MHCP PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: January 1, 2024 Notification Posted: December 17, 2023

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

• Program Summary: Miebo (perfluorohexyloctane)

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	Effective Date	Term Date
86807018002020	Miebo	perfluorohexyloctane ophth soln	1.338 GM/ML	4	Bottles	30	DAYS		08-17-2023	

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**

Module	Clinical Criteria for Approval
	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: Vowst (fecal microbiota spores, live-brpk)

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	Effective Date	Term Date
52522020100120	Vowst	fecal microbiota spores, live-brpk caps		12	Capsules	12	MONTHS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Target Agent(s) will be approved when ALL of the following are met: 1. The requested agent will be used to prevent the recurrence of Clostridioides difficile infection (CDI) **AND** 2. The patient has a diagnosis of recurrent CDI as defined by ALL of the following: A. Greater than or equal to 3 episodes of CDI in a 12 month period **AND** B. A positive C. difficile stool sample **AND** C. A CDI episode of diarrhea greater than or equal to 3 unformed stools per day for at least 2 consecutive days **AND** 3. The patient has completed a standard of care oral antibiotic regimen (e.g., vancomycin, fidaxomicin) for recurrent CDI at least 2 to 4 days before initiating treatment with the requested agent **AND** 4. The patient has had an adequate clinical response to a standard of care oral antibiotic regimen (e.g., vancomycin, fidaxomicin) as defined by less than 3 unformed stools in 24 hours for 2 or more consecutive days **AND** 5. The patient will NOT be using the requested agent in combination with any antibiotic regimen for any indication **AND** 6. 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** 7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., infectious disease, gastroenterologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 8. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** One course per 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 the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **Length of Approval:** One course every 12 months

POLICIES REVISED

• Program Summary: Antidepressant

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
58300040100310		Bupropion HCl Tab 100 MG	100 MG	120	Tablets	30	DAYS			
58300040100305		Bupropion HCl Tab 75 MG	75 MG	60	Tablets	30	DAYS			
58160020100120		Citalopram Hydrobromide Cap	30 MG	30	Capsules	30	DAYS			
581600201020		citalopram hydrobromide oral soln	10 MG/5ML	600	mLs	30	DAYS			
581800200075		desvenlafaxine tab er	100 MG; 50 MG	30	Tablets	30	DAYS			
58180025106740		Duloxetine HCl Enteric Coated Pellets Cap 40 MG (Base Eq)	40 MG	90	Capsules	30	DAYS			
581600341020		escitalopram oxalate soln	5 MG/5ML	600	mLs	30	DAYS			
58160040006530		Fluoxetine HCl Cap Delayed Release 90 MG	90 MG	4	Capsules	28	DAYS			
58160040002020		Fluoxetine HCl Solution 20 MG/5ML	20 MG/5ML	600	mLs	30	DAYS			
58160040000310		Fluoxetine HCl Tab 10 MG	10 MG	30	Tablets	30	DAYS			
58160040000320		Fluoxetine HCl Tab 20 MG	20 MG	120	Tablets	30	DAYS			
58160040000360		Fluoxetine HCl Tab 60 MG	60 MG	30	Tablets	30	DAYS			
581600451070		fluvoxamine maleate cap er	100 MG; 150 MG	60	Capsules	30	DAYS			
58160045100330		Fluvoxamine Maleate Tab 100 MG	100 MG	90	Tablets	30	DAYS			
58160045100310		Fluvoxamine Maleate Tab 25 MG	25 MG	30	Tablets	30	DAYS			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
58160045100320		Fluvoxamine Maleate Tab 50 MG	50 MG	30	Tablets	30	DAYS			
583000101003		Maprotiline HCl Tab 25 MG, 50 MG, 75 MG	25 MG; 50 MG; 75 mg	90	Tablets	30	DAYS			
58160070100130		Sertraline HCl Cap	150 MG	30	Capsules	30	DAYS			
58160070100140		Sertraline HCl Cap	200 MG	30	Capsules	30	DAYS			
58180090057520		Venlafaxine Besylate Tab ER	112.5 MG	30	Tablets	30	DAYS			
581800901003		venlafaxine hcl tab	100 MG; 25 MG; 37.5 MG; 50 MG; 75 MG	90	Tablets	30	DAYS			
58180090107530		Venlafaxine HCl Tab ER 24HR 150 MG (Base Equivalent)	150; 150 MG	30	Tablets	30	DAYS			
58180090107540		Venlafaxine HCl Tab ER 24HR 225 MG (Base Equivalent)	225; 225 MG	30	Tablets	30	DAYS			
58180090107510		Venlafaxine HCl Tab ER 24HR 37.5 MG (Base Equivalent)	37.5; 37.5 MG	30	Tablets	30	DAYS			
58180090107520		Venlafaxine HCl Tab ER 24HR 75 MG (Base Equivalent)	75; 75 MG	90	Tablets	30	DAYS			
583000402075	Aplenzin	bupropion hbr tab er	174 MG; 348 MG; 522 MG	30	Tablets	30	DAYS			
58999902300420	Auvelity	Dextromethorphan HBr-Bupropion HCl Tab ER	45-105 MG	60	Tablets	30	DAYS			
583000401074	Budeprion sr ; Wellbutrin sr	Bupropion HCl Tab ER ; bupropion hcl tab er	100 MG; 150 MG; 200 MG	60	Tablets	30	DAYS			
581600201003	Celexa	citalopram hydrobromide tab	10 MG; 20 MG; 40 MG	30	Tablets	30	DAYS			
58180025106720	Cymbalta	Duloxetine HCl Enteric Coated Pellets Cap 20 MG (Base Eq)	20 MG	60	Capsules	30	DAYS			
58180025106730	Cymbalta	Duloxetine HCl Enteric Coated Pellets Cap 30 MG (Base Eq)	30 MG	60	Capsules	30	DAYS			
58180025106750	Cymbalta	Duloxetine HCl Enteric Coated Pellets Cap 60 MG (Base Eq)	60 MG	60	Capsules	30	DAYS			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
5818002510H120	Drizalma sprinkle	Duloxetine HCl Cap Delayed Release Sprinkle 20 MG (Base Eq)	20 MG	60	Capsules	30	DAYS			
5818002510H130	Drizalma sprinkle	Duloxetine HCl Cap Delayed Release Sprinkle 30 MG (Base Eq)	30 MG	60	Capsules	30	DAYS			
5818002510H140	Drizalma sprinkle	Duloxetine HCl Cap Delayed Release Sprinkle 40 MG (Base Eq)	40 MG	60	Capsules	30	DAYS			
5818002510H160	Drizalma sprinkle	Duloxetine HCl Cap Delayed Release Sprinkle 60 MG (Base Eq)	60 MG	60	Capsules	30	DAYS			
58180090107050	Effexor xr	Venlafaxine HCl Cap ER 24HR 150 MG (Base Equivalent)	150 MG	30	Capsules	30	DAYS			
58180090107020	Effexor xr	Venlafaxine HCl Cap ER 24HR 37.5 MG (Base Equivalent)	37.5 MG	30	Capsules	30	DAYS			
58180090107030	Effexor xr	Venlafaxine HCl Cap ER 24HR 75 MG (Base Equivalent)	75 MG	90	Capsules	30	DAYS			
581800501070	Fetzima	levomilnacipran hcl cap er	120 MG; 20 MG; 40 MG; 80 MG	30	Capsules	30	DAYS			
5818005010B6	Fetzima titration pack	levomilnacipran hcl cap er	20 & 40 MG	28	Capsules	180	DAYS			
583000401075	Forfivo xl ; Wellbutrin xl	bupropion hcl tab er	150 MG; 300 MG; 450 MG	30	Tablets	30	DAYS			
581600341003	Lexapro	escitalopram oxalate tab	10; 10 MG; 20 MG; 5 MG	30	Tablets	30	DAYS			
581600600018	Paxil	paroxetine hcl oral susp	10 MG/5ML	900	mLs	30	DAYS			
58160060000310	Paxil	Paroxetine HCl Tab 10 MG	10 MG	30	Tablets	30	DAYS			
58160060000320	Paxil	Paroxetine HCl Tab 20 MG	20 MG	30	Tablets	30	DAYS			
58160060000330	Paxil	Paroxetine HCl Tab 30 MG	30 MG	60	Tablets	30	DAYS			
58160060000340	Paxil	Paroxetine HCl Tab 40 MG	40 MG	30	Tablets	30	DAYS			
58160060007520	Paxil cr	Paroxetine HCl Tab ER 24HR 12.5 MG	12.5 MG	30	Tablets	30	DAYS			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
58160060007530	Paxil cr	Paroxetine HCl Tab ER 24HR 25 MG	25 MG	60	Tablets	30	DAYS			
58160060007540	Paxil cr	Paroxetine HCl Tab ER 24HR 37.5 MG	37.5 MG	60	Tablets	30	DAYS			
58160060300310	Pexeva	Paroxetine Mesylate Tab 10 MG (Base Equiv)	10 MG	30	Tablets	30	DAYS			
58160060300320	Pexeva	Paroxetine Mesylate Tab 20 MG (Base Equiv)	20 MG	30	Tablets	30	DAYS			
58160060300330	Pexeva	Paroxetine Mesylate Tab 30 MG (Base Equiv)	30 MG	60	Tablets	30	DAYS			
58160060300340	Pexeva	Paroxetine Mesylate Tab 40 MG (Base Equiv)	40 MG	30	Tablets	30	DAYS			
581800202075	Pristiq	desvenlafaxine succinate tab er	100 MG; 25 MG; 50 MG	30	Tablets	30	DAYS			
58160040000110	Prozac	Fluoxetine HCl Cap 10 MG	10 MG	30	Capsules	30	DAYS			
58160040000120	Prozac	Fluoxetine HCl Cap 20 MG	20 MG	120	Capsules	30	DAYS			
58160040000140	Prozac	Fluoxetine HCl Cap 40 MG	40 MG	60	Capsules	30	DAYS			
580300500003	Remeron	mirtazapine tab	15 MG; 30 MG; 45 MG; 7.5 MG	30	Tablets	30	DAYS			
580300500072	Remeron soltab	mirtazapine orally disintegrating tab	15 MG; 30 MG; 45 MG	30	Tablets	30	DAYS			
581200931003	Trintellix	vortioxetine hbr tab	10 MG; 20 MG; 5 MG	30	Tablets	30	DAYS			
581200881003	Viibryd	vilazodone hcl tab	10 MG; 20 MG; 40 MG	30	Tablets	30	DAYS			
581200881064	Viibryd starter pack	vilazodone hcl tab starter kit	10 & 20 MG	1	Kit	180	DAYS			
58120088106410	Viibryd starter pack	Vilazodone HCl Tab Starter Kit 10 (7) & 20 (23) MG	10 & 20 MG	1	Kit	180	DAYS			
58160070101320	Zoloft	Sertraline HCl Oral Concentrate for Solution 20 MG/ML	20 MG/ML	300	mLs	30	DAYS			
58160070100320	Zoloft	Sertraline HCl Tab 100 MG	100 MG	60	Tablets	30	DAYS			
58160070100305	Zoloft	Sertraline HCl Tab 25 MG	25 MG	30	Tablets	30	DAYS			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
58160070100310	Zoloft	Sertraline HCl Tab 50 MG	50 MG	30	Tablets	30	DAYS			

