COMMERCIAL PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: June 1, 2024 Notification Posted: April 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:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
67604030002020	Elyxyb	Celecoxib Oral Soln	120 MG/4.8ML	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
	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 acute migraine treatment AND ALL of the following: 1. ONE of the following: A. The patient has tried and had an inadequate response to ONE triptan agent **OR** B. The patient has an intolerance or hypersensitivity to ONE 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 acute 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. ONE of the following:

Module	Clinical Criteria for Approval
	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 has another FDA labeled indication for the requested agent and route of administration **OR** C. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA labeled indication, 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:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been 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. 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** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. The 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:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** up to 12 months

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

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
61400020107048		Methylphenidate HCl Cap ER 24HR 60 MG (LA)	60 MG	30	Capsules	30	DAYS				
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	5 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
		Tab 5 MG									
61109902100307	Adderall	Amphetamine-Dextroamphetamine Tab 7.5 MG	7.5 MG	60	Tablets	30	DAYS				
61109902107010	Adderall xr	Amphetamine-Dextroamphetamine Cap ER 24HR 10 MG	10 MG	60	Capsules	30	DAYS				
61109902107015	Adderall xr	Amphetamine-Dextroamphetamine Cap ER 24HR 15 MG	15 MG	30	Capsules	30	DAYS				
61109902107020	Adderall xr	Amphetamine-Dextroamphetamine Cap ER 24HR 20 MG	20 MG	30	Capsules	30	DAYS				
61109902107025	Adderall xr	Amphetamine-Dextroamphetamine Cap ER 24HR 25 MG	25 MG	30	Capsules	30	DAYS				
61109902107030	Adderall xr	Amphetamine-Dextroamphetamine Cap ER 24HR 30 MG	30 MG	30	Capsules	30	DAYS				
61109902107005	Adderall xr	Amphetamine-Dextroamphetamine Cap ER 24HR 5 MG	5 MG	30	Capsules	30	DAYS				
61400020107068	Adhansia xr	Methylphenidate HCl Cap ER 24HR 25 MG	25 MG	30	Capsules	30	DAYS				
61400020107073	Adhansia xr	Methylphenidate HCl Cap ER 24HR 35 MG	35 MG	30	Capsules	30	DAYS				
61400020107078	Adhansia xr	Methylphenidate HCl Cap ER 24HR 45 MG	45 MG	30	Capsules	30	DAYS				
61400020107083	Adhansia xr	Methylphenidate HCl Cap ER 24HR 55 MG	55 MG	30	Capsules	30	DAYS				
61400020107088	Adhansia xr	Methylphenidate HCl Cap ER 24HR 70 MG	70 MG	30	Capsules	30	DAYS				
61400020107091	Adhansia xr	Methylphenidate HCl Cap ER 24HR 85 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	18.8 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
		Extended Release Disintegrating 18.8 MG									
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				
61400020107055	Aptensio xr	Methylphenidate HCl Cap ER 24HR 10 MG (XR)	10 MG	30	Capsules	30	DAYS				
61400020107060	Aptensio xr	Methylphenidate HCl Cap ER 24HR 15 MG (XR)	15 MG	30	Capsules	30	DAYS				
61400020107065	Aptensio xr	Methylphenidate HCl Cap ER 24HR 20 MG (XR)	20 MG	30	Capsules	30	DAYS				
61400020107070	Aptensio xr	Methylphenidate HCl Cap ER 24HR 30 MG (XR)	30 MG	30	Capsules	30	DAYS				
61400020107075	Aptensio xr	Methylphenidate HCl Cap ER 24HR 40 MG (XR)	40 MG	30	Capsules	30	DAYS				
61400020107080	Aptensio xr	Methylphenidate HCl Cap ER 24HR 50 MG (XR)	50 MG	30	Capsules	30	DAYS				
61400020107085	Aptensio xr	Methylphenidate HCl Cap ER 24HR 60 MG (XR)	60 MG	30	Capsules	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	18 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
		Release (OSM) 18 MG									
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				
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				
6110001000H210	Dyanavel xr	Amphetamine Chew Tab Extended Release	5 MG	30	Tablets	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6110001000H220	Dyanavel xr	Amphetamine Chew Tab Extended Release	10 MG	30	Tablets	30	DAYS				
6110001000H230	Dyanavel xr	Amphetamine Chew Tab Extended Release	15 MG	30	Tablets	30	DAYS				
6110001000H240	Dyanavel xr	Amphetamine Chew Tab Extended Release	20 MG	30	Tablets	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				
613530301075	Intuniv	guanfacine hcl tab er	1 MG; 2 MG; 3 MG; 4 MG	30	Tablets	30	DAYS				
61400020107094	Jornay pm	Methylphenidate HCl Cap Delayed ER 24HR 100 MG (PM)	100 MG	30	Capsules	30	DAYS				
61400020107067	Jornay pm	Methylphenidate HCl Cap Delayed ER 24HR 20 MG (PM)	20 MG	30	Capsules	30	DAYS				
61400020107077	Jornay pm	Methylphenidate HCl Cap Delayed ER 24HR 40 MG (PM)	40 MG	30	Capsules	30	DAYS				
61400020107087	Jornay pm	Methylphenidate HCl Cap Delayed ER 24HR 60 MG (PM)	60 MG	30	Capsules	30	DAYS				
61400020107090	Jornay pm	Methylphenidate HCl Cap Delayed ER 24HR 80 MG (PM)	80 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
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				
61109902107060	Mydayis	Amphetamine-Dextroamphetamine 3-Bead Cap ER 24HR 12.5 MG	12.5 MG	30	Capsules	30	DAYS				
61109902107065	Mydayis	Amphetamine-Dextroamphetamine 3-Bead Cap ER 24HR 25 MG	25 MG	30	Capsules	30	DAYS				
61109902107070	Mydayis	Amphetamine-Dextroamphetamine 3-Bead Cap ER 24HR 37.5 MG	37.5 MG	30	Capsules	30	DAYS				
61109902107075	Mydayis	Amphetamine-Dextroamphetamine 3-Bead Cap ER 24HR 50 MG	50 MG	30	Capsules	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	Quillichew er	Methylphenidate HCl Chew Tab Extended Release 20 MG	20 MG	30	Tablets	30	DAYS				
6140002010H230	Quillichew er	Methylphenidate HCl Chew Tab Extended Release 30 MG	30 MG	60	Tablets	30	DAYS				
6140002010H240	Quillichew er	Methylphenidate HCl Chew Tab Extended Release 40 MG	40 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
6140002010G220	Quillivant xr	Methylphenidate HCl For ER Susp 25 MG/5ML (5 MG/ML)	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				
61400020107010	Ritalin la	Methylphenidate HCl Cap ER 24HR 10 MG (LA)	10 MG	30	Capsules	30	DAYS				
61400020107020	Ritalin la	Methylphenidate HCl Cap ER 24HR 20 MG (LA)	20 MG	30	Capsules	30	DAYS				
61400020107030	Ritalin la	Methylphenidate HCl Cap ER 24HR 30 MG (LA)	30 MG	30	Capsules	30	DAYS				
61400020107040	Ritalin la	Methylphenidate HCl Cap ER 24HR 40 MG (LA)	40 MG	30	Capsules	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				
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				

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
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

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

• Program Summary: Atypical Antipsychotics

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	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				
59250015007220		Aripiprazole Orally Disintegrating Tab 10 MG	10 MG	60	Tablets	30	DAYS				
59250015007230		Aripiprazole Orally Disintegrating Tab 15 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				

