greater than or equal to 3 months **AND**
4. ONE of the following:
   A. The patient's medication history includes verapamil, melatonin, corticosteroids, topiramate, OR lithium AND ONE of the following:
      1. The patient has had an inadequate response to verapamil, melatonin, corticosteroids, topiramate, OR lithium **OR**
      2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over verapamil, melatonin, corticosteroids, topiramate, AND lithium **OR**
   B. The patient has an intolerance or hypersensitivity to verapamil, melatonin, corticosteroid, topiramate, OR lithium **OR**
   C. The patient has an FDA labeled contraindication to verapamil, melatonin, corticosteroid, topiramate, AND lithium **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 verapamil, melatonin, corticosteroids, topiramate, AND lithium cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable

functional ability in performing daily activities or cause physical or mental harm **AND**

5. Medication overuse headache has been ruled out **AND**
6. The requested agent and strength are FDA labeled for episodic cluster headache treatment **AND**
7. ONE of the following:
    A. The requested agent is a preferred agent **OR**
    B. The requested agent is a nonpreferred agent OR a covered drug AND ONE of the following:
        1. The patient's medication history includes TWO preferred agents AND ONE of the following:
            A. The patient has had an inadequate response TWO preferred agents **OR**
            B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL preferred agents **OR**
        2. The patient has an intolerance or hypersensitivity to TWO preferred agents that is not expected to occur with the requested agent **OR**
        3. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested agent **OR**
        4. The patient is currently being treated with the requested agent as indicated by ALL of the following:
            A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
            B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
            C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
        5. The prescriber has provided documentation that ALL preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

C. The requested agent is being used for acute migraine treatment AND ALL of the following:
1. ONE of the following:
    A. The patient's medication history includes at least one triptan agent AND ONE of the following:
        1. The patient has had an inadequate response to at least one triptan agent **OR**
        2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL triptan agents **OR**
    B. The patient has an intolerance or hypersensitivity to a triptan agent **OR**
    C. The patient has an FDA labeled contraindication to ALL triptan agents **OR**
    D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
        1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
        2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
        3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
    E. The prescriber has provided documentation that ALL triptan 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**

2. The patient will NOT be using the requested agent in combination with another acute migraine therapy (i.e., 5HT-1F, acute use CGRP, ergotamine, triptan) **AND**
3. Medication overuse headache has been ruled out **AND**
4. The requested agent and strength are FDA labeled for acute migraine treatment **AND**
5. ONE of the following:
    A. The requested agent is a preferred agent **OR**
    B. The requested agent is a nonpreferred agent OR a covered drug AND ONE of the following:
        1. The patient's medication history includes TWO preferred agents AND ONE of the following:
            A. The patient has had an inadequate response TWO preferred agents **OR**
            B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL preferred agents **OR**
        2. The patient has an intolerance or hypersensitivity to TWO preferred agents that is not expected to occur with the requested agent **OR**
        3. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested agent **OR**
        4. The patient is currently being treated with the requested agent as indicated by ALL of the following:
            A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
            B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
            C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
        5. The prescriber has provided documentation that ALL preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**
    D. The patient has another FDA labeled indication for the requested agent and route of administration **OR**
    E. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND**
2. If the patient has an FDA 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 does not have any FDA labeled contraindications to the requested agent

Compendia Allowed: CMS Approved Compendia

Length of Approval: Cluster headache treatment - 6 months; migraine prophylaxis - 6 months; all other indications - 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 approved for the requested agent previously 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. BOTH of the following:
        1. ONE of the following:
            - A. The requested agent is being used for migraine prophylaxis AND ALL of the following:
                1. The patient has had improvement in migraine prevention (e.g., reduced migraine headache days, reduced migraine frequency, reduced use of acute abortive migraine medication) with the requested agent **AND**
                2. The patient will NOT be using the requested agent in combination with another prophylactic use CGRP for the requested indication **AND**
                3. ONE of the following:
                    - A. BOTH of the following:
                        1. The patient has at least 15 headache days per month (chronic migraine) **AND**
                        2. The requested agent and strength are FDA labeled for chronic migraine **OR**
                    - B. BOTH of the following:
                        1. The patient has less than 15 headache days per month (episodic migraine) **AND**
                        2. The requested agent and strength are FDA labeled for episodic migraine **OR**
            - B. The requested agent is being used for episodic cluster headache treatment AND BOTH of the following:
                1. The patient has had improvement in cluster headaches management with the requested agent **AND**
                2. The requested agent and strength are FDA labeled for episodic cluster headache treatment **OR**
            - C. The requested agent is being used for acute migraine treatment AND ALL of the following:
                1. The patient has had improvement in acute migraine management with the requested agent **AND**
                2. The patient will NOT be using the requested agent in combination with another acute migraine therapy (i.e., 5HT-1F, acute use CGRP, ergotamine, triptan) for the requested indication **AND**
                3. The requested agent and strength are FDA labeled for acute migraine treatment **AND**
        2. Medication overuse headache has been ruled out **OR**
    - B. The requested agent is being used for an indication other than migraine prophylaxis, episodic cluster headache treatment, or acute migraine treatment AND has had clinical benefit with the requested agent **AND**
3. The patient does not have any FDA labeled contraindications to the requested agent

Compendia Allowed: CMS Approved Compendia

Length of Approval: 12 months

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

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
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 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. If the requested agent is being used for treatment of acute migraine, the patient has greater than 4 migraine headaches per month AND ONE of the following: 1. The patient is currently being treated with 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 [e.g., Aimovig, AJOVY, Emgality, Nurtec, QULIPTA, Vyepti], onabotulinum toxin A [Botox]) **OR** 2. The patient has an intolerance or hypersensitivity to therapy with migraine prophylactic medication [i.e., anticonvulsants (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 [e.g., Aimovig, AJOVY, Emgality, Nurtec, QULIPTA, Vyepti], OR onabotulinum toxin A [Botox]) **OR** 3. The patient has an FDA labeled contraindication to ALL migraine prophylactic medications [i.e., anticonvulsants (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 [e.g., Aimovig, AJOVY, Emgality, Nurtec, QULIPTA, Vyepti], AND onabotulinum toxin A [Botox]) **OR** 4. There is support that the patient's migraine is manageable with acute therapy alone **AND** D. There is support of therapy with a higher dose for the requested indication **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** Initial: For migraine prophylaxis: up to 6 months. 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 6 months. For cluster headache treatment: up to 6 months All other indications: up to 12 months Renewal: up to 12 months

● Program Summary: DPP-4 Inhibitors and Combinations

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
27992502700340	Janumet	Sitagliptin-Metformin HCl Tab 50-1000 MG	50-1000 MG	60	Tablets	30	DAYS				
27992502700320	Janumet	Sitagliptin-Metformin HCl Tab 50-500 MG	50-500 MG	60	Tablets	30	DAYS				
27992502707540	Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 100-1000 MG	100-1000 MG	30	Tablets	30	DAYS				
27992502707530	Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 50-1000 MG	50-1000 MG	60	Tablets	30	DAYS				
27992502707520	Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 50-500 MG	50-500 MG	30	Tablets	30	DAYS				
27550070100340	Januvia	Sitagliptin Phosphate Tab 100 MG (Base Equiv)	100 MG	30	Tablets	30	DAYS				
27550070100320	Januvia	Sitagliptin Phosphate Tab 25 MG (Base Equiv)	25 MG	30	Tablets	30	DAYS				
27550070100330	Januvia	Sitagliptin Phosphate Tab 50 MG (Base Equiv)	50 MG	30	Tablets	30	DAYS				
27992502400340	Jentadueto	Linagliptin-Metformin HCl Tab 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS				
27992502400320	Jentadueto	Linagliptin-Metformin HCl Tab 2.5-500 MG	2.5-500 MG	60	Tablets	30	DAYS				
27992502400330	Jentadueto	Linagliptin-Metformin HCl Tab 2.5-850 MG	2.5-850 MG	60	Tablets	30	DAYS				
27992502407520	Jentadueto xr	Linagliptin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS				
27992502407530	Jentadueto xr	Linagliptin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	30	Tablets	30	DAYS				
27992502100330	Kazano	Alogliptin-Metformin HCl Tab 12.5-1000 MG	12.5-1000 MG	60	Tablets	30	DAYS				
27992502100320	Kazano	Alogliptin-Metformin HCl Tab 12.5-500 MG	12.5-500 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
27992502607520	Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS				
27992502607540	Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	30	Tablets	30	DAYS				
27992502607530	Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 5-500 MG	5-500 MG	30	Tablets	30	DAYS				
27550010100320	Nesina	Alogliptin Benzoate Tab 12.5 MG (Base Equiv)	12.5 MG	30	Tablets	30	DAYS				
27550010100330	Nesina	Alogliptin Benzoate Tab 25 MG (Base Equiv)	25 MG	30	Tablets	30	DAYS				
27550010100310	Nesina	Alogliptin Benzoate Tab 6.25 MG (Base Equiv)	6.25 MG	30	Tablets	30	DAYS				
27550065100320	Onglyza	Saxagliptin HCl Tab 2.5 MG (Base Equiv)	2.5 MG	30	Tablets	30	DAYS				
27550065100330	Onglyza	Saxagliptin HCl Tab 5 MG (Base Equiv)	5 MG	30	Tablets	30	DAYS				
27994002100320	Oseni	Alogliptin-Pioglitazone Tab 12.5-15 MG	12.5-15 MG	30	Tablets	30	DAYS				
27994002100325	Oseni	Alogliptin-Pioglitazone Tab 12.5-30 MG	12.5-30 MG	30	Tablets	30	DAYS				
27994002100330	Oseni	Alogliptin-Pioglitazone Tab 12.5-45 MG	12.5-45 MG	30	Tablets	30	DAYS				
27994002100340	Oseni	Alogliptin-Pioglitazone Tab 25-15 MG	25-15 MG	30	Tablets	30	DAYS				
27994002100345	Oseni	Alogliptin-Pioglitazone Tab 25-30 MG	25-30 MG	30	Tablets	30	DAYS				
27994002100350	Oseni	Alogliptin-Pioglitazone Tab 25-45 MG	25-45 MG	30	Tablets	30	DAYS				
27550050000320	Tradjenta	Linagliptin Tab 5 MG	5 MG	30	Tablets	30	DAYS				
27550070000320	Zituvio	sitagliptin tab	25 MG	30	Tablets	30	DAYS				
27550070000330	Zituvio	sitagliptin tab	50 MG	30	Tablets	30	DAYS				
27550070000340	Zituvio	sitagliptin tab	100 MG	30	Tablets	30	DAYS				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

