MHCP PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: March 1, 2024 Notification Posted: February 16, 2024

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

No new policies effective March 1, 2024

POLICIES REVISED

• Program Summary: Acute Migraine Agents

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

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

1) the indication is FDA approved AND

2) the patient is using an enteral tube for feeding or medication administration

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
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

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

Initial Evaluation

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

1. ALL of the following:
   - A. ONE of the following:
     1. The requested agent is being used for acute migraine treatment AND ALL of the following:
        - A. ONE of the following:
          1. The patient's medication history includes at least one triptan agent AND ONE of the following:
             - A. The patient has had an inadequate response to at least one triptan agent **OR**

Module	Clinical Criteria for Approval
	B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over a triptan agent **OR** 2. The patient has an intolerance or hypersensitivity to triptan therapy **OR** 3. The patient has an FDA labeled contraindication to ALL triptan agents **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL triptan agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. ONE of the following: 1. The requested agent is NOT Reyvow **OR** 2. The requested agent is Reyvow and the patient will NOT be using the requested agent in combination with another acute migraine therapy (i.e., 5HT-1F, acute use CGRP, Elyxyb, ergotamine, triptan) **AND** C. Medication overuse headache has been ruled out **OR** 2. The patient has another FDA approved indication for the requested agent and route of administration **OR** 3. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** B. If the patient has an FDA labeled indication, ONE of the following: 1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** 2. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** C. ONE of the following: 1. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) for the requested indication **OR** 2. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) for the requested indication and ONE of the following: A. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** B. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) for the requested indication as indicated by BOTH of the following: 1. ONE of the following: A. Evidence of a paid claim(s) **OR**

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

Module	Clinical Criteria for Approval
	C. The patient does NOT have any FDA labeled contraindications to the requested agent **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Amifampridine

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
76000012100320	Firdapse	Amifampridine Phosphate Tab 10 MG (Base Equivalent)	10 MG	240	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The prescriber has provided information supporting that the patient has a diagnosis of Lambert Eaton myasthenic syndrome (LEMS) confirmed by at least ONE of the following: (medical records required) A. Decreased amplitude of compound muscle action potential (CMAP) to a single supramaximal stimulus **OR** B. Positive antibody test against voltage-gated calcium channels (VGCC) **AND** 2. If the patient has an FDA approved indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient has weakness that interferes with normal function **AND** 4. The patient does NOT have a history of seizures **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:** 6 months Note: If Quantity Limit applies, please see Quantity Limit criteria **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for an amifampridine containing agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with an amifampridine containing agent [e.g., improved weakness, improved fatigue, improvement in activities of daily living (ADLs)] **AND** 3. The patient has not developed a history of seizures while using the requested medication **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 see Quantity Limit criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limits** for the **Target Agent(s)** will be approved when the requested quantity (dose) does NOT exceed the program quantity limit **Length of Approval:** 6 months for initial 12 months for renewal

• Program Summary: Ampyra (dalfampridine)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
624060300074	Ampyra	dalfampridine tab er	10 MG	60	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of multiple sclerosis (MS) AND ALL of the following: 1. ONE of the following: A. The patient will be using a disease modifying agent for the treatment of MS (e.g., Aubagio, Avonex, Bafiertam, Betaseron, Briumvi, Copaxone, Extavia, Gilenya, Glatopa, Kesimpta, Lemtrada, Mavenclad, Mayzent, Ocrevus, Plegridy, Ponvory, Rebif, Rituxan, Tascenso ODT, Tecfidera, Tysabri, Vumerity, Zeposia) in combination with the requested agent **OR** B. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to ALL disease modifying agent drug classes used for the treatment of MS (see MS disease modifying agents drug class table) **AND** 2. Information has been provided that the patient has significant limitations attributable to slow ambulation **AND** 3. The patient is ambulatory with a baseline (prior to therapy with the requested agent) timed 25-foot walk of 8 to 45 seconds **AND** 4. Information has been provided that the patient has a current EDSS score less than 7 **OR** B. The patient has another FDA approved indication for the requested agent and route of administration **AND** 2. ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months for MS and 12 months for another FDA approved diagnosis NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

Module	Clinical Criteria for Approval
	Renewal Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization Review process **AND** 2. ONE of the following: A. The patient has a diagnosis of multiple sclerosis (MS) AND ALL of the following: 1. Information has been provided that the patient has had stabilization or improvement from baseline (before treatment with requested agent) in timed walking speed or EDSS score with the requested agent **AND** 2. The patient is ambulatory **AND** 3. Information has been provided that the patient has a current EDSS score of less than 7 **AND** 4. ONE of the following: A. BOTH of the following: 1. The patient is currently treated with a disease modifying agent for the treatment of MS (e.g., Aubagio, Avonex, Bafiertam, Betaseron, Briumvi, Copaxone, Extavia, Gilenya, Glatopa, Kesimpta, Lemtrada, Mavenclad, Mayzent, Ocrevus, Plegridy, Ponvory, Rebif, Rituxan, Tascenso ODT, Tecfidera, Tysabri, Vumerity, Zeposia) **AND** 2. The patient will continue a disease modifying agent for the treatment of MS in combination with the requested agent **OR** B. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to ALL disease modifying agent drug classes used for the treatment of MS (see MS disease modifying agents drug class table) **OR** B. The patient has another FDA approved indication for the requested agent AND has had stabilization or clinical improvement with the requested agent **AND** 3. 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** 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**: Initial: 6 months for MS and 12 months for another FDA approved diagnosis. Renewal: 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 classes: Fumarates	VUMERITY*Diroximel Fumarate Capsule Delayed Release
MS Disease Modifying Agents drug classes: Glatiramer	
MS Disease Modifying Agents drug classes: Glatiramer	COPAXONE*Glatiramer Acetate Soln Prefilled Syringe
MS Disease Modifying Agents drug classes: Glatiramer	GLATOPA*Glatiramer Acetate Soln Prefilled Syringe
MS Disease Modifying Agents drug classes: IgG4k monoclonal antibody	
MS Disease Modifying Agents drug classes: IgG4k monoclonal antibody	TYSABRI*Natalizumab for IV Inj Conc
MS Disease Modifying Agents drug classes: Interferons	
MS Disease Modifying Agents drug classes: Interferons	AVONEX*Interferon Beta-
MS Disease Modifying Agents drug classes: Interferons	BETASERON*Interferon Beta-
MS Disease Modifying Agents drug classes: Interferons	EXTAVIA*Interferon Beta-
MS Disease Modifying Agents drug classes: Interferons	PLEGRIDY*Peginterferon Beta-
MS Disease Modifying Agents drug classes: Interferons	REBIF*Interferon Beta-
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

Class	Class Drug Agents
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 Cap Pack

• Program Summary: ATTR Amyloidosis

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6270104010E520	Tegsedi	Inotersen Sod Subcutaneous Pref Syr 284 MG/1.5ML (Base Eq)	284 MG/1.5 ML	4	Syringes	28	DAYS				
40550080000120	Vyndamax	Tafamidis Cap 61 MG	61 MG	30	Capsules	30	DAYS				
40550080200120	Vyndaqel	Tafamidis Meglumine (Cardiac) Cap 20 MG	20 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. The patient has ONE of the following: A. ALL of the following: 1. A diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis confirmed by testing (e.g., genetic testing, biopsy) **AND** 2. The requested agent is FDA approved for use in polyneuropathy of hereditary transthyretin-mediated amyloidosis **AND** 3. The patient has clinical manifestations of polyneuropathy (e.g., neuropathic pain, altered sensation, numbness, tingling, impaired balance, motor disability) **OR** B. ALL of the following: 1. A diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis confirmed by testing [e.g., stannous pyrophosphate (PYP) scanning, monoclonal antibody studies, biopsy, scintigraphy, genetic testing (TTR genotyping)] **AND** 2. The requested agent is FDA approved for use in cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis **AND** 3. The patient has clinical manifestations of cardiomyopathy (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema) **OR**

Module	Clinical Criteria for Approval
	C. The patient has another FDA approved 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. 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 has NOT received a liver transplant **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, geneticist, neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient will NOT be using the requested agent in combination with another agent targeted in this program, Onpattro (patisiran), OR Amvuttra (vutrisiran) 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 **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, neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient has NOT received a liver transplant **AND** 5. The patient will NOT be using the requested agent in combination with another agent targeted in this program, Onpattro (patisiran), OR Amvuttra (vutrisiran) 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.

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:** 12 months

● Program Summary: Buprenorphine, Buprenorphine/Naloxone for Opioid Dependence

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
65200010100760		Buprenorphine HCl SL Tab 2 MG (Base Equiv)	2 MG	6	Tablets	90	DAYS				
65200010100780		Buprenorphine HCl SL Tab 8 MG (Base Equiv)	8 MG	6	Tablets	90	DAYS				
65200010200720		Buprenorphine HCl-Naloxone HCl SL Tab 2-0.5 MG (Base Equiv)	2-0.5 MG	120	Tablets	30	DAYS				
65200010200740		Buprenorphine HCl-Naloxone HCl SL Tab 8-2 MG (Base Equiv)	8-2 MG	90	Tablets	30	DAYS				
65200010208250	Suboxone	Buprenorphine HCl-Naloxone HCl SL Film 12-3 MG (Base Equiv)	12-3 MG	60	Films	30	DAYS				
65200010208220	Suboxone	Buprenorphine HCl-Naloxone HCl SL Film 2-0.5 MG (Base Equiv)	2-0.5 MG	120	Films	30	DAYS				
65200010208230	Suboxone	Buprenorphine HCl-Naloxone HCl SL Film 4-1 MG (Base Equiv)	4-1 MG	60	Films	30	DAYS				
65200010208240	Suboxone	Buprenorphine HCl-Naloxone HCl SL Film 8-2 MG (Base Equiv)	8-2 MG	60	Films	30	DAYS				
65200010200710	Zubsolv	Buprenorphine HCl-Naloxone HCl SL Tab 0.7-0.18 MG (Base Eq)	0.7-0.18 MG	30	Tablets	30	DAYS				
65200010200715	Zubsolv	Buprenorphine HCl-Naloxone HCl SL Tab 1.4-0.36 MG (Base Eq)	1.4-0.36 MG	90	Tablets	30	DAYS				
65200010200760	Zubsolv	Buprenorphine HCl-Naloxone HCl SL Tab 11.4-2.9 MG (Base Eq)	11.4-2.9 MG	30	Tablets	30	DAYS				
65200010200725	Zubsolv	Buprenorphine HCl-Naloxone HCl SL Tab 2.9-0.71 MG (Base Eq)	2.9-0.71 MG	30	Tablets	30	DAYS				
65200010200732	Zubsolv	Buprenorphine HCl-Naloxone HCl SL Tab 5.7-1.4 MG (Base Eq)	5.7-1.4 MG	30	Tablets	30	DAYS				
65200010200745	Zubsolv	Buprenorphine HCl-Naloxone HCl SL Tab 8.6-2.1 MG (Base Eq)	8.6-2.1 MG	60	Tablets	30	DAYS				

ADDITIONAL QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
65200010100760		Buprenorphine HCl SL Tab 2 MG (Base Equiv)	2 MG	Quantity limit per 90 days is to allow for a single course of induction treatment			
65200010100780		Buprenorphine HCl SL Tab 8 MG (Base Equiv)	8 MG	Quantity limit per 90 days is to allow for a single course of induction treatment			

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. If the requested agent is buprenorphine sublingual tablets, then ONE of the following: 1. The patient is pregnant **OR** 2. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to naloxone or naltrexone **OR** B. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **OR** C. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** D. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval:** • Buprenorphine sublinqual tablets: Approve for up to 6 months. For increased quantities, the quantity requested up to a maximum dose of 32 mg buprenorphine may be approved. • Buprenorphine/naloxone sublingual tablets and films: Approve for up to 6 months. NOTE: For increased quantities, the quantity requested up to a maximum dose of 32 mg buprenorphine may be approved. • Zubsolv: Approve for up to 6 months NOTE: For increased quantities, the quantity requested up to a maximum dose of 22.8 mg buprenorphine may be approved.

● Program Summary: Cholestasis Pruritus

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

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

1) the indication is FDA approved AND

2) the patient is using an enteral tube for feeding or medication administration

POLICY AGENT SUMMARY 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
	523500600001	Bylvay	odevixibat cap	1200 MCG; 400 MCG	M; N; O; Y				
	523500600068	Bylvay (pellets)	odevixibat pellets cap sprinkle	200 MCG; 600 MCG	M; N; O; Y				
	523500501020	Livmarli	maralixibat chloride oral soln	9.5 MG/ML	M; N; O; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Bylvay	**Initial Evaluation** **Bylvay (odevixibat)** will be approved when ONE of the following is met: 1. ALL of the following: A. ONE of the following: 1. BOTH of the following: A. The patient has a diagnosis of progressive familial intrahepatic cholestasis (PFIC) with pruritus (medical records required) **AND** B. The patient does NOT have a diagnosis of PFIC2 with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3) **OR** 2. The patient has a diagnosis of Alagille syndrome with pruritus (medical records required) **OR** 3. The patient has another FDA approved indication for the requested agent and route of administration **OR** 4. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** B. If the patient has an FDA approved 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. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** C. ONE of the following: 1. The patient has tried and had an inadequate response to a standard cholestasis pruritus treatment agent (i.e., ursodiol, cholestyramine, or rifampicin) AND ONE of the following: A. The patient has had an inadequate response to standard cholestasis pruritus treatment agent (i.e., ursodiol, cholestyramine, naltrexone, or rifampicin) **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over standard cholestasis pruritus treatment agent (i.e., ursodiol, cholestyramine, naltrexone, or rifampicin) **OR**

Module	Clinical Criteria for Approval
	2. The patient has an intolerance or hypersensitivity to therapy with a standard cholestasis pruritus treatment agent (i.e., ursodiol, cholestyramine, naltrexone, or rifampicin) **OR** 3. The patient has an FDA labeled contraindication to ALL standard cholestasis pruritus treatment agents (i.e., ursodiol, cholestyramine, naltrexone, and rifampicin) **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 standard cholestasis pruritus treatment agents (i.e., ursodiol, cholestyramine, naltrexone, and rifampicin) 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 function **AND** D. The patient's INR is less than 1.4 **AND** E. The patient has an ALT and total bilirubin that is less than 10-times the upper limit of normal **AND** F. The patient has a serum bile acid concentration above the upper limit of normal **AND** G. ONE of the following: 1. The patient has NOT had a liver transplant **OR** 2. The patient has had a liver transplant and the prescriber has provided information in support of using the requested agent post liver transplant **AND** H. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** I. The patient will NOT be using the requested agent in combination with another Ileal Bile Acid Transport (IBAT) inhibitor agent (e.g., Livmarli) **AND** J. The requested quantity (dose) is within FDA labeled dosing for the requested indication **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months **Renewal Evaluation** **Target Agent(s)** will be approved when ONE of the following is met: 1. ALL of the following: A. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** B. The patient has had clinical benefit with the requested agent **AND** C. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** D. The patient will NOT be using the requested agent in combination with another Ileal Bile Acid Transport (IBAT) inhibitor agent (e.g., Livmarli) **AND** E. The requested quantity (dose) is within FDA labeled dosing for the requested indication **OR**