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does not have a maximum FDA labeled dose for the requested indication **AND** 2. 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: 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. The requested agent is an oral liquid for a patient that uses an enteral tube for feedings 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 Multi-Source Code (MSC) O drug, ONE of the following:

A. The patient has tried and had an inadequate response to at least one formulary alternative which is the MSC Y equivalent drug, if available

OR

B. The prescriber has provided information stating that the available formulary MSC Y alternative 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: Recorlev (levoketoconazole)

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	Effective Date	Term Date
30022040000320	Recorlev	Levoketoconazole Tab	150 MG	240	Tablets	30				

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 Cushing's syndrome **AND** 2. ONE of the following: A. The patient had an inadequate response to pituitary surgery **OR** B. The patient is NOT a candidate for pituitary surgery **AND** 3. The patient's disease is persistent or recurrent as evidenced by ONE of the following: A. The patient has a mean of three 24-hour urine free cortisol (UFC) greater than 1.5 times the upper limit of normal **OR** B. Morning plasma adrenocorticotropic hormone (ACTH) above the lower limit of normal **AND** 4. ONE of the following: A. The patient's medication history includes a conventional agent (i.e., Mifepristone, Signifor/Signifor LAR (pasireotide), Isturisa (osilodrostat), Cabergoline Metyrapone or Lysodren (mitotane) AND ONE of the following: 1. The patient has had an inadequate response to conventional agents **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over mifepristone, pasireotide AND osilodrostat **OR** B. The patient has an intolerance or hypersensitivity to mifepristone, pasireotide, or osilodrostat **OR** C. The patient has an FDA labeled contraindication to mifepristone, pasireotide AND osilodrostat **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that mifepristone, pasireotide AND osilodrostat 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. ONE of the following: A. The patient's medication history includes ketoconazole tablets AND ONE of the following: 1. The patient has had an inadequate response to ketoconazole tablets **OR**

Module	Clinical Criteria for Approval
	2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ketoconazole tablets **OR** B. The patient has an intolerance or hypersensitivity to ketoconazole tablets that is NOT expected to occur with the requested agent (medical records required) **OR** C. The patient has an FDA labeled contraindication to ketoconazole tablets that is NOT expected to occur with the requested agent (medical records required) **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ketoconazole tablets cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 6. 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** 7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 8. The patient will NOT be using the requested agent in combination with glucocorticoid replacement therapy **AND** 9. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria. **Renewal Evaluation** **Target Agent** 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., endocrinologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient will NOT be using the requested agent in combination with glucocorticoid replacement therapy **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for Requested 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 Renewal - 12 months

• Program Summary: Strensiq (asfotase alpha)