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

Module	Clinical Criteria for Approval
	Jentadueto (linagliptin/metformin) **Jentadueto XR** (linagliptin/metformin ER) **Kombiglyze XR** (saxagliptin/metformin ER) **Nesina** (alogliptin) **Onglyza** (saxagliptin) **Tradjenta** (linagliptin) **Target Agent(s)** will be approved when ONE of the following is met: 1. Information has been provided that indicates the patient has been being 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** 3. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 4. The patient's medication history includes use of an agent containing metformin or insulin **OR** 5. The prescriber has stated that the patient has tried insulin or an agent containing metformin AND ONE of the following: A. Insulin or an agent containing metformin was discontinued due to lack of effectiveness or an adverse event **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over insulin or an agent containing metformin **OR** 6. The patient has an intolerance or hypersensitivity to ONE of the following: metformin or insulin **OR** 7. The patient has an FDA labeled contraindication to ALL of the following: metformin and insulins **OR** 8. The prescriber has provided documentation that metformin AND insulins cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval:** 12 months NOTE: If Quantity Limit program also applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL Standalone	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. 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:

Module	Clinical Criteria for Approval
	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: Empaveli (pegcetacoplan)

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
85804065002020	Empaveli	Pegcetacoplan Subcutaneous Soln	1080 MG/20 ML	8	Vials	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 patient has a diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) as 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) **OR** 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 Soliris (eculizumab) for the requested indication (NOTE: if the patient is switching from Soliris, Soliris should be continued for the first 4 weeks after starting the requested agent and then Soliris should be discontinued) **AND** 5. The patient will NOT be using the requested agent in combination with Fabhalta (iptacopan) or Ultomiris (ravulizumab-cwvz) 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.

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., 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 Fabhalta (iptacopan), 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
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. BOTH of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. ONE of the following: 1. The patient has a lactate dehydrogenase (LDH) level greater than 2X the upper limit of normal (lab test required) **OR** 2. ALL of the following: (medical records required) A. The patient had a prior LDH greater than 2X the upper limit of normal and required a dose increase **AND** B. The patient is currently using the requested dose **AND** C. The requested quantity (dose) does NOT exceed 1,080 mg every three days **Length of Approval:** up to 12 months NOTE: If approving for every three days dosing approve a quantity of 10 vials/30 days for 12 months

• Program Summary: Fintepla

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
72600028102020	Fintepla	Fenfluramine HCl Oral Soln 2.2 MG/ML	2.2 MG/ML	360	mLs	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ONE of the following is met: 1. ALL of the following: A. ONE of the following: 1. BOTH of the following: A. ONE of the following 1. The patient has been treated with the requested agent within the past 90 days (starting on samples is not approvable) **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 **AND** B. The patient has an FDA labeled indication for the requested agent **OR** 2. BOTH of the following: A. ONE of the following: 1. If the patient has a diagnosis of Dravet syndrome (DS) or Lennox-Gastaut syndrome (LGS), then ONE of the following: A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR** B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following: 1. The patient is currently being treated with the requested agent and is experiencing a positive therapeutic outcome AND the prescriber provides documentation that switching the member to a preferred drug is expected to cause harm to the member or that the preferred drug would be ineffective **OR** 2. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following: A. ONE of the following: 1. Evidence of a paid claim(s) **OR** 2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND** B. ONE of the following:

Module	Clinical Criteria for Approval
	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) **OR** 2. The patient has another FDA labeled indication for the requested agent and route of administration **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** B. If the patient has a diagnosis of seizure associated with Dravet syndrome (DS) or Lennox-Gastaut syndrome (LGS), the requested agent will NOT be used as monotherapy for seizure management **AND** C. An echocardiogram assessment will be obtained before and during treatment with the requested agent to evaluate for valvular heart disease and pulmonary arterial hypertension **AND** D. 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** E. The patient does NOT have any FDA labeled contraindications 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 labeled indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

Module	Clinical Criteria for Approval
	Renewal Evaluation **Target Agent(s)** will be approved when 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: 1. ALL of the following: A. The patient has had clinical benefit with the requested agent **AND** B. If using for seizure management associated with Dravet syndrome (DS) or Lennox-Gastaut syndrome (LGS), the requested agent will NOT be used as monotherapy **AND** C. An echocardiogram assessment will be obtained during treatment with the requested agent, to evaluate for valvular heart disease and pulmonary arterial hypertension **AND** D. 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** E. ONE of the following: 1. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR** 2. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following: A. The patient is currently being treated with the requested agent and is experiencing a positive therapeutic outcome AND the prescriber provides documentation that switching the member to a preferred drug is expected to cause harm to the member or that the preferred drug would be ineffective **OR** B. 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: 1. ONE of the following: A. Evidence of a paid claim(s) **OR** B. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND** 2. ONE of the following: A. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR** C. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** D. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** E. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **AND** F. The patient does NOT have any FDA labeled contraindications to the requested agent **OR**

Module	Clinical Criteria for Approval
	2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA labeled indication **AND** B. The patient uses an enteral tube for feeding or medication administration **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:** up to 12 months

• Program Summary: Hetlioz (tasimelteon)

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
60250070000130	Hetlioz	Tasimelteon Capsule 20 MG	20 MG	30	Capsules	30	DAYS				
60250070001820	Hetlioz lq	Tasimelteon Oral Susp	4 MG/ML	158	mLs	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. BOTH of the following: 1. The patient has a diagnosis of Non-24-hour sleep-wake disorder **AND** 2. The patient is totally blind (i.e., no light perception) **OR** B. BOTH of the following: 1. The patient has a diagnosis of Smith-Magenis Syndrome (SMS) confirmed by the presence of ONE of the following genetic mutations: A. A heterozygous deletion of 17p11.2 **OR** B. A heterozygous pathogenic variant involving RAI1 **AND** 2. The requested agent is being used to treat nighttime sleep disturbances associated with SMS **OR**

Module	Clinical Criteria for Approval
	C. 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** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., sleep specialist, neurologist, psychiatrist) or 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** **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 prescriber is a specialist in the area of the patient's diagnosis (e.g., sleep specialist, neurologist, psychiatrist) or 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** C. There is support of therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

● Program Summary: Multiple Sclerosis 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
624040700003	Aubagio	teriflunomide tab	14 MG; 7 MG	30	Tablets	30	DAYS				
6240306045F8	Avonex	interferon beta-	30 MCG/0.5ML	4	Syringes	28	DAYS				
6240306045F5	Avonex pen	interferon beta-	30 MCG/0.5ML	4	Pens	28	DAYS				
62405550006520	Bafiertam	Monomethyl Fumarate Capsule Delayed Release	95 MG	120	Capsules	30	DAYS				
624030605064	Betaseron	Interferon Beta-; interferon beta-	0.3 MG	14	Vials	28	DAYS	50419052401; 50419052435			
6240003010E520	Copaxone; Glatopa	Glatiramer Acetate Soln Prefilled Syringe 20 MG/ML	20 MG/ML	30	Syringes	30	DAYS				
6240003010E540	Copaxone; Glatopa	Glatiramer Acetate Soln Prefilled Syringe 40 MG/ML	40 MG/ML	12	Syringes	28	DAYS				
624030605064	Extavia	Interferon Beta-; interferon beta-	0.3 MG	15	Vials	30	DAYS	00078056912; 00078056961; 00078056999			
624070251001	Gilenya	fingolimod hcl cap	0.25 MG; 0.5 MG	30	Capsules	30	DAYS				
6240506500D520	Kesimpta	Ofatumumab Soln Auto-Injector	20 MG/0.4ML	1	Syringe	28	DAYS				
6240101500B744	Mavenclad	Cladribine Tab Therapy Pack 10 MG (10 Tabs)	10 MG	20	Tablets	301	DAYS				
6240101500B718	Mavenclad	Cladribine Tab Therapy Pack 10 MG (4 Tabs)	10 MG	8	Tablets	301	DAYS				
6240101500B722	Mavenclad	Cladribine Tab Therapy Pack 10 MG (5 Tabs)	10 MG	10	Tablets	301	DAYS				
6240101500B726	Mavenclad	Cladribine Tab Therapy Pack 10 MG (6 Tabs)	10 MG	12	Tablets	301	DAYS				
6240101500B732	Mavenclad	Cladribine Tab Therapy Pack 10 MG (7 Tabs)	10 MG	14	Tablets	301	DAYS				
6240101500B736	Mavenclad	Cladribine Tab Therapy Pack 10 MG (8 Tabs)	10 MG	8	Tablets	301	DAYS				
6240101500B740	Mavenclad	Cladribine Tab Therapy Pack 10 MG (9 Tabs)	10 MG	9	Tablets	301	DAYS				
62407070200330	Mayzent	Siponimod Fumarate Tab	1 MG	30	Tablets	30	DAYS				