Module	Clinical Criteria for Approval
	2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Length of Approval:** 12 months
Livmarli	**Initial Evaluation** **Livmarli (maralixibat)** will be approved when ONE of the following is met: 1. ALL of the following: A. ONE of the following: 1. The patient has a diagnosis of Alagille syndrome with pruritus (medical records required) **OR** 2. The patient has another FDA approved indication for the requested agent and route of administration **OR** 3. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** B. If the patient has an FDA approved 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. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** C. ONE of the following: 1. The patient has tried and had an inadequate response to a standard cholestasis pruritus treatment agent (i.e., ursodiol, cholestyramine, naltrexone, or rifampicin) AND ONE of the following: A. The patient has had an inadequate response to standard cholestasis pruritus treatment agent (i.e., ursodiol, cholestyramine, naltrexone, or rifampicin) **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over standard cholestasis pruritus treatment agent (i.e., ursodiol, cholestyramine, naltrexone, or rifampicin) **OR** 2. The patient has an intolerance or hypersensitivity to therapy with a standard cholestasis pruritus treatment agent (i.e., ursodiol, cholestyramine, naltrexone, or rifampicin) **OR** 3. The patient has an FDA labeled contraindication to ALL standard cholestasis pruritus treatment agents (i.e., ursodiol, cholestyramine, naltrexone, and rifampicin) **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 standard cholestasis pruritus treatment agents (i.e., ursodiol, cholestyramine, naltrexone, and rifampicin) 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 function **AND** D. The patient does NOT have decompensated cirrhosis **AND** E. The patient has NOT had surgical interruption of the enterohepatic circulation of bile acid **AND** F. The patient has a serum bile acid concentration above the upper limit of normal **AND** G. ONE of the following: 1. The patient has NOT had a liver transplant **OR**

Module	Clinical Criteria for Approval
	2. The patient has had a liver transplant and the prescriber has provided information in support of using the requested agent post liver transplant **AND** H. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** I. The patient will NOT be using the requested agent in combination with another Ileal Bile Acid Transport (IBAT) inhibitor agent (e.g., Bylvay) **AND** J. The requested quantity (dose) is within FDA labeled dosing for the requested indication **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months **Renewal Evaluation** **Target Agent(s)** will be approved when ONE of the following is met: 1. ALL of the following: A. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** B. The patient has had clinical benefit with the requested agent **AND** C. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** D. The patient will NOT be using the requested agent in combination with another Ileal Bile Acid Transport (IBAT) inhibitor agent (e.g., Bylvay) **AND** E. The requested quantity (dose) is within FDA labeled dosing for the requested indication **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Length of Approval:** 12 months

● Program Summary: Contraceptives

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
2599	Afirmelle; Altavera; Alyacen 1/35; Alyacen 7/7/7; Amethia; Amethyst; Apri; Aranelle; Ashlyna; Aubra; Aubra eq; Aurovela 1.5/30; Aurovela 1/20; Aurovela 24 fe; Aurovela fe 1.5/30; Aurovela fe 1/20; Aviane; Ayuna; Azurette; Balcoltra; Balziva; Beyaz; Blisovi 24 fe; Blisovi fe 1.5/30; Blisovi fe 1/20; Briellyn; Camrese; Camrese lo; Caziant; Chateal; Chateal eq; Cryselle-28; Cyclafem 1/35; Cyclafem 7/7/7; Cyred; Cyred eq; Dasetta 1/35; Dasetta 7/7/7; Daysee; Delyla; Elinest; Emoquette; Enpresse-28; Enskyce; Estarylla; Estrostep fe; Falmina; Fayosim; Femynor; Generess fe; Hailey 1.5/30; Hailey 24 fe; Introvale; Isibloom; Jaimiess; Jasmiel; Jolessa; Juleber; Junel 1.5/30; Junel 1/20; Junel fe 1.5/30; Junel fe 1/20; Junel fe 24; Kaitlib fe; Kalliga; Kariva; Kelnor 1/35; Kelnor 1/50; Kurvelo; Larin 1.5/30; Larin 1/20; Larin 24 fe; Larin fe 1.5/30;	desogest-eth estrad & eth estrad tab; desogest-ethin est tab; desogestrel & ethinyl estradiol tab; drospirenone-estetrol tab; drospirenone-ethinyl estrad-levomefolate tab; drospirenone-ethinyl estradiol tab; estradiol valerate-dienogest tab; ethynodiol diacetate & ethinyl estradiol tab; levonor-eth est tab; levonorg-eth est tab; levonorgestrel & ethinyl estradiol; levonorgestrel & ethinyl estradiol chew tab; levonorgestrel & ethinyl estradiol tab; levonorgestrel-eth estra tab; levonorgestrel-ethinyl estradiol (continuous) tab; levonorgestrel-ethinyl estradiol-fe tab; norethin-eth estradiol-fe tab; norethindrone & ethinyl estradiol tab; norethindrone & ethinyl estradiol-fe chew tab; norethindrone ac-ethinyl estrad-fe tab; norethindrone ace & ethinyl estradiol tab; norethindrone ace & ethinyl estradiol-fe tab; norethindrone ace-eth estradiol-fe chew tab;	0.1-0.02 & 0.01 MG ; 0.1-20 MG-MCG ; 0.1-20 MG-MCG(21) ; 0.1/0.125/0.15 -0.025 MG ; 0.15-0.02/0.01 MG (21/5) ; 0.15-0.03 & 0.01 MG; 0.15-0.03 MG; 0.15-30 MG-MCG; 0.18/0.215/0.25 MG-25 MCG; 0.18/0.215/0.25 MG-35 MCG; 0.25-35 MG-MCG; 0.3-30 MG-MCG; 0.4-35 MG-MCG; 0.5-35 MG-MCG; 0.5/0.75/1-35 MG-MCG; 0.5/1/0.5-35 MG-MCG; 0.8-25 MG-MCG; 1 MG-10 MCG /10 MCG; 1-20 MG-MCG; 1-20 MG-MCG(24); 1-20/1-30/1-35 MG-MCG; 1-35 MG-MCG; 1-50 MG-MCG; 1.5-30 MG-MCG; 3-0.02 MG; 3-0.02-0.451 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
	Larin fe 1/20; Larissia; Layolis fe; Leena; Lessina; Levonest; Levora 0.15/30-28; Lillow; Lo loestrin fe; Lo-zumandimine; Loestrin 1.5/30-21; Loestrin 1/20-21; Loestrin fe 1.5/30; Loestrin fe 1/20; Lojaimiess; Loryna; Loseasonique; Low-ogestrel; Lutera; Marlissa; Mibelas 24 fe; Microgestin 1.5/30; Microgestin 1/20; Microgestin 24 fe; Microgestin fe 1.5/30; Mili; Minastrin 24 fe; Mircette; Mono-linyah; Natazia; Necon 0.5/35-28; Necon 1/35; Nikki; Nortrel 0.5/35 (28); Nortrel 1/35; Nortrel 7/7/7; Ocella; Orsythia; Ortho tri-cyclen lo; Philith; Pimtrea; Pirmella 1/35; Pirmella 7/7/7; Portia-28; Previfem; Quartette; Reclipsen; Rivelsa; Safyral; Seasonique; Setlakin; Simliya; Simpesse; Solia; Sprintec 28; Sronyx; Syeda; Tarina 24 fe; Tarina fe 1/20; Tarina fe 1/20 eq; Taytulla; Tilia fe; Tri femynor; Tri-estarylla; Tri-legest fe; Tri-linyah; Tri-lo-estarylla; Tri-lo-marzia; Tri-lo-mili; Tri-lo-sprintec; Tri-mili; Tri-previfem; Tri-sprintec; Tri-vylibra; Tri-vylibra lo;	norethindrone ace-ethinyl estradiol-fe cap; norethindrone ace-ethinyl estradiol-fe tab; norethindrone-eth estradiol tab; norgestimate & ethinyl estradiol tab; norgestimate-eth estrad tab; norgestrel & ethinyl estradiol tab	3-0.03 MG; 3-0.03-0.451 MG; 3-14.2 MG; 3/2-2/2-3/1 MG; 42-21-21-7 DAYS; 50-30/75-40/ 125-30 MCG; 90-20 MCG								

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
	Trinessa; Trivora-28										
2597000260	Annovera	segesterone ace-ethinyl estradiol va ring	0.013-0.15 MG/24HR	1	System	365	DAYS				
2510	Camila; Deblitane; Errin; Heather; Incassia; Jencycla; Lyleq; Lyza; Nora-be; Norlyda; Norlyroc; Sharobel; Slynd; Tulana	drospirenone tab; norethindrone tab	0.35 MG; 4 MG	28	Tablets	21	DAYS				
2597	Eluryng; Enilloring; Haloette; Nuvaring	etonogestrel-ethinyl estradiol va ring	0.013-0.15 MG/24HR; 0.12-0.015 MG/24HR	1	Ring	21	DAYS				
2596	Twirla; Xulane; Zafemy	levonorgestrel-ethinyl estradiol td ptwk; norelgestromin-ethinyl estradiol td ptwk	120-30 MCG/24HR; 150-35 MCG/24HR	3	Patches	21	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. Information has been provided to support therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• Program Summary: Endari

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

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

1) the indication is FDA approved AND

2) the patient is using an enteral tube for feeding or medication administration

POLICY AGENT SUMMARY 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
	828010200030	Endari	glutamine (sickle cell) powd pack	5 GM	M; N; O; Y				04-01-2018

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ONE of the following is met: 1. ALL of the following A. The patient has a diagnosis of sickle cell disease **AND** B. The patient is using the requested agent to reduce the acute complications of sickle cell disease **AND** C. If the patient has an FDA approved 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. The prescriber has provided information in support of using the requested agent for the patient's age **AND** D. ONE of the following 1. The patient's medication history includes hydroxyurea AND ONE of the following: A. The patient has had an inadequate response to hydroxyurea **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over hydroxyurea **OR** 2. The patient has an intolerance or hypersensitivity to hydroxyurea **OR** 3. The patient has an FDA labeled contraindication to hydroxyurea **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 hydroxyurea cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** E. ONE of the following: 1. The patient will NOT be using the requested agent in combination with Adakevo (crizanlizumab-tmca) OR Oxbryta (voxelotor) **OR**

Module	Clinical Criteria for Approval
	2. Information has been provided supporting the use of the requested agent in combination with Adakveo (crizanlizumab-tmca) or Oxbryta (voxelotor) **AND** F. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** G. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **OR** 2. If the request is for an oral liquid form of medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Length of Initial Approval:** 12 months **Renewal Evaluation** **Target Agent(s)** will be approved when ONE of the following is met: 1. ALL of the following: A. The patient has been previously approved through the plan's Prior Authorization process **AND** B. The patient has had clinical benefit with the requested agent (i.e., reduction in acute complications of sickle cell disease since initiating therapy with the requested agent) **AND** C. ONE of the following: 1. The patient will NOT be using the requested agent in combination with Adakevo (crizanlizumab-tmca) OR Oxbryta (voxelotor) **OR** 2. Information has been provided supporting the use of the requested agent in combination with Adakevo (crizanlizumab-tmca) or Oxbryta (voxelotor) **AND** D. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** E. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **OR** 2. If the request is for an oral liquid form of medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Length of Renewal Approval:** 12 months

● Program Summary: Fintepla

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

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

1) the indication is FDA approved AND

2) the patient is using an enteral tube for feeding or medication administration

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
72600028102020	Fintepla	Fenfluramine HCl Oral Soln 2.2 MG/ML	2.2 MG/ML	360	mLs	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ONE of the following is met: 1. ALL of the following: A. ONE of the following: 1. ALL of the following: A. ONE of the following 1. Information has been provided that indicates the patient has been treated with the requested agent within the past 180 days **OR** 2. The prescriber states the patient has been treated with the requested agent within the past 180 days AND is at risk if therapy is changed **AND** B. The patient has an FDA labeled indication for the requested agent **AND** C. If the patient has a diagnosis of seizure associated with Dravet syndrome (DS) or Lennox-Gastaut syndrome (LGS), the requested agent will NOT be used as monotherapy for seizure management **OR** 2. ONE of the following: A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR** B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following: 1. The patient is currently being treated with the requested agent and is experiencing a positive therapeutic outcome AND the prescriber provides documentation that switching the member to a preferred drug is expected to cause harm to the member or that the preferred drug would be ineffective **OR** 2. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following: A. ONE of the following: 1. Evidence of a paid claim(s) **OR** 2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND** B. ONE of the following: 1. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR** 3. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** 4. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 5. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **AND**

Module	Clinical Criteria for Approval
	B. If the patient has an FDA approved indication, ONE of the following: 1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** 2. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** C. An echocardiogram assessment will be obtained before and during treatment with the requested agent, to evaluate for valvular heart disease and pulmonary arterial hypertension **AND** D. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** E. The patient does NOT have any FDA labeled contraindications to the requested agent **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ONE of the following is met: 1. ALL of the following: A. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** B. ONE of the following: 1. The patient has a diagnosis of DS or LGS AND has had clinical benefit with the requested agent (e.g., decreased seizure activity) **OR** 2. The patient has another FDA approved indication for the requested agent and route of administration AND has had clinical benefit with the requested agent **AND** C. If using for seizure management, the requested agent will NOT be used as monotherapy **AND** D. An echocardiogram assessment will be obtained during treatment with the requested agent, to evaluate for valvular heart disease and pulmonary arterial hypertension **AND** E. 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** F. ONE of the following: 1. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR** 2. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following: A. The patient is currently being treated with the requested agent and is experiencing a positive therapeutic outcome AND the prescriber provides documentation that switching the member to a preferred drug is expected to cause harm to the member or that the preferred drug would be ineffective **OR** B. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following: 1. ONE of the following: A. Evidence of a paid claim(s) **OR** B. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND** 2. ONE of the following:

Module	Clinical Criteria for Approval
	A. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR** C. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** D. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** E. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **AND** G. The patient does NOT have any FDA labeled contraindications to the requested agent **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Length of Approval:** 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 Limits for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of Approval:** 12 months

● Program Summary: Formulary Exception

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

APPLICATION

These criteria apply only to FDA approved legend drugs which are covered under the member's current benefit plan. Medications which are investigational or otherwise not a covered benefit should be forwarded for review under the appropriate process.