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

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	309056100020	Strensiq	asfotase alfa subcutaneous inj	18 MG/0.45ML; 28 MG/0.7ML; 40 MG/ML; 80 MG/0.8ML	M; N; O; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of either perinatal/infantile- OR juvenile-onset hypophosphatasia (HPP) AND ALL of the following: A. The patient was less than 18 years of age at onset **AND** B. The patient is experiencing active disease (e.g., bone pain, fractures, gait problems) **AND** C. The patient has/had clinical manifestations consistent with hypophosphatasia at the age of onset prior to age 18 (e.g., vitamin B6-dependent seizures, fractures, lost teeth with roots, skeletal abnormalities: such as rachitic chest deformity leading to respiratory problems or bowed arms/legs, “failure to thrive”) **AND** D. The patient has/had radiographic imaging to support the diagnosis of hypophosphatasia at the age of onset prior to age 18 (e.g., infantile rickets, alveolar bone loss, craniosynostosis) **AND** E. Molecular genetic test has been completed confirming mutations in the *ALPL* gene that encodes the tissue nonspecific isoenzyme of ALP (TNSALP) **AND** F. Reduced activity of unfractionated serum alkaline phosphatase (ALP) in the absence of bisphosphonate therapy (i.e., below the normal lab reference range for age and sex) **AND** G. ONE of the following: 1. Elevated serum concentration of pyridoxal 5'-phosphate (PLP) in the absence of vitamin supplements within one week prior to the test **OR** 2. Elevated urine concentration of phosphoethanolamine (PEA) **OR** 3. Elevated urinary inorganic pyrophosphate (PPi) **AND**

Module	Clinical Criteria for Approval
	2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient has had an ophthalmology examination and renal ultrasound at baseline (prior to starting therapy with the requested agent) **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. The requested quantity (dose) is within FDA labeled dosing for the requested indication based on the patient's weight **Length of Approval:** 6 months **Renewal Evaluation** **Target Agent(s)** will be approved when ALL the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. There is information supporting that the patient has had a decrease from baseline (before treatment with the requested agent) in at least ONE of the following: A. Serum concentration of pyridoxal 5'-phosphate (PLP) in the absence of vitamin supplements within one week prior to the test **OR** B. Urine concentration of phosphoethanolamine (PEA) **OR** C. Urinary inorganic pyrophosphate (PPi) **AND** 3. There is information supporting that the patient has had clinical improvement from baseline (prior to starting therapy with the requested agent) in at least ONE of the following: A. Respiratory status **OR** B. Growth **OR** C. Radiographic findings **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient has been monitored for signs and symptoms of ophthalmic and renal calcifications and for changes in vision or renal function **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 7. The requested quantity (dose) is within FDA labeled dosing for the requested indication based on the patient's weight **Length of Approval:** 12 months

• Program Summary: Sucraid (sacrosidase)

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	Effective Date	Term Date
51200060002030	Sucraid	Sacrosidase Soln 8500 Unit/ML	8500 UNIT/ML	300	mL	30	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of congenital sucrase-isomaltase deficiency (CSID) confirmed by ONE of the following: A. Genetic testing of the sucrase-isomaltase (SI) gene indicates a pathogenic mutation **OR** B. Endoscopic biopsy of the small bowel indicates normal small bowel morphology in the presence of decreased (or absent) sucrase activity, isomaltase activity varying from decreased to normal activity, and decreased maltase activity **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, geneticist, endocrinologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 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 had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, geneticist, endocrinologist), 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
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

Module	Clinical Criteria for Approval
	Length of Approval: Initial - 3 months; Renewal - 12 months

• Program Summary: Tarpeyo

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
22100012006520	Tarpeyo	Budesonide Delayed Release Cap	4 MG	120	Capsules	30	DAYS			09-01-2022	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Target Agent(s) will be approved when ALL of the following are met: 1. The patient has a diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy **AND** 2. ONE of the following: A. The patient has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g **OR** B. The patient has proteinuria greater than or equal to 1 g/day **AND** 3. The patient's eGFR is greater than or equal to 35 mL/min/1.73 m^2 **AND** 4. 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** 5. ONE of the following: A. The patient's medication history includes therapy with a maximally tolerated ACEI or ARB (e.g., benazepril, lisinopril, losartan), or a combination medication containing an ACEI or ARB AND ONE of the following: 1. BOTH of the following: A. The patient has had an inadequate response to a maximally tolerated ACEI or ARB (e.g., benazepril, lisinopril, losartan), or a combination medication containing an ACEI or ARB **AND** B. The patient will be using an ACEI or ARB or a combination medication containing an ACEI or ARB in combination with the requested agent **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over a maximally tolerated ACEI or ARB (e.g., benazepril, lisinopril, losartan), or a combination medication containing an ACEI or ARB **OR** B. The patient has an intolerance or hypersensitivity to an ACEI or ARB, or a combination medication containing an ACE or ARB **OR** C. The patient has an FDA labeled contraindication to ALL ACEI and ARB **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**

Module	Clinical Criteria for Approval
	3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL ACEI and ARBs cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 6. ONE of the following: A. The patient has an intolerance or hypersensitivity to oral generic budesonide that is not expected to occur with the requested agent **OR** B. The patient has an FDA labeled contraindication to the oral generic budesonide that is not expected to occur with the requested agent **OR** C. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** D. BOTH of the following: 1. The patient's medication history includesoral generic budesonide as indicated by ONE of the following: A. Evidence of a paid claim(s) within the past 999 days **OR** B. The presciber has stated that the patient has tried oral generic budesonide in the past 999 days **AND** 2. ONE of the following: A. Oral generic budesonide 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 oral generic budesonide **OR** E. The prescriber has provided documentation that oral generic budesonide 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. ONE of the following: A. The patient has not previously been treated with a course of therapy (9 months) with the requested agent **OR** B. The patient has previously been treated with a course of therapy with the requested agent, AND there is information to support an additional course of therapy with the requested agent **AND** 8. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 9. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 10 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. 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) exceeds 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:** 10 months

• Program Summary: Tezspire (tezepelumab-ekko)

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	Effective Date	Term Date
4460807525D520	Tezspire	tezepelumab-ekko subcutaneous soln auto-inj	210 MG/1.91ML	1	Pen	28	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** 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 **OR** B. The patient has a diagnosis of severe asthma AND ALL of the following: 1. The patient has a history of uncontrolled asthma while on asthma control therapy as demonstrated by ONE of the following: A. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months **OR** B. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months **OR** C. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered **OR** D. The patient has baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted **AND**

Module	Clinical Criteria for Approval
	2. ONE of the following: A. The patient is NOT currently being treated with the requested agent AND is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months **OR** B. The patient is currently being treated with the requested agent AND ONE of the following: 1. Is currently treated with an inhaled corticosteroid for at least 3 months that is adequately dosed to control symptoms **OR** 2. Is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months **OR** C. The patient has an intolerance or hypersensitivity to inhaled corticosteroid therapy **OR** D. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids **AND** 3. ONE of the following: A. The patient is currently being treated for at least 3 months with ONE of the following: 1. A long-acting beta-2 agonist (LABA) **OR** 2. A leukotriene receptor antagonist (LTRA) **OR** 3. Long-acting muscarinic antagonist (LAMA) **OR** 4. Theophylline **OR** B. The patient has an intolerance or hypersensitivity to therapy with LABA, LTRA, LAMA, or theophylline **OR** C. The patient has an FDA labeled contraindication to ALL LABA, LTRA, LAMA, AND theophylline therapies **AND** 4. The patient will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **OR** C. The patient has another FDA approved indication for the requested agent and route of administration **OR** D. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 6 months

