MHCP PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: February 1, 2024 Notification Posted: January 15, 2024

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

No new policies effective February 1, 2024

POLICIES REVISED

• Program Summary: Antifungals

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

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

1) the indication is FDA approved AND

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
11507040100320	Brexafemme	Ibrexafungerp Citrate Tab	150 MG	4	Tablets	90	DAYS				
1140805000B220	Vivjoa	Oteseconazole Cap Therapy Pack	150 MG	18	Capsules	180	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Brexafemme	**Brexafemme (ibrexafungerp)** will be approved when BOTH of the following are met 1. ONE of the following: A. BOTH of the following: 1. The patient is an adult or post-menarchal pediatric patient AND ONE of the following: A. The requested agent will be used for the treatment of vulvovaginal candidiasis (VVC) **OR** B. BOTH of the following: 1. The patient is using the requested agent to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) **AND** 2. The patient has experienced greater than or equal to 3 episodes of vulvovaginal candidiasis (VVC) in a 12 month period **AND** 2. ONE of the following: A. The patient's medication history includes fluconazole AND ONE of the following: 1. The patient has had an inadequate response to fluconazole **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over to fluconazole **OR** B. The patient has an intolerance or hypersensitivity to fluconazole **OR** C. The patient has an FDA labeled contraindication to fluconazole **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**

Module	Clinical Criteria for Approval
	E. The prescriber has provided documentation that fluconazole 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 **OR** B. The patient has another FDA approved indication for the requested agent and route of administration **AND** 2. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 3 months for treatment of vulvovaginal candidiasis, 6 months for recurrent vulvovaginal candidiasis and all other indications NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Cresemba	**Initial Evaluation** **Cresemba (isavuconazole)** will be approved when BOTH of the following are met: 1. ONE of the following: A. The patient has a diagnosis of invasive aspergillosis **OR** B. The patient has a diagnosis of invasive mucormycosis **OR** C. The patient has another FDA approved indication for the requested agent and route of administration **AND** 2. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 6 months **Renewal Evaluation** **Cresemba (isavuconazole)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization review process **AND** 2. ONE of the following: A. BOTH of the following: 1. The patient has a diagnosis of invasive aspergillosis **AND** 2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay) **OR** B. BOTH of the following: 1. The patient has a diagnosis of invasive mucormycosis **AND** 2. The patient has continued indicators of active disease (e.g., continued radiologic findings, direct microscopy findings, histopathology findings, positive cultures, positive serum galactomannan assay) **OR** C. BOTH of the following: 1. The patient has another FDA approved indication or another indication that is supported in compendia for the requested agent and route of administration **AND** 2. The prescriber has submitted information supporting continued use of the requested agent for the requested indication **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 6 months

Module	Clinical Criteria for Approval
Noxafil	**Initial Evaluation** **Noxafil (posaconazole)** will be approved when ONE of the following are met: 1. ALL of the following: A. ONE of the following: 1. The patient has a diagnosis of oropharyngeal candidiasis AND ONE of the following: A. The patient's medication history includes itraconazole or fluconazole AND ONE of the following: 1. The patient has had an inadequate response to itraconazole or fluconazole **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over itraconazole or fluconazole **OR** B. The patient has an intolerance or hypersensitivity to itraconazole or fluconazole **OR** C. The patient has an FDA labeled contraindication to BOTH fluconazole AND itraconazole **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 BOTH fluconazole AND itraconazole cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 2. BOTH of the following: A. The requested agent is prescribed for prophylaxis of invasive Aspergillus or Candida **AND** B. The patient is severely immunocompromised (e.g., hematopoietic stem cell transplant (HSCT) recipients, a hematologic malignancy with prolonged neutropenia from chemotherapy), or is a high-risk solid organ (lung, heart-lung, heart, pancreas, liver, kidney, small bowel) transplant patient **OR** 3. The patient has an infection caused by Scedosporium or Zygomycetes **OR** 4. The patient has a diagnosis of invasive Aspergillus AND ONE of the following: A. The patient's medication history includes voriconazole, amphotericin B, or isavuconazole AND ONE of the following: 1. The patient has had an inadequate response to voriconazole, amphotericin B, or isavuconazole **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over voriconazole, amphotericin B, or isavuconazole **OR** B. The patient has an intolerance or hypersensitivity to voriconazole, amphotericin B, or isavuconazole **OR** C. The patient has an FDA labeled contraindication to voriconazole, amphotericin B, AND isavuconazole **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**

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** E. The prescriber has provided documentation that voriconazole, amphotericin B, AND isavuconazole cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 5. The patient has another FDA approved indication for the requested agent and route of administration **OR** 6. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** B. If the patient has an FDA approved indication, then ONE of the following: 1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** 2. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** C. The patient does NOT have any FDA labeled contraindications to the requested agent **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feedings or medication administration **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 1 month for oropharyngeal candidiasis, 6 months for all other indications **Renewal Evaluation** **Noxafil (posaconazole)** will be approved when BOTH of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization review process (NOTE: See initial criteria for a diagnosis of oropharyngeal candidiasis) **AND** 2. ONE of the following: A. BOTH of the following: 1. ONE of the following: A. BOTH of the following: 1. The requested agent is being prescribed for prophylaxis of invasive Aspergillus or Candida **AND** 2. The patient continues to be severely immunocompromised (e.g., hematopoietic stem cell transplant (HSCT) recipients, a hematologic malignancy with prolonged neutropenia from chemotherapy), or is a high-risk solid organ (lung, heart-lung, heart, pancreas, liver, kidney, small bowel) transplant patient **OR** B. BOTH of the following: 1. The patient has a serious infection caused by Scedosporium or Zygomycetes **AND** 2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) **OR** C. BOTH of the following: 1. The patient has a diagnosis of invasive Aspergillus **AND**

Module	Clinical Criteria for Approval
	2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) **OR** D. BOTH of the following: 1. The patient has another FDA approved indication or another indication that is supported in compendia for the requested agent and route of administration **AND** 2. The prescriber has submitted information supporting continued use of the requested agent for the requested indication **AND** 2. The patient does NOT have any FDA labeled contraindications to the requested agent **OR** B. If the request is for an oral liquid form of a medication, then BOTH of the following: 1. The patient has an FDA approved indication **AND** 2. The patient uses an enteral tube for feedings or medication administration **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 6 months
Vfend	**Initial Evaluation** **Vfend (voriconazole)** will be approved when ONE of the following are met: 1. ALL of the following: A. ONE of the following: 1. The patient has a diagnosis of invasive Aspergillus **OR** 2. BOTH of the following: A. The requested agent is being prescribed for prophylaxis of invasive Aspergillus or Candida **AND** B. The patient is severely immunocompromised (e.g., hematopoietic stem cell transplant (HSCT) recipients, a hematologic malignancy with prolonged neutropenia from chemotherapy), or is a high-risk solid organ (lung, heart-lung, heart, pancreas, liver, kidney, small bowel) transplant patient **OR** 3. The patient has a diagnosis of esophageal candidiasis, candidemia, or other deep tissue Candida infection AND ONE of the following: A. The patient's medication history includes fluconazole AND ONE of the following: 1. The patient has had an inadequate response to fluconazole **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over fluconazole **OR** B. The patient has an intolerance or hypersensitivity to fluconazole **OR** C. The patient has an FDA labeled contraindication to fluconazole **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 fluconazole 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** 4. The patient has a serious infection caused by Scedosporium or Fusarium species **OR**

Module	Clinical Criteria for Approval
	5. The patient has a diagnosis of blastomycosis AND ONE of the following: A. The patient's medication history includes itraconazole AND ONE of the following: 1. The patient has had an inadequate response to itraconazole **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over itraconazole **OR** B. The patient has an intolerance or hypersensitivity to itraconazole **OR** C. The patient has an FDA labeled contraindication to itraconazole **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 itraconazole cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 6. The patient has another FDA approved indication for the requested agent and route of administration **OR** 7. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** B. If the patient has an FDA labeled indication, then ONE of the following: 1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** 2. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** C. The patient does NOT have any FDA labeled contraindications to the requested agent **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feedings or medication administration **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 1 month for esophageal candidiasis, 6 months for all other indications **Renewal Evaluation** **Vfend (voriconazole)** will be approved when BOTH of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization review process **AND** 2. ONE of the following: A. ALL of the following: 1. ONE of the following: A. BOTH of the following: 1. The patient has a diagnosis of invasive Aspergillus **AND** 2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) **OR**