FORMULARY EXCEPTION CRITERIA FOR APPROVAL

A coverage exception will be granted when BOTH of the following are met:

1. The request is NOT for a drug/drug class/medical condition that is on the list of drugs/drug classes/medical conditions which are excluded from coverage under the pharmacy benefit
   AND
2. ONE of the following:
   - A. The requested agent is an antipsychotic AND the prescribing physician has certified in writing that they have considered all equivalent drugs on the formulary and have determined that the medication prescribed will best treat the patient's condition
     OR
   - B. BOTH of the following:
     - i. ONE of the following:
       - a. The requested agent is an estrogen or testosterone product AND is being prescribed for a diagnosis related to gender reassignment
         OR
       - b. The patient's diagnosis is an FDA approved or CMS approved compendia accepted indication for the requested agent

       AND
     - ii. ONE of the following:
       - a. If the request is for an oral liquid form of a medication, then BOTH of the following:
         1. The patient has an FDA approved indication
            AND
         2. The patient uses an enteral tube for feeding or medication administration
            OR
       - b. The requested agent is a glucose test strip AND ONE of the following:
         1. The patient uses an insulin pump OR continuous glucose monitor which requires a specific non-formulary glucose test strip
            OR
         2. The prescriber has documented that the patient requires a non-formulary glucose test strip due to other physical or mental disability

         OR
       - c. The requested agent has formulary alternatives (tier 1, 3, or 4) that can be prescribed in a dose to fit the patient's needs AND ALL of the following:
         1. If the requested agent is a brand product with an available formulary generic equivalent, ONE of the following:
            - A. The patient has tried and had an inadequate response to at least one formulary generic equivalent(s) drug, if available
              OR
            - B. The prescriber has provided information stating that the available formulary generic equivalent(s) to the requested agent is contraindicated, is likely to be less effective, or will cause an adverse reaction or other harm for the patient

            AND
         2. If there is a formulary biosimilar agent(s) available for the requested agent, ONE of the following:
            - A. The patient has tried and had an inadequate response to at least three (or as many as available, if fewer than three) of the available formulary biosimilar agent(s) with at least a 3 month trial

OR

B. The prescriber has provided information stating that the available formulary biosimilar agent(s) is contraindicated, is likely to be less effective, or will cause an adverse reaction or other harm for the patient

AND

3. ONE of the following:
   A. The patient has tried and had an inadequate response to at least three (or as many as available, if fewer than three) formulary alternatives for the diagnosis being treated with the requested agent
   OR
   B. The prescriber has indicated that available formulary alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient
   OR
   C. The prescriber certifies that the patient had been stabilized on the requested agent for a minimum of 90 days and that switching could potentially cause harm or a health risk

OR

d. The requested agent does NOT have formulary alternatives that can be prescribed in a dose to fit the patient's needs

Length of Approval:

Due to drug shortage of formulary drug(s), 3 months, unless CPM/Client provides other duration approval length
All others: 12 months

Compendia Allowed: AHFS, DrugDex with 1 or 2A level of evidence, or NCCN with 1 or 2A level of evidence (for oncology agents also accept NCCN Compendium™ level of evidence 2B, DrugDex 2B, Wolters Kluwer Lexi-Drugs level A, and Clinical Pharmacology)

• Program Summary: Ketorolac

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
66100037100320		Ketorolac Tromethamine Tab 10 MG	10 MG	20	Tablets	5	DAYS				
66100037102090	Sprix	Ketorolac Tromethamine Nasal Spray 15.75 MG/SPRAY	15.75 MG/SPRAY	5	Bottles	5	DAYS				

ADDITIONAL QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
66100037100320		Ketorolac Tromethamine Tab 10 MG	10 MG	The quantity limit will allow for 20 tablets or 5 bottles of nasal spray per prescription to follow product labeling recommendations for no more than 5 days of therapy with no more than 4 doses/day			
66100037102090	Sprix	Ketorolac Tromethamine	15.75 MG/SPRAY	The quantity limit will allow for 20 tablets or 5 bottles of nasal spray per prescription to follow			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		Nasal Spray 15.75 MG/SPRAY		product labeling recommendations for no more than 5 days of therapy with no more than 4 doses/day			

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **Length of Approval**: up to 12 months

• Program Summary: Nasal Inhalers

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
42401015102020		Azelastine HCl Nasal Spray 0.1% (137 MCG/SPRAY)	0.1%; 137 MCG/SPRAY	2	Bottles	30	DAYS				
42200030002005		Flunisolide Nasal Soln 25 MCG/ACT (0.025%)	0.025%	3	Bottles	30	DAYS				
42300040102010		Ipratropium Bromide Nasal Soln 0.03% (21 MCG/SPRAY)	0.03%	2	Bottles	30	DAYS				
42300040102020		Ipratropium Bromide Nasal Soln 0.06% (42 MCG/SPRAY)	0.06%	3	Bottles	30	DAYS				
42200032301810	Allergy nasal spray 24 hour; Allergy relief; Clarispray; Cvs fluticasone propionate; Cvs fluticasone proprionate; Eq allergy relief; Eql fluticasone propionat; Flonase allergy relief; Flonase allergy relief ch; Gnp fluticasone propionate; Goodsense 24-hour allergy;	Fluticasone Propionate Nasal Susp 50 MCG/ACT	50 MCG/ACT	1	Bottle	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
	Hm allergy relief nasal spray; Kls aller-flo; Qc allergy relief; Sm allergy relief nasal spray										
42200060103210	Allergy nasal spray 24 hour; Cvs nasal allergy spray; Eq nasal allergy spray; Gnp 24 hour nasal allerg; Goodsense nasal allergy spray ; Hm 24 hour nasal allergy; Kls aller-cort; Nasacort allergy 24hr; Nasacort allergy 24hr childrens; Nasal allergy 24 hour; Nasal allergy 24 hour multi-symptom; Ra nasal allergy spray	Triamcinolone Acetonide Nasal Aerosol Suspension 55 MCG/ACT	55 MCG/ACT	1	Bottle	30	DAYS				
42401015102030	Astepro; Astepro childrens	Azelastine HCl Nasal Spray 0.15% (205.5 MCG/SPRAY)	0.15 %; 205.5 MCG/SPRAY	2	Bottles	30	DAYS				
42200010321810	Beconase aq	Beclomethasone Dipropionate Monohyd Nasal Susp 42 MCG/SPRAY	42 MCG/SPRAY	2	Bottles	30	DAYS				
42995502151820	Dymista	Azelastine HCl-Fluticasone Prop Nasal Spray 137-50 MCG/ACT	137-50 MCG/ACT	1	Bottle	30	DAYS				
42200045101820	Nasonex 24hr	Mometasone Furoate Nasal Susp 50 MCG/ACT	50 MCG/ACT	2	Bottles	30	DAYS				
42200018001820	Omnaris	Ciclesonide Nasal Susp 50 MCG/ACT	50 MCG/ACT	1	Bottle	30	DAYS				
42401060102020	Patanase	Olopatadine HCl Nasal Soln 0.6%	0.6%	1	Bottle	30	DAYS				
42200010303430	Qnasl	Beclomethasone Dipropionate Nasal Aerosol 80 MCG/ACT	80 MCG/ACT	1	Canister	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
42200010303408	Qnasl childrens	Beclomethasone Dipropionate Nasal Aerosol 40 MCG/ACT	40 MCG/ACT	1	Canister	30	DAYS				
42995502601820	Ryaltris	Olopatadine HCl-Mometasone Furoate Nasal Susp	665-25 MCG/ACT	1	Bottle	30	DAYS				
42200018003420	Zetonna	Ciclesonide Nasal Aerosol Soln 37 MCG/ACT (50 MCG/Valve)	37 MCG/ACT	1	Canister	30	DAYS				

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

● Program Summary: Non-preferred Drug Supplement with Continuation of Therapy

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

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

1) the indication is FDA approved AND

2) the patient is using an enteral tube for feeding or medication administration

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Non-Preferred Drug Prior Authorization Criteria[2] December 2023 **Approval Criteria:** A request for coverage of a non-preferred drug may be approved if the following criteria are met: 1. The drug is not excluded from coverage (for example, drugs for erectile dysfunction) **AND**

Module	Clinical Criteria for Approval
	2. The drug is prescribed for a medically accepted indication as defined in Section 1927 of the Social Security Act **AND** 3. The request is for an oral liquid form of a drug and the patient utilizes an enteral tube for feeding or medication administration **OR** 4. The member has been taking the requested nonpreferred drug to treat a mental illness or emotional disturbance as defined by Minnesota Statute, 62Q.527 for at least 90 days **OR** 5. The preferred drugs are experiencing documented drug shortages or recalls from a wholesaler, manufacturer, the ASHP (American Hospital of Health-System Pharmacist) Drug Shortage web page or The US Food and Drug Administration **OR** 6. The requested drug is being prescribed within recommended dosing guidelines **AND** 7. The member has had a trial of at least two preferred chemically unique drugs within the same drug class on the Preferred Drug List, or a trial of at least one preferred drug within the same drug class if there are not two chemically unique preferred drugs within the same drug class. The use of free goods or pharmaceutical samples will not be considered as meeting any step of the nonpreferred drug prior authorization criteria **AND (at least one of the following)** A. The prescriber must provide documentation (for example, pharmacy dispensing record, medication orders in members' health record, and so forth) at the time of request showing that: 1. the member adhered to the previous therapies during the trial(s) **AND** 2. the trial period was sufficient to allow for a positive treatment outcome, or that the drug was discontinued due to an adverse event **OR** B. The member is currently taking the requested nonpreferred drug and is experiencing a positive therapeutic outcome **AND** the prescriber provides documentation that switching the member to a preferred drug is expected to cause harm to the member, or that the preferred drug would be ineffective **OR** C. The preferred drug is contraindicated pursuant to the pharmaceutical manufacturer's prescribing information or, due to a documented adverse event or medical condition, is likely to result in the following: 1. cause an adverse reaction **OR** 2. decrease the ability of the member to achieve or maintain reasonable functional ability in performing daily activities **OR** 3. cause physical or mental harm to the member **Duration of Approval** • Requests due to drug shortages: o The Department of Human Services (DHS) may approve the request up to 3 months or up to the estimated known and verifiable resolution date, if the documented drug shortages are from the wholesaler (for example, wholesaler invoice, screenshot of wholesaler electronic ordering system, and so forth). o DHS may approve the request up to 6 months or up to the estimated known and verifiable resolution date, if the documented drug shortages are from the manufacturer (for example, manufacturer press release, screenshot of manufacturer web page, and so forth). o DHS may approve the request up to 12 months or up to the estimated known and verifiable resolution date, if the documented drug shortages are from the ASHP Drug Shortages web page or US Food and Drug Administration • DHS may approve requests due to other reasons up to 12 months **Quantity Limits** • Quantity limits pursuant to the FDA-approved label will apply **Note** • If applicable, the nonpreferred drug prior authorization criteria does not replace the requirement for a clinical prior authorization for a specific drug

Module	Clinical Criteria for Approval
	• The inability or unwillingness of the enrolled pharmacy to order or stock the preferred drug will not be considered as a basis for requests due to drug shortages **Definition** • Free goods or pharmaceutical samples: medication samples, medications obtained from any patient assistance programs or any discount programs, medications obtained through free trial programs, manufacturer vouchers, coupons or debit cards while the member is on Medical Assistance. **Continuation of Therapy Prior Authorization Criteria[3]** February 2019 **Definitions** • **Biosimilar Substitution:** Dispensing a biosimilar product rather than the reference biologic product. • **Cash Pay:** Allowing a member to pay for the entire cost of a non-covered prescription, after a member, in consultation with the prescriber and the pharmacist, has decided that covered alternatives are not options. A member may pay for the entire cost of a non-covered controlled substance prescription, including gabapentin, only when the member meets all conditions specified in the Advanced Recipient Notice of Non-Covered Prescription Form (DHS-3641-ENG) • **Continuation of Therapy:** Allowing a member who has been stabilized on a medication that requires prior authorization, but was previously covered by another payer (i.e., commercial insurance, MCO Medicaid plans), to continue the therapy without the prescriber having to satisfy the fee-for-service prior authorization criteria. • **Free goods/pharmaceutical samples:** Medication samples, medications obtained from any patient assistance programs, medications obtained through free trial programs, manufacturer vouchers, coupons or debit cards. • **Generic Substitution:** Dispensing a generically equivalent drug rather than the brand name drug. **Approval criteria** Continuation of Therapy override may be approved for nonpreferred or restricted drugs if the following conditions are met: 1. The requested nonpreferred or restricted drugs are not excluded from coverage (e.g., drugs for weight loss, drugs for erectile dysfunction) **AND** 2. The requested nonpreferred or restricted drugs are prescribed for a medically accepted indication as defined in Sec. 1927 of the Social Security Act **AND** 3. The member has been treated with a nonpreferred or restricted drug at a consistent dosage for at least 90 days and the prescriber indicates (orally or in writing) that the prescribed medication will best treat the member's condition **AND** 4. The pharmacy or prescriber must provide an attestation that the medication was covered by another payer and not obtained via cash pay, drug manufacturer-issued debit cards, or via free goods/pharmaceutical samples. **Duration of Approval** 1. Continuation of Therapy override may be approved for up to 90 days. After 90 days, the prescriber must obtain prior authorization for the nonpreferred or restricted drug or transition the member to an alternative therapy. Multiple Continuation of Therapy overrides will not be approved for the same drug **OR** 2. If the member has an existing approved prior authorization (PA) for the nonpreferred or restricted drugs, then the member's previously approved PA will be approved until the PA expires **OR** 3. If the member has received a prescribed drug to treat a mental illness or emotional disturbance as defined by Minnesota Statute 62Q.527, the member may continue to receive coverage for such prescribed drugs for up to one year.

Module	Clinical Criteria for Approval
	Continuation of Therapy criteria overrides are not available to bypass generic or biosimilar substitution (if applicable). **Free goods/Pharmaceutical Samples Policy** The use of free goods or pharmaceutical samples will not be considered as meeting the 90-day treatment requirement for Continuation of Therapy overrides. A member, after meeting all conditions for cash pay, must pay for the entire cost of the non-covered prescription.