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
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				
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				
59250015000320	Abilify	Aripiprazole Tab 10 MG	10 MG	30	Tablets	30	DAYS				
59250015000330	Abilify	Aripiprazole Tab 15 MG	15 MG	30	Tablets	30	DAYS				
59250015000305	Abilify	Aripiprazole Tab 2 MG	2 MG	30	Tablets	30	DAYS				
59250015000340	Abilify	Aripiprazole Tab 20 MG	20 MG	30	Tablets	30	DAYS				
59250015000350	Abilify	Aripiprazole Tab 30 MG	30 MG	30	Tablets	30	DAYS				
59250015000310	Abilify	Aripiprazole Tab 5 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	Aripiprazole Tab	20 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
	starter ki										
5925001503B750	Abilify mycite starter ki	Aripiprazole Tab	30 MG	30	Tablets	30	DAYS				
59400022400110	Caplyta	Lumateperone Tosylate Cap	10.5 MG	30	Capsules	30	DAYS				
59400022400115	Caplyta	Lumateperone Tosylate Cap	21 MG	30	Capsules	30	DAYS				
59400022400120	Caplyta	Lumateperone Tosylate Cap 42 MG	42 MG	30	Capsules	30	DAYS				
59152020000330	Clozaril	Clozapine Tab 100 MG	100 MG	270	Tablets	30	DAYS				
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				
59070035000310	Fanapt	Iloperidone Tab 1 MG	1 MG	60	Tablets	30	DAYS				
59070035000385	Fanapt	Iloperidone Tab 10 MG	10 MG	60	Tablets	30	DAYS				
59070035000390	Fanapt	Iloperidone Tab 12 MG	12 MG	60	Tablets	30	DAYS				
59070035000320	Fanapt	Iloperidone Tab 2 MG	2 MG	60	Tablets	30	DAYS				
59070035000340	Fanapt	Iloperidone Tab 4 MG	4 MG	60	Tablets	30	DAYS				
59070035000360	Fanapt	Iloperidone Tab 6 MG	6 MG	60	Tablets	30	DAYS				
59070035000380	Fanapt	Iloperidone Tab 8 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				
59400085100120	Geodon	Ziprasidone HCl Cap 20 MG	20 MG	60	Capsules	30	DAYS				
59400085100130	Geodon	Ziprasidone HCl Cap 40 MG	40 MG	60	Capsules	30	DAYS				
59400085100140	Geodon	Ziprasidone HCl Cap 60 MG	60 MG	60	Capsules	30	DAYS				
59400085100150	Geodon	Ziprasidone HCl Cap 80 MG	80 MG	60	Capsules	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				

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
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				
59250020000310	Rexulti	Brexpiprazole Tab 0.25 MG	0.25 MG	30	Tablets	30	DAYS				
59250020000320	Rexulti	Brexpiprazole Tab 0.5 MG	0.5 MG	30	Tablets	30	DAYS				
59250020000330	Rexulti	Brexpiprazole Tab 1 MG	1 MG	30	Tablets	30	DAYS				
59250020000340	Rexulti	Brexpiprazole Tab 2 MG	2 MG	30	Tablets	30	DAYS				
59250020000350	Rexulti	Brexpiprazole Tab 3 MG	3 MG	30	Tablets	30	DAYS				
59250020000360	Rexulti	Brexpiprazole Tab 4 MG	4 MG	30	Tablets	30	DAYS				
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	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
		MG									
59070070000340	Risperdal	Risperidone Tab 4 MG	4 MG	120	Tablets	30	DAYS				
59155015100730	Saphris	Asenapine Maleate SL Tab 10 MG (Base Equiv)	10 MG	60	Tablets	30	DAYS				
59155015100710	Saphris	Asenapine Maleate SL Tab 2.5 MG (Base Equiv)	2.5 MG	60	Tablets	30	DAYS				
59155015100720	Saphris	Asenapine Maleate SL Tab 5 MG (Base Equiv)	5 MG	60	Tablets	30	DAYS				
59155015008520	Secuado	Asenapine TD Patch 24 HR 3.8 MG/24HR	3.8 MG/24HR	30	Patches	30	DAYS				
59155015008530	Secuado	Asenapine TD Patch 24 HR 5.7 MG/24HR	5.7 MG/24HR	30	Patches	30	DAYS				
59155015008540	Secuado	Asenapine TD Patch 24 HR 7.6 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 ; 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				

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
59153070107505	Seroquel xr	Quetiapine Fumarate Tab ER 24HR 50 MG	50 MG	60	Tablets	30	DAYS				
59152020001820	Versacloz	Clozapine Susp 50 MG/ML	50 MG/ML	540	mLs	30	DAYS				
59400018100120	Vraylar	Cariprazine HCl Cap 1.5 MG (Base Equivalent)	1.5 MG	30	Capsules	30	DAYS				
59400018100130	Vraylar	Cariprazine HCl Cap 3 MG (Base Equivalent)	3 MG	30	Capsules	30	DAYS				
59400018100140	Vraylar	Cariprazine HCl Cap 4.5 MG (Base Equivalent)	4.5 MG	30	Capsules	30	DAYS				
59400018100150	Vraylar	Cariprazine HCl Cap 6 MG (Base Equivalent)	6 MG	30	Capsules	30	DAYS				
5940001810B220	Vraylar	Cariprazine HCl Cap Therapy Pack 1.5 MG (1) & 3 MG (6)	1.5 & 3 MG	7	Capsules	180	DAYS				
59157060000320	Zyprexa	Olanzapine Tab 10 MG	10 MG	30	Tablets	30	DAYS				
59157060000330	Zyprexa	Olanzapine Tab 15 MG	15 MG	30	Tablets	30	DAYS				
59157060000305	Zyprexa	Olanzapine Tab 2.5 MG	2.5 MG	30	Tablets	30	DAYS				
59157060000340	Zyprexa	Olanzapine Tab 20 MG	20 MG	30	Tablets	30	DAYS				
59157060000310	Zyprexa	Olanzapine Tab 5 MG	5 MG	30	Tablets	30	DAYS				
59157060000315	Zyprexa	Olanzapine Tab 7.5 MG	7.5 MG	30	Tablets	30	DAY				
59157060007220	Zyprexa zydis	Olanzapine Orally Disintegrating Tab 10 MG	10 MG	30	Tablets	30	DAYS				
59157060007230	Zyprexa zydis	Olanzapine Orally Disintegrating Tab 15 MG	15 MG	30	Tablets	30	DAYS				
59157060007240	Zyprexa zydis	Olanzapine Orally Disintegrating Tab 20 MG	20 MG	30	Tablets	30	DAYS				
59157060007210	Zyprexa zydis	Olanzapine Orally Disintegrating Tab 5 MG	5 MG	30	Tablets	30	DAYS				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Target Agent(s)	Prerequisite Agents
Abilify (aripiprazole)*	Any generic atypical antipsychotic Any generic antidepressant (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone) haloperidol or pimozide
Abilify Mycite (aripiprazole) **Rexulti** (brexpiprazole) **Seroquel XR** (quetiapine)* **Vraylar** (cariprazine)	Any generic atypical antipsychotic Any generic antidepressant (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone)
Zyprexa (olanzapine)* **Zyprexa Zydis** (olanzapine)*	Any generic atypical antipsychotic Generic fluoxetine
Caplyta (lumateperone) **Clozapine ODT** **Clozaril** (clozapine)* **Fanapt** (iloperidone) **Geodon** (ziprasidone)* **Invega** (paliperidone)* **Latuda** (lurasidone)* **Lybalvi** (olanzapine/samidorphan) **Risperdal** (risperidone)* **Risperidone ODT^/risperidone ODT** **Saphris** (asenapine)* **Secuado** (asenapine) **Seroquel** (quetiapine)* **Versacloz** (clozapine)	Any generic atypical antipsychotic

*generic available
^ branded generic product

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

1. The request is for Abilify (aripiprazole) AND ONE of the following:
    A. The patient has a medication history of use in the past 365 days, intolerance, or hypersensitivity to ONE generic antidepressant agent (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone), generic haloperidol, or pimozide **OR**
    B. The patient has an FDA labeled contraindication to ALL generic antidepressant agents (i.e., SSRI, SNRI, bupropion, mirtazapine, and vilazodone), haloperidol, and pimozide **OR**
2. The request is for Abilify Mycite, Rexulti, Seroquel XR, or Vraylar AND ONE of the following:
    A. The patient has a medication history of use in the past 365 days, intolerance, or hypersensitivity to ONE generic antidepressant agent (i.e., SSRI, SNRI, bupropion, mirtazapine, or vilazodone) **OR**
    B. The patient has an FDA labeled contraindication to ALL generic antidepressants (i.e., SSRI, SNRI, bupropion, mirtazapine, and vilazodone) **OR**
3. The request is for Zyprexa or Zyprexa Zydis AND ONE of the following:
    A. The patient has a medication history of use in the past 365 days, intolerance, or hypersensitivity to ONE generic fluoxetine **OR**
    B. The patient has an FDA labeled contraindication to ALL generic fluoxetine **OR**
4. The patient has been treated with the requested agent within the past 180 days **OR**
5. The prescriber states the patient has been treated with the requested agent within the past 180 days AND is at