Module	Clinical Criteria for Approval
	B. BOTH of the following: 1. The requested agent is being prescribed for prophylaxis of invasive Aspergillus or Candida **AND** 2. The patient is severely immunocompromised (e.g., hematopoietic stem cell transplant (HSCT) recipients, a hematologic malignancy with prolonged neutropenia from chemotherapy), or is a high-risk solid organ (lung, heart-lung, heart, pancreas, liver, kidney, small bowel) transplant patient **OR** C. BOTH of the following: 1. The patient has a diagnosis of esophageal candidiasis, candidemia, or other deep tissue Candida infection **AND** 2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) **OR** D. BOTH of the following: 1. The patient has a serious infection caused by Scedosporium or Fusarium species **AND** 2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) **OR** E. BOTH of the following: 1. The patient has a diagnosis of blastomycosis **AND** 2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) **OR** F. BOTH of the following: 1. The patient has another FDA approved indication or another indication that is supported in compendia for the requested agent and route of administration **AND** 2. The prescriber has submitted information supporting continued use of the requested agent for the intended diagnosis **AND** 2. The patient does NOT have any FDA labeled contraindications to the requested agent **OR** B. If the request is for an oral liquid form of a medication, then BOTH of the following: 1. The patient has an FDA approved indication **AND** 2. The patient uses an enteral tube for feedings or medication administration **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 1 month for esophageal candidiasis, 6 months for all other indications
Vivjoa	**Vivjoa (oteseconazole)** will be approved when BOTH of the following are met: 1. ONE of the following: A. ALL of the following: 1. The patient has a diagnosis of recurrent vulvovaginal candidiasis **AND** 2. The patient has experienced greater than or equal to 3 episodes of vulvovaginal candidiasis (VVC) in a 12 month period **AND** 3. ONE of the following: A. The patient's medication history includes fluconazole for the current infection AND ONE of the following: 1. The patient has had an inadequate response to fluconazole for the current infection **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 to fluconazole for the current infection **OR** B. The patient has an intolerance or hypersensitivity to fluconazole **OR** C. The patient has an FDA labeled contraindication to fluconazole **OR** D. The patient will be using fluconazole as part of the combination dosing (fluconazole with Vivjoa) for the current infection **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 fluconazole 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 **OR** B. The patient has another FDA approved indication for the requested agent and route of administration **OR** C. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 4 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Brexafemme, Vivjoa	**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**: Brexafemme: 3 months for treatment of vulvovaginal candidiasis

Module	Clinical Criteria for Approval	
		6 months for recurrent vulvovaginal candidiasis
		6 months for all other indications
	Vivjoa	4 months

• Program Summary: Bempedoic Acid

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
39380020000320	Nexletol	Bempedoic Acid Tab 180 MG	180 MG	30	Tablets	30	DAYS			10-01-2020	
39991002200320	Nexlizet	Bempedoic Acid-Ezetimibe Tab 180-10 MG	180-10 MG	30	Tablets	30	DAYS			10-01-2020	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. BOTH of the following: 1. The patient has ONE of the following: A. A diagnosis of heterozygous familial hypercholesterolemia (HeFH) confirmed by ONE of the following: 1. Genetic confirmation of one mutant allele at the LDLR, Apo-B, PCSK9, or ARH adaptor protein 1/LDLRAP1 gene locus **OR** 2. BOTH of the following: A. ONE of the following: 1. History of total cholesterol greater than 290 mg/dL (greater than 7.5 mmol/L) (pretreatment or highest level while on treatment) **OR** 2. History of LDL-C greater than 190 mg/dL (greater than 4.9 mmol/L) (pretreatment or highest level while on treatment) **AND** B. History of tendon xanthomas in ONE of the following: 1. The patient **OR** 2. The patient's first degree relative (i.e., parent, sibling, or child) **OR** 3. The patient's second degree relative (e.g., grandparent, uncle, or aunt) **OR** 3. The Patient has a Dutch Lipid Clinic Network Criteria score of greater than 5 **OR** B. A diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) defined as having ONE of the following: 1. Acute coronary syndrome

Module	Clinical Criteria for Approval
	2. History of myocardial infarction 3. Stable or unstable angina 4. Coronary or other arterial revascularization 5. Stroke 6. Transient ischemic attack 7. Peripheral arterial disease, including aortic aneurysm, presumed to be of atherosclerotic origin 8. Coronary heart disease **AND** 2. ONE of the following: A. The patient is on maximally tolerated statin therapy **OR** B. The patient has an intolerance or hypersensitivity to statin therapy **OR** C. The patient has an FDA labeled contraindication to ALL statins **OR** B. The patient has another FDA approved indication for the requested agent and route of administration **OR** C. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following criteria 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. If the patient has ASCVD or HeFH, then ONE of the following: A. The patient is on maximally tolerated statin therapy **OR** B. The patient has an intolerance or hypersensitivity to statin therapy **OR** C. The patient has an FDA labeled contraindication to ALL statins **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Prior Authorization with Quantity Limit	**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 **OR** C. ALL of the following: 1. The requested quantity (dose) exceeds the program quantity limit **AND** 2. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 3. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of approval:** 12 months

• Program Summary: Bisphosphonates

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
30042010102020		Alendronate Sodium Oral Soln 70 MG/75ML	70 MG/75ML	300	mLs	28	DAYS			
30042010100310		Alendronate Sodium Tab 10 MG	10 MG	30	Tablets	30	DAYS			
30042010100335		Alendronate Sodium Tab 35 MG	35 MG	4	Tablets	28	DAYS			
30042010100305		Alendronate Sodium Tab 5 MG	5 MG	30	Tablets	30	DAYS			
30042048102030		Ibandronate Sodium IV Soln 3 MG/3ML (Base Equivalent)	3 MG/3ML	3	mLs	90	DAYS			
30042065100320		Risedronate Sodium Tab 30 MG	30 MG	30	Tablets	30	DAYS			
30042065100305		Risedronate Sodium Tab 5 MG	5 MG	30	Tablets	30	DAYS			
30042065100380	Actonel	Risedronate Sodium Tab 150 MG	150 MG	1	Tablet	30	DAYS			
30042065100330	Actonel	Risedronate Sodium Tab 35 MG	35 MG	4	Tablets	28	DAYS			
30042065100635	Atelvia	Risedronate Sodium Tab Delayed Release 35 MG	35 MG	4	Tablet	28	DAYS			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
30042010100870	Binosto	Alendronate Sodium Effervescent Tab 70 MG	70 MG	4	Tablets	28	DAYS			
30042048100360	Boniva	Ibandronate Sodium Tab 150 MG (Base Equivalent)	150 MG	1	Tablet	30	DAYS			
30042010100370	Fosamax	Alendronate Sodium Tab 70 MG	70 MG	4	Tablets	28	DAYS			
30042010200370	Fosamax plus d	Alendronate Sodium-Cholecalciferol Tab 70-2800 MG-Unit	70-2800 MG-UNIT	4	Tablets	28	DAYS			
30042010200380	Fosamax plus d	Alendronate Sodium-Cholecalciferol Tab 70-5600 MG-Unit	70-5600 MG-UNIT	4	Tablets	28	DAYS			

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

● Program Summary: Constipation Agents

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
52450045000120	Amitiza	Lubiprostone Cap 24 MCG	24 MCG	60	Capsules	30	DAYS				
52450045000110	Amitiza	Lubiprostone Cap 8 MCG	8 MCG	120	Capsules	30	DAYS				
52580050102020	Relistor	methylnaltrexone bromide inj	12 MG/0.6ML	60	Vials	30	DAYS	65649055102			
52580050102020	Relistor	methylnaltrexone bromide inj	12 MG/0.6ML	30	Syringes	30	DAYS	65649055103; 65649055107			
52580050102015	Relistor	Methylnaltrexone Bromide Inj 8 MG/0.4ML (20 MG/ML)	8 MG/0.4ML	30	Syringes	30	DAYS				
52555060200320	Zelnorm	Tegaserod Maleate Tab 6 MG (Base Equivalent)	6 MG	60	Tablets	30	DAYS				
52557050000120	Linzess	Linaclotide Cap 145 MCG	145 MCG	30	Capsules	30	DAYS				
52557050000140	Linzess	Linaclotide Cap 290 MCG	290 MCG	30	Capsules	30	DAYS				
52557050000110	Linzess	Linaclotide Cap 72 MCG	72 MCG	30	Capsules	30	DAYS				
52558580100320	Ibsrela	Tenapanor HCl Tab	50 MG	60	Tablets	30	DAYS				
52560060200320	Motegrity	Prucalopride Succinate Tab 1 MG (Base Equivalent)	1 MG	30	Tablets	30	DAYS				
52560060200330	Motegrity	Prucalopride Succinate Tab 2 MG (Base Equivalent)	2 MG	30	Tablets	30	DAYS				
52580060300320	Movantik	Naloxegol Oxalate Tab 12.5 MG (Base Equivalent)	12.5 MG	30	Tablets	30	DAYS				
52580060300330	Movantik	Naloxegol Oxalate Tab 25 MG (Base Equivalent)	25 MG	30	Tablets	30	DAYS				
52580050100320	Relistor	Methylnaltrexone Bromide Tab 150 MG	150 MG	90	Tablets	30	DAYS				
52580057200320	Symproic	Naldemedine Tosylate Tab 0.2 MG (Base Equivalent)	0.2 MG	30	Tablets	30	DAYS				
52543060000320	Trulance	Plecanatide Tab 3 MG	3 MG	30	Tablets	30	DAYS				