Module	Clinical Criteria for Approval
	NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. ONE of the following: A. The patient has a diagnosis of severe asthma AND BOTH of the following: 1. The patient has had improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following: A. The patient has had an increase in percent predicted Forced Expiratory Volume (FEV1) **OR** B. The patient has had a decrease in the dose of inhaled corticosteroids required to control the patient's asthma **OR** C. The patient has had a decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma **OR** D. The patient has had a decrease in number of hospitalizations, need for mechanical ventilation, or visits to urgent care or emergency room due to exacerbations of asthma **AND** 2. The patient is currently treated and is compliant with asthma control therapy [e.g., inhaled corticosteroids, ICS/long-acting beta-2 agonist (ICS/LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), theophylline] **OR** B. The patient has another FDA approved indication for the requested agent and route of administration AND has had clinical benefit with the requested agent OR C. The patient has another indication that is supported in compendia for the requested agent and route of administration AND 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., allergist, immunologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 5. The patient does NOT have an FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Evaluation **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 - 6 months; Renewal - 12 months

CONTRAINDICATION AGENTS

Agents NOT to be used Concomitantly
Adbry (tralokinumab-ldrm) Actemra (tocilizumab) Amjevita (adalimumab-atto) Arcalyst (rilonacept) Avsola (infliximab-axxq) Benlysta (belimumab) Cibinqo (abrocitinib) Cimzia (certolizumab) Cinqair (reslizumab) Cosentyx (secukinumab) Dupixent (dupilumab) Enbrel (etanercept) Entyvio (vedolizumab) Fasenra (benralizumab) Humira (adalimumab) Ilaris (canakinumab) Ilumya (tildrakizumab-asmn) Inflectra (infliximab-dyyb) Infliximab Kevzara (sarilumab) Kineret (anakinra) Nucala (mepolizumab) Olumiant (baricitinib) Opzelura (ruxolitinib) Orencia (abatacept) Otezla (apremilast) Remicade (infliximab) Renflexis (infliximab-abda) Riabni (rituximab-arrx) Rinvoq (upadacitinib) Rituxan (rituximab)

Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tysabri (natalizumab)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Zeposia (ozanimod)

• Program Summary: Topical Antifungals – itraconazole, terbinafine

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	Effective Date	Term Date
11000080100310		Terbinafine HCl Tab 250 MG	250 MG	30	Tablets	30	DAYS			
90150030002020	Ciclodan	Ciclopirox Solution 8%	8%	6.6	mLs	30	DAYS			
90154037002020	Jublia	Efinaconazole Soln 10%	10%	4	mLs	30	DAYS			
90156080002010	Kerydin	Tavaborole Soln 5%	5%	4	mLs	30	DAYS			
11407035002020	Sporanox	Itraconazole Oral Soln 10 MG/ML	10 MG/ML	1200	mLs	30	DAYS			
11407035000120	Sporanox; Sporanox pulsepak	Itraconazole Cap 100 MG	100 MG	120	Capsules	30	DAYS			
11407035000113	Tolsura	Itraconazole Cap 65 MG	65 MG	120	Capsules	30	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Ciclopirox Efinaconazole Tavaborole	**Jublia (efinaconazole), Kerydin (tavaborole), or ciclopirox** will be approved when ALL of the following are met: 1. The patient has a diagnosis of onychomycosis (tinea unguium) **AND** 2. The patient has ONE of the following: diabetes mellitus, peripheral vascular insufficiency, immune deficiency due to medical condition or treatment (e.g. cancer chemotherapy, HIV/AIDS, anti-rejection therapy post organ transplant), pain limiting normal activity, or secondary bacterial infection in the surrounding skin or systemic dermatosis with impaired skin integrity **AND** 3. Treatment of the patient's onychomycosis (tinea unguium) is medically necessary and not entirely for cosmetic reasons **AND**

Module	Clinical Criteria for Approval
	4. The fungal nail infection is confirmed by laboratory testing (KOH preparation, fungal culture or nail biopsy) **AND** 5. ONE of the following: A. The patient's medication history includes an oral antifungal agent AND ONE of the following: 1. The patient has had an inadequate response an oral antifungal agent **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over an oral antifungal agent **OR** B. The patient has an intolerance or hypersensitivity to an oral antifungal agent **OR** C. The patient has an FDA labeled contraindication to ALL oral antifungal agents **OR** D. The prescriber has provided information that an oral antifungal agent is not clinically appropriate **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that ALL oral antifungal 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** 6. If the requested agent is ciclopirox 8% topical solution; treatment will include removal of the unattached, infected nail(s) by an appropriate health care professional **AND** 7. If the requested agent is a brand agent, ONE of the following: A. The patient's medication history includes a non-targeted generic antifungal onychomycosis agent (i.e., itraconazole, terbinafine, ciclopirox) AND ONE of the following: 1. The patient has had an inadequate response a non-targeted generic antifungal onychomycosis agent (i.e., itraconazole, terbinafine, ciclopirox) **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over a non-targeted generic antifungal onychomycosis agent (i.e., itraconazole, terbinafine, ciclopirox) **OR** B. The patient has an intolerance or hypersensitivity to a non-targeted generic antifungal onychomycosis agent **OR** C. The patient has an FDA labeled contraindication to ALL non-targeted generic antifungal onychomycosis agents **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL non-targeted generic antifungal onychomycosis 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** 8. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months

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

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td>Ciclopirox
Efinaconazole
Tavaborole</td><td>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 than 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 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 AND
C. The prescriber has submitted information in support of therapy with a higher dose for the requested indication

Length of Approval: 12 months</td></tr>
<tr><td>Itraconazole
Terbinafine</td><td>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 submitted information in support of therapy with a higher dose for the requested indication

Length of Approval for onychomycosis*
<table><tr><td>terbinafine</td><td>Fingernail infection:
6 weeks</td><td>Toenail infection:
12 weeks</td></tr><tr><td>Sporanox (itraconazole) capsules</td><td>Fingernail infection:
5 weeks

(2 treatment pulses, each consisting of one week of therapy separated by a 3-week period)</td><td>Toenails with or without fingernail involvement:
12 weeks</td></tr></table>*Tolsura, terbinafine and Sporanox (itraconazole) are limited to one approval per 12 month period for onychomycosis (tinea unguium)

Length of Approval for FDA approved diagnosis other than onychomycosis:</td></tr>
</table>

Module	Clinical Criteria for Approval	
	terbinafine	Tinea capitis or other FDA approved indications: 6 weeks
	Sporanox (itraconazole) capsules	Other FDA approved indications: 12 months
	Sporanox (itraconazole) solution	Oropharyngeal or esophageal candidiasis: 6 weeks
	Tolsura	Other FDA approved indications: 12 months