• Program Summary: Oral Inhalers

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
44209902708020	Advair diskus; Wixela inhub	Fluticasone-Salmeterol Aer Powder BA 100-50 MCG/DOSE	100-50 MCG/ACT	1	Inhaler	30	DAYS				
44209902708030	Advair diskus; Wixela inhub	Fluticasone-Salmeterol Aer Powder BA 250-50 MCG/DOSE	250-50 MCG/ACT	1	Inhaler	30	DAYS				
44209902708040	Advair diskus; Wixela inhub	Fluticasone-Salmeterol Aer Powder BA 500-50 MCG/DOSE	500-50 MCG/ACT	1	Inhaler	30	DAYS				
44209902703260	Advair hfa	Fluticasone-Salmeterol Inhal Aerosol 115-21 MCG/ACT	115-21 MCG/ACT	1	Inhaler	30	DAYS				
44209902703270	Advair hfa	Fluticasone-Salmeterol Inhal Aerosol 230-21 MCG/ACT	230-21 MCG/ACT	1	Inhaler	30	DAYS				
44209902703250	Advair hfa	Fluticasone-Salmeterol Inhal Aerosol 45-21 MCG/ACT	45-21 MCG/ACT	1	Inhaler	30	DAYS				
44209902718030	Airduo digihaler 113/14	Fluticasone-Salmeterol Aer Powder BA	113-14 MCG/ACT	1	Inhaler	30	DAYS				
44209902718040	Airduo digihaler 232/14	Fluticasone-Salmeterol Aer Powder BA	232-14 MCG/ACT	1	Inhaler	30	DAYS				
44209902718020	Airduo digihaler 55/14	Fluticasone-Salmeterol Aer Powder BA	55-14 MCG/ACT	1	Inhaler	30	DAYS				
44209902708015	Airduo respiclick 113/14	Fluticasone-Salmeterol Aer Powder BA 113-14 MCG/ACT	113-14 MCG/ACT	1	Inhaler	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
44209902708025	Airduo respiclick 232/14	Fluticasone-Salmeterol Aer Powder BA 232-14 MCG/ACT	232-14 MCG/ACT	1	Inhaler	30	DAYS				
44209902708010	Airduo respiclick 55/14	Fluticasone-Salmeterol Aer Powder BA 55-14 MCG/ACT	55-14 MCG/ACT	1	Inhaler	30	DAYS				
44209902783220	Airsupra	albuterol-budesonide inhalation aerosol	90-80 MCG/ACT	3	Inhalers	30	DAYS				
44400017003440	Alvesco	Ciclesonide Inhal Aerosol 160 MCG/ACT	160 MCG/ACT	2	Inhalers	30	DAYS				
44400017003420	Alvesco	Ciclesonide Inhal Aerosol 80 MCG/ACT	80 MCG/ACT	1	Inhaler	30	DAYS				
44209902958020	Anoro ellipta	Umeclidinium-Vilanterol Aero Powd BA 62.5-25 MCG/INH	62.5-25 MCG/ACT	1	Inhaler	30	DAYS				
44400033218020	Armonair digihaler	Fluticasone Propionate Aer Pow BA	55 MCG/ACT	1	Inhaler	30	DAYS				
44400033218030	Armonair digihaler	Fluticasone Propionate Aer Pow BA	113 MCG/ACT	1	Inhaler	30	DAYS				
44400033218040	Armonair digihaler	Fluticasone Propionate Aer Pow BA	232 MCG/ACT	1	Inhaler	30	DAYS				
44400033108020	Arnuity ellipta	Fluticasone Furoate Aerosol Powder Breath Activ 100 MCG/ACT	100 MCG/ACT	1	Inhaler	30	DAYS				
44400033108030	Arnuity ellipta	Fluticasone Furoate Aerosol Powder Breath Activ 200 MCG/ACT	200 MCG/ACT	1	Inhaler	30	DAYS				
44400033108010	Arnuity ellipta	Fluticasone Furoate Aerosol Powder Breath Activ 50 MCG/ACT	50 MCG/ACT	1	Inhaler	30	DAYS				
44400036203220	Asmanex hfa	Mometasone Furoate Inhal Aerosol Suspension 100 MCG/ACT	100 MCG/ACT	1	Inhaler	30	DAYS				
44400036203230	Asmanex hfa	Mometasone Furoate Inhal Aerosol Suspension 200 MCG/ACT	200 MCG/ACT	1	Inhaler	30	DAYS				
44400036203210	Asmanex hfa	Mometasone Furoate Inhal Aerosol Suspension 50 MCG/ACT	50 MCG/ACT	1	Inhaler	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
44400036208020	Asmanex twisthaler 120 me; Asmanex twisthaler 14 metered doses; Asmanex twisthaler 30 metered doses; Asmanex twisthaler 60 metered doses	Mometasone Furoate Inhal Powd 220 MCG/INH (Breath Activated)	220 MCG/INH	1	Inhaler	30	DAYS				
44400036208010	Asmanex twisthaler 30 metered doses; Asmanex twisthaler 7 metered doses	Mometasone Furoate Inhal Powd 110 MCG/INH (Breath Activated)	110 MCG/INH	1	Inhaler	30	DAYS				
44100030123420	Atrovent hfa	Ipratropium Bromide HFA Inhal Aerosol 17 MCG/ACT	17 MCG/ACT	2	Inhalers	30	DAYS				
44209902543220	Bevespi aerosphere	Glycopyrrolate-Formoterol Fumarate Aerosol 9-4.8 MCG/ACT	9-4.8 MCG/ACT	1	Inhaler	30	DAYS				
44209902758010	Breo ellipta	fluticasone furoate-vilanterol aero powd ba	50-25 MCG/INH	1	Inhaler	30	DAYS				
44209902758020	Breo ellipta	Fluticasone Furoate-Vilanterol Aero Powd BA 100-25 MCG/INH	100-25 MCG/ACT	1	Inhaler	30	DAYS				
44209902758020	Breo ellipta	Fluticasone Furoate-Vilanterol Aero Powd BA 100-25 MCG/INH	100-25 MCG/ACT	60	Blisters	30	DAYS				
44209902758030	Breo ellipta	Fluticasone Furoate-Vilanterol Aero Powd BA 200-25 MCG/INH	200-25 MCG/ACT	1	Inhaler	30	DAYS				
44209902758030	Breo ellipta	Fluticasone Furoate-Vilanterol Aero Powd BA 200-25 MCG/INH	200-25 MCG/ACT	60	Blisters	30	DAYS				
44209902413240	Breyna; Symbicort	Budesonide-Formoterol Fumarate Dihyd Aerosol 160-4.5 MCG/ACT	160-4.5 MCG/ACT	3	Inhalers	30	DAYS				
44209902413220	Breyna; Symbicort	Budesonide-Formoterol Fumarate Dihyd Aerosol 80-4.5 MCG/ACT	80-4.5 MCG/ACT	3	Inhalers	30	DAYS				
44209903303220	Breztri aerosphere	Budesonide-Glycopyrrolate-Formoterol Aers	160-9-4.8 MCG/ACT	1	Inhaler	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
44209902013420	Combivent respimat	Ipratropium-Albuterol Inhal Aerosol Soln 20-100 MCG/ACT	20-100 MCG/ACT	2	Inhalers	30	DAYS				
44209902268030	Duaklir pressair	Aclidinium Br-Formoterol Fum Aero Pow Br Act 400-12 MCG/ACT	400-12 MCG/ACT	1	Inhaler	30	DAYS				
44209902903220	Dulera	Mometasone Furoate-Formoterol Fumarate Aerosol 100-5 MCG/ACT	100-5 MCG/ACT	3	Inhalers	30	DAYS				
44209902903240	Dulera	Mometasone Furoate-Formoterol Fumarate Aerosol 200-5 MCG/ACT	200-5 MCG/ACT	3	Inhalers	30	DAYS				
44209902903210	Dulera	Mometasone Furoate-Formoterol Fumarate Aerosol 50-5 MCG/ACT	50-5 MCG/ACT	3	Inhalers	30	DAYS				
44400033208020	Flovent diskus	Fluticasone Propionate Aer Pow BA 100 MCG/BLISTER	100 MCG/ACT; 100 MCG/BLIST	1	Inhaler	30	DAYS				
44400033208030	Flovent diskus	Fluticasone Propionate Aer Pow BA 250 MCG/BLISTER	250 MCG/ACT; 250 MCG/BLIST	4	Inhalers	30	DAYS				
44400033208010	Flovent diskus	Fluticasone Propionate Aer Pow BA 50 MCG/BLISTER	50 MCG/ACT; 50 MCG/BLIST	1	Inhaler	30	DAYS				
44400033223230	Flovent hfa	Fluticasone Propionate HFA Inhal Aer 110 MCG/ACT (125/Valve)	110 MCG/ACT	1	Inhaler	30	DAYS				
44400033223240	Flovent hfa	Fluticasone Propionate HFA Inhal Aer 220 MCG/ACT (250/Valve)	220 MCG/ACT	2	Inhalers	30	DAYS				
44400033223220	Flovent hfa	Fluticasone Propionate HFA Inhal Aero 44 MCG/ACT (50/Valve)	44 MCG/ACT	1	Inhaler	30	DAYS				
44100090208030	Incruse ellipta	Umeclidinium Br Aero Powd Breath Act 62.5 MCG/INH (Base Eq)	62.5 MCG/INH	1	Inhaler	30	DAYS				
44201010128020	Proair digihaler	Albuterol Sulfate Aer Pow BA	108 MCG/ACT	2	Inhalers	30	DAYS				
44201010103410	Proair hfa; Proventil hfa; Ventolin hfa	Albuterol Sulfate Inhal Aero 108 MCG/ACT (90MCG Base Equiv)	108 MCG/ACT	2	Inhalers	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
44201010108020	Proair respiclick	Albuterol Sulfate Aer Pow BA 108 MCG/ACT (90 MCG Base Equiv)	108 MCG/ACT	2	Inhalers	30	DAYS				
44400015008018	Pulmicort flexhaler	Budesonide Inhal Aero Powd 180 MCG/ACT (Breath Activated)	180 MCG/ACT	2	Inhalers	30	DAYS				
44400015008009	Pulmicort flexhaler	Budesonide Inhal Aero Powd 90 MCG/ACT (Breath Activated)	90 MCG/ACT	1	Inhaler	30	DAYS				
44400010128120	Qvar redihaler	Beclomethasone Diprop HFA Breath Act Inh Aer 40 MCG/ACT	40 MCG/ACT	1	Inhaler	30	DAYS				
44400010128140	Qvar redihaler	Beclomethasone Diprop HFA Breath Act Inh Aer 80 MCG/ACT	80 MCG/ACT	2	Inhalers	30	DAYS				
44201058108020	Serevent diskus	Salmeterol Xinafoate Aer Pow BA 50 MCG/DOSE (Base Equiv)	50 MCG/DOSE	1	Inhaler	30	DAYS				
44100080100120	Spiriva handihaler	Tiotropium Bromide Monohydrate Inhal Cap 18 MCG (Base Equiv)	18 MCG	30	Capsules	30	DAYS				
44100080103410	Spiriva respimat	Tiotropium Bromide Monohydrate Inhal Aerosol 1.25 MCG/ACT	1.25 MCG/ACT	1	Inhaler	30	DAYS				
44100080103420	Spiriva respimat	Tiotropium Bromide Monohydrate Inhal Aerosol 2.5 MCG/ACT	2.5 MCG/ACT	1	Inhaler	30	DAYS				
44209902923420	Stiolto respimat	Tiotropium Br-Olodaterol Inhal Aero Soln 2.5-2.5 MCG/ACT	2.5-2.5 MCG/ACT	1	Inhaler	30	DAYS				
44201052203410	Striverdi respimat	Olodaterol HCl Inhal Aerosol Soln 2.5 MCG/ACT (Base Equiv)	2.5 MCG/ACT	1	Inhaler	30	DAYS				
44209903408040	Trelegy ellipta	Fluticasone-Umeclidinium-Vilanterol AEPB	200-62.5-25 MCG/ACT	1	Inhaler	30	DAYS				
44209903408020	Trelegy ellipta	Fluticasone-Umeclidinium-Vilanterol AEPB 100-62.5-25 MCG/INH	100-62.5-25 MCG/ACT	1	Inhaler	30	DAYS				
44100007108020	Tudorza pressair	Aclidinium Bromide Aerosol Powd Breath	400;	1	Inhaler	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
		Activated 400 MCG/ACT	400 MCG/ACT								
44201045503220	Xopenex hfa	Levalbuterol Tartrate Inhal Aerosol 45 MCG/ACT (Base Equiv)	45 MCG/ACT	2	Inhalers	30	DAYS				

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

● Program Summary: Oral Pulmonary Arterial Hypertension (PAH)

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

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

1) the indication is FDA approved AND

2) the patient is using an enteral tube for feeding or medication administration

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
401430800003	Adcirca; Alyq	tadalafil tab	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	244	mLs	30	DAYS				
4016005000	Opsumit	macitentan tab	10 MG	30	Tablets	30	DAYS				
4017008005C110	Orenitram titr kit Month 1	Treprostinil tab er Mo 1 titr kit	0.125 & 0.25 MG	1	Pack	180	DAYS				
4017008005C120	Orenitram titr kit Month 2	Treprostinil tab er Mo 2 titr kit	0.125 & 0.25 MG	1	Pack	180	DAYS				
4017008005C130	Orenitram titr kit Month 3	Treprostinil tab er Mo 3 titr kit	0.125 & 0.25 &1 MG	1	Pack	180	DAY				
401430601019	Revatio	sildenafil citrate for suspension	10 MG/ML	2	Bottles	30	DAYS				
401430601003	Revatio	sildenafil citrate tab	20 MG	90	Tablets	30	DAYS				
40143080001820	Tadliq	Tadalafil Oral Susp	20 MG/5ML	300	mLs	30	DAYS				
401600150003	Tracleer	bosentan tab	125 MG; 62.5 MG	60	Tablets	30	DAYS				
401600150073	Tracleer	bosentan tab for oral susp	32 MG	120	Tablets	30	DAYS				
40170080002020	Tyvaso	treprostinil inhalation solution	0.6 MG/ML	7	Packages	28	DAYS	66302020603			
40170080002920	Tyvaso dpi maintenance ki	Treprostinil Inh Powder	16 MCG	112	Cartridges	28	DAYS				
40170080002930	Tyvaso dpi maintenance ki	Treprostinil Inh Powder	32 MCG	112	Cartridges	28	DAYS				
40170080002940	Tyvaso dpi maintenance ki	Treprostinil Inh Powder	48 MCG	112	Cartridges	28	DAYS				
40170080002950	Tyvaso dpi maintenance ki	Treprostinil Inh Powder	64 MCG	112	Cartridges	28	DAYS				
40170080002960	Tyvaso dpi maintenance ki	Treprostinil Inh Powder	112 x 32MCG & 112 x48MCG	224	Cartridges	28	DAYS				

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
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				
40120070000310	Uptravi	selexipag tab	200 MCG	140	Tablets	180	DAYS	66215060214			
40120070000310	Uptravi	selexipag tab	200 MCG	60	Tablets	30	DAYS	66215060206			
4012007000B7	Uptravi titration pack	selexipag tab therapy pack	200 & 800 MCG	1	Package	180	DAYS				
401700600020	Ventavis	iloprost inhalation solution	10 MCG/ML; 20 MCG/ML	270	Ampules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ONE of the following is met: 1. ALL of the following: A. ONE of the following: 1. BOTH of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Target Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **AND** B. The patient has an FDA approved indication for the requested agent **OR**