ADDITIONAL QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
52580050102020	Relistor	methylnaltrexone bromide inj	12 MG/0.6ML	Quantity Limit allows for dosing for individuals at least 90th percentile weight	65649055102		

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Through Preferred	**TARGET AGENT(S)** **<u>Preferred Agent(s)</u>** **Amitiza** (lubiprostone)* **Linzess** (linaclotide) **<u>Nonpreferred Agent(s)</u>** **Ibsrela** (tenapanor) **Motegrity** (prucalopride) **Movantik** (naloxegol) **Relistor** (methylnaltrexone) **Symproic** (naldemedine) **Trulance** (plecanatide) **Zelnorm** (tegaserod) *-generic available **Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of irritable bowel syndrome with constipation (IBS-C) AND ALL of the following: 1. The patient has had IBS-C symptoms for greater than or equal to 3 months **AND** 2. ONE of the following: A. The requested agent is Trulance (plecanatide), Linzess (linaclotide) OR Ibsrela (tenapanor) **OR** B. The requested agent is Amitiza (lubiprostone) OR Zelnorm (tegaserod) AND ONE of the following: 1. The patient's sex is female **OR** 2. The prescriber has provided information that the requested agent is medically appropriate for the patient's sex and the intended diagnosis **AND** 3. ONE of the following: A. The patient's medication history includes at least 2 standard laxative therapy classes (e.g., bulk-forming, stimulant, enema, osmotic, or stool softener) AND ONE of the following: 1. The patient has had an inadequate response to at least 2 standard laxative therapy classes **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over at least 2 standard laxative therapy classes **OR** B. The patient has an intolerance or hypersensitivity to at least 2 standard laxative therapy classes **OR** C. The patient has an FDA labeled contraindication to ALL standard laxative therapy classes **OR**

Module	Clinical Criteria for Approval
	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 standard laxative therapy classes (e.g., bulk-forming, stimulant, enema, osmotic, or stool softener) 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 chronic idiopathic constipation (CIC) AND ALL of the following: 1. The patient has had CIC symptoms for greater than or equal to 3 months **AND** 2. The requested agent is Amitiza (lubiprostone), Linzess (linaclotide), Motegrity (prucalopride), or Trulance (plecanatide) **AND** 3. ONE of the following: A. The patient's medication history includes at least 2 standard laxative therapy classes (e.g., bulk-forming, stimulant, enema, osmotic, or stool softener) AND ONE of the following: 1. The patient has had an inadequate response to at least 2 standard laxative therapy classes **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over at least 2 standard laxative therapy classes **OR** B. The patient has an intolerance or hypersensitivity to at least 2 standard laxative therapy classes **OR** C. The patient has an FDA labeled contraindication to ALL standard laxative therapy classes **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 standard laxative therapy classes (e.g., bulk-forming, stimulant, enema, osmotic, or stool softener) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has a diagnosis of opioid-induced constipation (OIC) AND ALL of the following: 1. ONE of the following: A. BOTH of the following: 1. ONE of the following: A. The requested agent is Symproic (naldemedine), Movantik (naloxegol), OR Relistor (methylnaltrexone) tablet **OR** B. The requested agent is Amitiza (lubiprostone), AND the patient is not currently receiving a diphenylheptane opioid (e.g., methadone) **AND**

Module	Clinical Criteria for Approval
	2. ONE of the following: A. The patient has chronic non-cancer pain **OR** B. The patient has chronic pain related to prior cancer or its treatment **OR** C. The patient has active cancer pain **OR** B. The requested agent is Linzess (linaclotide) AND the patient has active cancer pain **OR** C. The request is for Relistor (methylnaltrexone) injection and the patient is receiving palliative care AND ONE of the following: 1. The patient has advanced illness **OR** 2. The patient has pain caused by active cancer **AND** 2. The patient has chronic use of an opioid agent in the past 30 days **AND** 3. ONE of the following: A. The patient's medication history includes at least 2 standard laxative therapy classes (e.g., stimulant, enema, osmotic, or stool softener, but not including fiber or bulking agents) AND ONE of the following: 1. The patient has had an inadequate response to at least 2 standard laxative therapy classes **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over at least 2 standard laxative therapy classes **OR** B. The patient has an intolerance or hypersensitivity to at least 2 standard laxative therapy classes **OR** C. The patient has an FDA labeled contraindication to ALL standard laxative therapy classes **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 standard laxative therapy classes (e.g., stimulant, enema, osmotic, or stool softener, but not including fiber or bulking agents) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. The patient has a diagnosis of pediatric functional constipation and ONE of the following: 1. The patient's medication history includes at least 2 standard laxative therapy classes (e.g., bulk-forming, stimulant, enema, osmotic, or stool softener) AND ONE of the following: A. The patient has had an inadequate response to at least 2 standard laxative therapy classes **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over at least 2 standard laxative therapy classes **OR** 2. The patient has an intolerance or hypersensitivity to at least 2 standard laxative therapy classes **OR** 3. The patient has an FDA labeled contraindication to ALL standard laxative therapy classes **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following:

Module	Clinical Criteria for Approval

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

5. The prescriber has provided documentation that ALL standard laxative therapy classes (e.g., bulk-forming, stimulant, enema, osmotic, or stool softener) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

2. If the patient has an FDA approved indication, then ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
   B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**
3. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following:

Brand	Generic
Amitiza	lubiprostone

   A. The patient's medication history includes the generic equivalent AND ONE of the following:
      1. The patient has had an inadequate response to the generic equivalent that is not expected to occur with the brand agent **OR**
      2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the generic equivalent over the brand agent **OR**
   B. The patient has an intolerance or hypersensitivity to generic equivalent that is not expected to occur with the brand agent **OR**
   C. The patient has an FDA labeled contraindication to generic equivalent that is not expected to occur with the brand agent **OR**
   D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
      2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
      3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
   E. The prescriber has provided documentation that generic equivalent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
4. ONE of the following:
   A. The request is for Linzess (linaclotide) for use in pediatric functional constipation **OR**
   B. The requested agent is for use in IBS-C AND ONE of the following:
      1. The patient's sex is female and ONE of the following:
         A. The requested agent is lubiprostone **OR**
         B. The patient's medication history includes lubiprostone AND ONE of the following:
            1. The patient has had an inadequate response to lubiprostone **OR**
            2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over lubiprostone **OR**
         C. The patient has an intolerance or hypersensitivity to lubiprostone that is not expected to occur with the requested agent **OR**

Module	Clinical Criteria for Approval
	D. The patient has an FDA labeled contraindication to lubiprostone that is not expected to occur with the requested agent **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 lubiprostone cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 2. The patient's sex is male and ONE of the following: A. The requested agent is Linzess (linaclotide) **OR** B. The patient's medication history includes Linzess (linaclotide) AND ONE of the following: 1. The patient has had an inadequate response to Linzess (linaclotide) **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over lubiprostone **OR** C. The patient has an intolerance or hypersensitivity to Linzess (linaclotide) that is not expected to occur with the requested agent **OR** D. The patient has an FDA labeled contraindication to Linzess (linaclotide) that is not expected to occur with the requested agent **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 Linzess (linaclotide) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The requested agent is for use in CIC or OIC AND ONE of the following: 1. The requested agent is lubiprostone **OR** 2. The patient's medication history includes lubiprostone AND ONE of the following: A. The patient has had an inadequate response to lubiprostone **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over lubiprostone **OR** 3. The patient has an intolerance or hypersensitivity to lubiprostone that is not expected to occur with the requested agent **OR** 4. The patient has an FDA labeled contraindication to lubiprostone that is not expected to occur with the requested agent **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following:

Module	Clinical Criteria for Approval
	A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that lubiprostone cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 5. The patient will NOT be using the requested agent in combination with another constipation agent in this program for the requested indication **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient has had clinical benefit with the requested agent **AND** 4. The patient will NOT be using the requested agent in combination with another constipation agent in this program for the requested indication **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

Module	Clinical Criteria for Approval
	C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: 12 months

• Program Summary: Cystic Fibrosis Transmembrane Conductance Regulator (CFTR)