Module	Clinical Criteria for Approval
	risk if therapy is changed **OR** 6. The patient has a medication history of use in the past 365 days, intolerance, or hypersensitivity to ONE generic atypical antipsychotic **OR** 7. The patient has an FDA labeled contraindication to ALL generic atypical antipsychotics **OR** 8. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 9. The patient has an intolerance or hypersensitivity to a prerequisite agent **OR** 10. The patient has an FDA labeled contraindication to ALL prerequisite agents **OR** 11. The prescriber has provided documentation that ALL prerequisite agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval:** For dementia-related psychosis: 3 months for initial approval; 6 months for renewals For all other indications: 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. 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 (caplacixumab-yhdp)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

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

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. The patient has a diagnosis of acquired thrombotic thrombocytopenia purpura (aTTP) **AND** 2. The diagnosis has been confirmed by ONE of the following (medical records required): A. BOTH of the following: 1. The patient has severe thrombocytopenia (i.e., a platelet count less than 100 X 10^9/L) **AND** 2. The patient has microangiopathic hemolytic anemia (e.g., hemoglobin and hematocrit below the lower limit of the reference range, low haptoglobin, elevated lactase dehydrogenase, the presence of schistocytes in peripheral blood smear) **OR** B. The patient has a positive ADAMTS13 activity result (i.e., less than 10 IU/dL [or less than 10% of normal]) **AND** 3. If the patient has an FDA labeled indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 4. ONE of the following: A. The patient will be using immunosuppressive therapy (e.g., corticosteroids, rituximab, cyclophosphamide, mycophenolate mofetil) in combination with the requested agent **OR** B. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to immunosuppressive therapy **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. The patient 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 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

Module	Clinical Criteria for Approval
	during the current course of therapy **OR** 3. 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:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
67701060707220	Nurtec	Rimegepant Sulfate Tab Disint 75 MG	75 MG	16	Tablets	30	DAYS				
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	Units	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				
6770203020D520	Ajovy	Fremanezumab-vfrm Subcutaneous Soln Auto-inj 225	225 MG/1.5ML	3	Injection Devices	84	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
		MG/1.5ML									
6770203020E520	Ajovy	Fremanezumab-vfrm Subcutaneous Soln Pref Syr 225 MG/1.5ML	225 MG/1.5ML	3	Syringes	84	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Indication	Preferred Agent(s)	Non-Preferred Agent(s)	Stand Alone Target Agent(s)
	Preferred and non-preferred target agents - to be determined by client	Preferred and non-preferred target agents - to be determined by client	
Chronic Migraine Prophylaxis	Aimovig, Ajovy, Emgality		
Episodic Migraine Prophylaxis	Aimovig, Ajovy, Emgality, Nurtec, Qulipta		
Episodic Cluster Headaches	Emgality		
Acute Migraine Treatment	Nurtec, Ubrelvy		Zavzpret

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

Module	Clinical Criteria for Approval
	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 has contraindications to acute therapies **OR** E. The patient has tried and received inadequate response 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 **AND** 3. The requested agent and strength are FDA labeled for episodic migraine prophylaxis **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to at least one migraine prophylaxis class [i.e., anticonvulsants (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 class (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

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	medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. If the client has a preferred agent, then ONE of the following: A. The requested agent is a preferred agent for the requested indication **OR** B. The requested agent is a non-preferred agent and ONE of the following: 1. The patient has tried and had an inadequate response to ONE preferred agent for the requested indication **OR** 2. The patient has tried has an intolerance or hypersensitivity to ONE preferred agent for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL preferred agent(s) for the requested indication **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 for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. Medication overuse headache has been ruled out **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 has tried and had an inadequate response to verapamil, melatonin, corticosteroids, topiramate, OR 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, OR lithium cannot be used due to a documented

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	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 **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 has tried and had an inadequate response to at least one triptan agent **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, triptan, ergotamine) **AND** 3. If the client has a preferred agent, then ONE of the following: A. The requested agent is a preferred agent for the requested indication **OR** B. The requested agent is a non-preferred agent and ONE of the following: 1. The patient has tried and had an inadequate response to ONE preferred agent for the requested indication **OR** 2. The patient has tried has an intolerance or hypersensitivity to ONE preferred agent for the requested indication **OR** 3. The patient has an FDA labeled contraindication to ALL preferred agent(s) for the requested indication **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 for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

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	4. Medication overuse headache has been ruled out **AND** 5. The requested agent and strength are FDA labeled for acute migraine treatment **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:** AHFS, or DrugDex 1 or 2a level of evidence **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

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	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, triptan, ergotamine) 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:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

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,

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	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: Dipeptidyl Peptidase-4 (DPP-4) Inhibitors and Combinations

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
279925027003	Janumet	sitagliptin-metformin hcl tab	50-1000 MG; 50-500 MG	60	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				
275500701003	Januvia	sitagliptin phosphate tab	100 MG; 25 MG; 50 MG	30	Tablets	30	DAYS				
279925024003	Jentadueto	linagliptin-metformin hcl tab	2.5-1000 MG; 2.5-500 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-	5-1000 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
		1000 MG									
279925021003	Kazano	alogliptin-metformin hcl tab	12.5-1000 MG; 12.5-500 MG	30	Tablets	30	DAYS				
27992502607520	Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS				
27992502607540	Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	30	Tablets	30	DAYS				
27992502607530	Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 5-500 MG	5-500 MG	30	Tablets	30	DAYS				
275500101003	Nesina	alogliptin benzoate tab	12.5 MG; 25 MG; 6.25 MG	30	Tablets	30	DAYS				
275500651003	Onglyza	saxagliptin hcl tab	2.5 MG; 5 MG	30	Tablets	30	DAYS				
279940021003	Oseni	alogliptin-pioglitazone tab	12.5-15 MG; 12.5-30 MG; 12.5-45 MG; 25-15 MG; 25-30 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	
1-Step Through Preferred	**Preferred Agents**	**Non-preferred Agents**
	Januvia (sitagliptin) **Janumet** (sitagliptin/metformin) **Janumet XR** (sitagliptin/metformin extended-release)	**Alogliptin** **Alogliptin/metformin** **Alogliptin/pioglitazone** **Jentadueto** (linagliptin/metformin) **Jentadueto XR** (linagliptin/metformin ER) **Kazano** (alogliptin/metformin) **Kombiglyze XR** (saxagliptin/metformin ER)* **Nesina** (alogliptin) **Onglyza** (saxagliptin)* **Oseni** (alogliptin/pioglitazone) **Tradjenta** (linagliptin) **Zituvio** (sitagliptin)
	* available as generic; not a prerequisite or target in the step therapy program	

Module	Clinical Criteria for Approval
	Target Agent(s) will be approved when ONE of the following is met: 1. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. The patient's medication history includes use of one or more of the following: Januvia, Janumet, Janumet XR **OR** 3. BOTH of the following: A. The prescriber has stated that the patient has tried Januvia, Janumet, or Janumet XR **AND** B. Januvia, Janumet, or Janumet XR was discontinued due to lack of effectiveness or an adverse event **OR** 4. The patient has an intolerance or hypersensitivity to a preferred sitagliptin agent **OR** 5. The patient has an FDA labeled contraindication to a preferred sitagliptin agent that is not expected to occur with the requested agent **OR** 6. The prescriber has provided documentation that a preferred sitagliptin agent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **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: 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:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMITS

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/20ML	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. **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

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	(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 (fenfluramine)

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

POLICY AGENT SUMMARY QUANTITY LIMITS

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 ALL of the following are met: 1. ONE of the following: A. BOTH of the following: 1. ONE of the following: A. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** B. The prescriber states the patient has been treated with the requested agent