Module	Clinical Criteria for Approval
	2. The patient has a diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH), WHO Group 4 and ALL of the following: A. The requested agent is Adempas **AND** B. The patient's diagnosis has been confirmed by a ventilation-perfusion scan and a confirmatory selective pulmonary angiography **AND** C. The patient has a mean pulmonary artery pressure of greater than 20 mmHg **AND** D. The patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg **AND** E. The patient has a pulmonary vascular resistance greater than or equal to 3 Wood units **AND** F. ONE of the following: 1. The patient is NOT a candidate for surgery **OR** 2. The patient has had a pulmonary endarterectomy AND has persistent or recurrent disease **AND** G. The patient will NOT be using the requested agent in combination with a PDE5 inhibitor (e.g., tadalafil [Adcirca or Cialis] or sildenafil [Revatio or Viagra]) **OR** 3. The patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 and ALL of the following: A. The patient's diagnosis has been confirmed by right heart catheterization (medical records required) **AND** B. The patient's mean pulmonary arterial pressure is greater than 20 mmHg **AND** C. The patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg **AND** D. The patient has a pulmonary vascular resistance greater than or equal to 3 Wood units **AND** E. The patient's World Health Organization (WHO) functional class is II or greater **AND** F. If the requested agent is 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** G. ONE of the following: 1. The requested agent will be utilized as monotherapy **OR** 2. The requested agent will be utilized as dual therapy that consists of an endothelin receptor antagonist (ERA) plus phosphodiesterase 5 inhibitor (PDE5i) as initial therapy **OR** 3. The requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy) [except combo requests for endothelin receptor antagonist (ERA) plus phosphodiesterase 5 inhibitor (PDE5i) for dual therapy], and BOTH of following: A. The patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy **AND** B. The requested agent is in a different therapeutic class **OR** 4. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy) and ALL of the following: A. The patient is WHO functional class III or IV **AND** B. ONE of the following: 1. A prostanoid has been started as one of the agents in the triple therapy **OR** 2. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ALL prostanoids **AND** C. The patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy **AND**

Module	Clinical Criteria for Approval
	D. All three agents in the triple therapy are from a different therapeutic class **OR** 4. The patient has a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD, WHO group 3) AND ALL of the following: A. The requested agent is Tyvaso **AND** B. The patient's diagnosis has been confirmed by right heart catheterization (medical records required) **AND** C. The patient's mean pulmonary arterial pressure is greater than 20 mmHg **AND** D. The patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg **AND** E. The patient has a pulmonary vascular resistance greater than or equal to 3 Wood units **AND** F. The patient has an FVC less than 70% of predicted **AND** G. The patient has extensive parenchymal changes on computed tomography (CT) **AND** H. BOTH of the following: 1. The patient is currently treated with standard of care therapy for ILD (e.g., Ofev) **AND** 2. The patient will continue standard of care therapy for ILD (e.g., Ofev) **OR** 5. The patient has another FDA approved indication for the requested agent **AND** B. If the patient has an FDA approved 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. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** C. ONE of the following: 1. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR** 2. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following: A. The patient is currently being treated with the requested agent and is experiencing a positive therapeutic outcome AND the prescriber provides documentation that switching the member to a preferred drug is expected to cause harm to the member or that the preferred drug would be ineffective **OR** B. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following: 1. ONE of the following: A. Evidence of a paid claim(s) **OR** B. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND** 2. ONE of the following: A. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR** C. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR**

Module	Clinical Criteria for Approval
	D. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** E. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **AND** D. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** E. The patient does NOT have any FDA labeled contraindications to the requested agent **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ONE of the following is met: 1. ALL of the following: A. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** B. The patient has had clinical benefit with the requested agent (e.g., stabilization, decreased disease progression) (medical records required) **AND** C. If the requested agent is Tyvaso for a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD, WHO group 3), then the patient will continue standard of care therapy for ILD (e.g., Ofev) **AND** D. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** E. The patient does NOT have any FDA labeled contraindications to the requested agent **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

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**

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

• Program Summary: Oxbryta (voxelotor)

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

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

1) the indication is FDA approved AND

2) the patient is using an enteral tube for feeding or medication administration

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
82805080000310	Oxbryta	Voxelotor Tab	300 MG	90	Tablets	30	DAYS			01-23-2023	12-31-9999
82805080000320	Oxbryta	Voxelotor Tab 500 MG	500 MG	90	Tablets	30	DAYS				
82805080007320	Oxbryta	Voxelotor Tab For Oral Susp	300 MG	90	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ONE of the following is met: 1. ALL of the following: A. The patient has a diagnosis of sickle cell disease **AND** B. If the patient has an FDA approved 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. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** C. The patient's medication history includes hydroxyurea AND ONE of the following: 1. The patient has had an inadequate response to maximally tolerated hydroxyurea **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over hydroxyurea **OR** 3. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to hydroxyurea **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following:

Module	Clinical Criteria for Approval
	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 hydroxyurea cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** D. ONE of the following: 1. The patient's baseline (before treatment with the requested agent) hemoglobin is greater than or equal to 5.5 and less than or equal to 10.5 g/dL **OR** 2. The patient's baseline (before treatment with the requested agent) hemoglobin is below the lab reference range for the patient's age and gender **AND** E. ONE of the following: 1. The patient will NOT be using the requested agent in combination with Adakveo (crizanlizumab-tmca) OR Endari (L-glutamine) for the requested indication **OR** 2. Information has been provided supporting the use of the requested agent in combination with Adakveo (crizanlizumab-tmca) or Endari (L-glutamine) for the requested indication **AND** F. The patient does NOT have any FDA labeled contraindications to the requested agent **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Length of Initial Approval:** 6 months NOTE if Quantity Limit applies, please refer to Quantity Limit criteria **Renewal Evaluation** **Target Agent(s)** will be approved when ONE of the following is met: 1. ALL of the following: A. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** B. The patient has had clinical benefit with the requested agent indicated by one of the following: 1. The patient had an increase in hemoglobin level of greater than 1 g/dL from baseline (before treatment with the requested agent) **OR** 2. The patient has a hemoglobin level within the normal range for age and gender **OR** 3. Information has been provided supporting continuation with the requested agent (medical records required) **AND** C. ONE of the following: 1. The patient will NOT be using the requested agent in combination with Adakveo (crizanlizumab-tmca) OR Endari (L-glutamine) for the requested indication **OR** 2. Information supporting the use of the requested agent in combination with Adakveo (crizanlizumab-tmca) or Endari (L-glutamine) for the requested indication **AND** D. The patient does NOT have any FDA labeled contraindications to the requested agent **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feeding or medication administration

Module	Clinical Criteria for Approval
	Length of Renewal 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 Limits for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit AND ONE of the following: 1. The requested agent is Oxbryta 500 mg tablets **OR** 2. The requested agent is Oxbryta 300 mg tablets for oral suspension AND information has been provided to support why the patient cannot take 3 tablets of Oxbryta 500 mg strength **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **Length of Approval:** Initial 6 months; Renewal 12 months

• Program Summary: Pain Medications

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
64991002120105		Butalbital-Acetaminophen Cap 50-300 MG	50-300 MG	180	Capsules	30	DAYS				
64991003300120		Butalbital-Aspirin-Caffeine Cap 50-325-40 MG	50-325-40 MG	180	Capsules	30	DAYS				
64991002120304	Allzital	Butalbital-Acetaminophen Tab 25-325 MG	25 MG; 25-325 MG	360	Tablets	30	DAYS				
64991003100310	Bac; Esgic	Butalbital-Acetaminophen-Caffeine Tab 50-325-40 MG	50-325-40 MG	180	Tablets	30	DAYS				
64991002120308	Bupap	Butalbital-Acetaminophen Tab 50-300 MG	50-300 MG	180	Tablets	30	DAYS				
64991003100110	Esgic; Zebutal	Butalbital-Acetaminophen-Caffeine Cap 50-325-40 MG	50-325-40 MG	180	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
64991003100108	Fioricet	Butalbital-Acetaminophen-Caffeine Cap 50-300-40 MG	50-300-40 MG	180	Capsules	30	DAYS				
64991002120310	Tencon	Butalbital-Acetaminophen Tab 50-325 MG	50-325 MG	180	Tablets	30	DAYS				
64991003102020	Vtol lq	Butalbital-Acetaminophen-Caffeine Soln 50-325-40 MG/15ML	50-325-40 MG/15 ML	2700	mLs	30	DAYS				

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND BOTH of the following: A. ONE of the following: 1. BOTH of the following: A. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** B. Information has been provided to support therapy with a higher dose for the requested indication **OR** 2. BOTH of the following: A. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** B. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. BOTH of the following: A. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** B. Information has been provided to support therapy with a higher dose for the requested indication **AND** B. If the requested agent contains acetaminophen, the daily dose of acetaminophen does NOT exceed over 4 grams per 24 hours **Length of Approval**: Approval duration is 1 month for dose titration requests and up to 6 months for all other requests

• Program Summary: Phenylketonuria

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

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

1) the indication is FDA approved AND

2) the patient is using an enteral tube for feeding or medication administration

POLICY AGENT SUMMARY 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
	309085651030	Javygtor; Kuvan	sapropterin dihydrochloride powder packet	100 MG; 500 MG	M; N; O; Y				
	309085651003	Javygtor; Kuvan	sapropterin dihydrochloride tab	100 MG	M; N; O; Y				
	3090855040E5	Palynziq	pegvaliase-pqpz subcutaneous soln pref syringe	10 MG/0.5ML; 2.5 MG/0.5ML; 20 MG/ML	M; N; O; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	INITIAL EVALUATION **Target Agent(s)** will be approved when ONE of the following is met: 1. ALL of the following: A. The patient has a diagnosis of phenylketonuria (PKU) **AND** B. If the patient has an FDA approved 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. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** C. ONE of the following: 1. BOTH of the following: A. Phenylalanine levels cannot be maintained within the recommended maintenance range with dietary intervention (phenylalanine-restriction) despite strict compliance **AND** B. The Phe-restricted diet will continue while being treated with the requested agent **OR** 2. If the requested agent is Palynziq, the patient's current phenylalanine level is less than 360 micromol/L (6 mg/dL) **AND** D. If the requested agent is Kuvan or sapropterin, then ONE of the following: 1. The patient is less than 12 years of age AND has a baseline (prior to therapy for the requested indication) blood Phe level greater than 360 micromol/L (6 mg/dL) **OR** 2. The patient is 12 years of age or over AND has a baseline (prior to therapy for the requested indication) blood Phe level greater than 600 micromol/L (10 mg/dL) **OR** 3. The patient is planning on becoming pregnant OR is currently pregnant AND has a baseline (prior to therapy for the requested indication) Phe level greater than 360 micromol/L (6 mg/dL) **AND** E. If the requested agent is Palynziq, the patient has a baseline (prior to therapy for the requested indication) blood Phe level greater than 600 micromol/L (10 mg/dL) **AND** F. If the request is for a brand agent, then ONE of the following:

Module	Clinical Criteria for Approval
	1. The patient's medication history includes generic sapropterin AND ONE of the following: A. The patient has had an inadequate response to generic sapropterin despite monitored adherence to treatment **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over generic sapropterin **OR** 2. The patient has an intolerance or hypersensitivity to generic sapropterin that is not expected to occur with the brand agent **OR** 3. The patient has an FDA labeled contraindication to generic sapropterin that is not expected to occur with the brand agent **OR** 4. The prescriber has provided information to support the use of the requested brand agent over generic sapropterin (e.g., presence of two null mutations in trans) **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 generic sapropterin 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** G. The prescriber is a specialist in the area of the patient's diagnosis (e.g., metabolic disorders) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** H. The patient will NOT be using the requested agent in combination with another targeted agent included in this program **AND** I. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** J. The requested quantity (dose) is within FDA labeled dosing for the requested indication **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Length of Approval:** **Kuvan (sapropterin):** Approve for 2 months if initial dose is 5 mg/kg/day to less than 20 mg/kg/day, and for 1 month if initial dose is 20 mg/kg/day **Palynziq (pegvaliase-pqpz):** 9 months **RENEWAL EVALUATION** **Target Agent(s)** will be approved when ONE of the following is met: 1. ALL of the following: A. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** B. The patient has had improvements or stabilization with the requested agent as indicated by ONE of the following: 1. If the requested agent is Kuvan or sapropterin, then ONE of the following: A. The patient's blood Phe levels are being maintained within the acceptable range [less than 12 years of age and for females currently pregnant or planning on

Module	Clinical Criteria for Approval
	becoming pregnant: 120-360 micromol/L (2-6 mg/dL); greater than or equal to 12 years of age: 120-600 micromol/L (2-10 mg/dL)] **OR** B. The patient has had at least a 30% decrease in blood Phe level from baseline (prior to therapy for the requested indication) **OR** 2. If the requested agent is Palynziq, then ONE of the following: A. The patient's blood Phe level is less than or equal to 600 micromol/L (10 mg/dL) **OR** B. The patient has had at least a 20% decrease in blood Phe level from baseline (prior to therapy for the requested indication) **OR** C. The patient has NOT received 16 weeks of therapy at the maximum recommended dose in approved labeling AND the prescriber will evaluate for a dose escalation to induce clinical response **AND** C. ONE of the following: 1. The patient is currently on a phenylalanine (Phe) restricted diet and will continue while being treated with the requested agent **OR** 2. If the requested agent is Palynziq, the patient's phenylalanine level is less than 360 micromol/L (6 mg/dL) **AND** D. If the request is for a brand agent, then ONE of the following: 1. The patient's medication history includes generic sapropterin AND ONE of the following: A. The patient has had an inadequate response to generic sapropterin despite monitored adherence to treatment **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over generic sapropterin **OR** 2. The patient has an intolerance or hypersensitivity to generic sapropterin that is not expected to occur with the brand agent **OR** 3. The patient has an FDA labeled contraindication to generic sapropterin that is not expected to occur with the brand agent **OR** 4. The prescriber has provided information to support the use of the requested brand agent over generic sapropterin (e.g., presence of two null mutations in trans) **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 generic sapropterin 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** E. The prescriber is a specialist in the area of the patient's diagnosis (e.g., metabolic disorders) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** F. The patient will NOT be using the requested agent in combination with another targeted agent included in this program **AND** G. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** H. The requested quantity (dose) is within FDA labeled dosing for the requested indication **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Length of Approval:** 12 months