• Program Summary: Topical Corticosteroids

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	Effective Date	Term Date
90550005103710		Alclometasone Dipropionate Cream 0.05%	0.05%	120	Grams	30	DAYS			
90550005104210		Alclometasone Dipropionate Oint 0.05%	0.05%	120	Grams	30	DAYS			
90550010003705		Amcinonide Cream 0.1%	0.1%	120	Grams	30	DAYS			
90550010004105		Amcinonide Lotion 0.1%	0.1%	120	mLs	30	DAYS			
90550010004205		Amcinonide Oint 0.1%	0.1%	120	Grams	30	DAYS			
90550020054005		Betamethasone Dipropionate Augmented Gel 0.05%	0.05%	200	Grams	28	DAYS			
90550020054105		Betamethasone Dipropionate Augmented Lotion 0.05%	0.05%	210	mLs	30	DAYS			
90550020003705		Betamethasone Dipropionate Cream 0.05%	0.05%	135	Grams	30	DAYS			
90550020004105		Betamethasone Dipropionate Lotion 0.05%	0.05%	120	mLs	30	DAYS			
90550020004205		Betamethasone Dipropionate Oint 0.05%	0.05%	135	Grams	30	DAYS			
90550020103710		Betamethasone Valerate Cream 0.1% (Base Equivalent)	0.1%	135	Grams	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	Effective Date	Term Date
90550020104105		Betamethasone Valerate Lotion 0.1% (Base Equivalent)	0.1%	120	mLs	30	DAYS			
90550020104205		Betamethasone Valerate Oint 0.1% (Base Equivalent)	0.1%	135	Grams	30	DAYS			
90550025104010		Clobetasol Propionate Gel 0.05%	0.05%	210	Grams	28	DAYS			
90550025102005		Clobetasol Propionate Soln 0.05%	0.05%	200	mLs	28	DAYS			
90550035004105		Desonide Lotion 0.05%	0.05%	118	mLs	30	DAYS			
90550035004205		Desonide Oint 0.05%	0.05%	120	Grams	30	DAYS			
90550050103705		Diflorasone Diacetate Cream 0.05%	0.05%	120	Grams	30	DAYS			
90550050104205		Diflorasone Diacetate Oint 0.05%	0.05%	120	Grams	30	DAYS			
90550055103705		Fluocinolone Acetonide Cream 0.01%	0.01%	120	Grams	30	DAYS			
90550060003705		Fluocinonide Cream 0.05%	0.05%	120	Grams	30	DAYS			
90550060103705		Fluocinonide Emulsified Base Cream 0.05%	0.05%	120	Grams	30	DAYS			
90550060004005		Fluocinonide Gel 0.05%	0.05%	120	Grams	30	DAYS			
90550060004205		Fluocinonide Oint 0.05%	0.05%	120	Grams	30	DAYS			
90550060002005		Fluocinonide Soln 0.05%	0.05%	120	mLs	30	DAYS			
90550068103710		Fluticasone Propionate Cream 0.05%	0.05%	120	Grams	30	DAYS			
90550068104210		Fluticasone Propionate Oint 0.005%	0.005%	120	Grams	30	DAYS			
90550073103710		Halobetasol Propionate Cream 0.05%	0.05%	200	Grams	28	DAYS			
90550073104210		Halobetasol Propionate Oint 0.05%	0.05%	200	Grams	28	DAYS			
90550075303705		Hydrocortisone Butyrate Cream 0.1%	0.1%	135	Grams	30	DAYS			
90550075304205		Hydrocortisone Butyrate Oint 0.1%	0.1%	135	Grams	30	DAYS			
90550075302020		Hydrocortisone Butyrate Soln 0.1%	0.1%	120	mLs	30	DAYS			
90550075003725		Hydrocortisone Cream 2.5%	2.5%	454	Grams	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	Effective Date	Term Date
90550075004120		Hydrocortisone Lotion 2.5%	2.5%	118	mLs	30	DAYS			
90550075004215		Hydrocortisone Oint 2.5%	2.5%	454	Grams	30	DAYS			
90550075203705		Hydrocortisone Valerate Cream 0.2%	0.2%	120	Grams	30	DAYS			
90550075204205		Hydrocortisone Valerate Oint 0.2%	0.2%	120	Grams	30	DAYS			
90550082103710		Mometasone Furoate Cream 0.1%	0.1%	135	Grams	30	DAYS			
90550082104210		Mometasone Furoate Oint 0.1%	0.1%	135	Grams	30	DAYS			
90550082102010		Mometasone Furoate Solution 0.1% (Lotion)	0.1%	120	mLs	30	DAYS			
90550083004210		Prednicarbate Oint 0.1%	0.1%	120	Grams	30	DAYS			
90550085103705		Triamcinolone Acetonide Cream 0.025%	0.025%	454	Grams	30	DAYS			
90550085104105		Triamcinolone Acetonide Lotion 0.025%	0.025%	120	mLs	30	DAYS			
90550085104110		Triamcinolone Acetonide Lotion 0.1%	0.1%	120	mLs	30	DAYS			
90550085104205		Triamcinolone Acetonide Oint 0.025%	0.025%	454	Grams	30	DAYS			
90550085104210		Triamcinolone Acetonide Oint 0.1%	0.1%	454	Grams	30	DAYS			
90550085104215		Triamcinolone Acetonide Oint 0.5%	0.5%	120	Grams	30	DAYS			
90550075003720	Ala-cort; Anti-itch maximum strength; Aveeno anti-itch maximum; Cortizone-10 feminine itch; Cortizone-10 intensive he; Cortizone-10 intensive mo; Cortizone-10 overnight; Cortizone-10 overnight it; Cortizone-10 plus; Cortizone-10 sensitive sk; Cortizone-10 soothing aloe; Cortizone-10 ultra	Hydrocortisone Cream 1%	1%	454	Grams	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	Effective Date	Term Date
	soothing; Cortizone-10/aloe; Cvs anti-itch maximum str; Cvs cortisone intense heal; Cvs cortisone maximum str; Cvs eczema anti-itch maxi; Cvs hydrocortisone anti-itch; Cvs hydrocortisone maximum; Eq 1% hydrocortisone; Eq hydrocortisone maximum; Eql anti-itch intensive h; Eql anti-itch maximum str; Gnp hydrocortisone plus; Gnp hydrocortisone/aloe; Goodsense anti-itch maxim; Hm hydrocortisone plus; Hm hydrocortisone/aloe ma; Hydrocortisone anti-itch; Hydrocortisone maximum st; Hydrocortisone plus; Hydrocortisone/aloe maxim; Kericort 10; Medpura hydrocortisone; Meijer hydrocortisone; Monistat soothing care it; Preparation h; Px hydrocream; Qc anti-itch/aloe; Qc hydrocortisone maximum; Ra anti-itch maximum stre; Ra hydrocortisone plus; Ra hydrocortisone plus 12; Sb hydrocortisone; Sm hydrocortisone; Sm hydrocortisone plus; Sm									