Module	Clinical Criteria for Approval
	(starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **AND** 2. The patient has an FDA labeled indication for the requested agent **OR** B. BOTH of the following: 1. ONE of the following: A. If the patient has a diagnosis of Dravet syndrome (DS), then ONE of the following: 1. The patient has tried and had an inadequate response to TWO generic antiseizure agents used in the treatment of DS (e.g., valproate, clobazam, stiripentol, topiramate) **OR** 2. The patient has an intolerance or hypersensitivity to TWO generic antiseizure agents used in the treatment of DS (e.g., valproate, clobazam, stiripentol, topiramate) **OR** 3. The patient has an FDA labeled contraindication to ALL generic antiseizure agents used in the treatment of DS (e.g., valproate, clobazam, stiripentol, topiramate) **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 generic antiseizure agents used in the treatment of DS (e.g., valproate, clobazam, stiripentol, topiramate) 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. If the patient has a diagnosis of Lennox-Gastaut syndrome (LGS), then ONE of the following: 1. The patient has tried and had an inadequate response to TWO generic antiseizure agents used in the treatment of LGS (e.g., valproate, lamotrigine, rufinamide, topiramate, clobazam, felbamate) **OR** 2. The patient has an intolerance or hypersensitivity to TWO generic antiseizure agents used in the treatment of LGS (e.g., valproate, lamotrigine, rufinamide, topiramate, clobazam, felbamate) **OR** 3. The patient has an FDA labeled contraindication to ALL generic antiseizure agents used in the treatment of LGS (e.g., valproate, lamotrigine, rufinamide, topiramate, clobazam, felbamate) **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

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	5. The prescriber has provided documentation that ALL generic antiseizure agents used in the treatment of LGS (e.g., valproate, lamotrigine, rufinamide, topiramate, clobazam, felbamate) 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** 2. If the patient has a diagnosis of seizures associated with Dravet syndrome (DS) or Lennox-Gastaut syndrome (LGS), the requested agent will NOT be used as monotherapy for seizure management **AND** 3. 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** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **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. 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** 4. An echocardiogram assessment will be obtained during treatment with the requested agent, to evaluate for valvular heart disease and pulmonary arterial hypertension **AND** 5. 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** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following:

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 12 months

• Program Summary: Hetlioz (tasimelteon)

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

POLICY AGENT SUMMARY QUANTITY LIMITS

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** 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

Module	Clinical Criteria for Approval
	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: Methotrexate Injectable

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

POLICY AGENT SUMMARY STEP THERAPY

Final Module	Target Agent GPI	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status	Effective Date	Targeted NDCs When Exclusions Exist
	6625005000D5	Otrexup; Rasuvo	methotrexate soln pf auto-injector	10 MG/0.2ML; 10 MG/0.4ML; 12.5 MG/0.25ML; 12.5 MG/0.4ML; 15 MG/0.3ML;	M ; N ; O	N				

Final Module	Target Agent GPI	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status	Effective Date	Targeted NDCs When Exclusions Exist
				15 MG/0.4ML; 17.5 MG/0.35ML; 17.5 MG/0.4ML; 20 MG/0.4ML; 22.5 MG/0.45ML; 22.5 MG/0.4ML; 25 MG/0.4ML; 25 MG/0.5ML; 30 MG/0.6ML; 7.5 MG/0.15ML						
	6625005000E5	Reditrex	methotrexate soln prefilled syringe	10 MG/0.4ML; 12.5 MG/0.5ML; 15 MG/0.6ML; 17.5 MG/0.7ML; 20 MG/0.8ML; 22.5 MG/0.9ML; 25 MG/ML; 7.5 MG/0.3ML	M ; N ; O	N				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	TARGET AGENT(S) **Otrexup®** (methotrexate auto-injector) **Rasuvo®** (methotrexate auto-injector) **RediTrex®** (methotrexate prefilled syringe) **Target Agent(s)** will be approved when ONE of the following is met: 1. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. The patient has a medication history of use of a generic methotrexate injectable agent as indicated by ONE of the following: A. Evidence of a paid claim(s) **OR** B. The prescriber has stated that the patient has tried a generic methotrexate injectable agent AND it was discontinued due to lack of effectiveness or an adverse event **OR** 3. The patient has an intolerance or hypersensitivity to a generic methotrexate injectable agent **OR** 4. The patient has an FDA labeled contraindication to ALL generic methotrexate injectable agents **OR** 5. The prescriber has provided information that the patient has a physical or a mental disability that would prevent the patient from using ALL generic methotrexate injectable agents **OR** 6. The prescriber has provided documentation that ALL generic methotrexate injectable 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 **Length of Approval:** 12 months

• Program Summary: Multiple Sclerosis Agents

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

POLICY AGENT SUMMARY QUANTITY LIMITS

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
62405530006520		Diroximel Fumarate Capsule DR Starter Bottle 231 MG		106	Capsules	180	DAYS				
624040700003	Aubagio	teriflunomide tab	14 MG; 7 MG	30	Tablets	30	DAYS				
6240306045F830	Avonex	Interferon Beta-1a IM Prefilled Syringe Kit 30 MCG/0.5ML	30 MCG/0.5ML	1	Kit	28	DAYS				
6240306045F530	Avonex pen	Interferon Beta-1a IM Auto-Injector Kit 30 MCG/0.5ML	30 MCG/0.5ML	1	Kit	28	DAYS				
62405550006520	Bafiertam	Monomethyl Fumarate Capsule Delayed Release	95 MG	120	Capsules	30	DAYS				
62403060506420	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				
62403060506420	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	Pen	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	10 MG	12	Tablets	301	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		Therapy Pack 10 MG (6 Tabs)									
6240101500B732	Mavenclad	Cladribine Tab Therapy Pack 10 MG (7 Tabs)	10 MG	14	Tablets	301	DAYS				
6240101500B736	Mavenclad	Cladribine Tab Therapy Pack 10 MG (8 Tabs)	10 MG	8	Tablets	301	DAYS				
6240101500B740	Mavenclad	Cladribine Tab Therapy Pack 10 MG (9 Tabs)	10 MG	9	Tablets	301	DAYS				
62407070200330	Mayzent	Siponimod Fumarate Tab	1 MG	30	Tablets	30	DAYS				
62407070200320	Mayzent	Siponimod Fumarate Tab 0.25 MG (Base Equiv)	0.25 MG	120	Tablets	30	DAYS				
62407070200340	Mayzent	Siponimod Fumarate Tab 2 MG (Base Equiv)	2 MG	30	Tablets	30	DAYS				
6240707020B710	Mayzent starter pack	Siponimod Fumarate Tab	0.25 MG	1	Pack	180	DAYS				
6240707020B720	Mayzent starter pack	Siponimod Fumarate Tab 0.25 MG (12) Starter Pack	0.25 MG	1	Pack	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	1	Pack	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				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6240306045D520	Rebif rebidose	Interferon Beta-1a Soln Auto-Inj 22 MCG/0.5ML (12MU/ML)	22 MCG/0.5ML	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				
62407025207220	Tascenso odt	Fingolimod Lauryl Sulfate Tablet Disintegrating	0.25 MG	30	Tablets	30	DAYS				
62407025207230	Tascenso odt	Fingolimod Lauryl Sulfate Tablet Disintegrating	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				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	TARGET AGENT(S)

Preferred generic agent(s)*	Preferred brand agent(s)	Nonpreferred agent(s)
dimethyl fumarate fingolimod glatiramer **Glatopa** (glatiramer) teriflunomide	**Avonex** (interferon beta-1a) **Betaseron** (interferon beta-1b) **Kesimpta** (ofatumumab) **Mavenclad** (cladribine) **Mayzent** (siponimod) **Plegridy** (peginterferon beta-1a) **Rebif** (interferon beta-1a)	**Aubagio** (teriflunomide)** **Bafiertam** (monomethyl fumarate) **Copaxone** (glatiramer)** **Extavia** (interferon beta-1b) **Gilenya** (fingolimod)** **Ponvory** (ponesimod) **Tascenso ODT** (fingolimod) **Tecfidera** (dimethyl

Module	Clinical Criteria for Approval

	Vumerity (diroximel fumarate)	fumarate)**

* – These agents are subject to duplicate therapy check only
** – generic available