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
62407070200320	Mayzent	Siponimod Fumarate Tab 0.25 MG (Base Equiv)	0.25 MG	120	Tablets	30	DAYS				
62407070200340	Mayzent	Siponimod Fumarate Tab 2 MG (Base Equiv)	2 MG	30	Tablets	30	DAYS				
6240707020B710	Mayzent starter pack	Siponimod Fumarate Tab	0.25 MG	7	Tablets	180	DAYS				
6240707020B720	Mayzent starter pack	Siponimod Fumarate Tab 0.25 MG (12) Starter Pack	0.25 MG	12	Tablets	180	DAYS				
6240307530E521	Plegridy	Peginterferon Beta-	125 MCG/0.5ML	2	Syringes	28	DAYS				
6240307530D220	Plegridy	Peginterferon Beta-1a Soln Pen-injector 125 MCG/0.5ML	125 MCG/0.5ML	2	Pens	28	DAYS				
6240307530E520	Plegridy	Peginterferon Beta-1a Soln Prefilled Syringe 125 MCG/0.5ML	125 MCG/0.5ML	2	Syringes	28	DAYS				
6240307530D250	Plegridy starter pack	Peginterferon Beta-1a Soln Pen-inj 63 & 94 MCG/0.5ML Pack	63 & 94 MCG/0.5ML	1	Kit	180	DAYS				
6240307530E550	Plegridy starter pack	Peginterferon Beta-1a Soln Pref Syr 63 & 94 MCG/0.5ML Pack	63 & 94 MCG/0.5ML	1	Kit	180	DAYS				
62407060000320	Ponvory	Ponesimod Tab	20 MG	30	Tablets	30	DAYS				
6240706000B720	Ponvory 14-day starter pa	Ponesimod Tab Starter Pack	2-3-4-5-6-7-8-9 & 10 MG	14	Tablets	180	DAYS				
6240306045E520	Rebif	Interferon Beta-1a Soln Pref Syr 22 MCG/0.5ML (12MU/ML)	22 MCG/0.5ML	12	Syringes	28	DAYS				
6240306045E540	Rebif	Interferon Beta-1a Soln Pref Syr 44 MCG/0.5ML (24MU/ML)	44 MCG/0.5ML	12	Syringes	28	DAYS				
6240306045D520	Rebif rebidose	Interferon Beta-1a Soln Auto-Inj 22 MCG/0.5ML (12MU/ML)	22 MCG/0.5ML	12	Syringes	28	DAYS				
6240306045D540	Rebif rebidose	Interferon Beta-1a Soln Auto-inj 44 MCG/0.5ML (24MU/ML)	44 MCG/0.5ML	12	Syringes	28	DAYS				
6240306045D560	Rebif rebidose titration	Interferon Beta-1a Auto-inj 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6X8.8 & 6X22 MCG	1	Kit	180	DAYS				
6240306045E560	Rebif titration pack	Interferon Beta-1a Pref Syr 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6X8.8 & 6X22 MCG	1	Kit	180	DAYS				

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
624070252072	Tascenso odt	fingolimod lauryl sulfate tablet disintegrating	0.25 MG; 0.5 MG	30	Tablets	30	DAYS				
62405525006520	Tecfidera	Dimethyl Fumarate Capsule Delayed Release 120 MG	120 MG	56	Capsules	180	DAYS				
62405525006540	Tecfidera	Dimethyl Fumarate Capsule Delayed Release 240 MG	240 MG	60	Capsules	30	DAYS				
6240552500B320	Tecfidera starter pack	dimethyl fumarate capsule dr starter pack	120 & 240 MG	1	Kit	180	DAYS				
62405530006540	Vumerity	Diroximel Fumarate Capsule Delayed Release 231 MG	231 MG	120	Capsules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Mavenclad	**TARGET AGENT(S) - Preferred agents are the MN Medicaid Preferred Drug List (PDL) preferred drugs** **Preferred Agents** **Avonex®** (interferon beta-1a) **Betaseron®** (interferon beta-1b) **Copaxone®** 20 mg/mL (glatiramer)* **dimethyl fumarate** **fingolimod** **Rebif®** (interferon beta-1a) **teriflunomide** **Nonpreferred Agents** **Aubagio®** (teriflunomide)* **Bafiertam™** (monomethyl fumarate) **Copaxone®** 40 mg/mL (glatiramer)* **dimethyl fumarate Starter Pack** **Extavia®** (interferon beta-1b)Glatiramer 20 mg/mL **Gilenya®** (fingolimod)* **Glatiramer 40 mg/mL** **Glatopa®** (glatiramer)* **Kesimpta®** (ofatumumab) **Mavenclad®** (cladribine) **Mayzent®** (siponimod) **Plegridy®** (peginterferon beta-1a) **Ponvory™** (ponesimod) **Tecfidera®** (dimethyl fumarate)* **Tascenso ODT™** (fingolimod) **Vumerity®** (diroximel fumarate) * -generic available **FDA Labeled Indication** / **FDA Approved Agent(s)** Clinically Isolated Syndrome (CIS) — Aubagio, Avonex, Bafiertam, Betaseron, Copaxone, Extavia, Gilenya, Glatopa,

Module	Clinical Criteria for Approval

	Kesimpta, Mayzent, Plegridy, Ponvory, Rebif, Tascenso ODT, Tecfidera, Vumerity
Relapsing Remitting Multiple Sclerosis (RRMS)	Aubagio, Avonex, Bafiertam, Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Kesimpta, Mavenclad, Mayzent, Plegridy, Ponvory, Rebif, Tascenso ODT, Tecfidera, Vumerity
Active Secondary Progressive Multiple Sclerosis (SPMS)	Aubagio, Avonex, Bafiertam, Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Kesimpta, Mavenclad, Mayzent, Plegridy, Ponvory, Rebif, Tascenso ODT, Tecfidera, Vumerity

Initial Evaluation

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

1. ONE of the following:
    - A. ONE of the following:
        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 the patient is at risk if therapy is changed **OR**
    - B. ALL of the following
        1. The patient has ONE of the following relapsing forms of multiple sclerosis (MS):
            - A. Relapsing-remitting disease (RRMS) **OR**
            - B. Active secondary progressive disease (SPMS) **AND**
        2. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following:
            - A. The patient is currently being treated with the requested agent as indicated by ALL of the following:
                1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
                2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
                3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
            - B. The patient's medication history includes two preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) AND ONE of the following:
                1. The patient had an inadequate response to two preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) **OR**
                2. The prescriber has submitted an evidence-based and peer reviewed clinical practice guideline supporting the use of the requested agent over the preferred agent(s) **OR**
            - C. The patient has an intolerance or hypersensitivity to two preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR**
            - D. The patient has an FDA labeled contraindication to ALL preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR**
            - E. The prescriber has provided information that the required preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to

Module	Clinical Criteria for Approval
	achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** F. The prescriber has provided information supporting the use of the non-preferred agent over the preferred agent(s) **AND** 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** 2. If the patient has been previously treated with the requested agent, BOTH of the following: A. The prescriber has provided the number of courses the patient has completed (one course consists of 2 cycles of 4-5 days each) **AND** B. The patient has NOT completed 2 courses of the requested agent (one course consists of 2 cycles of 4-5 days each) **AND** 3. A complete CBC with differential including lymphocyte count has been performed **AND** 4. The lymphocyte count is within normal limits **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (i.e., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. ONE of the following: A. The patient will NOT be using the requested agent with an additional disease modifying agent (DMA) for the requested indication **OR** B. BOTH of the following: 1. The patient is currently using the requested agent **AND** 2. There is support for the use of the additional DMA (e.g., relapse between cycles) **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 8. The requested quantity (dose) does not exceed the FDA labeled maximum dose based on the patient's weight **Length of Approval:** 36 weeks for new starts OR if patient is currently taking the requested agent, approve for remainder of the annual course (1 course consists of 2 cycles of 4-5 days) NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria **Renewal Evaluation** **Mavenclad (cladribine)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (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. A complete CBC with differential including lymphocyte count has been performed **AND** 4. The patient has a lymphocyte count of at least 800 cells/microliter **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (i.e., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. ONE of the following: A. The patient will NOT be using the requested agent in combination with an additional disease modifying agent (DMA) for the requested indication **OR** B. There is support for the use of the additional DMA (e.g., relapse between cycles) **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 8. It has been at least 35 weeks but not more than 67 weeks since the last dose of the requested agent **AND** 9. BOTH of the following: A. The prescriber has provided the number of courses the patient has completed (one course consists of 2 cycles of 4-5 days each) **AND**

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td></td><td>B. The patient has NOT completed 2 courses with the requested agent (one course consists of 2 cycles of 4-5 days) AND
10. The requested quantity (dose) does not exceed the FDA labeled maximum dose based on the patient's weight

Length of Approval: 3 months

NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</td></tr>
<tr><td>MS Agents other than Mavenclad</td><td>TARGET AGENT(S) - Preferred agents are the MN Medicaid Preferred Drug List (PDL) preferred drugs