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
	hydrocortisone/aloe ma									
90550075004118	Ala-scalp	Hydrocortisone Lotion 2%	2%	118.4	mLs	30	DAYS			
90550050153705	Apexicon e	Diflorasone Diacetate Emollient Base Cream 0.05%	0.05%	120	Grams	30	DAYS			
90550075004210	Aquaphor itch relief chil; Aquaphor itch relief maxi; Cortizone-10; Cortizone-10 water resist; Cvs cortisone maximum str; Eql anti-itch maximum str; Gnp hydrocortisone maximum; Goodsense anti-itch maxim; Hydrocortisone maximum st; Kp hydrocortisone maximum; Ra anti-itch/maximum stre; Sb hydrocortisone maximum; Sm hydrocortisone maximum	Hydrocortisone Oint 1%	1%	453.6	Grams	30	DAYS			
90550068104120	Beser; Cutivate	Fluticasone Propionate Lotion 0.05%	0.05%	120	mLs	30	DAYS			
90550073104105	Bryhali	Halobetasol Propionate Lotion 0.01%	0.01%	200	Grams	28	DAYS			
90550055104501	Capex	Fluocinolone Acetonide Shampoo 0.01%	0.01%	840	mLs	28	DAYS			
90550025153705	Clobetasol propionate e; Clobetasol propionate emo	Clobetasol Propionate Emollient Base Cream 0.05%	0.05%	210	Grams	28	DAYS			
90550025104110	Clobex	Clobetasol Propionate Lotion 0.05%	0.05%	177	mLs	28	DAYS			
90550025100910	Clobex	Clobetasol Propionate Spray 0.05%	0.05%	236	mLs	28	DAYS			
90550025104520	Clobex; Clodan	Clobetasol Propionate Shampoo 0.05%	0.05%	236	mLs	30	DAYS			
90550030103705	Cloderm	Clocortolone Pivalate Cream 0.1%	0.1%	135	Grams	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	Effective Date	Term Date
90550065003705	Cordran	Flurandrenolide Cream 0.025%	0.025%	120	Grams	30	DAYS			
90550065004210	Cordran	Flurandrenolide Oint 0.05%	0.05%	120	Grams	30	DAYS			
90550065004605	Cordran	Flurandrenolide Tape 4 MCG/SQCM	4 MCG/SQ CM	1	Box	30	DAYS			
90550065003710	Cordran; Nolix	Flurandrenolide Cream 0.05%	0.05%	120	Grams	30	DAYS			
90550065004105	Cordran; Nolix	Flurandrenolide Lotion 0.05%	0.05%	120	mLs	30	DAYS			
90550055101712	Derma-smoothe/fs body	Fluocinolone Acetonide Oil 0.01% (Body Oil)	0.01%	118.28	mLs	30	DAYS			
90550055101714	Derma-smoothe/fs scalp	Fluocinolone Acetonide Oil 0.01% (Scalp Oil)	0.01%	118.28	mLs	30	DAYS			
90550035003705	Desowen; Tridesilon	Desonide Cream 0.05%	0.05%	120	Grams	30	DAYS			
90550035004020	Desrx	Desonide Gel 0.05%	0.05%	120	Grams	30	DAYS			
90550020054205	Diprolene	Betamethasone Dipropionate Augmented Oint 0.05%	0.05%	200	Grams	28	DAYS			
90550020053705	Diprolene af	Betamethasone Dipropionate Augmented Cream 0.05%	0.05%	200	Grams	28	DAYS			
90550070003710	Halog	Halcinonide Cream 0.1%	0.1%	120	Grams	30	DAYS			
90550070004205	Halog	Halcinonide Oint 0.1%	0.1%	120	Grams	30	DAYS			
90550070002005	Halog	Halcinonide Soln 0.1%	0.1%	120	mLs	30	DAYS			
90550025104150	Impeklo	Clobetasol Propionate Lotion	0.15 MG/ACT	204	Grams	28	DAYS			
90550025103703	Impoyz	Clobetasol Propionate Cream 0.025%	0.025%	200	Grams	28	DAYS			
90550085103400	Kenalog	Triamcinolone Acetonide Aerosol Soln 0.147 MG/GM	0.147 MG/GM	126	Grams	30	DAYS			
90550073103920	Lexette	Halobetasol Propionate Foam 0.05%	0.05%	200	Grams	28	DAYS			
90550075304120	Locoid	Hydrocortisone Butyrate Lotion 0.1%	0.1%	118	mLs	30	DAYS			
90550075323705	Locoid lipocream	Hydrocortisone Butyrate Hydrophilic Lipo Base Cream 0.1%	0.1%	120	Grams	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	Effective Date	Term Date
90550020103920	Luxiq	Betamethasone Valerate Aerosol Foam 0.12%	0.12%	150	Grams	30	DAYS			
90550025103920	Olux	Clobetasol Propionate Foam 0.05%	0.05%	200	Grams	28	DAYS			
90550025203920	Olux-e; Tovet	Clobetasol Propionate Emulsion Foam 0.05%	0.05%	200	Grams	28	DAYS			
90550075273720	Pandel	Hydrocortisone Probutate Cream 0.1%	0.1%	160	Grams	30	DAYS			
90550020001620	Sernivo	Betamethasone Dipropionate Spray Emulsion 0.05% (Base Equiv)	0.05%	120	mLs	30	DAYS			
90550055103710	Synalar	Fluocinolone Acetonide Cream 0.025%	0.025%	120	Grams	30	DAYS			
90550055104205	Synalar	Fluocinolone Acetonide Oint 0.025%	0.025%	120	Grams	30	DAYS			
90550055102005	Synalar	Fluocinolone Acetonide Soln 0.01%	0.01; 0.01%	120	mLs	30	DAYS			
90550025103705	Temovate	Clobetasol Propionate Cream 0.05%	0.05%	210	Grams	28	DAYS			
90550025104205	Temovate	Clobetasol Propionate Oint 0.05%	0.05%	210	Grams	28	DAYS			
90550075002020	Texacort	Hydrocortisone Soln 2.5%	2.5%	120	mLs	30	DAYS			
90550040003705	Topicort	Desoximetasone Cream 0.05%	0.05%	120	Grams	30	DAYS			
90550040003710	Topicort	Desoximetasone Cream 0.25%	0.25%	120	Grams	30	DAYS			
90550040004005	Topicort	Desoximetasone Gel 0.05%	0.05%	120	Grams	30	DAYS			
90550040004203	Topicort	Desoximetasone Oint 0.05%	0.05%	120	Grams	30	DAYS			
90550040004205	Topicort	Desoximetasone Oint 0.25%	0.25%	120	Grams	30	DAYS			
90550040000910	Topicort	Desoximetasone Spray 0.25%	0.25%	100	mLs	30	DAYS			
90550085104207	Trianex; Tritocin	Triamcinolone Acetonide Oint 0.05%	0.05%	430	Grams	30	DAYS			
90550085103710	Triderm	Triamcinolone Acetonide Cream 0.1%	0.1%	454	Grams	30	DAYS			
90550085103720	Triderm	Triamcinolone Acetonide Cream 0.5%	0.5%	454	Grams	30	DAYS			
90550073104110	Ultravate	Halobetasol Propionate Lotion 0.05%	0.05%	240	mLs	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	Effective Date	Term Date
90550060003710	Vanos	Fluocinonide Cream 0.1%	0.1%	240	Grams	28	DAYS			
90550035003920	Verdeso	Desonide Foam 0.05%	0.05%	100	Grams	30	DAYS			