• Program Summary: Pseudobulbar Affect (PBA)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
62609902300120	Nuedexta	Dextromethorphan HBr-Quinidine Sulfate Cap 20-10 MG	20-10 MG	60	Capsules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of pseudobulbar affect (PBA) **AND** 2. The patient has a diagnosis of amyotrophic lateral sclerosis (ALS) or multiple sclerosis (MS) **AND** 3. The prescriber has determined a baseline (prior to therapy with the requested agent) number of laughing and/or crying episodes experienced by the patient **AND** 4. ONE of the following: A. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** B. The patient's medication history includes a tricyclic antidepressant (TCA) (e.g., amitriptyline, clomipramine, desipramine, doxepin, imipramine, nortriptyline) OR a selective serotonin reuptake inhibitor (SSRI) (e.g., citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline) used for the requested indication AND ONE of the following: 1. The patient has had an inadequate response to a tricyclic antidepressant (TCA) (e.g., amitriptyline, clomipramine, desipramine, doxepin, imipramine, nortriptyline) OR a selective serotonin reuptake inhibitor (SSRI) (e.g., citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline) used for the requested indication **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over a tricyclic antidepressant (TCA) (e.g., amitriptyline, clomipramine, desipramine, doxepin, imipramine, nortriptyline) AND a selective serotonin reuptake inhibitor (SSRI) (e.g., citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline) used for the requested indication **OR** C. The patient has an intolerance or hypersensitivity to TCA or SSRI therapy **OR** D. The patient has an FDA labeled contraindication to ALL TCAs AND SSRIs **OR** E. 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 **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, neuropsychologist, psychiatrist) 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

Module	Clinical Criteria for Approval
	Length of Approval: 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has a diagnosis of pseudobulbar affect (PBA) **AND** 3. The patient has a diagnosis of amyotrophic lateral sclerosis (ALS) or multiple sclerosis (MS) **AND** 4. The patient has had clinical benefit with the requested agent as indicated by a decrease in laughing and/or crying episodes from baseline (prior to therapy with the requested agent) **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, neuropsychologist, psychiatrist) 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. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: Initial: 3 months; Renewal: 12 months

• Program Summary: Relyvrio (sodium phenylbutyrate/taurursodiol)

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

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

1) the indication is FDA approved AND

2) the patient is using an enteral tube for feeding or medication administration

POLICY AGENT SUMMARY QUANTITY LIMIT

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

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ONE of the following is met: 1. ALL of the following: A. The patient has a diagnosis of amyotrophic lateral sclerosis (ALS) [also known as Lou Gehrig's disease] **AND** B. BOTH of the following: 1. The requested agent will be or was started within 18 months of symptom onset **AND** 2. The patient has a baseline percent predicted forced vital capacity (FVC) or slow vital capacity (SVC) greater than 60% **AND** C. If the patient has an FDA approved 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. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** D. The patient is able to perform most activities of daily living, defined as scores of 2 points or better on each individual item of the ALS Functional Rating Scale-Revised [ALSFRS-R] **AND** E. ONE of the following: 1. The patient is currently being treated with riluzole **OR** 2. The patient's medication history includes riluzole AND ONE of the following: A. The patient has had an inadequate response to riluzole **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over riluzole **OR** 3. The patient has an intolerance or hypersensitivity to riluzole **OR** 4. The patient has an FDA labeled contraindication to riluzole **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that riluzole cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse

Module	Clinical Criteria for Approval
	reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** F. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** G. The patient does NOT have any FDA labeled contraindications to the requested agent **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Length of Approval:** 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ONE of the following is met: 1. ALL of the following: A. The patient has been previously approved for the requested agent through the plan's Prior Authorization criteria **AND** B. The patient has had clinical benefit with the requested agent **AND** C. The patient is NOT dependent on invasive ventilation or tracheostomy **AND** D. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** E. The patient does NOT have any FDA labeled contraindications to the requested agent **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Length of Approval:** 12 months 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	**Quantities above the program quantity limit for the Target Agent(s)** will be approved when the following is met: 1. ONE of the following: A. The requested quantity (dose) does NOT exceed the program quantity limit **OR** B. ALL of the following: 1. The requested quantity (dose) is greater than the program quantity limit **AND** 2. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 3. 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:** 6 months for initial; 12 months for renewal

● Program Summary: Self-Administered Oncology Agents

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

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

1) the indication is FDA approved AND

2) the patient is using an enteral tube for feeding or medication administration

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
21406010200310		Abiraterone Acetate Tab 125 MG		120	Tablets	30	DAYS				
2156006000B730		Selinexor Tab Therapy Pack 20 MG (100 MG Once Weekly)		20	Tablets	28	DAYS				
2156006000B712		Selinexor Tab Therapy Pack 20 MG (40 MG Once Weekly)		8	Tablets	28	DAYS				
2156006000B715		Selinexor Tab Therapy Pack 20 MG (40 MG Twice Weekly)		16	Tablets	28	DAYS				
2156006000B750		Selinexor Tab Therapy Pack 20 MG (60 MG Once Weekly)		12	Tablets	28	DAYS				
2156006000B740		Selinexor Tab Therapy Pack 20 MG (80 MG Once Weekly)		16	Tablets	28	DAYS				
215325300003	Afinitor	everolimus tab	10 MG; 2.5 MG; 5 MG; 7.5 MG	30	Tablets	30	DAYS				
21532530007310	Afinitor disperz	Everolimus Tab for Oral Susp 2 MG	2 MG	60	Tablets	30	DAYS				
21532530007320	Afinitor disperz	Everolimus Tab for Oral Susp 3 MG	3 MG	90	Tablets	30	DAYS				
21532530007340	Afinitor disperz	Everolimus Tab for Oral Susp 5 MG	5 MG	60	Tablets	30	DAYS				
21409902120320	Akeega	niraparib tosylate-abiraterone acetate tab	50-500 MG	60	Tablets	30	DAYS				
21409902120330	Akeega	niraparib tosylate-abiraterone acetate tab	100-500 MG	60	Tablets	30	DAYS				
215305071001	Alecensa	alectinib hcl cap	150 MG	240	Capsules	30	DAYS				
21530510000330	Alunbrig	Brigatinib Tab	30 MG	120	Tablets	30	DAYS				
21530510000350	Alunbrig	Brigatinib Tab	90 MG	30	Tablets	30	DAYS				
21530510000365	Alunbrig	Brigatinib Tab	180 MG	30	Tablets	30	DAYS				

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
2153051000B720	Alunbrig	Brigatinib Tab Initiation Therapy Pack	90 & 180 MG	30	Tablets	180	DAYS				
21533865000120	Augtyro	repotrectinib cap	40 MG	240	Capsules	30	DAYS				
214900090003	Ayvakit	avapritinib tab	100 MG; 200 MG; 25 MG; 300 MG; 50 MG	30	Tablets	30	DAYS				
21532225000320	Balversa	Erdafitinib Tab 3 MG	3 MG	90	Tablets	30	DAYS				
21532225000325	Balversa	Erdafitinib Tab 4 MG	4 MG	60	Tablets	30	DAYS				
21532225000330	Balversa	Erdafitinib Tab 5 MG	5 MG	30	Tablets	30	DAYS				
2170007750E520	Besremi	Ropeginterferon alfa-	500 MCG/ML	2	Syringes	28	DAYS				
21531812000120	Bosulif	bosutinib cap	50 MG	30	Capsules	30	DAYS				
21531812000130	Bosulif	bosutinib cap	100 MG	90	Capsules	30	DAYS				
21531812000320	Bosulif	Bosutinib Tab	100 MG	90	Tablets	30	DAYS				
21531812000327	Bosulif	Bosutinib Tab	400 MG	30	Tablets	30	DAYS				
21531812000340	Bosulif	Bosutinib Tab	500 MG	30	Tablets	30	DAYS				
215320400001	Braftovi	encorafenib cap	75 MG	180	Capsules	30	DAYS				
21532195000120	Brukinsa	Zanubrutinib Cap	80 MG	120	Capsules	30	DAYS				
21533010100320	Cabometyx	Cabozantinib S-Malate Tab	20 MG	30	Tablets	30	DAYS				
21533010100330	Cabometyx	Cabozantinib S-Malate Tab	40 MG	30	Tablets	30	DAYS				
21533010100340	Cabometyx	Cabozantinib S-Malate Tab	60 MG	30	Tablets	30	DAYS				
215321030001	Calquence	acalabrutinib cap	100 MG	60	Capsules	30	DAYS				
215321035003	Calquence	acalabrutinib maleate tab	100 MG	60	Tablets	30	DAYS				
21533085000320	Caprelsa	Vandetanib Tab	100 MG	60	Tablets	30	DAYS				
21533085000340	Caprelsa	Vandetanib Tab	300 MG	30	Tablets	30	DAYS				
21533010106470	Cometriq	Cabozantinib S-Mal Cap	80 & 20 MG	1	Carton	28	DAYS				
21533010106480	Cometriq	Cabozantinib S-Mal Cap	3 x 20 MG & 80 MG	1	Carton	28	DAYS				
21533010106460	Cometriq	Cabozantinib S-Malate Cap	20 MG	1	Carton	28	DAYS				
215380300001	Copiktra	duvelisib cap	15 MG; 25 MG	56	Capsules	28	DAYS				
215335302003	Cotellic	cobimetinib fumarate tab	20 MG	63	Tablets	28	DAYS				

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
21370030300335	Daurismo	Glasdegib Maleate Tab 100 MG (Base Equivalent)	100 MG	30	Tablets	30	DAYS				
21370030300320	Daurismo	Glasdegib Maleate Tab 25 MG (Base Equivalent)	25 MG	60	Tablets	30	DAYS				
21370070000120	Erivedge	Vismodegib Cap 150 MG	150 MG	30	Capsules	30	DAYS				
21402410000360	Erleada	apalutamide tab	240 MG	30	Tablets	30	DAYS				
21402410000320	Erleada	Apalutamide Tab 60 MG	60 MG	120	Tablets	30	DAYS				
21360050600120	Exkivity	Mobocertinib Succinate Cap	40 MG	120	Capsules	30	DAYS				
215315501001	Farydak	panobinostat lactate cap	10 MG; 15 MG; 20 MG	6	Capsules	21	DAYS				
21533076250120	Fotivda	Tivozanib HCl Cap	0.89 MG	21	Capsules	28	DAYS				
21533076250130	Fotivda	Tivozanib HCl Cap	1.34 MG	21	Capsules	28	DAYS				
21335035000120	Fruzaqla	fruquintinib cap	1 MG	84	Capsules	28	DAYS				
21335035000140	Fruzaqla	fruquintinib cap	5 MG	21	Capsules	28	DAYS				
215357500001	Gavreto	pralsetinib cap	100 MG	120	Capsules	30	DAYS				
213600061003	Gilotrif	afatinib dimaleate tab	20 MG; 30 MG; 40 MG	30	Tablets	30	DAYS				
21531835100320	Gleevec	Imatinib Mesylate Tab	100 MG	90	Tablets	30	DAYS				
21531835100340	Gleevec	Imatinib Mesylate Tab	400 MG	60	Tablets	30	DAYS				
215310600001	Ibrance	palbociclib cap	100 MG; 125 MG; 75 MG	21	Capsules	28	DAYS				
215310600003	Ibrance	palbociclib tab	100 MG; 125 MG; 75 MG	21	Tablets	28	DAYS				
21531875100315	Iclusig	Ponatinib HCl Tab	10 MG	30	Tablets	30	DAYS				
21531875100320	Iclusig	Ponatinib HCl Tab	15 MG	30	Tablets	30	DAYS				
21531875100330	Iclusig	Ponatinib HCl Tab	30 MG	30	Tablets	30	DAYS				
21531875100340	Iclusig	Ponatinib HCl Tab	45 MG	30	Tablets	30	DAYS				
21535030200340	Idhifa	Enasidenib Mesylate Tab 100 MG (Base Equivalent)	100 MG	30	Tablets	30	DAYS				
21535030200320	Idhifa	Enasidenib Mesylate Tab 50 MG (Base Equivalent)	50 MG	30	Tablets	30	DAYS				
21532133000110	Imbruvica	Ibrutinib Cap	70 MG	30	Capsules	30	DAYS				
21532133000120	Imbruvica	Ibrutinib Cap	140 MG	90	Capsules	30	DAYS				

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
21532133001820	Imbruvica	Ibrutinib Oral Susp	70 MG/ML	2	Bottles	30	DAYS				
215321330003	Imbruvica	ibrutinib tab	140 MG; 280 MG; 420 MG; 560 MG	30	Tablets	30	DAYS				
21335013000320	Inlyta	Axitinib Tab	1 MG	180	Tablets	30	DAYS				
21335013000340	Inlyta	Axitinib Tab	5 MG	120	Tablets	30	DAYS				
219900022503	Inqovi	decitabine-cedazuridine tab	35-100 MG	5	Tablets	28	DAYS				
21537520200120	Inrebic	Fedratinib HCl Cap 100 MG	100 MG	120	Capsules	30	DAYS				
213600300003	Iressa	gefitinib tab	250 MG	30	Tablets	30	DAYS				
21757220300320	Iwilfin	eflornithine hcl tab	192 MG	240	Tablets	30	DAYS				
215375602003	Jakafi	ruxolitinib phosphate tab	10 MG; 15 MG; 20 MG; 25 MG; 5 MG	60	Tablets	30	DAYS				
21532165000320	Jaypirca	pirtobrutinib tab	50 MG	30	Tablets	30	DAYS				
21532165000330	Jaypirca	pirtobrutinib tab	100 MG	60	Tablets	30	DAYS				
2153107050B720	Kisqali	Ribociclib Succinate Tab Pack 200 MG Daily Dose	200 MG	21	Tablets	28	DAYS				
2153107050B740	Kisqali	Ribociclib Succinate Tab Pack 400 MG Daily Dose (200 MG Tab)	200 MG	42	Tablets	28	DAYS				
2153107050B760	Kisqali	Ribociclib Succinate Tab Pack 600 MG Daily Dose (200 MG Tab)	200 MG	63	Tablets	28	DAYS				
2199000260B730	Kisqali femara 200 dose	Ribociclib 200 MG Dose (200 MG Tab) & Letrozole 2.5 MG TBPK	200 & 2.5 MG	49	Tablets	28	DAYS				
2199000260B740	Kisqali femara 400 dose	Ribociclib 400 MG Dose (200 MG Tab) & Letrozole 2.5 MG TBPK	200 & 2.5 MG	70	Tablets	28	DAYS				
2199000260B760	Kisqali femara 600 dose	Ribociclib 600 MG Dose (200 MG Tab) & Letrozole 2.5 MG TBPK	200 & 2.5 MG	91	Tablets	28	DAYS				
21533565500110	Koselugo	Selumetinib Sulfate Cap 10 MG	10 MG	240	Capsules	30	DAYS				
21533565500125	Koselugo	Selumetinib Sulfate Cap 25 MG	25 MG	120	Capsules	30	DAYS				
21532410000320	Krazati	Adagrasib Tab	200 MG	180	Tablets	30	DAYS				