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

1. ONE of following:
   - A. The patient has been treated with the requested agent within the past 90 days **OR**
   - B. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR**
   - C. The patient is currently being treated with the requested agent as indicated by ALL of the following:
     1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
     2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
     3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
   - D. The requested agent is a preferred generic agent **OR**
   - E. The patient has highly active MS disease activity AND BOTH of the following:
     1. The patient has greater than or equal to 2 relapses in the previous year **AND**
     2. ONE of the following:
        - A. The patient has greater than or equal to 1 gadolinium enhancing lesion on MRI **OR**
        - B. The patient has significant increase in T2 lesion load compared with a previous MRI **OR**
   - F. The patient has been treated with at least 3 MS agents from different drug classes (see MS disease modifying agents drug class table) **OR**
   - G. The requested agent is a preferred brand agent AND ONE of the following:
     1. The patient's medication history includes use of ONE preferred generic agent **OR**
     2. BOTH of the following:
        - A. The prescriber has stated that the patient has tried one preferred generic agent **AND**
        - B. The preferred generic agent was discontinued due to lack of effectiveness or an adverse event **OR**
     3. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE preferred generic agent **OR**
     4. The patient has an FDA labeled contraindication to ALL preferred generic agents **OR**
     5. The prescriber has provided documentation that ALL preferred generic 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**
   - H. The requested agent is a nonpreferred agent AND ONE of the following:
     1. The patient is 17 years of age or younger AND ONE of the following:
        - A. The requested agent does NOT have a corresponding preferred generic strength **OR**
        - B. The patient has tried and had an inadequate response to ONE preferred generic agent FDA labeled for the patient's age for the requested indication (medical records required) **OR**
        - C. The patient has an intolerance (defined as an intolerance to drug or its excipients, not to the route of administration) or hypersensitivity to ONE preferred generic agent FDA labeled for the patient's age for the requested indication **OR**
        - D. The patient has an FDA labeled contraindication to ALL preferred generic agents FDA labeled for the patient's age for the requested indication **OR**
        - E. The prescriber has provided documentation that ALL preferred generic agents FDA labeled for the patient's age for the requested indication cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable

Module	Clinical Criteria for Approval

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

2. The patient is 18 years of age or older AND BOTH of the following:
    A. ONE of the following:
        1. The patient's medication history incudes use of ONE preferred generic agent **OR**
        2. BOTH of the following:
            A. The prescriber has stated that the patient has tried one preferred generic agent **AND**
            B. The preferred generic agent was discontinued due to lack of effectiveness or an adverse event **OR**
        3. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE preferred generic agent **OR**
        4. The patient has an FDA labeled contraindication to ALL preferred generic agents **OR**
        5. The prescriber has provided documentation that ALL preferred generic 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 patient's medication history includes the use of ONE preferred brand agent or Zeposia (ozanimod) **OR**
        2. BOTH of the following:
            A. The prescriber has stated that the patient has tried one preferred brand agent or Zeposia **AND**
            B. The preferred brand agent or Zeposia was discontinued due to lack of effectiveness or an adverse event **OR**
        3. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE preferred brand agent or Zeposia **OR**
        4. The patient has an FDA labeled contraindication to ALL preferred brand agents AND Zeposia **OR**
        5. The prescriber has provided documentation that ALL preferred brand agents AND Zeposia cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

2. If the requested agent is a brand agent with a generic equivalent (listed below) AND ONE of the following:

Non-Preferred Agents	Corresponding generic equivalent
Aubagio	teriflunomide
Copaxone	Glatopa/glatiramer
Gilenya 0.5 mg	Fingolimod 0.5 mg
Tecfidera	dimethyl fumarate

    A. The patient's medication history includes use of the generic equivalent **OR**
    B. 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
	C. The patient has an intolerance or hypersensitivity to the generic equivalent agent that is not expected to occur with the requested agent **OR** D. The patient has an FDA labeled contraindication to the generic equivalent agent that is not expected to occur with the requested agent **OR** E. The prescriber has provided documentation that ALL generic equivalents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The patient will NOT be taking an additional disease modifying agent (DMA) for the requested indication **Length of Approval:** 12 months. **NOTE:** For agents requiring a starter dose for initial use, the starter dose will be approved for the FDA labeled starting dose and the maintenance dose will be approved for the remainder of 12 months. NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

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

Class	Class Drug Agents
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

CONTRAINDICATION AGENTS

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

Contraindicated as Concomitant Therapy
Tysabri (natalizumab) **Vumerity** (diroximel fumarate) **Zeposia** (ozanimod) * -generic available

• Program Summary: Oral Nonsteroidal Anti-Inflammatory Drugs (NSAID)

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

POLICY AGENT SUMMARY STEP THERAPY

Final Module	Target Agent GPI	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status	Effective Date	Targeted NDCs When Exclusions Exist
	661000120003		flurbiprofen tab	100 MG; 50 MG	M; N; O	N; Y				
	661000350070		ketoprofen cap er	200 MG	M; N; O	N				
	661000401001		meclofenamate sodium cap	100 MG; 50 MG	M; N; O	N				
	661000901001		tolmetin sodium cap	400 MG	M; N; O	N				
	661000901003		tolmetin sodium tab	600 MG	M; N; O	N				
	661000601003	Aleve; Aleve arthritis; All day pain relief; All day relief; Anaprox ds; Cvs all day pain relief; Cvs naproxen sodium; Eq all day pain relief; Eq naproxen sodium; Eql naproxen sodium; Ft all day pain relief; Gnp naproxen; Goodsense naproxen sodium; Hm naproxen sodium; Hy-vee all day relief; Mediproxen; Pamprin all day maximum s; Px all day relief; Qc naproxen sodium; Ra naproxen sodium; Sb naproxen sodium; Sm naproxen sodium	naproxen sodium tab	220 MG; 275 MG; 550 MG	M; N; O	O; Y				
	6610990220	Arthrotec 50; Arthrotec 75	diclofenac w/ misoprostol tab delayed release	50-0.2 MG; 75-0.2 MG	M; N; O	O; Y				
	676000401030	Cambia	diclofenac potassium (migraine) packet	50 MG	M; N; O	O; Y				
	661005250001	Celebrex	celecoxib cap	100 MG; 200 MG; 400 MG;	M; N; O	O; Y				

Final Module	Target Agent GPI	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status	Effective Date	Targeted NDCs When Exclusions Exist
				50 MG						
	661000650001	Coxanto	oxaprozin cap	300 MG	M; N; O	M				
	661000650003	Daypro	oxaprozin tab	600 MG	M; N; O	O; Y				
	661000600006	Ec-naprosyn; Ec-naproxen	naproxen tab ec	375 MG; 500 MG	M; N; O	O; Y				
	661000700001	Feldene	piroxicam cap	10 MG; 20 MG	M; N; O	O; Y				
	661000101001	Fenortho; Nalfon	fenoprofen calcium cap	200 MG; 400 MG	M; N; O	M; Y				
	661000300018	Indocin	indomethacin susp	25 MG/5ML	M; N; O	O; Y				
	661000350001	Kiprofen	ketoprofen cap	25 MG; 50 MG; 75 MG	M; N; O	M; N				
	661000080003	Lodine	etodolac tab	400 MG; 500 MG	M; N; O	O; Y				
	661000520003	Mobic	meloxicam tab	15 MG; 7.5; 7.5 MG	M; N; O	O; Y				
	661000101003	Nalfon	fenoprofen calcium tab	600 MG	M; N; O	O; Y				
	661000601075	Naprelan	naproxen sodium tab er	375 MG; 500 MG; 750 MG	M; N; O	O; Y				
	661000600018	Naprosyn	naproxen susp	125 MG/5ML	M; N; O	O; Y				
	661000600003	Naprosyn	naproxen tab	250 MG; 375 MG; 500 MG	M; N; O	O; Y				
	661000550003	Relafen; Relafen ds	nabumetone tab	1000 MG; 500 MG; 750 MG	M; N; O	N; Y				
	661000300001	Tivorbex	indomethacin cap	20 MG; 25 MG; 50 MG	M; N; O	M; N; Y				
	661000071001	Zipsor	diclofenac potassium cap	25 MG	M; N; O	O; Y				
	661000070001	Zorvolex	diclofenac cap	18 MG; 35 MG	M; N; O	M; N				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	TARGET AGENT(S) (brands only) **Anaprox DS** (naproxen) -a **Arthrotec** (diclofenac/misoprostol) -a **Cambia** (diclofenac) -b **Celebrex** (celecoxib) -a **Coxanto** (oxaprozin) **Daypro** (oxaprozin) -a **EC-Naprosyn** (naproxen) -a **Feldene** (piroxicam) -a **Fenortho** (fenoprofen) **Flurbiprofen** tablet -ab **Indocin** (indomethacin) suspension -a **Ketoprofen** capsule -b **Ketoprofen ER** capsule -b **Lodine** (etodolac) -a **Meclofenamate** capsule-b **Meloxicam** suspension -b **Mobic** (meloxicam) tablet -a **Nalfon** (fenoprofen) capsule and tablet -a **Naprelan CR** (naproxen) tablet -a **Naprosyn** (naproxen) tablet and suspension -a **Relafen DS** (nabumetone) tablet **Tivorbex, Indomethacin** capsule -ab **Tolmetin** capsule and tablet -b **Zipsor** (diclofenac) capsule -a **Zorvolex, Diclofenac** capsule -b a – Available as a generic; included as a prerequisite in the step therapy program b – Branded generic product(s) available; targeted in the step therapy program **Target Agent** will be approved when ONE of the following is met: 1. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. The patient's medication history includes use of at least two prescription strength generic oral NSAIDs within the past 999 days **OR** 3. BOTH of the following: A. The prescriber has stated that the patient has tried at least TWO prescription strength generic oral NSAID agents **AND** B. Prescription strength generic oral NSAID agents were discontinued due to lack of effectiveness or an adverse event **OR** 4. The patient has an intolerance or hypersensitivity to at least two prescription strength generic oral NSAIDs **OR** 5. The patient has an FDA labeled contraindication to ALL prescription strength generic oral NSAIDs **OR** 6. The prescriber has provided documentation that ALL prescription strength generic oral NSAID 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 **Length of Approval:** 12 months