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

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	Effective Date	Term Date
90220015103710	Prudoxin; Zonalon	Doxepin HCl Cream 5%	5%	45	Grams	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
90220015103710	Prudoxin; Zonalon	Doxepin HCl Cream 5%	5%	Quantity Limit is cumulative across agents			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	PRIOR AUTHORIZATION CRITERIA FOR APPROVAL **Target Agent** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of moderate pruritus associated with atopic dermatitis AND ONE of the following: 1. The patient's medication history includes BOTH a topical corticosteroid AND a topical calcineurin inhibitor AND ONE of the following: A. The patient has had an inadequate response to BOTH a topical corticosteroid AND a topical calcineurin inhibitor **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL topical corticosteroids AND topical calcineurin inhibitors **OR** 2. The patient has an intolerance or hypersensitivity to a topical corticosteroid AND a topical calcineurin inhibitor **OR** 3. The patient has an FDA labeled contraindication to ALL topical corticosteroids AND topical calcineurin inhibitors **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 topical corticosteroids AND topical calcineurin inhibitors cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has a diagnosis of moderate pruritus associated with lichen simplex chronicus AND ONE of the following: 1. The patient's medication history includes ONE topical corticosteroid AND ONE of the following: A. The patient has had an inadequate response to ONE topical corticosteroid **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL topical corticosteroids **OR** 2. The patient has an intolerance or hypersensitivity to ONE topical corticosteroid **OR** 3. The patient has an FDA labeled contraindication to ALL topical corticosteroids **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL topical corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td></td><td>
C. The patient has another FDA approved indication for the requested agent AND
2. If the patient has an FDA labeled indication, then ONE of the following:
A. The patient's age is within FDA labeling for the requested indication for the requested agent OR
B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication AND
3. If the request is for one of the following brand agents with an available generic (listed below), then ONE of the following:
<table>
<tr><th>Brand</th><th>Generic</th></tr>
<tr><td>Prudoxin cream
Zonalon cream</td><td>doxepin hydrochloride cream 5%</td></tr>
</table>
A. The patient has an intolerance or hypersensitivity to the generic that is not expected to occur with the brand agent OR
B. The patient has an FDA labeled contraindication to the generic 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 AND
4. The patient will NOT be using the requested agent in combination with another topical doxepin agent for the requested indication AND
5. The patient has NOT already received 8 days of therapy with a topical doxepin agent for the current course of therapy AND
6. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 1 month

NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
</td></tr>
</table>

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td></td><td>
Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:

1. The requested quantity (dose) does NOT exceed the program quantity limit OR
2. BOTH of the following:
A. The requested quantity (dose) exceeds the program quantity limit AND
B. The prescriber has provided information in support of therapy with a higher dose for the requested indication

Length of Approval: 1 month
</td></tr>
</table>

• Program Summary: Topical Lidocaine

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	Effective Date	Term Date
90850060102015		Lidocaine HCl Soln 4%	4%	150	mLs	30	DAYS			
90850060104006		Lidocaine HCl Urethral/Mucosal Gel 2%	2%	150	mLs	30	DAYS			
90850060104005	7t lido gel; Proxivol; Regenecare ha; Xeroburn	Lidocaine HCl Gel 2%	2%	150	mLs	30	DAYS			
9085006010E420	Glydo	Lidocaine HCl Urethral/Mucosal Gel Prefilled Syringe 2%	2%	150	mLs	30	DAYS			
90850060005930	Lidocan; Lidoderm	Lidocaine Patch 5%	5%	90	Patches	30	DAYS			
90859902843730	Pliaglis	Lidocaine-Tetracaine Cream 7-7%	7-7%	120	Grams	30	DAYS			
90850060004210	Premium lidocaine	Lidocaine Oint 5%	5%	100	Grams	30	DAYS			
90859902845920	Synera	Lidocaine-Tetracaine Topical Patch 70-70 MG	70-70 MG	4	Patches	30	DAYS			
90850060005910	Ztlido	Lidocaine Patch 1.8% (36 MG)	1.8%	90	Systems	30	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
lidocaine topical jelly 2%	**lidocaine topical jelly 2%** will be approved when ALL of the following are met: 1. The requested agent will be used for ONE of the following indications: A. Prevention and control of pain in procedures involving the urethra **OR** B. Topical treatment of painful urethritis **OR** C. Anesthetic lubricant for endotracheal intubation (oral and nasal) **OR** D. Mucositis associated with cancer treatment **OR** E. BOTH of the following: 1. The patient has ONE of the following: A. Neuropathic pain associated with cancer pain or cancer treatment **OR** B. Another FDA approved indication for the requested agent and route of administration **OR** C. Another indication that is supported in compendia for the requested agent and route of administration **AND** 2. ONE of the following: A. The patient's medication history over-the-counter topical lidocaine AND ONE of the following: 1. The patient has had an inadequate response to over-the-counter topical lidocaine **OR**

Module	Clinical Criteria for Approval
	2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL over-the-counter topical lidocaine **OR** B. The prescriber has provided information that indicates over-the-counter topical lidocaine is not clinically appropriate **OR** C. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** D. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
lidocaine topical ointment 5%	**lidocaine topical ointment 5%** will be approved when ALL of the following are met: 1. The requested agent will be used for ONE of the following indications: A. Anesthesia of accessible mucous membranes of the oropharynx **OR** B. Anesthetic lubricant for intubation **OR** C. BOTH of the following: 1. The patient has ONE of the following: A. Temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites **OR** B. Another FDA approved indication for the requested agent and route of administration **OR** C. Another indication that is supported in compendia for the requested agent and route of administration **AND** 2. ONE of the following: A. The patient's medication history over-the-counter topical lidocaine AND ONE of the following: 1. The patient has had an inadequate response to over-the-counter topical lidocaine **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL over-the-counter topical lidocaine **OR** B. The prescriber has provided information that indicates over-the-counter topical lidocaine is not clinically appropriate **OR** C. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND**

Module	Clinical Criteria for Approval
	2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** D. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
lidocaine topical solution 4%	**lidocaine topical solution 4%** will be approved when ALL of the following are met: 1. The requested agent will be used for ONE of the following indications: A. Topical anesthesia of accessible mucous membranes of the oral and nasal cavities and proximal portions of the digestive tract **OR** B. Mucositis associated with cancer treatment **OR** C. BOTH of the following: 1. The patient has ONE of the following: A. Another FDA approved indication for the requested agent and route of administration **OR** B. Another indication that is supported in compendia for the requested agent and route of administration **AND** 2. ONE of the following: A. The patient's medication history over-the-counter topical lidocaine AND ONE of the following: 1. The patient has had an inadequate response to over-the-counter topical lidocaine **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL over-the-counter topical lidocaine **OR** B. The prescriber has provided information that indicates over-the-counter topical lidocaine is not clinically appropriate **OR** C. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** D. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient does NOT have any FDA labeled contraindications to the requested agent

Module	Clinical Criteria for Approval
	Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Lidoderm (lidocaine patch 5%) and ZTlido (lidocaine topical system 1.8%)	**Lidoderm (lidocaine patch 5%) and ZTlido (lidocaine topical system 1.8%)** will be approved when ALL of the following are met: 1. The requested agent will be used for ONE of the following indications: A. Pain associated with post-herpetic neuralgia (PHN) **OR** B. Neuropathic pain associated with cancer or cancer treatment **OR** C. Another FDA approved indication for the requested agent and route of administration **OR** D. Another indication that is supported in compendia for the requested agent and route of administration **AND** 2. The patient has ONE of the following: A. The patient's medication history over-the-counter topical lidocaine AND ONE of the following: 1. The patient has had an inadequate response to over-the-counter topical lidocaine **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL over-the-counter topical lidocaine **OR** B. The prescriber has provided information that indicates over-the-counter topical lidocaine is not clinically appropriate **OR** C. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** D. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Pliaglis (lidocaine 7%/tetracaine cream 7%)	**Pliaglis (lidocaine 7%/tetracaine cream 7%)** will be approved when ALL of the following are met: 1. The requested agent will be used for ONE of the following indications: A. Analgesia for superficial dermatological procedures such as dermal filler injection, pulsed dye laser therapy, facial laser resurfacing, and laser-assisted tattoo removal **OR** B. BOTH of the following: 1. ONE of the following: A. Another FDA approved indication for the requested agent and route of administration **OR** B. Another indication that is supported in compendia for the requested agent and route of administration **AND**