<u>Preferred Agents</u>
Avonex® (interferon beta-1a)
Betaseron® (interferon beta-1b)
Copaxone® 20 mg/mL (glatiramer)*
dimethyl fumarate
fingolimod
Rebif® (interferon beta-1a)
teriflunomide

<u>Nonpreferred Agents</u>
Aubagio® (teriflunomide)
Bafiertam™ (monomethyl fumarate)
Copaxone® 40 mg/mL (glatiramer)*
dimethyl fumarate Starter Pack
Extavia® (interferon beta-1b)
Glatiramer 20 mg/mL
Gilenya® (fingolimod)*
Glatiramer 40 mg/mL
Glatopa® (glatiramer)*
Kesimpta® (ofatumumab)
Mavenclad® (cladribine)
Mayzent® (siponimod)
Plegridy® (peginterferon beta-1a)
Ponvory™ (ponesimod)
Tecfidera® (dimethyl fumarate)*
Tascenso ODT™ (fingolimod)
Vumerity® (diroximel fumarate)
* -generic available

<table>
<tr><th>FDA Labeled Indication</th><th>FDA Approved Agent(s)</th></tr>
<tr><td>Clinically Isolated Syndrome (CIS)</td><td>Aubagio, Avonex, Bafiertam, Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Kesimpta, Mayzent, Plegridy, Ponvory, Rebif, Tascenso ODT, Tecfidera, Vumerity</td></tr>
<tr><td>Relapsing Remitting Multiple Sclerosis (RRMS)</td><td>Aubagio, Avonex, Bafiertam, Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Kesimpta, Mavenclad, Mayzent, Plegridy, Ponvory, Rebif, Tascenso ODT, Tecfidera, Vumerity</td></tr>
<tr><td>Active Secondary Progressive Multiple Sclerosis (SPMS)</td><td>Aubagio, Avonex, Bafiertam, Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Kesimpta, Mavenclad, Mayzent, Plegridy,</td></tr>
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Module	Clinical Criteria for Approval

	Ponvory, Rebif, Tascenso ODT, Tecfidera, Vumerity

Initial Evaluation

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

1. ONE of the following:
    - A. Information has been provided that the patient has been treated with the requested agent within the past 90 days **OR**
    - B. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR**
    - C. BOTH of the following:
        1. ONE of the following:
            - A. The patient has a diagnosis of a relapsing form of MS AND ALL of the following:
                1. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following:
                    - A. The patient is currently being treated with the requested agent as indicated by ALL of the following:
                        1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
                        2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
                        3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
                    - B. The patient's medication history includes two preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) AND ONE of the following:
                        1. The patient had an inadequate response to two preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) **OR**
                        2. The prescriber has submitted an evidence-based and peer reviewed clinical practice guideline supporting the use of the requested agent over the preferred agent(s) **OR**
                    - C. The patient has an intolerance or hypersensitivity to two preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR**
                    - D. The patient has an FDA labeled contraindication to ALL preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR**
                    - E. The prescriber has provided information that the required preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**
                    - F. The prescriber has provided information supporting the use of the non-preferred agent over the preferred agent(s) **AND**

Module	Clinical Criteria for Approval
	2. If the requested agent is Aubagio (teriflunomide), the prescriber has obtained transaminase and bilirubin levels within 6 months prior to initiating treatment **AND** 3. If the requested agent is Gilenya (fingolimod) or Tascenso ODT (fingolimod) the prescriber has performed an electrocardiogram within 6 months prior to initiating treatment **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 labeled indication, the 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 is a specialist in the area of the patient's diagnosis (i.e., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. ONE of the following: A. The patient will NOT be using the requested agent in combination with an additional disease modifying agent (DMA) for the requested indication **OR** B. The patient will be using the requested agent in combination with another DMA used for the treatment of the requested indication AND BOTH of the following: 1. The requested agent will be used in combination with Mavenclad (cladribine) **AND** 2. There is support for the use of the requested agent in combination with Mavenclad (e.g., relapse between cycles of Mavenclad) **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months. NOTE: For agents requiring a starter dose for initial use, the starter dose can be approved for the FDA labeled starting dose and the maintenance dose can be approved for the remainder of 12 months. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria **Renewal Evaluation** **Target agent(s) (excluding Mavenclad [cladribine])** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (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 prescriber is a specialist in the area of the patient's diagnosis (i.e., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following: A. The patient will NOT be using the requested agent in combination with an additional disease modifying agent (DMA) for the requested indication **OR** B. The patient will be using the requested agent in combination with another DMA used for the requested indication AND BOTH of the following: 1. The requested agent will be used in combination with Mavenclad cladribine) **AND** 2. There is support for the use of the requested agent in combination with Mavenclad (e.g., relapse between cycles of Mavenclad) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Examples of Contraindicated Concomitant Disease Modifying Agents (DMAs) **Aubagio** (teriflunomide)* **Avonex** (interferon β-1a) **Bafiertam** (monomethyl fumarate) **Betaseron** (interferon β-1b) **Briumvi** (ublituximab-xiiy) **Copaxone** (glatiramer)* dimethyl fumarate **Extavia** (interferon β-1b) fingolimod **Gilenya** (fingolimod)* **Glatopa** (glatiramer) glatiramer **Kesimpta** (ofatumumab) **Lemtrada** (alemtuzumab) **Mavenclad** (cladribine) **Mayzent** (siponimod)

Contraindicated as Concomitant Therapy
Ocrevus (ocrelizumab) **Plegridy** (peginterferon β-1a) **Ponvory** (ponesimod) **Rebif** (interferon β-1a) **Tascenso ODT** (fingolimod) **Tecfidera** (dimethyl fumarate)* teriflunomide **Tysabri** (natalizumab) **Vumerity** (diroximel fumarate) **Zeposia** (ozanimod) * -generic available

CLASS AGENTS

Class	Class Drug Agents
Class Ia antiarrhythmics	
Class Ia antiarrhythmics	NORPACE*Disopyramide Phosphate Cap
Class Ia antiarrhythmics	Pronestyl (procainamide)
Class Ia antiarrhythmics	quinidine
Class III antiarrhythmics	
Class III antiarrhythmics	BETAPACE*Sotalol HCl Tab
Class III antiarrhythmics	Cordarone, Pacerone (amiodarone)
Class III antiarrhythmics	CORVERT*Ibutilide Fumarate Inj
Class III antiarrhythmics	MULTAQ*Dronedarone HCl Tab
Class III antiarrhythmics	TIKOSYN*Dofetilide Cap
MS Disease Modifying Agents drug class: CD20 monoclonal antibody	
MS Disease Modifying Agents drug class: CD20 monoclonal antibody	BRIUMVI*ublituximab-xiiy soln for iv infusion
MS Disease Modifying Agents drug class: CD20 monoclonal antibody	KESIMPTA*Ofatumumab Soln Auto-Injector
MS Disease Modifying Agents drug class: CD20 monoclonal antibody	OCREVUS*Ocrelizumab Soln For IV Infusion
MS Disease Modifying Agents drug class: CD52 monoclonal antibody	
MS Disease Modifying Agents drug class: CD52 monoclonal antibody	LEMTRADA*Alemtuzumab IV Inj
MS Disease Modifying Agents drug class: Fumarates	
MS Disease Modifying Agents drug class: Fumarates	BAFIERTAM*Monomethyl Fumarate Capsule Delayed Release
MS Disease Modifying Agents drug class: Fumarates	TECFIDERA*Dimethyl Fumarate Capsule Delayed Release
MS Disease Modifying Agents drug class: Fumarates	VUMERITY*Diroximel Fumarate Capsule Delayed Release
MS Disease Modifying Agents drug class: Glatiramer	
MS Disease Modifying Agents drug class: Glatiramer	COPAXONE*Glatiramer Acetate Soln Prefilled Syringe
MS Disease Modifying Agents drug class: Glatiramer	GLATOPA*Glatiramer Acetate Soln Prefilled Syringe
MS Disease Modifying Agents drug class: IgG4k monoclonal antibody	

Class	Class Drug Agents
MS Disease Modifying Agents drug class: IgG4k monoclonal antibody	TYSABRI*Natalizumab for IV Inj Conc
MS Disease Modifying Agents drug class: Interferons	
MS Disease Modifying Agents drug class: Interferons	AVONEX*Interferon beta-1a injection
MS Disease Modifying Agents drug class: Interferons	BETASERON*Interferon beta-1b injection
MS Disease Modifying Agents drug class: Interferons	EXTAVIA*Interferon beta-1b injection
MS Disease Modifying Agents drug class: Interferons	PLEGRIDY*Peginterferon beta-1a injection
MS Disease Modifying Agents drug class: Interferons	REBIF*Interferon Beta-
MS Disease Modifying Agents drug class: Purine antimetabolite	
MS Disease Modifying Agents drug class: Purine antimetabolite	MAVENCLAD*Cladribine Tab Therapy Pack
MS Disease Modifying Agents drug class: Pyrimidine synthesis inhibitor	
MS Disease Modifying Agents drug class: Pyrimidine synthesis inhibitor	AUBAGIO*Teriflunomide Tab
MS Disease Modifying Agents drug class: Sphingosine 1-phosphate (SIP) receptor modulator	
MS Disease Modifying Agents drug class: Sphingosine 1-phosphate (SIP) receptor modulator	GILENYA*Fingolimod HCl Cap
MS Disease Modifying Agents drug class: Sphingosine 1-phosphate (SIP) receptor modulator	MAYZENT*Siponimod Fumarate Tab
MS Disease Modifying Agents drug class: Sphingosine 1-phosphate (SIP) receptor modulator	PONVORY*Ponesimod Tab
MS Disease Modifying Agents Drug Class: Sphingosine 1-phosphate (SIP) receptor modulator	
MS Disease Modifying Agents Drug Class: Sphingosine 1-phosphate (SIP) receptor modulator	TASCENSO*fingolimod lauryl sulfate tablet disintegrating
MS Disease Modifying Agents drug class: Sphingosine 1-phosphate (SIP) receptor modulator	
MS Disease Modifying Agents drug class: Sphingosine 1-phosphate (SIP) receptor modulator	ZEPOSIA*Ozanimod capsule