• Program Summary: Pancreatic Enzymes

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

POLICY AGENT SUMMARY STEP THERAPY

Final Module	Target Agent GPI	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status	Effective Date	Targeted NDCs When Exclusions Exist
	51200024006703	Pancreaze	Pancrelipase (Lip-Prot-Amyl) DR Cap	2600-8800 UNIT	M; N; O; Y	N				
	51200024006781	Pancreaze	Pancrelipase (Lip-Prot-Amyl) DR Cap	37000-97300 UNIT	M; N; O; Y	N				
	51200024006734	Pancreaze	Pancrelipase (Lip-Prot-Amyl) DR Cap 10500-35500-61500 Unit	10500-35500 UNIT	M; N; O; Y	N				
	51200024006750	Pancreaze	Pancrelipase (Lip-Prot-Amyl) DR Cap 16800-56800-98400 Unit	16800-56800 UNIT	M; N; O; Y	N				
	51200024006754	Pancreaze	Pancrelipase (Lip-Prot-Amyl) DR Cap 21000-54700-83900 Unit	21000-54700 UNIT	M; N; O; Y	N				
	51200024006710	Pancreaze	Pancrelipase (Lip-Prot-Amyl) DR Cap 4200-14200-24600 Unit	4200-14200 UNIT	M; N; O; Y	N				
	51200024006749	Pertzye	Pancrelipase (Lip-Prot-Amyl) DR Cap 16000-57500-60500 Unit	16000-57500 UNIT	M; N; O; Y	N				
	51200024006762	Pertzye	Pancrelipase (Lip-Prot-Amyl) DR Cap 24000-86250-90750 Unit	24000-86250 UNIT	M; N; O; Y	N				
	51200024006709	Pertzye	Pancrelipase (Lip-Prot-Amyl) DR Cap 4000-14375-15125 Unit	4000-14375 UNIT	M; N; O; Y	N				
	51200024006725	Pertzye	Pancrelipase (Lip-Prot-Amyl) DR Cap 8000-28750-30250 Unit	8000-28750 UNIT	M; N; O; Y	N				
	512000240003	Viokace	pancrelipase (lip-prot-amyl) tab	10440-39150 UNIT; 20880-78300 UNIT	M; N; O; Y	N				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

TARGET AGENT(S)	PREREQUISITE AGENT(S)
Pancreaze Pertzye Viokace	Creon Zenpep

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

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

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

   A. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**
   B. 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**
2. The patient's medication history includes BOTH Creon and Zenpep as indicated by ONE of the following:
   A. Evidence of a paid claim(s) **OR**
   B. The prescriber has stated that the patient has tried BOTH Creon and Zenpep AND BOTH Creon and Zenpep were discontinued due to lack of effectiveness or an adverse event **OR**
3. The patient is currently being treated with the requested agent as indicated by ALL of the following:
   A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
   B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
   C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
4. The prescriber has provided documentation that BOTH Creon and Zenpep 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

• Program Summary: Peanut Allergy

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

POLICY AGENT SUMMARY QUANTITY LIMITS

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				

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
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:

Module	Clinical Criteria for Approval
	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) – *fka Oral Pulmonary Arterial Hypertension*

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

POLICY AGENT SUMMARY QUANTITY LIMITS

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; 1 MG; 1.5 MG; 2 MG; 2.5 MG	90	Tablets	30	DAYS				
4016000700	Letairis	ambrisentan tab	10 MG; 5 MG	30	Tablets	30	DAYS				
40143060101825	Liqrev	sildenafil citrate oral susp	10 MG/ML	2	Bottles	30	DAYS				
4016005000	Opsumit	macitentan tab	10 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
4017008005C110	Orenitram titr kit Month 1	Treprostinil tab er Mo 1 titr kit	0.125 & 0.25 MG	1	Kit	180	DAYS				
4017008005C120	Orenitram titr kit Month 2	Treprostinil tab er Mo 2 titr kit	0.125 & 0.25 MG	1	Kit	180	DAYS				
4017008005C130	Orenitram titr kit Month 3	Treprostinil tab er Mo 3 titr kit	0.125 & 0.25 &1 MG	1	Kit	180	DAYS				
401430601019	Revatio	sildenafil citrate for suspension	10 MG/ML	224	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			
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				

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
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	Pack	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 ALL of the following are met: 1. ONE of the following: A. BOTH of the following: 1. 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 A. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** B. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **AND** 2. The patient has an FDA labeled indication for the requested agent and route of administration **OR** B. The patient has a diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH), WHO Group 4 and ALL of the following: 1. The requested agent is Adempas **AND** 2. The patient's diagnosis has been confirmed by a ventilation-perfusion scan and a confirmatory selective pulmonary angiography **AND** 3. The patient has a mean pulmonary artery pressure of greater than 20 mmHg **AND** 4. The patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg **AND** 5. The patient has a pulmonary vascular resistance greater than or equal to 3 Wood units **AND** 6. ONE of the following: A. The patient is NOT a candidate for surgery **OR** B. The patient has had a pulmonary endarterectomy AND has persistent or recurrent disease **AND** 7. 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** C. The patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 and ALL of the following: 1. The patient's diagnosis has been confirmed by right heart catheterization (medical records required) **AND** 2. The patient's mean pulmonary arterial pressure is greater than 20 mmHg **AND** 3. The patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg **AND** 4. The patient has a pulmonary vascular resistance greater than or equal to 3 Wood units

Module	Clinical Criteria for Approval
	AND 5. The patient's World Health Organization (WHO) functional class is II or greater **AND** 6. If the requested agent is sotatercept, then BOTH of the following: A. 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** B. The patient is not pregnant or planning to become pregnant while on therapy with the requested agent **AND** 7. 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** 8. If the requested agent is NOT sotatercept, then ONE of the following: A. The requested agent will be utilized as monotherapy **OR** B. 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** C. 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: 1. The patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy **AND** 2. The requested agent is in a different therapeutic class **OR** D. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy) and ALL of the following: 1. The patient is WHO functional class III or IV **AND** 2. ONE of the following: A. A prostanoid has been started as one of the agents in the triple therapy **OR** B. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ALL prostanoids **AND** 3. The patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy **AND** 4. All three agents in the triple therapy are from a different therapeutic class **OR** 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** D. The patient has a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD, WHO group 3) AND ALL of the following: 1. The requested agent is Tyvaso **AND** 2. The patient's diagnosis has been confirmed by right heart catheterization (medical records required) **AND** 3. The patient's mean pulmonary arterial pressure is greater than 20 mmHg **AND** 4. The patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg **AND** 5. The patient has a pulmonary vascular resistance greater than or equal to 3 Wood units **AND**

Module	Clinical Criteria for Approval

6. The patient has an FVC less than 70% of predicted **AND**
7. The patient has extensive parenchymal changes on computed tomography (CT) **AND**
8. BOTH of the following:
    A. The patient is currently treated with standard of care therapy for ILD (e.g., Ofev) **AND**
    B. The patient will continue standard of care therapy for ILD (e.g., Ofev) **OR**