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

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

1) the indication is FDA approved AND

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
45302030003002	Kalydeco	ivacaftor packet	5.8 MG	60	Packets	30	DAYS				
45302030003005	Kalydeco	ivacaftor packet	13.4 MG	60	Packets	30	DAYS				
45302030003010	Kalydeco	Ivacaftor Packet 25 MG	25 MG	60	Packets	30	DAYS				
45302030003020	Kalydeco	Ivacaftor Packet 50 MG	50 MG	60	Packets	30	DAYS				
45302030003030	Kalydeco	Ivacaftor Packet 75 MG	75 MG	60	Packets	30	DAYS				
45302030000320	Kalydeco	Ivacaftor Tab 150 MG	150 MG	60	Tablets	30	DAYS				
45309902303005	Orkambi	Lumacaftor-Ivacaftor Granules Packet	75-94 MG	60	Packets	30	DAYS				
45309902303010	Orkambi	lumacaftor-ivacaftor granules packet	100-125 MG	60	Packets	30	DAYS				
45309902303020	Orkambi	lumacaftor-ivacaftor granules packet	150-188 MG	60	Packets	30	DAYS				
45309902300310	Orkambi	lumacaftor-ivacaftor tab	100-125 MG	120	Tablets	30	DAYS				
45309902300320	Orkambi	Lumacaftor-Ivacaftor Tab 200-125 MG	200-125 MG	120	Tablets	30	DAYS				
4530990280B720	Symdeko	Tezacaftor-Ivacaftor 100-150 MG & Ivacaftor 150 MG Tab TBPK	100-150 & 150 MG	60	Tablets	30	DAYS				
4530990280B710	Symdeko	Tezacaftor-Ivacaftor 50-75 MG & Ivacaftor 75 MG Tab TBPK	50-75 & 75 MG	60	Tablets	30	DAYS				
4530990340B120	Trikafta	elexacaf-tezacaf-ivacaf	80-40-60 & 59.5 MG	56	Packets	28	DAYS				
4530990340B140	Trikafta	elexacaf-tezacaf-ivacaf	100-50-75 & 75 MG	56	Packets	28	DAYS				
4530990340B720	Trikafta	Elexacaf-Tezacaf-Ivacaf	50-25-37.5 & 75 MG	90	Tablets	30	DAYS				
4530990340B740	Trikafta	Elexacaf-Tezacaf-Ivacaf 100-50-75 MG &Ivacaftor 150 MG TBPK	100-50-75 & 150 MG	90	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	PRIOR AUTHORIZATION CRITERIA FOR APPROVAL **Initial Evaluation** **Target Agent(s)** will be approved when ONE of the following are met: 1. ALL of the following: A. ONE of the following: 1. ALL of the following: A. The patient has a diagnosis of cystic fibrosis **AND** B. Information has been provided that indicates the patient has a CFTR gene mutation(s), confirmed by genetic testing, according to the FDA label for the requested agent (medical records required) **AND** C. If the requested agent is Kalydeco, the patient does NOT have F508del mutation on BOTH alleles of CFTR gene (NOT homozygous) **OR** 2. The patient has another FDA approved indication for the requested agent **AND** B. If the patient has an FDA approved indication, then ONE of the following: 1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** 2. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** C. The patient will NOT be using the requested agent in combination with another CFTR modulator agent for the requested indication **AND** D. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cystic fibrosis, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** E. The patient does NOT have any FDA labeled contraindications to the requested agent **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Length of Approval:** 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ONE of the following are met: 1. ALL of the following: A. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** B. ONE of the following: 1. If the patient has a diagnosis of cystic fibrosis, the prescriber has provided information that the patient has had clinical improvement or stabilization with the requested agent from baseline (prior to treatment with the requested agent) [e.g., improvement in FEV1, increase in weight/BMI, improvement in Cystic Fibrosis Questionnaire-Revised (CFQ-R) Respiratory Domain score, improvements in respiratory symptoms related to patients with CF (cough, sputum production, and difficulty breathing), and/or reduced number of pulmonary exacerbations] **OR** 2. If the patient has another FDA approved indication for the requested agent, the patient has had clinical benefit with the requested agent **AND** C. The patient will NOT be using the requested agent in combination with another CFTR modulator agent for the requested indication **AND**

Module	Clinical Criteria for Approval
	D. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cystic fibrosis, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** E. The patient does NOT have any FDA labeled contraindications to the requested agent **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: Initial: 6 months; Renewal: 12 months

• Program Summary: Elagolix/Relugolix

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
24993503800320	Myfembree	Relugolix-Estradiol-Norethindrone Acetate Tab	40-1-0.5 MG	30	Tablets	30	DAYS			
2499350340B220	Oriahnn	Elagolix-Estrad-Noreth 300-1-0.5MG & Elagolix 300MG Cap Pack	300-1-0.5 & 300 MG	56	Capsules	28	DAYS			
30090030100320	Orilissa	Elagolix Sodium Tab 150 MG (Base Equiv)	150 MG	30	Tablets	30	DAYS			
30090030100330	Orilissa	Elagolix Sodium Tab 200 MG (Base Equiv)	200 MG	60	Tablets	30	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Myfembree	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) and BOTH of the following: 1. The patient's diagnosis of uterine fibroids was confirmed via imaging (e.g., ultrasound) **AND** 2. The patient has NOT had a hysterectomy **OR** B. The patient has a diagnosis of moderate to severe pain associated with endometriosis **AND** 2. The patient is premenopausal (e.g., less than 12 months since last menstrual period) **AND** 3. The prescriber has confirmed the patient's bone health allows for initiating therapy with the requested agent **AND** 4. ONE of the following: A. The patient's medication history includes at least ONE hormonal contraceptive used in the treatment of the requested indication AND ONE of the following: 1. The patient has had an inadequate response to at least ONE hormonal contraceptive used in the treatment of the requested indication **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over hormonal contraceptives used in the treatment of the requested indication **OR** B. The patient has an intolerance or hypersensitivity to at least ONE hormonal contraceptive used in the treatment of the requested indication **OR** C. The patient has an FDA labeled contraindication to ALL hormonal contraceptive therapy (i.e., oral, topical patches, implants, injections, IUD) **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 hormonal contraceptive therapy (i.e., oral, topical patches, implants, injections, IUD) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 5. The patient will NOT be using the requested agent in combination with another GnRH antagonist agent targeted in this program (e.g., elagolix, relugolix) for the requested indication **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 7. ONE of the following: A. The patient is initiating therapy with the requested agent **OR** B. The patient is not initiating therapy with the requested agent and BOTH of the following: 1. The prescriber has provided information indicating the number of months the patient has been on therapy **AND** 2. The total duration of treatment with the requested agent has NOT exceeded 24 months per lifetime **Length of Approval:** Up to 6 months, with a lifetime maximum of 24 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. The patient is premenopausal (e.g., less than 12 months since last menstrual period) **AND** 3. The patient has had clinical benefit with the requested agent **AND** 4. The prescriber has assessed the patient's bone health AND confirmed the patient's bone health allows for continued therapy with the requested agent **AND** 5. The patient has NOT had a fragility fracture since starting therapy with the requested agent **AND** 6. The patient will NOT be using the requested agent in combination with another GnRH antagonist agent targeted in this program (e.g., elagolix, relugolix) for the requested indication **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 8. BOTH of the following: A. The prescriber has provided information indicating the number of months the patient has been on therapy **AND** B. The total duration of treatment with the requested agent has NOT exceeded 24 months per lifetime **Length of Approval:** Up to 6 months, with a lifetime maximum of 24 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Oriahnn	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) **AND** 2. The patient's diagnosis of uterine fibroids was confirmed via imaging (e.g., ultrasound) **AND** 3. The patient has NOT had a hysterectomy **AND** 4. The patient is premenopausal (e.g., less than 12 months since last menstrual period) **AND** 5. The prescriber has confirmed the patient's bone health allows for initiating therapy with the requested agent **AND** 6. ONE of the following: A. The patient's medication history includes at least ONE hormonal contraceptive used in the treatment of the requested indication AND ONE of the following: 1. The patient has had an inadequate response to at least ONE hormonal contraceptive used in the treatment of the requested indication **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over hormonal contraceptives used in the treatment of the requested indication **OR** B. The patient has an intolerance or hypersensitivity to at least ONE hormonal contraceptive used in the treatment of the requested indication **OR** C. The patient has an FDA labeled contraindication to ALL hormonal contraceptive therapy (i.e., oral, topical patches, implants, injections, IUD) **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 hormonal contraceptive therapy (i.e., oral, topical patches, implants, injections, IUD) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 7. The patient will NOT be using the requested agent in combination with another GnRH antagonist agent targeted in this program (e.g., elagolix, relugolix) for the requested indication **AND** 8. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 9. ONE of the following: A. The patient is initiating therapy with the requested agent **OR** B. The patient is not initiating therapy with the requested agent and BOTH of the following: 1. The prescriber has provided information indicating the number of months the patient has been on therapy **AND** 2. The total duration of treatment with the requested agent has NOT exceeded 24 months per lifetime **Length of Approval:** Up to 6 months, with a lifetime maximum of 24 months **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 is premenopausal (e.g., less than 12 months since last menstrual period) **AND** 3. The patient has had clinical benefit with the requested agent **AND** 4. The prescriber has assessed the patient's bone health AND confirmed the patient's bone health allows for continued therapy with the requested agent **AND** 5. The patient has NOT had a fragility fracture since starting therapy with the requested agent **AND** 6. The patient will NOT be using the requested agent in combination with another GnRH antagonist agent targeted in this program (e.g., elagolix, relugolix) for the requested indication **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 8. BOTH of the following: A. The prescriber has provided information indicating the number of months the patient has been on therapy **AND** B. The total duration of treatment with the requested agent has NOT exceeded 24 months per lifetime **Length of Approval:** Up to 6 months, with a lifetime maximum of 24 months
Orilissa	**Initial Evaluation** **Target Agent** will be approved when ALL of the following are met: 1. The patient has a diagnosis of moderate to severe pain associated with endometriosis **AND** 2. The patient is premenopausal (e.g., less than 12 months since last menstrual period) **AND** 3. ONE of the following: A. The patient's medication history includes ONE hormonal contraceptive therapy used in the treatment of the requested indication AND ONE of the following: 1. The patient has had an inadequate response to ONE hormonal contraceptive therapy used in the treatment of the requested indication **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over hormonal contraceptive therapy used in the treatment of the requested indication **OR**