Module	Clinical Criteria for Approval
	2. The patient has ONE of the following: A. The patient's medication history over-the-counter topical lidocaine AND ONE of the following: 1. The patient has had an inadequate response to over-the-counter topical lidocaine **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL over-the-counter topical lidocaine **OR** B. The prescriber has provided information that indicates over-the-counter topical lidocaine is not clinically appropriate **OR** C. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** D. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Synera (lidocaine 70 mg/tetracaine 70 mg patch)	**Synera (lidocaine 70 mg/tetracaine 70 mg patch)** will be approved when ALL of the following are met: 1. The requested agent will be used for ONE of the following indications: A. Local dermal analgesia for superficial venous access **OR** B. Local dermal analgesia for superficial dermatological procedures such as excision, electrodessication, and shave biopsy of skin lesions **OR** C. BOTH of the following: 1. ONE of the following: A. Another FDA approved indication for the requested agent and route of administration **OR** B. Another indication that is supported in compendia for the requested agent and route of administration **AND** 2. The patient has ONE of the following: A. The patient's medication history over-the-counter topical lidocaine AND ONE of the following: 1. The patient has had an inadequate response to over-the-counter topical lidocaine **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL over-the-counter topical lidocaine **OR** B. The prescriber has provided information that indicates over-the-counter topical lidocaine is not clinically appropriate **OR**

Module	Clinical Criteria for Approval
	C. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** D. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months 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**: 12 months

● Program Summary: Urea Cycle Disorders

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

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	309080600029	Buphenyl	sodium phenylbutyrate oral powder	3 GM/TSP	M; N; O; Y				
	309080600003	Buphenyl	sodium phenylbutyrate tab	500 MG	M; N; O; Y				
	3090806000B1	Olpruva	sodium phenylbutyrate packet for susp	2 GM; 3 GM; 4 GM; 5 GM; 6 GM; 6.67 GM	M; N; O; Y				
	309080600089	Pheburane	sodium phenylbutyrate oral pellets	483 MG/GM	M; N; O; Y				
	309080300009	Ravicti	glycerol phenylbutyrate liquid	1.1 GM/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 ALL of the following are met: 1. The patient has a diagnosis of hyperammonemia AND ALL of the following: A. The patient has elevated ammonia levels according to the patient's age [Neonate: plasma ammonia level 150 micromol/L (greater than 260 micrograms/dL) or higher; Older child or adult: plasma ammonia level greater than 100 micromol/L (175 micrograms/dL)] **AND** B. The patient has a normal anion gap **AND** C. The patient has a normal blood glucose level **AND** 2. The patient has a diagnosis of ONE of the following urea cycle disorders confirmed by enzyme analysis OR genetic testing: A. carbamoyl phosphate synthetase I deficiency [CPSID] **OR** B. ornithine transcarbamylase deficiency [OTCD] **OR** C. argininosuccinic acid synthetase deficiency [ASSD] **OR** D. argininosuccinic acid lyase deficiency [ASLD] **OR** E. arginase deficiency [ARG1D] **AND** 3. The requested agent will NOT be used as treatment of acute hyperammonemia **AND** 4. The patient is unable to maintain a plasma ammonia level within the normal range with the use of a protein restricted diet and, when clinically appropriate, essential amino acid supplementation **AND** 5. The patient will be using the requested agent as adjunctive therapy to dietary protein restriction **AND** 6. ONE of the following: A. If the requested agent is Buphenyl or Pheburane, then ONE of the following: 1. The patient has an intolerance or hypersensitivity to generic sodium phenylbutyrate that is not expected to occur with the brand agent **OR** 2. The patient has an FDA labeled contraindication to generic sodium phenylbutyrate that is not expected to occur with the brand agent **OR** 3. The prescriber has provided information to support the use of the requested brand agent over generic sodium phenylbutyrate **OR** 4. BOTH of the following:

Module	Clinical Criteria for Approval
	A. The patient's medication history includes generic sodium phenylbutyrate or a drug in the same pharmacological class with the same mechanism of action as indicated by ONE of the following: 1. Evidence of a paid claim(s) **OR** 2. The prescriber has stated that the patient has tried generic sodium phenylbutyrate or a drug in the same pharmacological class with the same mechanism of action **AND** B. ONE of the following: 1. Generic sodium phenylbutyrate or drug in the same pharmacological class with the same mechanism of action 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 generic sodium phenylbutyrate **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 sodium phenylbutyrate cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. If the requested agent is Ravicti, ONE of the following: 1. The patient's medication history includes generic sodium phenylbutyrate AND Pheburane AND ONE of the following: A. The patient has had an inadequate response to generic sodium phenylbutyrate AND Pheburane **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over generic sodium phenylbutyrate AND Pheburane **OR** 2. The patient has an intolerance or hypersensitivity to generic sodium phenylbutyrate AND Pheburane **OR** 3. The patient has an FDA labeled contraindication to generic sodium phenylbutyrate AND Pheburane **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 generic sodium phenylbutyrate AND Pheburane 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 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**

Module	Clinical Criteria for Approval
	8. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 9. The requested quantity (dose) is within FDA labeled dosing for the requested indication **Length of Approval:** 12 months **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent (e.g., plasma ammonia level within the normal range) **AND** 3. The requested agent will NOT be used as treatment of acute hyperammonemia **AND** 4. The patient will be using the requested agent as adjunctive therapy to dietary protein restriction **AND** 5. ONE of the following: A. If the requested agent is Buphenyl or Pheburane, then ONE of the following: 1. The patient has an intolerance or hypersensitivity to generic sodium phenylbutyrate that is not expected to occur with the brand agent **OR** 2. The patient has an FDA labeled contraindication to generic sodium phenylbutyrate that is not expected to occur with the brand agent **OR** 3. The prescriber has provided information to support the use of the requested brand agent over generic sodium phenylbutyrate **OR** 4. BOTH of the following: A. The patient's medication history includes generic sodium phenylbutyrate or a drug in the same pharmacological class with the same mechanism of action as indicated by ONE of the following: 1. Evidence of a paid claim(s) **OR** 2. The prescriber has stated that the patient has tried generic sodium phenylbutyrate or a drug in the same pharmacological class with the same mechanism of action **AND** B. ONE of the following: 1. Generic sodium phenylbutyrate or drug in the same pharmacological class with the same mechanism of action 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 generic sodium phenylbutyrate **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 sodium phenylbutyrate cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. If the requested agent is Ravicti, ONE of the following: 1. The patient's medication history includes generic sodium phenylbutyrate AND Pheburane AND ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient has had an inadequate response to generic sodium phenylbutyrate AND Pheburane **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over generic sodium phenylbutyrate AND Pheburane **OR** 2. The patient has an intolerance or hypersensitivity to generic sodium phenylbutyrate AND Pheburane **OR** 3. The patient has an FDA labeled contraindication to generic sodium phenylbutyrate AND Pheburane **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 generic sodium phenylbutyrate AND Pheburane cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., metabolic disorders) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 8. The requested quantity (dose) is within FDA labeled dosing for the requested indication **Length of Approval:** 12 months