E. The patient has another FDA approved 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. If the request is for ONE of the following brand agents with an available generic equivalent (listed below), then ONE of the following:

Brand	Generic Equivalent
Revatio (tablet, oral suspension)	sildenafil (tablet, oral suspension)
Adcirca	tadalafil
Tracleer 6.25 mg and 125 mg tablets	bosentan 6.25 mg and 125 mg tablets
Letaris	ambrisentan

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

Module	Clinical Criteria for Approval
	E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that generic tadalafil tablets 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. If the request is for Liqrev, then one of the following: A. The patient's medication history includes generic sildenafil oral suspension as indicated by: 1. Evidence of a paid claim(s) **OR** 2. The prescriber has stated that the patient has tried generic sildenafil oral suspension AND generic sildenafil oral suspension was discontinued due to lack of effectiveness or an adverse event **OR** B. The patient has an intolerance or hypersensitivity to generic sildenafil oral suspension that is not expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to generic sildenafil oral suspension that is not expected to occur with the requested agent **OR** D. The prescriber has provided information to support the use of the requested agent over generic sildenafil oral suspension **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that generic sildenafil oral suspension cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **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 (e.g., stabilization, decreased disease progression) (medical records required) **AND**

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3. 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**
4. 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**
5. If the request is for ONE of the following brand agents with an available generic equivalent (listed below), then ONE of the following:

Brand	Generic Equivalent
Revatio (tablet, oral suspension)	sildenafil (tablet, oral suspension)
Adcirca	tadalafil
Tracleer 6.25 mg and 125 mg tablets	bosentan 6.25 mg and 125 mg tablets
Letaris	ambrisentan

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

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	2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that generic tadalafil tablets 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** 7. If the request is for Liqrev, then one of the following: A. The patient's medication history includes generic sildenafil oral suspension as indicated by: 1. Evidence of a paid claim(s) **OR** 2. The prescriber has stated that the patient has tried generic sildenafil oral suspension AND generic sildenafil oral suspension was discontinued due to lack of effectiveness or an adverse event **OR** B. The patient has an intolerance or hypersensitivity to generic sildenafil oral suspension that is not expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to generic sildenafil oral suspension that is not expected to occur with the requested agent **OR** D. The prescriber has provided information to support the use of the requested agent over generic sildenafil oral suspension **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that generic sildenafil oral suspension 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** 8. 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** 9. 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**

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

POLICY AGENT SUMMARY QUANTITY LIMITS

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 ALL of the following are met: 1. The patient has a diagnosis of amyotrophic lateral sclerosis (ALS) [also known as Lou Gehrig's disease] **AND** 2. BOTH of the following: A. The requested agent will be or was started within 18 months of symptom onset **AND** B. The patient has a baseline percent predicted forced vital capacity (FVC) or slow vital capacity (SVC) greater than 60% **AND** 3. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 4. The patient is able to perform most activities of daily living, defined as scores of 2 points or better on each individual item of the ALS Functional Rating Scale-Revised [ALSFRS-R] **AND** 5. ONE of the following: A. BOTH of the following: 1. The patient is currently treated with riluzole **AND** 2. The patient will continue riluzole in combination with the requested agent **OR** B. The patient has tried and had an inadequate response to riluzole **OR** C. The patient has an intolerance or hypersensitivity to riluzole **OR** D. The patient has an FDA labeled contraindication to riluzole **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

Module	Clinical Criteria for Approval
	therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that 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** 6. 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** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months NOTE: If Quantity Limit applies, please 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 criteria (Note: patients not previously approved for the requested agent will require initial evaluation review) **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient is NOT dependent on invasive ventilation or tracheostomy **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
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: Topiramate ER

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

POLICY AGENT SUMMARY QUANTITY LIMITS

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
7260007500F330	Qudexy xr	Topiramate Cap ER 24HR Sprinkle 100 MG	100 MG	30	Capsules	30	DAYS				
7260007500F340	Qudexy xr	Topiramate Cap ER 24HR Sprinkle 150 MG	150 MG	30	Capsules	30	DAYS				
7260007500F350	Qudexy xr	Topiramate Cap ER 24HR Sprinkle 200 MG	200 MG	60	Capsules	30	DAYS				
7260007500F310	Qudexy xr	Topiramate Cap ER 24HR Sprinkle 25 MG	25 MG	30	Capsules	30	DAYS				
7260007500F320	Qudexy xr	Topiramate Cap ER 24HR Sprinkle 50 MG	50 MG	30	Capsules	30	DAYS				
72600075007040	Trokendi xr	Topiramate Cap ER 24HR 100 MG	100 MG	30	Capsules	30	DAYS				
72600075007050	Trokendi xr	Topiramate Cap ER 24HR 200 MG	200 MG	60	Capsules	30	DAYS				
72600075007020	Trokendi xr	Topiramate Cap ER 24HR 25 MG	25 MG	30	Capsules	30	DAYS				
72600075007030	Trokendi xr	Topiramate Cap ER 24HR 50 MG	50 MG	30	Capsules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has been treated with an anti-seizure medication that is not topiramate **OR** B. The patient has ONE of the following diagnoses: 1. Partial onset seizures **OR** 2. Primary generalized tonic-clonic seizures **OR** 3. Lennox-Gastaut Syndrome **OR** 4. Migraine **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. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent

Module	Clinical Criteria for Approval
	Length of Approval: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. ONE of the following: A. The patient has a medication history of use of an anti-seizure medication that is not topiramate **OR** B. The patient has had clinical benefit with the requested agent **AND** 3. 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 **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• Program Summary: Vijoice (alpelisib)

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

POLICY AGENT SUMMARY QUANTITY LIMITS

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				

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
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** 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

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

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	446030600021	Xolair	omalizumab for inj	150 MG	M; N; O; Y				
	4460306000E5	Xolair	omalizumab subcutaneous soln prefilled syringe	150 MG/ML; 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** 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

Module	Clinical Criteria for Approval
	to cause or worsen urticaria is not appropriate **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to the FDA labeled 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 titrated 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 titrated up to 4 times the FDA labeled maximum dose of a second-generation H-1 antihistamine **OR** B. The patient has an intolerance or hypersensitivity to second-generation H-1 antihistamine therapy **OR** C. The patient has an FDA labeled contraindication to ALL second-generation H-1 antihistamines **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 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

Module	Clinical Criteria for Approval
	intranasal corticosteroids **OR** D. The patient has another FDA labeled indication for the requested agent AND the requested dose is within FDA labeled dosing for the requested indication **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. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **OR** 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 **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL inhaled corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. ONE of the following: 1. The patient 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** 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

Module	Clinical Criteria for Approval
	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 within FDA labeled dosing for the requested indication 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:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 6 months for asthma, chronic idiopathic urticaria, and nasal polyps 12 months for all other indications **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

Module	Clinical Criteria for Approval
	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** 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:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **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)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)

Contraindicated as Concomitant Therapy
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 (ozanimod)

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

POLICY AGENT SUMMARY QUANTITY LIMITS

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
624070502001	Zeposia	ozanimod hcl cap	0.92 MG	30	Capsules	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 with MS Step	**Initial Evaluation** **Target Agent(s)** will be approved when ONE of the following is met: 1. The requested agent is eligible for continuation of therapy AND ONE of following:

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Agents Eligible for Continuation of Therapy
Zeposia (ozanimod)

A. 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**

2. The patient has a diagnosis of multiple sclerosis (MS) AND BOTH of the following:
   A. ONE of the following:
      1. The patient has highly active MS disease activity AND BOTH of the following:
         A. The patient has greater than or equal to 2 relapses in the previous year **AND**
         B. ONE of the following:
            1. The patient has greater than or equal to 1 gadolinium enhancing lesion on MRI **OR**
            2. The patient has significant increase in T2 lesion load compared with a previous MRI **OR**
      2. The patient has been treated with at least 3 MS agents from different drug classes (see MS disease modifying agents drug class table) **OR**
      3. 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 incudes use of ONE Preferred generic MS agent* **OR**
         C. BOTH of the following:
            1. The prescriber has stated that the patient has tried a preferred generic MS agent* **AND**
            2. The preferred generic MS agent* was discontinued due to lack of effectiveness or an adverse event **OR**
         D. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE preferred generic MS agent* **OR**
         E. The patient has an FDA labeled contraindication to ALL preferred generic MS agents* **OR**
         F. The prescriber has provided documentation that ALL preferred generic MS agents* cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
   B. The patient will NOT be using the requested agent in combination with another MS disease modifying agent (DMA) (Please refer to "Multiple Sclerosis Disease Modifying Agents" contraindicated use table) **OR**
3. The patient has a diagnosis of moderately to severely active ulcerative colitis (UC) AND ALL of the following:
   A. ONE of the following:
      1. The patient is currently being treated with the requested agent as indicated by ALL of the following:
         A. A statement by the prescriber that the patient is currently taking the requested