● Program Summary: Peanut Allergy

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
2010004020H510	Palforzia initial dose es	Peanut Powder-dnfp Starter Pack 0.5 & 1 & 1.5 & 3 & 6 MG	0.5 & 1 & 1.5 & 3 & 6 MG	1	Kit	180	DAYS				
2010004020H525	Palforzia level 1	Peanut Powder-dnfp Cap Sprinkle Pack 3 x 1 MG (3 MG Dose)	1 MG	90	Capsules	30	DAYS				
2010004020H570	Palforzia level 10	Peanut Powder-dnfp Pack 2 x 20 MG & 2 x 100 MG (240 MG Dose)	2 x 20 MG & 2 x 100 MG	120	Capsules	30	DAYS				
20100040203050	Palforzia level 11 (maint	Peanut Allergen Powder-dnfp Maintenance Packet 300 MG	300 MG	30	Packets	30	DAYS				
20100040203030	Palforzia level 11 (titra	Peanut Allergen Powder-dnfp Titration Packet 300 MG	300 MG	30	Packets	30	DAYS				
2010004020H530	Palforzia level 2	Peanut Powder-dnfp Cap Sprinkle Pack 6 x 1 MG (6 MG Dose)	1 MG	180	Capsules	30	DAYS				
2010004020H535	Palforzia level 3	Peanut Powder-dnfp Pack 2 x 1 MG & 10 MG (12 MG Dose)	2 x 1 MG & 10 MG	90	Capsules	30	DAYS				
2010004020H540	Palforzia level 4	Peanut Powder-dnfp Cap Sprinkle Pack 20 MG (20 MG Dose)	20 MG	30	Capsules	30	DAYS				
2010004020H545	Palforzia level 5	Peanut Powder-dnfp Cap Sprinkle Pack 2 x 20 MG (40 MG Dose)	20 MG	60	Capsules	30	DAYS				
2010004020H550	Palforzia level 6	Peanut Powder-dnfp Cap Sprinkle Pack 4 x 20 MG (80 MG Dose)	20 MG	120	Capsules	30	DAYS				
2010004020H555	Palforzia level 7	Peanut Powder-dnfp Pack 20 MG & 100 MG (120 MG Dose)	20 MG & 100 MG	60	Capsules	30	DAYS				
2010004020H560	Palforzia level 8	Peanut Powder-dnfp Pack 3 x 20 MG & 100 MG (160 MG Dose)	3 x 20 MG & 100 MG	120	Capsules	30	DAYS				
2010004020H565	Palforzia level 9	Peanut Powder-dnfp Pack 2 x 100 MG (200 MG Dose)	100 MG	60	Capsules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has been treated with the requested agent within the past 30 days **OR** B. The prescriber states the patient has been treated with the requested agent within the past 30 days AND is at risk if therapy is changed **OR** C. BOTH of the following: 1. The patient has a diagnosed peanut allergy confirmed by ONE of the following: A. A serum peanut-specific IgE level greater than or equal to 0.35 kUA/L **OR** B. A positive skin-prick test determined by a mean wheal diameter that is at least 3mm larger than the negative control upon skin-prick testing for peanut **OR** C. The patient has a positive result to an oral peanut food challenge **AND** 2. If the requested agent is Palforzia, the patient was 4-17 years of age at the time of initiating therapy **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient has injectable epinephrine on hand **AND** 4. The requested agent is to be used in conjunction with a peanut-avoidance diet **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	**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:** up to 12 months

• Program Summary: Pulmonary Arterial Hypertension (PAH)

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

For injectable agents refer to BCBSMN medical policy.

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
401430800003	Adcirca; Alyq	tadalafil tab	20; 20 MG	60	Tablets	30	DAYS				
4013405000	Adempas	riociguat tab	0.5 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
			1 MG; 5 MG; 2 MG; 2.5 MG								
4016000700	Letairis	ambrisentan tab	10 MG; 5 MG	30	Tablets	30	DAYS				
40143060101825	Liqrev	sildenafil citrate oral susp	10 MG/ML	244	mLs	30	DAYS				
4016005000	Opsumit	macitentan tab	10 MG	30	Tablets	30	DAYS				
4017008005C110	Orenitram titr kit Month 1	Treprostinil tab er Mo 1 titr kit	0.125 & 0.25 MG	1	Pack	180	DAYS				
4017008005C120	Orenitram titr kit Month 2	Treprostinil tab er Mo 2 titr kit	0.125 & 0.25 MG	1	Pack	180	DAYS				
4017008005C130	Orenitram titr kit Month 3	Treprostinil tab er Mo 3 titr kit	0.125 & 0.25 &1 MG	1	Pack	180	DAY				
401430601019	Revatio	sildenafil citrate for suspension	10 MG/ML	2	Bottles	30	DAYS				
401430601003	Revatio	sildenafil citrate tab	20 MG	90	Tablets	30	DAYS				
40143080001820	Tadliq	Tadalafil Oral Susp	20 MG/5ML	300	mLs	30	DAYS				
401600150003	Tracleer	bosentan tab	125 MG; 62.5 MG	60	Tablets	30	DAYS				
401600150073	Tracleer	bosentan tab for oral susp	32 MG	120	Tablets	30	DAYS				
40170080002020	Tyvaso	treprostinil inhalation solution	0.6 MG/ML	7	Packages	28	DAYS	66302020603			
40170080002920	Tyvaso dpi maintenance ki	Treprostinil Inh Powder	16 MCG	112	Cartridges	28	DAYS				
40170080002930	Tyvaso dpi maintenance ki	Treprostinil Inh Powder	32 MCG	112	Cartridges	28	DAYS				
40170080002940	Tyvaso dpi maintenance ki	Treprostinil Inh Powder	48 MCG	112	Cartridges	28	DAYS				
40170080002950	Tyvaso dpi maintenance ki	Treprostinil Inh Powder	64 MCG	112	Cartridges	28	DAYS				
40170080002960	Tyvaso dpi maintenance ki	Treprostinil Inh Powder	112 x 32MCG & 112 x48MCG	224	Cartridges	28	DAYS				
40170080002980	Tyvaso dpi titration kit	Treprostinil Inh Powd	16 & 32 & 48 MCG	252	Cartridges	180	DAYS				
40170080002970	Tyvaso dpi titration kit	Treprostinil Inh Powder	112 x 16MCG & 84 x 32MCG	196	Cartridges	180	DAYS				
40170080002020	Tyvaso refill	treprostinil inhalation solution	0.6 MG/ML	1	Kit	28	DAYS	66302020602			

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
40170080002020	Tyvaso starter	treprostinil inhalation solution	0.6 MG/ML	1	Kit	180	DAYS	66302020604			
40170080002020	Tyvaso starter	treprostinil inhalation solution	0.6 MG/ML	1	Kit	180	DAYS	66302020601			
401200700003	Uptravi	selexipag tab	1000 MCG; 1200 MCG; 1400 MCG; 1600 MCG; 200 MCG; 400 MCG; 600 MCG; 800 MCG	60	Tablets	30	DAYS				
40120070000310	Uptravi	selexipag tab	200 MCG	140	Tablets	180	DAYS	66215060214			
40120070000310	Uptravi	selexipag tab	200 MCG	60	Tablets	30	DAYS	66215060206			
4012007000B7	Uptravi titration pack	selexipag tab therapy pack	200 & 800 MCG	1	Package	180	DAYS				
401700600020	Ventavis	iloprost inhalation solution	10 MCG/ML; 20 MCG/ML	270	Ampules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ONE of the following is met: 1. ALL of the following: A. ONE of the following: 1. BOTH of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Target 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 **AND** B. The patient has an FDA labeled indication for the requested agent and route of administration **OR** 2. The patient has a diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH), WHO Group 4 and ALL of the following: A. The requested agent is Adempas **AND** B. The patient's diagnosis has been confirmed by a ventilation-perfusion scan and a confirmatory selective pulmonary angiography **AND** C. The patient has a mean pulmonary artery pressure of greater than 20 mmHg **AND**