Module	Clinical Criteria for Approval
	B. The patient has an intolerance or hypersensitivity to ONE hormonal contraceptive used in the treatment of the requested indication **OR** C. The patient has an FDA labeled contraindication to ALL hormonal contraceptive therapy (i.e., oral, topical patches, implants, injections, IUD) **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 hormonal contraceptive therapy (i.e., oral, topical patches, implants, injections, IUD) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The prescriber has confirmed the patient's bone health allows for initiating therapy with the requested agent **AND** 5. The patient will NOT be using the requested agent in combination with another GnRH antagonist agent targeted in this program (e.g., elagolix, relugolix) for the requested indication **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 7. ONE of the following: A. The patient does NOT have coexisting moderate hepatic impairment (Child-Pugh [CP]/ Child-Turcotte-Pugh [CTP] Class B) AND ONE of the following: 1. The patient is initiating therapy with the requested agent and strength **OR** 2. The patient is not initiating therapy with the requested agent and strength and BOTH of the following: A. The prescriber has provided information indicating the number of months the patient has been on therapy **AND** B. ONE of the following: 1. The requested strength is 150 mg AND the total duration of treatment with the requested strength has NOT exceeded 24 months per lifetime **OR** 2. The requested strength is 200 mg AND the total duration of treatment with the requested strength has NOT exceeded 6 months per lifetime **OR** B. The patient does have coexisting moderate hepatic impairment (Child-Pugh [CP]/ Child-Turcotte-Pugh [CTP] Class B) AND BOTH of the following: 1. The requested strength is 150 mg **AND** 2. ONE of the following: A. The patient is initiating therapy with the requested agent and strength **OR** B. The patient is not initiating therapy with the requested agent and strength and BOTH of the following: 1. The prescriber has provided information indicating the number of months the patient has been on therapy **AND** 2. The total duration of treatment with the requested strength has NOT exceeded 6 months per lifetime **Length of Approval:** Up to 6 months with a lifetime maximum of 24 months with the 150 mg without coexisting moderate hepatic impairment, a lifetime maximum of 6 months with the 150 mg with coexisting moderate hepatic impairment, and a lifetime maximum of 6 months with the 200 mg

Module	Clinical Criteria for Approval
	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 (*please note requests for 200 mg strength should always be reviewed under initial criteria) **AND** 2. The patient is premenopausal (e.g., less than 12 months since last menstrual period) **AND** 3. The patient has had clinical benefit with the requested agent **AND** 4. The prescriber has assessed the patient's bone health AND confirmed the patient's bone health allows for continued therapy with the requested agent **AND** 5. The patient has NOT had a fragility fracture since starting therapy with the requested agent **AND** 6. The patient will NOT be using the requested agent in combination with another GnRH antagonist agent targeted in this program (e.g., elagolix, relugolix) for the requested indication **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 8. BOTH of the following: A. The prescriber has provided information indicating the number of months the patient has been on therapy with the requested agent and strength **AND** B. ONE of the following: 1. The patient does NOT have coexisting moderate hepatic impairment (Child-Pugh [CP]/ Child-Turcotte-Pugh [CTP] Class B) AND the total duration of treatment with the requested strength has NOT exceeded 24 months per lifetime **OR** 2. The patient does have coexisting moderate hepatic impairment (Child-Pugh [CP]/ Child-Turcotte-Pugh [CTP] Class B) AND the total duration of treatment with the requested strength has NOT exceeded 6 months per lifetime **Length of Approval:** Up to 6 months with a lifetime maximum of 24 months with the 150 mg without coexisting moderate hepatic impairment OR a lifetime maximum of 6 months with the 150 mg with coexisting moderate hepatic impairment

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 the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **Length of Approval:** Myfembree and Oriahnn: Up to 6 months with a lifetime maximum of 24 months. Orilissa: Up to 6 months with a lifetime maximum of 24 months with the 150 mg without coexisting moderate hepatic impairment, a lifetime maximum of 6 months with the 150 mg with coexisting moderate hepatic impairment, and a lifetime maximum of 6 months with the 200 mg

● Program Summary: Emflaza (deflazacort)

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
22100017000350	Emflaza	Deflazacort Tab 18 MG	18 MG	30	Tablets	30	DAYS			
22100017000340	Emflaza	Deflazacort Tab 6 MG	6 MG	60	Tablets	30	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of Duchenne Muscular Dystrophy confirmed by genetic analysis (i.e., dystrophin deletion or duplication mutation) (genetic test required) **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information supporting the use of the requested agent for the patient's age for the requested indication **AND** 3. ONE of the following: A. The patient's medication history includes generic prednisone (or prednisolone) AND ONE of the following: 1. The patient has had an inadequate response generic prednisone (or prednisolone) **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over generic prednisone (or prednisolone) **OR** B. The prescriber has provided information that the patient has an intolerance or hypersensitivity to generic prednisone (or prednisolone) that is NOT expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to generic prednisone (or prednisolone) **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that generic prednisone (or prednisolone) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., pediatric neurologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 6. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose based on the patient's weight (i.e., 0.9 mg/kg/day) **Length of Approval:** 12 months

Module	Clinical Criteria for Approval
	NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit or disease stabilization with the requested agent (e.g., improved strength, timed motor function, pulmonary function; reduced need for scoliosis surgery) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., pediatric neurologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose based on the patient's weight (i.e., 0.9 mg/kg/day) **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Empaveli (pegcetacoplan)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
85804065002020	Empaveli	Pegcetacoplan Subcutaneous Soln	1080 MG/20ML	8	Vials	28	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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

Module	Clinical Criteria for Approval
	A. The patient has a diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) as confirmed by flow cytometry with at least 2 independent flow cytometry reagents on at least 2 cell lineages (e.g., RBCs and WBCs) demonstrating that the patient's peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI) – linked proteins (lab tests required) **OR** B. The patient has another FDA approved indication for the requested agent **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient will NOT be using the requested agent in combination with Soliris (eculizumab) for the requested indication (NOTE: if the patient is switching from Soliris, Soliris should be continued for the first 4 weeks after starting the requested agent and then Soliris should be discontinued) **AND** 5. The patient will NOT be using the requested agent in combination with Ultomiris (ravulizumab-cwvz) for the requested indication **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had improvements or stabilization with the requested agent (e.g., decreased requirement of RBC transfusions, stabilization/improvement of hemoglobin, reduction of lactate dehydrogenase (LDH), stabilization/improvement of symptoms) (medical records required) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient will NOT be using the requested agent in combination with Soliris (eculizumab) or Ultomiris (ravulizumab-cwvz) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. ONE of the following: 1. The patient has a lactate dehydrogenase (LDH) level greater than 2X the upper limit of normal (lab test required) **OR** 2. ALL of the following: (medical records required)

Module	Clinical Criteria for Approval
	A. The patient had a prior LDH greater than 2X the upper limit of normal and required a dose increase **AND** B. The patient is currently using the requested dose **AND** C. The requested quantity (dose) does NOT exceed 1,080 mg every three days **Length of Approval:** 12 months NOTE: If approving for every three days dosing approve a quantity of 10 vials/30 days for 12 months

● Program Summary: Enspryng (satralizumab-mwge)