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	agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. The patient has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC **OR** 3. The patient has severely active ulcerative colitis **OR** 4. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of UC **OR** 5. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of UC **OR** 6. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of UC **OR** 7. The prescriber has provided documentation that ALL of the conventional agents (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, steroid suppositories, sulfasalazine) used in the treatment of UC cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. ONE of the following: 1. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. The patient has tried and had an inadequate response to TWO Step 1a and/or Step 1b immunomodulatory agents (see Immunomodulatory Agent Step table) **OR** 3. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to at least TWO Step 1a and/or Step 1b immunomodulatory agents **OR** 4. The patient has an FDA labeled contraindication to ALL Step 1a AND Step1b immunomodulatory agents **OR** 5. The prescriber has provided documentation that ALL Step 1a AND Step1b immunomodulatory 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** C. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) (Please refer to "Immunomodulatory Agents NOT to be used Concomitantly" table) **AND** D. 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** E. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**

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F. 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: AHFS, or DrugDex 1 or 2a level of evidence

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

Renewal Evaluation

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

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (Note: patients not previously approved for the requested agent will require initial evaluation review) **AND**
2. ONE of the following:
   - A. The patient has a diagnosis of multiple sclerosis (MS) AND BOTH of the following:
     1. ONE of the following:
        - A. The requested agent is eligible for continuation of therapy AND ONE of 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. The patient has highly active MS disease activity AND BOTH of the following:
          1. The patient has greater than or equal to 2 relapses in the previous year **AND**
          2. ONE of the following:
             - A. The patient has greater than or equal to 1 gadolinium enhancing lesion on MRI **OR**
             - B. The patient has significant increase in T2 lesion load compared with a previous MRI OR
        - C. The patient has been treated with at least 3 MS agents from different drug classes (see MS disease modifying agents drug class table) **OR**
        - D. ONE of the following:
          1. The patient is currently being treated with the requested agent as indicated by ALL of the following:
             - A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
             - B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
             - C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
          2. The patient's medication history incudes use of ONE Preferred generic MS agent* **OR**
          3. BOTH of the following:
             - A. The prescriber has stated that the patient has tried a

Module	Clinical Criteria for Approval
	preferred generic MS agent* **AND** B. The preferred generic MS agent* was discontinued due to lack of effectiveness or an adverse event **OR** 4. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE preferred generic MS agent* **OR** 5. The patient has an FDA labeled contraindication to ALL preferred generic MS agents* **OR** 6. The prescriber has provided documentation that ALL preferred generic MS 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 MS disease modifying agent (DMA) (Please refer to "Multiple Sclerosis Disease Modifying Agents" contraindicated use table) **OR** B. The patient has a diagnosis of ulcerative colitis AND ALL of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (see "Immunomodulatory Agents NOT to be used Concomitantly" table) **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. *** Preferred and Non-preferred MS agents** **Preferred generic agents** dimethyl fumarate fingolimod **Glatopa** (glatiramer) glatiramer teriflunomide **Preferred brand agents** **Avonex** (interferon b-1a) **Betaseron** (interferon b-1b) **Kesimpta** (ofatumumab) **Mavenclad** (cladribine) **Mayzent** (siponimod)*** **Plegridy** (peginterferon b-1a) **Rebif** (interferon b-1a) **Vumerity** (diroximel fumarate) **Zeposia (**ozanimod) **Non-Preferred Agents** **Aubagio** (teriflunomide)**

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Bafiertam (monomethyl fumarate)
Copaxone (glatiramer)**
Extavia (interferon b-1b)
Gilenya (fingolimod)**
Ponvory (ponesimod)
Tascenso ODT (fingolimod)
Tecfidera (dimethyl fumarate)**
** generic available
*** Mayzent preferred or non-preferred status is determined by the client

Immunomodulatory Agent Step table**

Formulary ID	Step 1a	Step 1b (Directed to ONE TNF inhibitor) NOTE please see Step 1a for preferred TNF inhibitors	Step 2 (Directed to ONE step 1 agent)	Step 3a (Directed to TWO Step 1 agents)	Step 3b (Directed to TWO agents from step 1a and/or Step 1b)	Step 3c (Directed to THREE step 1 agents)
FocusRx	SQ: Cyltezo, Humira, Stelara	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Cyltezo, Hadlima, or Humira is required Step 1 agent)	N/A	Zeposia (Cyltezo, Humira, Rinvoq, Stelara, OR Xeljanz/Xeljanz XR are required Step 1 agents)	SQ: Abrilada*, Amjevita*, Entyvio, Hadlima*, Hulio*, Hyrimoz*, Idacio*, Omvoh, Yuflyma*, Yusimry*, Zymfentra Oral Velsipity *Cyltezo or Humira is required Step 1 agent
FlexRx, GenRx, KeyRx, BasicRx	SQ: Hadlima, Humira, Stelara	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Hadlima or Humira is required Step 1 agent)	N/A	Zeposia (Hadlima, Humira, Rinvoq, Stelara, OR Xeljanz/Xeljanz XR are required Step 1 agents)	SQ: Abrilada*, Amjevita*, Cyltezo*, Entyvio, Hulio*, Hyrimoz*, Idacio*, Omvoh, Yuflyma*, Yusimry*, Zymfentra Oral Velsipity

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	<table><tr><td></td><td></td><td></td><td></td><td></td><td></td><td>*Hadlima and Humira are required Step 1 agents</td></tr></table> **** Noted preferred status is effective upon launch

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Zeposia PA through preferred and Zeposia PA with MS step	**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: 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.

CLASS AGENTS

Class	Class Drug Agents
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 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: CD52 monoclonal antibody	
MS Disease Modifying Agents drug classes: CD52 monoclonal antibody	LEMTRADA*Alemtuzumab IV Inj
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	VUMERITY*Diroximel Fumarate Capsule Delayed Release

Class	Class Drug Agents
classes: Fumarates	
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: Purine antimetabolite	
MS Disease Modifying Agents drug classes: Purine antimetabolite	MAVENCLAD*Cladribine Tab Therapy Pack
MS Disease Modifying Agents drug classes: Pyrimidine synthesis inhibitor	
MS Disease Modifying Agents drug classes: Pyrimidine synthesis inhibitor	AUBAGIO*Teriflunomide Tab
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	TASCENSO*fingolimod lauryl sulfate tablet disintegrating
MS Disease Modifying Agents drug classes: Sphingosine 1-phosphate (SIP) receptor modulator	ZEPOSIA*Ozanimod capsule

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)
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)

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

• Program Summary: Zokinvy

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

POLICY AGENT SUMMARY QUANTITY LIMITS

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** 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

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

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	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:

Module	Clinical Criteria for Approval
	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 has tried and had an inadequate response to a topical corticosteroid **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 the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that 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 has tried and had an inadequate response to another topical psoriasis agent with a different mechanism of action (e.g., vitamin D analogs, calcineurin inhibitors, tazarotene) **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 the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that 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 has tried and had an inadequate response to ONE topical antifungal OR ONE topical corticosteroid **OR** B. The patient has an intolerance or hypersensitivity to ONE topical antifungal OR ONE topical corticosteroid **OR** C. The patient has an FDA labeled contraindication to ALL topical antifungals

Module	Clinical Criteria for Approval
	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 the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that 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 has seborrheic dermatitis of the scalp **OR** B. The patient has tried and had an inadequate response to ONE topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) **OR** C. The patient has an intolerance or hypersensitivity to ONE topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) **OR** D. The patient has an FDA labeled contraindication to ALL topical calcineurin inhibitors (e.g., pimecrolimus, tacrolimus) **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 the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that 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

Module	Clinical Criteria for Approval
	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