Module	Clinical Criteria for Approval
	D. The patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg **AND** E. The patient has a pulmonary vascular resistance greater than or equal to 3 Wood units **AND** F. ONE of the following: 1. The patient is NOT a candidate for surgery **OR** 2. The patient has had a pulmonary endarterectomy AND has persistent or recurrent disease **AND** G. The patient will NOT be using the requested agent in combination with a PDE5 inhibitor (e.g., tadalafil [Adcirca or Cialis] or sildenafil [Revatio or Viagra]) **OR** 3. The patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 and ALL of the following: A. The patient's diagnosis has been confirmed by right heart catheterization (medical records required) **AND** B. The patient's mean pulmonary arterial pressure is greater than 20 mmHg **AND** C. The patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg **AND** D. The patient has a pulmonary vascular resistance greater than or equal to 3 Wood units **AND** E. The patient's World Health Organization (WHO) functional class is II or greater **AND** F. If the requested agent is sotatercept, then BOTH of the following: 1. The patient has been stable on background PAH therapy for at least 90 days (Please note: Background therapy refers to combination therapy consisting of drugs from two or more of the following drug classes: ERA, PDE5i, soluble guanylate cyclase stimulator, and/or prostacyclin analogue or receptor agonist) **AND** 2. The patient is not pregnant or planning to become pregnant while on therapy with the requested agent **AND** G. If the requested agent is Adcirca, Adempas, Revatio, sildenafil, or tadalafil, the patient will NOT be using the requested agent in combination with a PDE5 inhibitor (e.g., tadalafil [Adcirca or Cialis] or sildenafil [Revatio or Viagra]) **AND** H. If the requested agent is NOT sotatercept, then ONE of the following: 1. The requested agent will be utilized as monotherapy **OR** 2. The requested agent will be utilized as dual therapy that consists of an endothelin receptor antagonist (ERA) plus phosphodiesterase 5 inhibitor (PDE5i) as initial therapy **OR** 3. The requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy) [except combo requests for endothelin receptor antagonist (ERA) plus phosphodiesterase 5 inhibitor (PDE5i) for dual therapy], and BOTH of following: A. The patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy **AND** B. The requested agent is in a different therapeutic class **OR** 4. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy) and ALL of the following: A. The patient is WHO functional class III or IV **AND** B. ONE of the following: 1. A prostanoid has been started as one of the agents in the triple therapy **OR** 2. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ALL prostanoids **AND**

Module	Clinical Criteria for Approval
	C. The patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy **AND** D. All three agents in the triple therapy are from a different therapeutic class **AND** E. The requested agent will be utilized as part of triple therapy in a treatment naive patient AND both of the following: 1. The patient is WHO functional class IV **AND** 2. The 3 agents being utilized consist of: endothelin receptor antagonist (ERA) plus PDE5i plus prostanoid **OR** 4. The patient has a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD, WHO group 3) AND ALL of the following: A. The requested agent is Tyvaso **AND** B. The patient's diagnosis has been confirmed by right heart catheterization (medical records required) **AND** C. The patient's mean pulmonary arterial pressure is greater than 20 mmHg **AND** D. The patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg **AND** E. The patient has a pulmonary vascular resistance greater than or equal to 3 Wood units **AND** F. The patient has an FVC less than 70% of predicted **AND** G. The patient has extensive parenchymal changes on computed tomography (CT) **AND** H. BOTH of the following: 1. The patient is currently treated with standard of care therapy for ILD (e.g., Ofev) **AND** 2. The patient will continue standard of care therapy for ILD (e.g., Ofev) **OR** 5. The patient has another FDA approved indication 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 agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR** 2. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following: A. The patient is currently being treated with the requested agent and is experiencing a positive therapeutic outcome AND the prescriber provides documentation that switching the member to a preferred drug is expected to cause harm to the member or that the preferred drug would be ineffective **OR** B. 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: 1. ONE of the following: A. Evidence of a paid claim(s) **OR** B. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND** 2. ONE of the following: A. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR**

Module	Clinical Criteria for Approval
	B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR** C. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** D. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** E. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **AND** D. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** E. The patient does NOT have any FDA labeled contraindications 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:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ONE of the following is met: 1. ALL of the following: A. 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** B. The patient has had clinical benefit with the requested agent (e.g., stabilization, decreased disease progression) (medical records required) **AND** C. If the requested agent is Tyvaso for a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD, WHO group 3), then the patient will continue standard of care therapy for ILD (e.g., Ofev) **AND** D. If the requested agent is sotatercept for a diagnosis of pulmonary arterial hypertension (PAH), the patient will continue to use background PAH therapy (Please note: Background therapy refers to combination therapy consisting of drugs from two or more of the following drug classes: ERA, PDE5i, soluble guanylate cyclase stimulator, and/or prostacyclin analogue or receptor agonist) **AND** E. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** F. The patient does NOT have any FDA labeled contraindications 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:** 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**: 12 months

• Program Summary: Relyvrio (sodium phenylbutyrate/taurursodiol)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
74509902703020	Relyvrio	Sodium Phenylbutyrate-Taurursodiol Powd Pack	3-1 GM	1	Box	28	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ONE of the following is met: 1. ALL of the following: A. The patient has a diagnosis of amyotrophic lateral sclerosis (ALS) [also known as Lou Gehrig's disease] **AND** B. BOTH of the following: 1. The requested agent will be or was started within 18 months of symptom onset **AND** 2. The patient has a baseline percent predicted forced vital capacity (FVC) or slow vital capacity (SVC) greater than 60% **AND** C. 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**

Module	Clinical Criteria for Approval
	D. 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** E. ONE of the following: 1. BOTH of the following: A. The patient is currently treated with riluzole **AND** B. The patient will continue riluzole in combination with the requested agent **OR** 2. The patient's medication history includes riluzole AND ONE of the following: A. The patient has had an inadequate response to riluzole **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over riluzole **OR** 3. The patient has an intolerance or hypersensitivity to riluzole **OR** 4. The patient has an FDA labeled contraindication to riluzole **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 the 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 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** F. 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** G. The patient does NOT have any FDA labeled contraindications 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:** 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ONE of the following is met: 1. ALL of the following: A. The patient has been previously approved for the requested agent through the plan's Prior Authorization criteria (Note: patients not previously approved for the requested agent will require initial evaluation review) **AND** B. The patient has had clinical benefit with the requested agent **AND** C. The patient is NOT dependent on invasive ventilation or tracheostomy **AND** D. 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** E. The patient does NOT have any FDA labeled contraindications 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:** 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
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 **Length of Approval:** up to 6 months for initial; up to 12 months for renewal

• Program Summary: Vijoice (alpelisib)

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
9948601000B740	Vijoice	Alpelisib (PROS) Pak	200 & 50 MG	56	Tablets	28	DAYS				
9948601000B720	Vijoice	Alpelisib (PROS) Tab Therapy Pack	50 MG	28	Tablets	28	DAYS				
9948601000B730	Vijoice	Alpelisib (PROS) Tab Therapy Pack	125 MG	28	Tablets	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** Vijoice 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 PIK3CA-Related Overgrowth Spectrum (PROS) confirmed by ALL of the following: A. Presence of somatic PIK3CA mutation **AND** B. Congenital or early childhood onset **AND** C. Overgrowth sporadic and mosaic **AND**

Module	Clinical Criteria for Approval
	D. ONE of the following: 1. The patient has at least TWO of the following features: A. Overgrowth B. Vascular malformations C. Epidermal nevus **OR** 2. The patient has at least ONE of the following features: A. Large isolated lymphatic malformations B. Isolated macrodactyly OR overgrown splayed feet/hands, overgrown limbs C. Truncal adipose overgrowth D. Hemimegalencephaly (bilateral)/dysplastic megalencephaly/focal cortical dysplasia E. Epidermal nevus F. Seborrheic keratoses G. Benign lichenoid keratoses **AND** 2. The patient has severe manifestations of PROS that requires systemic therapy **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** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., experienced in PROS) 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: 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 has NOT had disease progression (e.g., increase in lesion number, increase in lesion volume) with the requested agent (medical records required) **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., experienced in PROS) 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
	Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following:

Module	Clinical Criteria for Approval
	A. The requested quantity (dose) 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 6 months for initial; up to 12 months for renewal

• Program Summary: Xolair (omalizumab)

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

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	4460306000D5	Xolair	omalizumab subcutaneous soln auto-injector	150 MG/ML; 300 MG/2ML; 75 MG/0.5ML	M; N; O; Y				
	4460306000E5	Xolair	omalizumab subcutaneous soln prefilled syringe	150 MG/ML; 300 MG/2ML; 75 MG/0.5ML	M; N; O; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** No Target Agents are eligible for continuation of therapy 1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. BOTH of the following: 1. ONE of the following: A. The patient has a diagnosis of moderate to severe persistent asthma AND ALL of the following: 1. ONE of the following: A. The patient is 6 to less than 12 years of age AND BOTH of the following: 1. The pretreatment IgE level is 30 IU/mL to 1300 IU/mL **AND** 2. The patient's weight is 20 kg to 150 kg **OR** B. The patient is 12 years of age or over AND BOTH of the following: 1. The pretreatment IgE level is 30 IU/mL to 700 IU/mL **AND** 2. The patient's weight is 30 kg to 150 kg **AND**

Module	Clinical Criteria for Approval
	2. Allergic asthma has been confirmed by a positive skin test or in vitro reactivity test to a perennial aeroallergen **AND** 3. The patient has a history of uncontrolled asthma while on asthma control therapy as demonstrated by ONE of the following: A. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months **OR** B. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months **OR** C. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered **OR** D. The patient has baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted **OR** B. The patient has a diagnosis of chronic spontaneous urticaria (CSU) (otherwise known as chronic idiopathic urticaria [CIU]) AND ALL of the following: 1. The patient has had over 6 weeks of hives and itching **AND** 2. If the patient is currently being treated with medications known to cause or worsen urticaria, then ONE of the following: A. The prescriber has reduced the dose or discontinued any medications known to cause or worsen urticaria (e.g., NSAIDs) **OR** B. A reduced dose or discontinuation of any medications known to cause or worsen urticaria is not appropriate **AND** 3. ONE of the following: A. The patient has had an inadequate response to the FDA maximum dose of a second-generation H-1 antihistamine (e.g., cetirizine, levocetirizine, fexofenadine, loratadine, desloratadine) AND ONE of the following: 1. The patient has tried and had an inadequate response to a dose above the FDA labeled maximum dose (e.g., up to 4 times the FDA labeled maximum dose) of a second-generation H-1 antihistamine **OR** 2. The patient cannot be treated with a dose above the FDA labeled maximum dose of a second-generation H-1 antihistamine **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over second-generation H-1 antihistamine therapy **OR** C. The patient has an intolerance or hypersensitivity to second-generation H-1 antihistamine therapy **OR** D. The patient has an FDA labeled contraindication to ALL second-generation H-1 antihistamines **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