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
9940507040E520	Enspryng	Satralizumab-mwge Subcutaneous Soln Pref Syringe	120 MG/ML	1	Syringe	28	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) **AND** 2. The patient is anti-aquaporin-4 (AQP4) antibody positive **AND** 3. The diagnosis was confirmed by at least ONE of the following: A. Optic neuritis **OR** B. Acute myelitis **OR** C. Area postrema syndrome (episode of otherwise unexplained hiccups or nausea and vomiting) **OR** D. Acute brainstem syndrome **OR** E. Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions **OR** F. Symptomatic cerebral syndrome with NMOSD-typical brain lesions **AND** 4. The patient has had at least 1 discrete clinical attack of CNS symptoms **AND** 5. Alternative diagnoses (e.g., multiple sclerosis, ischemic optic neuropathy) have been ruled out **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 supporting the use of 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., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 8. The prescriber has screened the patient for hepatitis B viral (HBV) infection AND BOTH of the following: A. The patient does NOT have an active HBV infection **AND** B. If the patient has had a previous HBV infection or is a carrier for HBV infection the prescriber has consulted with a gastroenterologist or a hepatologist before initiating and during treatment with the requested agent **AND** 9. The patient does NOT have active or untreated tuberculosis **AND** 10. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**

Module	Clinical Criteria for Approval
	11. The patient will not be using the requested agent in combination with rituximab, Soliris, or Uplizna for the requested indication **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent (e.g., decreased relapses, improvement or stabilization of vision or paralysis) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. BOTH of the following: A. The patient does not have active hepatitis B infection **AND** B. If the patient has had a previous HBV infection or is a carrier for HBV infection the prescriber continues to consult with a gastroenterologist or a hepatologist during treatment with the requested agent **AND** 5. The patient does not have active or latent tuberculosis **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 7. The patient will NOT be using the requested agent in combination with rituximab, Soliris, or Uplizna for the requested indication **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **Length of Approval:** 12 months NOTE: may approve initial loading dose of 3 syringes for 1 month and the maintenance dose for the remainder of 12 months

● Program Summary: Growth Hormone

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

All products in this program are targeted, formulary and non-formulary. Additional FE review required for non-formulary drugs.

For Medicaid, the preferred products are the MN Medicaid Preferred Drug List (PDL) preferred drugs: Norditropin and Nutropin AQ.

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
	3010	Genotropin; Genotropin miniquick; Humatrope; Ngenla; Norditropin flexpro; Nutropin aq nuspin 10; Nutropin aq nuspin 20; Nutropin aq nuspin5; Omnitrope; Saizen; Saizenprep reconstitution; Serostim; Skytrofa; Sogroya; Zomacton; Zorbtive	lonapegsomatropin-tcgd for subcutaneous inj cart; lonapegsomatropin-tcgd for subcutaneous inj cartridge; somapacitan-beco solution pen-injector; somatrogon-ghla solution pen-injector; somatropin (non-refrigerated) for inj; somatropin (non-refrigerated) for subcutaneous inj; somatropin for inj; somatropin for inj cartridge; somatropin for subcutaneous inj; somatropin for subcutaneous inj cartridge; somatropin for subcutaneous inj prefilled syr; somatropin solution cartridge; somatropin solution pen-injector	0.2 MG; 0.4 MG; 0.6 MG; 0.8 MG; 1 MG; 1.2 MG; 1.4 MG; 1.6 MG; 1.8 MG; 10 MG; 10 MG/1.5ML; 10 MG/2ML; 11 MG; 12 MG; 13.3 MG; 15 MG/1.5ML; 2 MG; 20 MG/2ML; 24 MG; 24 MG/1.2ML; 3 MG; 3.6 MG; 30 MG/3ML; 4 MG; 4.3 MG; 5 MG; 5 MG/1.5ML; 5 MG/2ML; 5.2 MG; 5.8 MG; 6 MG; 6.3 MG; 60 MG/1.2ML; 7.6 MG; 8.8 MG; 9.1 MG	M; N; O; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Adult	**TARGET AGENTS:** **For Medicaid, the preferred products are the MN Medicaid Preferred Drug List (PDL) preferred drugs: Norditropin and Nutropin AQ** Omnitrope® (somatropin) Genotropin®, Genotropin® MiniQuick (somatropin) Humatrope® (somatropin) Ngenla™ (somatrogon-ghla) Norditropin FlexPro® (somatropin) Nutropin AQ NuSpin® (somatropin) Saizen®, Saizenprep® (somatropin)

Module	Clinical Criteria for Approval

Serostim® (somatropin)
Skytrofa™ (lonapegsomatropin-tcgd)
Sogroya® (somapacitan-beco)
Zomacton® (somatropin)
Zorbtive® (somatropin)

Adults – Initial Evaluation

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

1. The patient is an adult (as defined by the prescriber) **AND**
2. The patient has ONE of the following diagnoses:
    - A. If the request is for Serostim, the patient has a diagnosis of AIDS wasting/cachexia AND ALL of the following:
        1. The patient is currently treated with antiretroviral therapy **AND**
        2. The patient will continue antiretroviral therapy in combination with the requested agent **AND**
        3. BOTH of the following:
            - A. ONE of the following:
                1. The patient has had weight loss that meets ONE of the following:
                    - A. 10% unintentional weight loss over 12 months **OR**
                    - B. 7.5% unintentional weight loss over 6 months **OR**
                2. The patient has a body cell mass (BCM) loss greater than or equal to 5% within 6 months **OR**
                3. The patient's sex is male and has BCM less than 35% of total body weight and body mass index (BMI) less than 27 kg/m^2 **OR**
                4. The patient's sex is female and has BCM less than 23% of total body weight and BMI less than 27 kg/m^2 **OR**
                5. The prescriber has provided information that the patient's BCM less than 35% or less than 23% and BMI less than 27 kg/m^2 are medically appropriate for diagnosing AIDS wasting/cachexia for the patient's sex **OR**
                6. The patient's BMI is less than 20 kg/m^2 **AND**
            - B. All other causes of weight loss have been ruled out **OR**
    - B. If the request is for Zorbtive, then BOTH of the following:
        1. The patient has a diagnosis of short bowel syndrome (SBS) **AND**
        2. The patient is receiving specialized nutritional support **OR**
    - C. The patient has a diagnosis of growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone AND ONE of the following:
        1. The patient had a diagnosis of childhood-onset growth hormone deficiency AND has failed at least one growth hormone (GH) stimulation test as an adult **OR**
        2. The patient has a low insulin-like growth factor-1 (IGF-1) level AND ONE of the following:
            - A. Organic hypothalamic-pituitary disease **OR**
            - B. Pituitary structural lesion or trauma **OR**
            - C. The patient has panhypopituitarism or multiple (greater than or equal to 3) pituitary hormone deficiency **OR**
        3. The patient has an established causal genetic mutation OR hypothalamic-pituitary structural defect other than ectopic posterior pituitary **OR**
        4. The patient has failed at least two growth hormone (GH) stimulation tests as an adult **OR**
        5. The patient has failed at least one GH stimulation test as an adult AND the patient has an organic pituitary disease **OR**

Module	Clinical Criteria for Approval
	D. The patient has another FDA approved indication for the requested agent and route of administration **OR** E. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. 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** 5. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication **AND** 6. ONE of the following: A. The request is for a preferred agent or Serostim or Zorbtive **OR** B. ONE of the following: 1. The patient's medication history includes two preferred agents AND ONE of the following: A. The patient has had an inadequate response to two preferred agents **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL the preferred agents **OR** 2. The patient has an intolerance or hypersensitivity to two preferred agents that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 3. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 4. The prescriber has provided information to support the efficacy of the requested non-preferred agent over the preferred agents, for the intended diagnosis (medical record required) **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 information that ALL preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** SBS: 4 weeks AIDS wasting/cachexia: 12 weeks Any other indication: 12 months **Adults – Renewal Evaluation** **Target Growth Hormone Agent(s)** will be approved when ALL of the following are met: 1. The patient has been approved for therapy with GH previously through the plan's Prior Authorization process **AND** 2. The patient is an adult (as defined by the prescriber) **AND**

Module	Clinical Criteria for Approval
	3. ONE of the following: A. The request is for a preferred agent or Serostim or Zorbtive **OR** B. ONE of the following: 1. The patient's medication history includes two preferred agents AND ONE of the following: A. The patient has had an inadequate response to two preferred agents **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL the preferred agents **OR** 2. The patient has an intolerance or hypersensitivity to two preferred agents that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 3. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 4. The prescriber has provided information to support the efficacy of the requested non-preferred agent over the preferred agents, for the intended diagnosis (medical record required) **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 information that ALL preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. ONE of the following: A. The patient has a diagnosis of short bowel syndrome (SBS) AND has had clinical benefit with the requested agent **OR** B. The patient has a diagnosis of AIDS wasting/cachexia AND ALL of the following: 1. The patient is currently treated with antiretroviral therapy **AND** 2. The patient will continue antiretroviral therapy in combination with the requested agent **AND** 3. The patient has had clinical benefit with the requested agent (i.e., an increase in weight or weight stabilization) **OR** C. The patient has growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone AND BOTH of the following: 1. The patient's IGF-I level has been evaluated to confirm the appropriateness of the current dose **AND** 2. The patient has had clinical benefit with the requested agent (i.e., body composition, hip-to-waist ratio, cardiovascular health, bone mineral density, serum cholesterol, physical strength, or quality of life) **OR** D. The patient has a diagnosis other than SBS, AIDS wasting/cachexia, GHD, or growth failure due to inadequate secretion of endogenous growth hormone AND has had clinical benefit with the requested agent **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or has consulted with a specialist in the area of the patient's diagnosis **AND** 7. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication **AND** 8. The patient is being monitored for adverse effects of GH