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
2133505420B220	Lenvima 10 mg daily dose	Lenvatinib Cap Therapy Pack	10 MG	30	Capsules	30	DAYS				
2133505420B223	Lenvima 12mg daily dose	Lenvatinib Cap Therapy Pack	4 MG	90	Capsules	30	DAYS				
2133505420B240	Lenvima 14 mg daily dose	Lenvatinib Cap Therapy Pack	10 & 4 MG	60	Capsules	30	DAYS				
2133505420B244	Lenvima 18 mg daily dose	Lenvatinib Cap Ther Pack	10 MG & 2 x 4 MG	90	Capsules	30	DAYS				
2133505420B230	Lenvima 20 mg daily dose	Lenvatinib Cap Therapy Pack	10 MG	60	Capsules	30	DAYS				
2133505420B250	Lenvima 24 mg daily dose	Lenvatinib Cap Ther Pack	2 x 10 MG & 4 MG	90	Capsules	30	DAYS				
2133505420B210	Lenvima 4 mg daily dose	Lenvatinib Cap Therapy Pack	4 MG	30	Capsules	30	DAYS				
2133505420B215	Lenvima 8 mg daily dose	Lenvatinib Cap Therapy Pack	4 MG	60	Capsules	30	DAYS				
21990002750320	Lonsurf	Trifluridine-Tipiracil Tab 15-6.14 MG	15-6.14 MG	60	Tablets	28	DAYS				
21990002750330	Lonsurf	Trifluridine-Tipiracil Tab 20-8.19 MG	20-8.19 MG	80	Tablets	28	DAYS				
21530556000320	Lorbrena	Lorlatinib Tab	25 MG	90	Tablets	30	DAYS				
21530556000330	Lorbrena	Lorlatinib Tab	100 MG	30	Tablets	30	DAYS				
21532480000340	Lumakras	sotorasib tab	320 MG	90	Tablets	30	DAYS				
21532480000320	Lumakras	Sotorasib Tab	120 MG	240	Tablets	30	DAYS				
215355600003	Lynparza	olaparib tab	100 MG; 150 MG	120	Tablets	30	DAYS				
2153222800B720	Lytgobi	Futibatinib Tab Therapy Pack	4 MG	84	Tablets	28	DAYS				
2153222800B725	Lytgobi	Futibatinib Tab Therapy Pack	4 MG	112	Tablets	28	DAYS				
2153222800B730	Lytgobi	Futibatinib Tab Therapy Pack	4 MG	140	Tablets	28	DAYS				
21533570102120	Mekinist	trametinib dimethyl sulfoxide for soln	0.05 MG/ML	1170	mLs	28	DAYS				
21533570100310	Mekinist	Trametinib Dimethyl Sulfoxide Tab 0.5 MG (Base Equivalent)	0.5 MG	90	Tablets	30	DAYS				
21533570100330	Mekinist	Trametinib Dimethyl Sulfoxide Tab 2 MG (Base Equivalent)	2 MG	30	Tablets	30	DAYS				
215335200003	Mektovi	binimetinib tab	15 MG	180	Tablets	30	DAYS				
21533035100320	Nerlynx	Neratinib Maleate Tab	40 MG	180	Tablets	30	DAYS				
21533060400320	Nexavar	Sorafenib Tosylate Tab 200 MG (Base Equivalent)	200 MG	120	Tablets	30	DAYS				

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
215360451001	Ninlaro	ixazomib citrate cap	2.3 MG; 3 MG; 4 MG	3	Capsules	28	DAYS				
21402425000320	Nubeqa	Darolutamide Tab 300 MG	300 MG	120	Tablets	30	DAYS				
213700602001	Odomzo	sonidegib phosphate cap	200 MG	30	Capsules	30	DAYS				
21532350200320	Ogsiveo	nirogacestat hydrobromide tab	50 MG	180	Tablets	30	DAYS				
21537540300320	Ojjaara	momelotinib dihydrochloride tab	100 MG	30	Tablets	30	DAYS				
21537540300330	Ojjaara	momelotinib dihydrochloride tab	150 MG	30	Tablets	30	DAYS				
21537540300340	Ojjaara	momelotinib dihydrochloride tab	200 MG	30	Tablets	30	DAYS				
213000030003	Onureg	azacitidine tab	200 MG; 300 MG	14	Tablets	28	DAYS				
214055700003	Orgovyx	relugolix tab	120 MG	30	Tablets	30	DAYS				
21403720100320	Orserdu	elacestrant hydrochloride tab	86 MG	90	Tablets	30	DAYS				
21403720100340	Orserdu	elacestrant hydrochloride tab	345 MG	30	Tablets	30	DAYS				
21532260000340	Pemazyre	Pemigatinib Tab 13.5 MG	13.5 MG	14	Tablets	21	DAYS				
21532260000320	Pemazyre	Pemigatinib Tab 4.5 MG	4.5 MG	14	Tablets	21	DAYS				
21532260000330	Pemazyre	Pemigatinib Tab 9 MG	9 MG	14	Tablets	21	DAYS				
2153801000B720	Piqray 200mg daily dose	Alpelisib Tab Therapy Pack 200 MG Daily Dose	200 MG	28	Tablets	28	DAYS				
2153801000B725	Piqray 250mg daily dose	Alpelisib Tab Pack 250 MG Daily Dose (200 MG & 50 MG Tabs)	200 & 50 MG	56	Tablets	28	DAYS				
2153801000B730	Piqray 300mg daily dose	Alpelisib Tab Pack 300 MG Daily Dose (2x150 MG Tab)	150 MG	56	Tablets	28	DAYS				
214500800001	Pomalyst	pomalidomide cap	1 MG; 2 MG; 3 MG; 4 MG	21	Capsules	28	DAYS				
21533053000320	Qinlock	Ripretinib Tab	50 MG	90	Tablets	30	DAYS				
21535779000120	Retevmo	Selpercatinib Cap	40 MG	180	Capsules	30	DAYS				
21535779000140	Retevmo	Selpercatinib Cap	80 MG	120	Capsules	30	DAYS				
99394050000130	Revlimid	Lenalidomide Cap 10 MG	10 MG	30	Capsules	30	DAYS				
99394050000140	Revlimid	Lenalidomide Cap 15 MG	15 MG	21	Capsules	28	DAYS				

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
99394050000145	Revlimid	Lenalidomide Cap 20 MG	20 MG	21	Capsules	28	DAYS				
99394050000150	Revlimid	Lenalidomide Cap 25 MG	25 MG	21	Capsules	28	DAYS				
99394050000120	Revlimid	Lenalidomide Cap 5 MG	5 MG	30	Capsules	30	DAYS				
99394050000110	Revlimid	Lenalidomide Caps 2.5 MG	2.5 MG	30	Capsules	30	DAYS				
21534960000120	Rezlidhia	Olutasidenib Cap	150 MG	60	Capsules	30	DAYS				
21533820000120	Rozlytrek	Entrectinib Cap 100 MG	100 MG	30	Capsules	30	DAYS				
21533820000130	Rozlytrek	Entrectinib Cap 200 MG	200 MG	90	Capsules	30	DAYS				
21533820003020	Rozlytrek	entrectinib pellet pack	50 MG	336	Packets	28	DAYS				
21535570200320	Rubraca	Rucaparib Camsylate Tab 200 MG (Base Equivalent)	200 MG	120	Tablets	30	DAYS				
21535570200325	Rubraca	Rucaparib Camsylate Tab 250 MG (Base Equivalent)	250 MG	120	Tablets	30	DAYS				
21535570200330	Rubraca	Rucaparib Camsylate Tab 300 MG (Base Equivalent)	300 MG	120	Tablets	30	DAYS				
21533030000130	Rydapt	Midostaurin Cap 25 MG	25 MG	240	Capsules	30	DAYS				
21531806100320	Scemblix	Asciminib HCl Tab	20 MG	60	Tablets	30	DAYS				
21531806100340	Scemblix	Asciminib HCl Tab	40 MG	300	Tablets	30	DAYS				
21531820000320	Sprycel	Dasatinib Tab	20 MG	90	Tablets	30	DAYS				
21531820000340	Sprycel	Dasatinib Tab	50 MG	30	Tablets	30	DAYS				
21531820000350	Sprycel	Dasatinib Tab	70 MG	30	Tablets	30	DAYS				
21531820000354	Sprycel	Dasatinib Tab	80 MG	30	Tablets	30	DAYS				
21531820000360	Sprycel	Dasatinib Tab	100 MG	30	Tablets	30	DAYS				
21531820000380	Sprycel	Dasatinib Tab	140 MG	30	Tablets	30	DAYS				
215330500003	Stivarga	regorafenib tab	40 MG	84	Tablets	28	DAYS				
21533070300120	Sutent	Sunitinib Malate Cap 12.5 MG (Base Equivalent)	12.5 MG	90	Capsules	30	DAYS				
21533070300130	Sutent	Sunitinib Malate Cap 25 MG (Base Equivalent)	25 MG	30	Capsules	30	DAYS				
21533070300135	Sutent	Sunitinib Malate Cap 37.5 MG (Base Equivalent)	37.5 MG	30	Capsules	30	DAYS				
21533070300140	Sutent	Sunitinib Malate Cap 50 MG (Base Equivalent)	50 MG	30	Capsules	30	DAYS				

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

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
2153223540B225	Truseltiq	Infigratinib Phos Cap Ther Pack	25 MG	63	Capsules	28	DAYS				
2153223540B230	Truseltiq	Infigratinib Phos Cap Ther Pack	100 MG	21	Capsules	28	DAYS				
21170080000320	Tukysa	Tucatinib Tab	50 MG	300	Tablets	30	DAYS				
21170080000340	Tukysa	Tucatinib Tab	150 MG	120	Tablets	30	DAYS				
21533045010110	Turalio	Pexidartinib HCl Cap	125 MG	120	Capsules	30	DAYS				
21533045010120	Turalio	Pexidartinib HCl Cap	200 MG	120	Capsules	30	DAYS				
21533026100320	Tykerb	Lapatinib Ditosylate Tab	250 MG	180	Tablets	30	DAYS				
21533047100320	Vanflyta	quizartinib dihydrochloride tab	17.7 MG	28	Tablets	28	DAYS				
21533047100325	Vanflyta	quizartinib dihydrochloride tab	26.5 MG	56	Tablets	28	DAYS				
21470080000320	Venclexta	Venetoclax Tab 10 MG	10 MG	60	Tablets	30	DAYS				
21470080000360	Venclexta	Venetoclax Tab 100 MG	100 MG	180	Tablets	30	DAYS				
21470080000340	Venclexta	Venetoclax Tab 50 MG	50 MG	30	Tablets	30	DAYS				
2147008000B720	Venclexta starting pack	Venetoclax Tab Therapy Starter Pack 10 & 50 & 100 MG	10 & 50 & 100 MG	1	Pack	180	DAYS				
215310100003	Verzenio	abemaciclib tab	100 MG; 150 MG; 200 MG; 50 MG	60	Tablets	30	DAYS				
21533835200150	Vitrakvi	Larotrectinib Sulfate Cap 100 MG (Base Equivalent)	100 MG	60	Capsules	30	DAYS				
21533835200120	Vitrakvi	Larotrectinib Sulfate Cap 25 MG (Base Equivalent)	25 MG	180	Capsules	30	DAYS				
21533835202020	Vitrakvi	Larotrectinib Sulfate Oral Soln 20 MG/ML (Base Equivalent)	20 MG/ML	300	mLs	30	DAYS				
213600190003	Vizimpro	dacomitinib tab	15 MG; 30 MG; 45 MG	30	Tablets	30	DAYS				
215375501001	Vonjo	pacritinib citrate cap	100 MG	120	Capsules	30	DAYS				
21533042100320	Votrient	Pazopanib HCl Tab	200 MG	120	Tablets	30	DAYS				
21421020000320	Welireg	Belzutifan Tab	40 MG	90	Tablets	30	DAYS				
215305170001	Xalkori	crizotinib cap	200 MG; 250 MG	120	Capsules	30	DAYS				
21530517006820	Xalkori	crizotinib cap sprinkle	20 MG	120	Capsules	30	DAYS				
21530517006830	Xalkori	crizotinib cap sprinkle	50 MG	120	Capsules	30	DAYS				
21530517006850	Xalkori	crizotinib cap sprinkle	150 MG	180	Capsules	30	DAYS				

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
21533020200320	Xospata	Gilteritinib Fumarate Tablet	40 MG	90	Tablets	30	DAYS				
2156006000B760	Xpovio	Selinexor Tab Therapy Pack	40 MG	4	Tablets	28	DAYS				
2156006000B765	Xpovio	Selinexor Tab Therapy Pack	40 MG	8	Tablets	28	DAYS				
2156006000B770	Xpovio	Selinexor Tab Therapy Pack	40 MG	8	Tablets	28	DAYS				
2156006000B775	Xpovio	Selinexor Tab Therapy Pack	50 MG	8	Tablets	28	DAYS				
2156006000B780	Xpovio	Selinexor Tab Therapy Pack	60 MG	4	Tablets	28	DAYS				
2156006000B755	Xpovio 60 mg twice weekly	Selinexor Tab Therapy Pack 20 MG (60 MG Twice Weekly)	20 MG	24	Tablets	28	DAYS				
2156006000B720	Xpovio 80 mg twice weekly	Selinexor Tab Therapy Pack 20 MG (80 MG Twice Weekly)	20 MG	32	Tablets	28	DAYS				
214024300001	Xtandi	enzalutamide cap	40 MG	120	Capsules	30	DAYS				
21402430000320	Xtandi	Enzalutamide Tab	40 MG	120	Tablets	30	DAYS				
21402430000340	Xtandi	Enzalutamide Tab	80 MG	60	Tablets	30	DAYS				
21406010250310	Yonsa	abiraterone acetate tab 125 mg	125 MG	120	Tablets	30	DAYS				
215355502001	Zejula	niraparib tosylate cap	100 MG	90	Capsules	30	DAYS				
21535550200320	Zejula	niraparib tosylate tab	100 MG	30	Tablets	30	DAYS				
21535550200330	Zejula	niraparib tosylate tab	200 MG	30	Tablets	30	DAYS				
21535550200340	Zejula	niraparib tosylate tab	300 MG	30	Tablets	30	DAYS				
21532080000320	Zelboraf	Vemurafenib Tab 240 MG	240 MG	240	Tablets	30	DAYS				
21531575000120	Zolinza	Vorinostat Cap 100 MG	100 MG	120	Capsules	30	DAYS				
215380400003	Zydelig	idelalisib tab	100 MG; 150 MG	60	Tablets	30	DAYS				
215305140003	Zykadia	ceritinib tab	150 MG	90	Tablets	30	DAYS				
21406010200320	Zytiga	Abiraterone Acetate Tab 250 MG	250 MG	120	Tablets	30	DAYS				
21406010200330	Zytiga	Abiraterone Acetate Tab 500 MG	500 MG	60	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA QL	**Initial Evaluation** **Target Agent(s)** will be approved when ONE of the following are met: 1. ALL of the following: A. ONE of the following:

Module	Clinical Criteria for Approval
	1. Information has been provided that indicates the patient is currently being treated with the requested agent within the past 180 days **OR** 2. The prescriber states the patient is being treated with the requested agent within the past 180 days AND is at risk if therapy is changed **OR** 3. ALL of the following: A. ONE of the following: 1. The patient has an FDA approved indication for the requested agent **OR** 2. The patient has an indication that is supported by NCCN 1, 2A, or 2B recommended use, AHFS, DrugDex level of evidence of 1, IIa, or IIb, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) [i.e., this indication must be supported by ALL requirements in the compendia (e.g., performance status, disease severity, previous failures, monotherapy vs combination therapy, etc.)] for the requested agent **AND** B. If the patient has an FDA approved 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. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** C. ONE of the following: 1. The requested indication does NOT require genetic/specific diagnostic testing per FDA labeling or compendia (NCCN 1, 2A, or 2B recommended use, AHFS, DrugDex level of evidence of 1, IIa, or IIb, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested agent **OR** 2. The requested indication requires genetic/specific diagnostic testing per FDA labeling or compendia (NCCN 1, 2A, or 2B recommended use, AHFS, DrugDex level of evidence of 1, IIa, or IIb, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested agent AND BOTH of the following: A. Genetic/specific diagnostic testing has been completed **AND** B. The results of the genetic/specific diagnostic testing indicate therapy with the requested agent is appropriate **AND** D. ONE of the following: 1. The requested agent is being used as monotherapy and is approved for use as monotherapy in the FDA labeling or compendia (NCCN 1, 2A, or 2B recommended use, AHFS, DrugDex level of evidence of 1, IIa, or IIb, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested indication **OR** 2. The requested agent will be used as combination therapy with all agent(s) and/or treatments (e.g., radiation) listed for concomitant use in the FDA labeling or compendia (NCCN 1, 2A, or 2B recommended use, AHFS, DrugDex level of evidence of 1, IIa, or IIb, Wolters Kluwer Lexi-Drugs

Module	Clinical Criteria for Approval
	level of evidence A, Clinical Pharmacology) for the requested indication **AND** E. ONE of the following: 1. The requested agent will be used as a first-line agent and is FDA labeled or compendia (NCCN 1, 2A, or 2B recommended use, AHFS, DrugDex level of evidence of 1, IIa, or IIb, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) as a first-line agent for the requested indication **OR** 2. The patient has tried and had an inadequate response to the appropriate number and type(s) of prerequisite agent(s) listed in the FDA labeling or compendia (NCCN 1, 2A, or 2B recommended use, AHFS, DrugDex level of evidence of 1, IIa, or IIb, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested indication **OR** 3. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to the appropriate number and type(s) of prerequisite agent(s) listed in the FDA labeling or compendia (NCCN 1, 2A, or 2B recommended use, AHFS, DrugDex level of evidence of 1, IIa, or IIb, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested indication **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that the appropriate prerequisite agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. The patient does not have any FDA labeled contraindications to the requested agent **AND** C. The patient does not have any FDA labeled limitation(s) of use that is otherwise not supported in NCCN to the requested agent **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Length of Approval:** Up to 3 months for dose titration requests over the program quantity limit and Vitrakvi; Up to 12 months for all other requests, approve starter packs and loading doses where appropriate and maintenance dose for the remainder of the authorization NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

Module	Clinical Criteria for Approval
	Renewal Evaluation **Target Agent(s)** will be approved when BOTH of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. ONE of the following: A. ALL of the following: 1. ONE of the following: A. The requested agent is Vitrakvi AND the patient has experienced clinical benefit (i.e., partial response, complete response, or stable disease) with the requested agent **OR** B. The requested agent is NOT Vitrakvi **AND** 2. The patient does not have any FDA labeled contraindications to the requested agent **AND** 3. The patient does not have any FDA labeled limitation(s) of use that is otherwise not supported in NCCN to the requested agent **OR** B. If the request is for an oral liquid form of a medication, then BOTH of the following: 1. The patient has an FDA approved indication **AND** 2. The patient uses an enteral tube for feeding or medication administration Length of Approval: Up to 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. FDA Companion Diagnostics: https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: Up to 3 months for dose titration requests over the program quantity limit and Vitrakvi; Up to 12 months for all other requests, approve starter packs/loading doses where appropriate and maintenance doses for the remainder of the authorization

● Program Summary: Transmucosal Immediate Release Fentanyl (TIRF)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
65100025108475	Actiq	Fentanyl Citrate Lozenge on a Handle 1200 MCG	1200 MCG	120	Lozenges	30	DAYS				
65100025108485	Actiq	Fentanyl Citrate Lozenge on a Handle 1600 MCG	1600 MCG	120	Lozenges	30	DAYS				
65100025108450	Actiq	Fentanyl Citrate Lozenge on a Handle 200 MCG	200 MCG	120	Lozenges	30	DAYS				
65100025108455	Actiq	Fentanyl Citrate Lozenge on a Handle 400 MCG	400 MCG	120	Lozenges	30	DAYS				
65100025108460	Actiq	Fentanyl Citrate Lozenge on a Handle 600 MCG	600 MCG	120	Lozenges	30	DAYS				
65100025108465	Actiq	Fentanyl Citrate Lozenge on a Handle 800 MCG	800 MCG	120	Lozenges	30	DAYS				
65100025100310	Fentora	Fentanyl Citrate Buccal Tab 100 MCG (Base Equiv)	100 MCG	120	Tablets	30	DAYS				
65100025100320	Fentora	Fentanyl Citrate Buccal Tab 200 MCG (Base Equiv)	200 MCG	120	Tablets	30	DAYS				
65100025100330	Fentora	Fentanyl Citrate Buccal Tab 400 MCG (Base Equiv)	400 MCG	120	Tablets	30	DAYS				
65100025100340	Fentora	Fentanyl Citrate Buccal Tab 600 MCG (Base Equiv)	600 MCG	120	Tablets	30	DAYS				
65100025100350	Fentora	Fentanyl Citrate Buccal Tab 800 MCG (Base Equiv)	800 MCG	120	Tablets	30	DAYS				
65100025102050	Lazanda	Fentanyl Citrate Nasal Spray 100 MCG/ACT (Base Equiv)	100 MCG/ACT	30	Bottles	30	DAYS				
65100025102060	Lazanda	Fentanyl Citrate Nasal Spray 400 MCG/ACT (Base Equiv)	400 MCG/ACT	30	Bottles	30	DAYS				
65100025000910	Subsys	Fentanyl Sublingual Spray 100 MCG	100 MCG	120	Sprays	30	DAYS				
65100025000960	Subsys	Fentanyl Sublingual Spray 1200 MCG (600 MCG X 2)	1200 MCG	240	Sprays	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
65100025000970	Subsys	Fentanyl Sublingual Spray 1600 MCG (800 MCG X 2)	1600 MCG	240	Sprays	30	DAYS				
65100025000920	Subsys	Fentanyl Sublingual Spray 200 MCG	200 MCG	120	Sprays	30	DAYS				
65100025000930	Subsys	Fentanyl Sublingual Spray 400 MCG	400 MCG	120	Sprays	30	DAYS				
65100025000940	Subsys	Fentanyl Sublingual Spray 600 MCG	600 MCG	120	Sprays	30	DAYS				
65100025000950	Subsys	Fentanyl Sublingual Spray 800 MCG	800 MCG	120	Sprays	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of chronic cancer pain due to active malignancy **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 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 is currently opioid tolerant (taking, for one week or longer, around-the-clock medicine consisting of at least 60 mg of oral morphine per day, at least 25 mcg per hour of transdermal fentanyl, at least 30 mg of oral oxycodone per day, at least 8 mg of oral hydromorphone per day, at least 25 mg oral oxymorphone per day, at least 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid daily) **AND** 4. The patient is taking a long-acting opioid concurrently with the requested TIRF agent **AND** 5. The patient will NOT be using the requested agent with any other TIRF agent in any other strength **AND** 6. ONE of the following: A. The request is for a generic TIRF agent **OR** B. The request is for a brand TIRF agent AND ONE of the following: 1. The patient's medication history includes use of at least ONE generic TIRF agent **OR** 2. Information has been provided that indicates the patient is currently being treated with the requested agent within the past 90 days **OR** 3. The prescriber states the patient is currently being treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR** 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 patient has an intolerance or hypersensitivity to at least ONE generic TIRF agent that is not expected to occur with the requested agent **OR** 6. The patient has an FDA labeled contraindication to ALL generic TIRF agents that is not expected to occur with the requested agent **OR**

Module	Clinical Criteria for Approval
	7. The prescriber has provided documentation that ALL generic TIRF 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** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Opioid MME conversion factors:** https://www.cdc.gov/drugoverdose/prescribing/guideline.html **Length of Approval:** 1 month for increased dose requests during a dose titration period Up to 6 months for all other requests

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Through Generic	**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. ALL of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose **AND** 2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **AND** 3. Episodes of breakthrough pain cannot be controlled by modifying the dose of the maintenance long-acting opioid used for underlying persistent pain **AND** 4. The prescriber has provided information in support of therapy with a higher quantity (dose) **OR** B. ALL of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose **AND** 2. Episodes of breakthrough pain cannot be controlled by modifying the dose of the maintenance long-acting opioid used for underlying persistent pain **AND** 3. The prescriber has provided information in support of therapy with a higher quantity (dose) **Length of Approval:** 1 month for increased dose requests during a dose titration period Up to 6 months for all other requests

● Program Summary: Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
62380030000330	Austedo	Deutetrabenazine Tab 12 MG	12 MG	120	Tablets	30	DAYS				
62380030000310	Austedo	Deutetrabenazine Tab 6 MG	6 MG	60	Tablets	30	DAYS				
62380030000320	Austedo	Deutetrabenazine Tab 9 MG	9 MG	120	Tablets	30	DAYS				
62380030007510	Austedo xr	deutetrabenazine tab er	6 MG	30	Tablets	30	DAYS				
62380030007520	Austedo xr	deutetrabenazine tab er	12 MG	30	Tablets	30	DAYS				
62380030007530	Austedo xr	deutetrabenazine tab er	24 MG	60	Tablets	30	DAYS				
6238003000C120	Austedo xr patient titrat	deutetrabenazine tab er titration pack	6 & 12 & 24 MG	42	Tablets	180	DAYS				
62380080200130	Ingrezza	Valbenazine Tosylate Cap	60 MG	30	Capsules	30	DAYS				
62380080200120	Ingrezza	Valbenazine Tosylate Cap 40 MG (Base Equiv)	40 MG	30	Capsules	30	DAYS				
62380080200140	Ingrezza	Valbenazine Tosylate Cap 80 MG (Base Equiv)	80 MG	30	Capsules	30	DAYS				
6238008020B220	Ingrezza	Valbenazine Tosylate Cap Therapy Pack 40 MG (7) & 80 MG (21)	40 & 80 MG	28	Capsules	180	DAYS				
62380070000310	Xenazine	Tetrabenazine Tab 12.5 MG	12.5 MG	240	Tablets	30	DAYS				
62380070000320	Xenazine	Tetrabenazine Tab 25 MG	25 MG	120	Tablets	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 Austedo/deutetrabenazine, Austedo XR/deutetrabenazine ER, or Ingrezza/valbenazine AND ONE of the following: 1. The patient has a diagnosis of tardive dyskinesia AND BOTH of the following: A. ONE of the following: 1. The prescriber has reduced the dose or discontinued any medications known to cause tardive dyskinesia (i.e., dopamine receptor blocking agents) **OR** 2. The prescriber has provided clinical rationale indicating that a reduced dose or discontinuation of any medications known to cause tardive dyskinesia is not appropriate **AND** B. The prescriber has documented the patient's baseline Abnormal Involuntary Movement Scale (AIMS) score **OR**

Module	Clinical Criteria for Approval

2. The patient has a diagnosis of chorea associated with Huntington's disease **OR**
3. The patient has another FDA approved indication for the requested agent **OR**
4. The patient has another indication that is supported in compendia for the requested agent **OR**

B. The requested agent is Xenazine/tetrabenazine and ONE of the following:
1. The patient has a diagnosis of chorea associated with Huntington's disease **OR**
2. The patient has another FDA approved indication for the requested agent **OR**
3. The patient has another indication that is supported in compendia for the requested agent **AND**

2. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following:
   A. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**
   B. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR**
   C. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent **OR**

Brand	Generic Equivalent
Xenazine	tetrabenazine

   D. BOTH of the following:
      1. The prescriber has stated that the patient has tried the generic equivalent **AND**
      2. ONE of the following:
         A. The generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**
         B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the 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**
3. If the patient has an FDA labeled indication ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
   B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**
4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., psychiatrist, neurologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
5. The patient will NOT be using the requested agent in combination with another agent included in this Prior Authorization program **AND**
6. The patient does NOT have any FDA labeled contraindications to the requested agent

Compendia Allowed: CMS Approved Compendia

Module	Clinical Criteria for Approval

Length of Approval: Tardive dyskinesia - 3 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 previously approved for the requested agent through the plan's Prior Authorization process **AND**
2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., psychiatrist, neurologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
3. ONE of the following:
    A. The patient has a diagnosis of tardive dyskinesia AND has had improvements or stabilization from baseline in their Abnormal Involuntary Movement Scale (AIMS) score **OR**
    B. The patient has a diagnosis is other than tardive dyskinesia AND the patient has had clinical benefit with the requested agent **AND**
4. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following:
    A. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**
    B. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR**
    C. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent **OR**

Brand	Generic Equivalent
Xenazine	tetrabenazine

    D. BOTH of the following:
        1. The prescriber has stated that the patient has tried the generic equivalent **AND**
        2. ONE of the following:
            A. The generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**
            B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the 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**
5. The patient will NOT be using the requested agent in combination with another agent included in this Prior Authorization program **AND**
6. The patient does NOT have any FDA labeled contraindications to the requested agent

Compendia Allowed: CMS Approved Compendia

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

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Xhance

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
4220003230G720	Xhance	Fluticasone Propionate Nasal Exhaler Susp 93 MCG/ACT	93 MCG/ACT	2	Bottles	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. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **OR** B. BOTH of the following:

Module	Clinical Criteria for Approval
	1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months