Module	Clinical Criteria for Approval
	F. The prescriber has provided documentation that ALL second-generation H-1 antihistamines cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND ALL of the following: 1. The patient has at least TWO of the following symptoms consistent with chronic rhinosinusitis (CRS): A. Nasal discharge (rhinorrhea or post-nasal drainage) B. Nasal obstruction or congestion C. Loss or decreased sense of smell (hyposmia) D. Facial pressure or pain **AND** 2. The patient has had symptoms consistent with chronic rhinosinusitis (CRS) for at least 12 consecutive weeks **AND** 3. The patient's diagnosis was confirmed by ONE of the following: A. Anterior rhinoscopy or endoscopy **OR** B. Computed tomography (CT) of the sinuses **AND** 4. ONE of the following: A. The patient has tried and had an inadequate response to intranasal corticosteroids (e.g., fluticasone, Sinuva) **OR** B. The patient has an intolerance or hypersensitivity to therapy with intranasal corticosteroids (e.g., fluticasone, Sinuva) **OR** C. The patient has an FDA labeled contraindication to ALL intranasal corticosteroids **OR** D. 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** C. The patient has another indication that is supported in compendia for the requested agent **AND** 2. If the patient has a diagnosis of moderate to severe persistent asthma, ALL of the following: A. ONE of the following: 1. The patient is NOT currently being treated with the requested agent AND is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months **OR** 2. The patient is currently being treated with the requested agent AND ONE of the following: A. Is currently treated with an inhaled corticosteroid for at least 3 months that is adequately dosed to control symptoms **OR** B. Is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months **OR** 3. The patient has an intolerance or hypersensitivity to inhaled corticosteroid therapy **OR** 4. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids **AND** B. ONE of the following: 1. The patient is currently being treated for at least 3 months with ONE of the following: A. A long-acting beta-2 agonist (LABA) **OR** B. Long-acting muscarinic antagonist (LAMA) **OR** C. A Leukotriene receptor antagonist (LTRA) **OR** D. Theophylline **OR**

Module	Clinical Criteria for Approval
	2. The patient has an intolerance or hypersensitivity to therapy with long-acting beta-2 agonists (LABA), long-acting muscarinic antagonists (LAMA), leukotriene receptor antagonist (LTRA), or theophylline **OR** 3. The patient has an FDA labeled contraindication to ALL long-acting beta-2 agonists (LABA) AND long-acting muscarinic antagonists (LAMA) **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL long-acting beta-2 agonists (LABA) AND long-acting muscarinic antagonists (LAMA) 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. The patient will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **AND** D. The requested dose is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 375 mg every 2 weeks **AND** 3. If the patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP), ALL of the following: A. The patient is currently treated with standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) **AND** B. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **AND** C. The requested dose is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 600 mg every 2 weeks **AND** 4. If the patient has a diagnosis of chronic spontaneous urticaria (CSU) (otherwise known as chronic idiopathic urticaria [CIU]), the requested dose is within FDA labeled dosing AND does NOT exceed 300 mg every 4 weeks **AND** 5. If the patient has another FDA labeled indication for the requested agent, the requested dose is within FDA labeled dosing for the requested indication **AND** 6. If the patient has another indication that is supported in compendia for the requested agent, the requested dose is supported in compendia for the requested indication **AND** 7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, otolaryngologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 8. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) **AND** 9. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 6 months for asthma, chronic idiopathic urticaria, and nasal polyps 12 months for all other indications

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. ONE of the following: A. The patient has a diagnosis of moderate to severe persistent asthma AND ALL of the following: 1. The patient has had improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following: A. Increase in percent predicted Forced Expiratory Volume (FEV_1) **OR** B. Decrease in the dose of inhaled corticosteroid required to control the patient's asthma **OR** C. Decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma **OR** D. Decrease in the number of hospitalizations, need for mechanical ventilation, or visits to the emergency room or urgent care due to exacerbations of asthma **AND** 2. The patient is currently treated and is compliant with standard therapy [i.e., inhaled corticosteroids (ICS), ICS/long-acting beta-2 agonist (ICS/LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), theophylline] **AND** 3. The requested dose is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 375 mg every 2 weeks **OR** B. The patient has a diagnosis of chronic spontaneous urticaria (CSU) (otherwise known as chronic idiopathic urticaria [CIU]) AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The requested dose is within FDA labeled dosing for the requested indication AND does NOT exceed 300 mg every 4 weeks **OR** C. The patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND ALL of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **AND** 3. The requested dose is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 600 mg every 2 weeks **OR** D. The patient has another FDA labeled indication for the requested agent AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The requested dose is within FDA labeled dosing for the requested indication **OR** E. The patient has another indication that is supported in compendia for the requested agent AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The requested dose is supported in compendia for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, otolaryngologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**

Module	Clinical Criteria for Approval
	2. There is support for the use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 12 months

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly
Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
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)

Contraindicated as Concomitant Therapy
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tysabri (natalizumab)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)
Zymfentra (infliximab-dyyb)

• Program Summary: Zeposia

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
62407050200120	Zeposia	Ozanimod HCl Cap 0.92 MG	0.92 MG	30	Capsule	30	DAYS				
6240705020B210	Zeposia 7-day starter pac	Ozanimod Cap Pack 4 x 0.23 MG & 3 x 0.46 MG	4 x 0.23MG & 3 x 0.46MG	7	Capsules	180	DAYS				
6240705020B215	Zeposia starter kit	ozanimod cap pack	0.23MG &0.46MG 0.92MG(21)	28	Capsules	180	DAYS				
6240705020B220	Zeposia starter kit	Ozanimod Cap Pack 4 x 0.23 MG & 3 x 0.46 MG & 30 x 0.92 MG	0.23MG & 0.46MG & 0.92MG	37	Capsules	180	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Zeposia PA through preferred	**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** Zeposia (ozanimod) 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. BOTH of the following: 1. ONE of the following: A. The patient has a relapsing form of multiple sclerosis (MS) AND BOTH of the following: 1. ONE of the following: A. The patient is currently being treated with the requested agent and is experiencing a positive therapeutic outcome AND the prescriber provides documentation that switching the member to a preferred drug is expected to cause harm to the member or that the preferred drug would be ineffective **OR** B. 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: 1. ONE of the following: A. Evidence of a paid claim(s) **OR** B. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND** 2. ONE of the following: A. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR** C. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** D. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

Module	Clinical Criteria for Approval
	E. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **AND** 2. ONE of the following: A. The patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) used for the requested indication (Please refer to "MS DMA Agents" contraindicated table) **OR** B. The patient will be using the requested agent in combination with another DMA used for the treatment of MS AND BOTH of the following: 1. The requested agent will be used in combination with Mavenclad (cladribine) **AND** 2. There is support for the use of the requested agent in combination with Mavenclad (e.g., relapse between cycles of Mavenclad (cladribine) **OR** B. The patient has a diagnosis of moderately to severely active ulcerative colitis (UC) AND ALL of the following: 1. ONE of the following: A. The patient is currently being treated with the requested agent as indicated by ALL of the following 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** B. The patient's medication history includes ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC AND ONE of the following: 1. The patient has had an inadequate response to a conventional agent used in the treatment of UC **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 UC **OR** C. The patient has severely active ulcerative colitis **OR** D. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of UC **OR** E. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of UC **OR** F. 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** G. 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 **AND** 2. ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient is currently being treated with the requested agent and is experiencing a positive therapeutic outcome AND the prescriber provides documentation that switching the member to Humira or Xeljanz is expected to cause harm to the member or that the preferred drug would be ineffective **OR** B. The patient has tried and had an inadequate response to Humira or Xeljanz as indicated by BOTH of the following: 1. ONE of the following: A. Evidence of a paid claim(s) **OR** B. The prescriber has stated that the patient has tried Humira or Xeljanz **AND** 2. ONE of the following: A. Humira or Xeljanz were 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 Humira or Xeljanz **OR** C. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to Humira AND Xeljanz that is not expected to occur with the requested agent **OR** D. The prescriber has provided documentation that Humira AND Xeljanz cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** E. The prescriber has submitted documentation supporting the use of the non-preferred agent over Humira AND Xeljanz **OR** F. 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 **AND** 3. ONE of the following (Please refer to "Immunomodulatory Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with an immunomodulatory (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with an 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 (copy of support required, i.e., clinical trials, phase III studies, guidelines) **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 performed an electrocardiogram within 6 months prior to initiating treatment **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist for the diagnosis of multiple sclerosis, gastroenterologist for the diagnosis of ulcerative colitis) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**

Module	Clinical Criteria for Approval
	4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months. NOTE: The starter dose can be approved for the FDA labeled starting dose and the maintenance dose can be approved for the remainder of 12 months. **Compendia Allowed:** CMS Approved Compendia 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 prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist for the diagnosis of multiple sclerosis, gastroenterologist for the diagnosis of ulcerative colitis) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following: A. The patient has a diagnosis of multiple sclerosis AND ONE of the following: 1. The patient will NOT be using the requested agent in combination with another disease modifying agent (DMA) for the requested indication (Please refer to "MS DMA Agents" contraindicated use table **OR** 2. The patient will be using the requested agent in combination with another DMA used for the treatment of the requested indication AND BOTH of the following: A. The requested agent will be used in combination with Mavenclad (cladribine) **AND** B. There is support for the use of the requested agent in combination with Mavenclad (e.g., relapse between cycles of Mavenclad) **OR** B. The patient has a diagnosis of ulcerative colitis AND ONE of the following (Please refer to "Immunomodulatory Agents NOT to be used Concomitantly" table: 1. The patient will NOT be using the requested agent in combination with an immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** 2. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: A. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** B. There is support for the use of combination therapy (copy of support required, i.e., clinical trials, phase III studies, guidelines) **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
Zeposia PA through preferred and	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following:

Module	Clinical Criteria for Approval
Zeposia PA with MS step	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. NOTE: The starter dose can be approved for the FDA labeled starting dose and the maintenance dose can be approved for the remainder of 12 months.

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
MS Disease Modifying Agents
Aubagio (teriflunomide)
Avonex (interferon b-1a)
Bafiertam (monomethyl fumarate)
Betaseron (interferon b-1b)
Briumvi (ublituximab-xiiy)
Copaxone (glatiramer)
dimethyl fumarate
Extavia (interferon b-1b)
fingolimod
Gilenya (fingolimod)
Glatopa (glatiramer)
glatiramer
Kesimpta (ofatumumab)
Mavenclad (cladribine)
Mayzent (siponimod)
Plegridy (peginterferon b-1a)
Ponvory (ponesimod)
Rebif (interferon b-1a)
Tascenso ODT (fingolimod)
Tecfidera (dimethyl fumarate)
Vumerity (diroximel fumarate)
Zeposia (ozanimod)
Immunomodulatory Agents NOT to be used concomitantly
Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)

Contraindicated as Concomitant Therapy
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)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tremfya (guselkumab)
Truxima (rituximab-abbs)

Contraindicated as Concomitant Therapy
Tysabri (natalizumab)
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)

CLASS AGENTS

Class	Class Drug Agents
MS Disease Modifying Agents drug classes: CD 52 monoclonal antibody	
MS Disease Modifying Agents drug classes: CD 52 monoclonal antibody	LEMTRADA*Alemtuzumab IV Inj
MS Disease Modifying Agents drug classes: CD20 monoclonal antibody	
MS Disease Modifying Agents drug classes: CD20 monoclonal antibody	KESIMPTA*Ofatumumab Soln Auto-Injector
MS Disease Modifying Agents drug classes: CD20 monoclonal antibody	OCREVUS*Ocrelizumab Soln For IV Infusion
MS Disease Modifying Agents drug classes: Fumarates	
MS Disease Modifying Agents drug classes: Fumarates	BAFIERTAM*Monomethyl Fumarate Capsule Delayed Release
MS Disease Modifying Agents drug classes: Fumarates	TECFIDERA*Dimethyl Fumarate Capsule Delayed Release
MS Disease Modifying Agents drug classes: Fumarates	VUMERITY*Diroximel Fumarate Capsule Delayed Release
MS Disease Modifying Agents drug classes: Glatiramer	
MS Disease Modifying Agents drug classes: Glatiramer	COPAXONE*Glatiramer Acetate Soln Prefilled Syringe
MS Disease Modifying Agents drug classes: Glatiramer	GLATOPA*Glatiramer Acetate Soln Prefilled Syringe
MS Disease Modifying Agents drug classes: IgG4k monoclonal antibody	
MS Disease Modifying Agents drug classes: IgG4k monoclonal antibody	TYSABRI*Natalizumab for IV Inj Conc
MS Disease Modifying Agents drug classes: Interferons	
MS Disease Modifying Agents drug classes: Interferons	AVONEX*Interferon beta-1a injection
MS Disease Modifying Agents drug classes: Interferons	BETASERON*Interferon beta-1b injection
MS Disease Modifying Agents drug classes: Interferons	EXTAVIA*Interferon beta-1b injection
MS Disease Modifying Agents drug classes: Interferons	PLEGRIDY*Peginterferon beta-1a injection
MS Disease Modifying Agents drug classes: Interferons	REBIF*Interferon beta-1a injection
MS Disease Modifying Agents drug classes: MS Disease Modifying Agents drug classes	

Class	Class Drug Agents
MS Disease Modifying Agents drug classes: MS Disease Modifying Agents drug classes	AUBAGIO*Teriflunomide Tab
MS Disease Modifying Agents drug classes: Purine antimetabolite	
MS Disease Modifying Agents drug classes: Purine antimetabolite	MAVENCLAD*Cladribine Tab Therapy Pack
MS Disease Modifying Agents drug classes: Sphingosine 1-phosphate (SIP) receptor modulator	
MS Disease Modifying Agents drug classes: Sphingosine 1-phosphate (SIP) receptor modulator	GILENYA*Fingolimod HCl Cap
MS Disease Modifying Agents drug classes: Sphingosine 1-phosphate (SIP) receptor modulator	MAYZENT*Siponimod Fumarate Tab
MS Disease Modifying Agents drug classes: Sphingosine 1-phosphate (SIP) receptor modulator	PONVORY*Ponesimod Tab
MS Disease Modifying Agents drug classes: Sphingosine 1-phosphate (SIP) receptor modulator	ZEPOSIA*Ozanimod capsule

• Program Summary: Zokinvy

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
99463045000120	Zokinvy	Lonafarnib Cap	50 MG	120	Capsules	30	DAYS				
99463045000130	Zokinvy	Lonafarnib Cap	75 MG	120	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 requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy**: Zokinvy 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. BOTH of the following: 1. The patient has a diagnosis of Hutchinson-Gilford progeria syndrome (HGPS) **AND**

Module	Clinical Criteria for Approval
	2. Genetic testing has confirmed a pathogenic variant in the *LMNA* gene that results in production of progerin (medical record required) **OR** B. The patient has a processing-deficient progeroid laminopathy AND ONE of the following: 1. Genetic testing has confirmed heterozygous *LMNA* mutation with progerin-like protein accumulation (medical record required) **OR** 2. Genetic testing has confirmed homozygous or compound heterozygous *ZMPSTE24* mutations (medical record required) **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 patient has a body surface area (BSA) of greater than or equal to 0.39 m^2 **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, 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** **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 prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, 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 **Length of Approval:** up to 12 months

● Program Summary: Zoryve (roflumilast)

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

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	902500450037	Zoryve	roflumilast cream	0.3 %	M; N; O; Y				
	903000450039	Zoryve	roflumilast foam	0.3 %	M; N; O; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is Zoryve cream AND ALL of the following: 1. The patient has a diagnosis of plaque psoriasis **AND** 2. The patient's affected body surface area (BSA) is less than or equal to 20% **AND** 3. ONE of the following: A. The patient's medication history includes therapy with a topical corticosteroid AND ONE of the following: 1. The patient has had an inadequate response to a topical corticosteroid **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over topical corticosteroids **OR** B. The patient has an intolerance or hypersensitivity to therapy with topical corticosteroids **OR** C. The patient has an FDA labeled contraindication to ALL topical corticosteroids **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that topical corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. ONE of the following: A. The patient's medication history includes therapy with another topical psoriasis agent with a different mechanism of action (e.g., vitamin D analogs, calcineurin inhibitors, tazarotene) AND ONE of the following: 1. The patient has had an inadequate response to another topical psoriasis agent with a different mechanism of action **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent

Module	Clinical Criteria for Approval
	over another topical psoriasis agent with a different mechanism of action **OR** B. The patient has an intolerance or hypersensitivity to another topical psoriasis agent with a different mechanism of action **OR** C. The patient has an FDA labeled contraindication to ALL other topical psoriasis agents with a different mechanism of action **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL other topical psoriasis agents with a different mechanism of action cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The requested agent is Zoryve foam AND ALL of the following: 1. The patient has a diagnosis of seborrheic dermatitis **AND** 2. ONE of the following: A. The patient's medication history includes therapy with a topical antifungal OR a topical corticosteroid AND ONE of the following: 1. The patient has had an inadequate response to a topical antifungal OR topical corticosteroid **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over topical antifungals AND topical corticosteroids **OR** B. The patient has an intolerance or hypersensitivity to therapy with topical antifungals OR topical corticosteroids **OR** C. The patient has an FDA labeled contraindication to ALL topical antifungals AND topical corticosteroids **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that topical antifungals AND topical corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. ONE of the following: A. The patient's medication history includes therapy with a topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) AND ONE of the following: 1. The patient has had an inadequate response to a topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) **OR**

Module	Clinical Criteria for Approval
	2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over topical calcineurin inhibitors (e.g., pimecrolimus, tacrolimus) **OR** B. The patient has an intolerance or hypersensitivity to therapy with topical calcineurin inhibitors (e.g., pimecrolimus, tacrolimus) **OR** C. The patient has an FDA labeled contraindication to ALL topical calcineurin inhibitors (e.g., pimecrolimus, tacrolimus) **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 topical calcineurin inhibitors (e.g., pimecrolimus, tacrolimus) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has another FDA labeled indication for the requested agent and route of administration **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. 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., dermatologist) 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:** diagnosis of plaque psoriasis 12 months, diagnosis of seborrheic dermatitis 8 weeks, All other FDA approved indications 12 months **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [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 prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist) 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