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td></td><td>Compendia Allowed: CMS Approved Compendia

Length of Approval:
<table>
<tr><td>SBS</td><td>4 weeks</td></tr>
<tr><td>AIDS wasting/cachexia</td><td>12 weeks</td></tr>
<tr><td>Any other indication</td><td>12 months</td></tr>
</table></td></tr>
<tr><td>Child</td><td>
<table>
<tr><td>TARGET AGENTS:

For Medicaid, the preferred products are the MN Medicaid Preferred Drug List (PDL) preferred drugs: Norditropin and Nutropin AQ</td></tr>
<tr><td>Omnitrope® (somatropin)
Genotropin® , Genotropin® MiniQuick (somatropin)
Humatrope® (somatropin)
Ngenla™ (somatrogon-ghla)
Norditropin FlexPro® (somatropin)
Nutropin AQ NuSpin® (somatropin)
Saizen®, Saizenprep® (somatropin)
Serostim® (somatropin)
Skytrofa™ (lonapegsomatropin-tcgd)
Sogroya® (somapacitan-beco)
Zomacton® (somatropin)
Zorbtive® (somatropin)</td></tr>
</table>

Growth Hormone (GH) products will be approved as below.

For Children – Initial Evaluation when ALL of the following are met:
1. The patient is a child (as defined by the prescriber) AND
2. The patient has ONE of the following diagnoses:
A. ALL of the following:
1. The patient is a newborn (less than or equal to 4 months of age) with hypoglycemia AND
2. The patient has a serum growth hormone (GH) concentration less than or equal to 5 mcg/L AND
3. ONE of the following:
A. Congenital pituitary abnormality (e.g., ectopic posterior pituitary and pituitary hypoplasia with abnormal stalk) OR
B. Deficiency of at least one additional pituitary hormone OR
B. ALL of the following:
1. The patient is a newborn (less than or equal to 4 months of age) with hypoglycemia AND
2. The patient has a growth hormone (GH) concentration less than 20 mcg/L AND
3. The patient does not have a known metabolic disorder AND
4. The patient has a reduced IGFBP-3 level (e.g., less than -2 SD) OR
C. The patient has a diagnosis of Turner syndrome OR
D. The patient has a diagnosis of Noonan syndrome OR
E. The patient has a diagnosis of Prader-Willi syndrome OR
F. The patient has a diagnosis of SHOX gene deficiency OR</td></tr>
</table>

Module	Clinical Criteria for Approval
	G. If the request is for Zorbtive, the patient has a diagnosis of short bowel syndrome (SBS) AND is receiving specialized nutritional support AND ONE of the following: 1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** 2. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **OR** H. The patient has a diagnosis of panhypopituitarism or has deficiencies in at least 3 or more pituitary axes AND serum IGF-I levels below the age- and sex-appropriate reference range when off GH therapy **OR** I. The patient has a diagnosis of chronic renal insufficiency and BOTH of the following: 1. The patient's height velocity (HV) for age is less than -1.88 standard deviations (SD) OR HV for age is less than the third percentile **AND** 2. Other etiologies for growth impairment have been addressed **OR** J. The patient has a diagnosis of small for gestational age (SGA) and ALL of the following: 1. The patient is 2 years of age or older **AND** 2. The patient has a documented birth weight and/or birth length that is 2 or more standard deviations (SD) below the mean for gestational age **AND** 3. At 24 months of age, the patient failed to manifest catch-up growth evidenced by a height that remains 2 or more standard deviations (SD) below the mean for age and sex **OR** K. The patient has a diagnosis of idiopathic short stature (ISS) AND ALL of the following: 1. The patient has a height less than or equal to -2.25 SD below the corresponding mean height for age and sex **AND** 2. The patient has open epiphyses **AND** 3. ONE of the following: A. The patient has a predicted adult height that is below the normal range AND ONE of the following: 1. The patient's sex is male and predicted adult height is less than 63 inches **OR** 2. The patient's sex is female and predicted adult height is less than 59 inches **OR** B. The patient is more than 2 SD below their mid-parental target height **AND** 4. BOTH of the following: A. The patient has been evaluated for constitutional delay of growth and puberty (CDGP) **AND** B. The patient does NOT have a diagnosis of CDGP **OR** L. The patient has a diagnosis of growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone AND ONE of the following: 1. The patient has extreme short stature (e.g., height less than or equal to -3 SD), normal nutrition, significantly reduced IGF-1 and IGFBP-3 (e.g., less than -2 SD), and delayed bone age **OR** 2. BOTH of the following: A. The patient has ONE of the following: 1. Height more than 2 SD below the mean for age and sex **OR** 2. Height more than 1.5 SD below the midparental height **OR** 3. A decrease in height SD of more than 0.5 over one year in children greater than 2 years of age **OR** 4. Height velocity (HV) more than 2 SD below the mean over one year or more than 1.5 SD sustained over two years **OR** 5. Height-for-age curve that has deviated downward across two major height percentile curves (e.g., from above the 25th percentile to below the 10th percentile) **OR** 6. BOTH of the following: A. The patient's age is 2-4 years **AND**

Module	Clinical Criteria for Approval
	B. The patient has a HV less than 5.5 cm/year (less than 2.2 inches/year) **OR** 7. BOTH of the following: A. The patient's age is 4-6 years **AND** B. The patient has a HV less than 5 cm/year (less than 2 inches/year) **OR** 8. The patient's age is 6 years to puberty AND ONE of the following: A. The patient's sex is male and HV is less than 4 cm/year (less than 1.6 inches/year) **OR** B. The patient's sex is female and HV is less than 4.5 cm/year (less than 1.8 inches/year) **AND** B. ONE of the following: 1. The patient has failed at least 2 GH stimulation tests (e.g., peak GH value of less than 10 mcg/L after stimulation, or otherwise considered abnormal as determined by testing lab) **OR** 2. The patient has failed at least 1 GH stimulation test (e.g., peak GH value of less than 10 mcg/L after stimulation, or otherwise considered abnormal as determined by testing lab) AND ONE of the following: A. Pathology of the central nervous system **OR** B. History of irradiation **OR** C. Other pituitary hormone defects (e.g., multiple pituitary hormone deficiency [MPHD]) **OR** D. A genetic defect **OR** 3. The patient has a pituitary abnormality and a known deficit of at least one other pituitary hormone **OR** M. The patient has another FDA approved indication for the requested agent and route of administration **OR** N. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 3. ONE of the following: A. The request is for a preferred agent or Zorbtive or Serostim **OR** B. ONE of the following: 1. The patient's medication history includes two preferred agents AND ONE of the following: A. The patient has had an inadequate response to two preferred agents **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL the preferred agents **OR** 2. The patient has an intolerance or hypersensitivity to two preferred agents that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 3. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 4. The prescriber has provided information to support the efficacy of the requested non-preferred agent over the preferred agents, for the intended diagnosis (medical record required) **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**

Module	Clinical Criteria for Approval
	6. The prescriber has provided information that ALL preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or has consulted with a specialist in the area of the patient's diagnosis **AND** 6. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 4 weeks for SBS 12 months for other indications **Children – Renewal Evaluation** **Target Growth Hormone Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for therapy with GH through the plan's prior authorization process **AND** 2. The patient is a child (as defined by the prescriber) **AND** 3. ONE of the following: A. The request is for a preferred agent or Zorbtive or Serostim **OR** B. ONE of the following: 1. The patient's medication history includes two preferred agents AND ONE of the following: A. The patient has had an inadequate response to two preferred agents **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL the preferred agents **OR** 2. The patient has an intolerance or hypersensitivity to two preferred agents that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 3. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested nonpreferred agent (medical record required) **OR** 4. The prescriber has provided information to support the efficacy of the requested non-preferred agent over the preferred agents, for the intended diagnosis (medical record required) **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 information that ALL preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. ONE of the following: A. The patient has a diagnosis of short bowel syndrome (SBS) AND has had clinical benefit with the requested agent AND ONE of the following:

Module	Clinical Criteria for Approval
	1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** 2. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **OR** B. The patient has a diagnosis of ISS and BOTH of the following: 1. Growth velocity is greater than 2 cm/year **AND** 2. Bone age is less than 16 years in patients with a sex of male and 15 years in patients with a sex of female AND the patient has open epiphyses **OR** C. The patient has a diagnosis of growth hormone deficiency (GHD), growth failure due to inadequate secretion of endogenous growth hormone, short stature disorder (i.e., Noonan's syndrome, SHOX deficiency, Turner Syndrome, small for gestational age), or renal function impairment with growth failure AND BOTH of the following: 1. The patient does NOT have closed epiphyses **AND** 2. The patient's height has increased or height velocity has improved since initiation or last GH approval **OR** D. The patient has a diagnosis of Prader-Willi syndrome AND has had clinical benefit with the requested agent **OR** E. The patient has a diagnosis other than SBS, ISS, GHD, growth failure due to inadequate secretion of endogenous growth hormone, short stature disorder (i.e., Noonan's syndrome, SHOX deficiency, Turner syndrome, small for gestational age), or renal function impairment with growth failure, and Prader-Willi AND has had clinical benefit with the requested agent **AND** 5. The patient is being monitored for adverse effects of GH **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or has consulted with a specialist in the area of the patient's diagnosis **AND** 8. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 4 weeks for SBS 12 months for other indications

• Program Summary: Hyftor (sirolimus)

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
90784070004020	Hyftor	Sirolimus Gel	0.2 %	7	Tubes	84	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. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of Approval:** 12 months

• Program Summary: Insulin Pumps

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

Target agents for MN Medicaid are Omnipod, Omnipod DASH, and Omnipod GO products.

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
97201030506400	Omnipod 5 g6 intro kit (gen 5)	Insulin infusion disposable pump kit		1	Kit	720	DAYS	08508300001			
97201030506300	Omnipod 5 g6 pods (gen 5); Omnipod classic pods (gen 3); Omnipod dash pods (gen 4)	Insulin Infusion disposable pump supplies		30	Pods	30	DAYS				
97201030506400	Omnipod classic pdm start	Insulin infusion disposable pump kit		1	Kit	720	DAYS	08508114002			
97201030506400	Omnipod dash intro kit (g	Insulin infusion disposable pump kit		1	Kit	720	DAYS	08508200032			
97201030506400	Omnipod dash pdm kit (gen	Insulin infusion disposable pump kit		1	Kit	720	DAYS	08508200000			
97201030506410	Omnipod go 10 units/day	Insulin infusion disposable pump kit	10 UNIT/24HR	10	Kits	30	DAYS				
97201030506415	Omnipod go 15 units/day	Insulin infusion disposable pump kit	15 UNIT/24HR	10	Kits	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
97201030506420	Omnipod go 20 units/day	Insulin infusion disposable pump kit	20 UNIT/24HR	10	Kits	30	DAYS	08508400020			
97201030506425	Omnipod go 25 units/day	Insulin infusion disposable pump kit	25 UNIT/24HR	10	Kits	30	DAYS				
97201030506430	Omnipod go 30 units/day	Insulin infusion disposable pump kit	30 UNIT/24HR	10	Kits	30	DAYS	08508400030			
97201030506435	Omnipod go 35 units/day	Insulin infusion disposable pump kit	35 UNIT/24HR	10	Kits	30	DAYS				
97201030506440	Omnipod go 40 units/day	Insulin infusion disposable pump kit	40 UNIT/24HR	10	Kits	30	DAYS	08508400040			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Omnipod GO	**Omnipod GO** will be approved when BOTH of the following are met: 1. ONE of the following: A. Information has been provided that indicates the patient has been using the requested product within the past 90 days **OR** B. The prescriber states the patient has been using the requested product within the past 90 days AND is at risk if therapy is changed **OR** C. ALL of the following: 1. The patient has diabetes mellitus type 2 AND requires insulin therapy **AND** 2. The patient has completed a comprehensive diabetes education program **AND** 3. The patient has demonstrated willingness and ability to play an active role in diabetes self-management **AND** 2. ONE of the following: A. The patient's age is within the manufacturer recommendations for the requested indication for the requested product **OR** B. The prescriber has provided information in support of using the requested product for the patient's age **Length of Approval:** 12 months
Omnipod, Omnipod 5 G6, Omnipod DASH	**Omnipod, Omnipod 5 G6, and Omnipod Dash** will be approved when BOTH of the following are met: 1. ONE of the following: A. Information has been provided that indicates the patient has been using the requested product within the past 90 days **OR** B. The prescriber states the patient has been using the requested product within the past 90 days AND is at risk if therapy is changed **OR** C. ALL of the following: 1. The patient has diabetes mellitus AND requires insulin therapy **AND** 2. BOTH of the following: A. The patient is on an insulin regimen of 3 or more injections per day **AND** B. The patient performs 4 or more blood glucose tests per day or is using Continuous Glucose Monitoring (CGM) **AND** 3. The patient has completed a comprehensive diabetes education program **AND** 4. The patient has demonstrated willingness and ability to play an active role in diabetes self-management **AND**

Module	Clinical Criteria for Approval
	5. The patient has had ONE of the following while compliant on an optimized multiple daily insulin injection regimen: A. Glycosylated hemoglobin level (HbA1C) greater than 7% **OR** B. History of recurring hypoglycemia **OR** C. Wide fluctuations in blood glucose before mealtime **OR** D. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL **OR** E. History of severe glycemic excursions **AND** 2. ONE of the following: A. The patient's age is within the manufacturer recommendations for the requested indication for the requested product **OR** B. The prescriber has provided information in support of using the requested product for the patient's age **Length of Approval:** 12 months

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target agent(s)** will be approved for prescribed quantities 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) is greater than the program quantity limit **AND** B. Information has been provided in support of therapy with a higher dose for the requested indication **Length of Approval:** 12 months

• Program Summary: Nocturia - *Discontinued*

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

This program will be discontinued, effective 2/1/2024

• Program Summary: Opioids Immediate Release (IR) and Extended Release (ER) New To Therapy with Daily Quantity Limit

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

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

1) the indication is FDA approved AND

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

Opioids IR and ER New To Therapy with Daily Quantity Limit

OBJECTIVE

The program will check if a patient is new to opioid therapy as defined as having no prior opioid use in the past 120 days. If the patient is new to therapy, the patient will be restricted to ≤7 days of therapy. The program will allow for exceptions for uses beyond this limit based on program requirements. The program will also check for appropriate age for requests for products containing tramadol, dihydrocodeine, and codeine. Requests for these agents will be limited to patients 12 years of age and

older, and patients 12 to 18 years will be restricted from use for post-operative pain management following a tonsillectomy and/or adenoidectomy.

TARGET AGENT(S) FOR NEW TO THERAPY[b]

OPIOID IR SINGLE INGREDIENT AGENT(S)			
Brand (generic)	**GPI**	**Daily Quantity Limit**	**Age Limit**
butorphanol[a]			
10 mg/mL nasal spray	65200020102050	0.25 mL	NA
Codeine			
15 mg tablet	65100020200305	6 tablets	≥18 years
30 mg tablet[a]	65100020200310	6 tablets	≥18 years
60 mg tablet	65100020200315	6 tablets	≥18 years
Dilaudid (hydromorphone)[a]			
2 mg tablet	65100035100310	6 tablets	NA
4 mg tablet	65100035100320	6 tablets	NA
8 mg tablet	65100035100330	6 tablets	NA
1 mg/mL liquid	65100035100920	48 mL	NA
Levorphanol[a]			
2 mg tablet	65100040100305	4 tablets	NA
3 mg tablet	65100040100310	4 tablets	NA
Meperidine			
50 mg tablet	65100045100305	12 tablets	NA
50 mg/5 mL solution	65100045102060	60 mL	NA
Dolophine (methadone)[a]			
5 mg tablet	65100050100305	3 tablets	NA
10 mg tablet	65100050100310	3 tablets	NA
Methadose, Methadone[a]			
40 mg soluble tablet	65100050107320	3 tablets	NA
5 mg/5 mL solution	65100050102010	30 mL	NA
10 mg/5 mL solution	65100050102015	15 mL	NA
10 mg/mL concentrate	65100050101310	3 mL	NA
Morphine sulfate[a]			
15 mg tablet	65100055100310	12 tablets	NA
30 mg tablet	65100055100315	6 tablets	NA
10 mg/5 mL solution	65100055102065	90 mL	NA
20 mg/5 mL solution	65100055102070	45 mL	NA
20 mg/mL concentrate	65100055102090	9 mL	NA
Oxaydo, Roxybond, Roxicodone (oxycodone)			
5 mg capsule[a]	65100075100110	12 capsules	NA
5 mg tablet[a]	65100075100310	12 tablets	NA
5 mg tablet	6510007510A530	12 tablets	NA
7.5 mg tablet	65100075100315	6 tablets	NA
10 mg tablet[a]	65100075100320	6 tablets	NA
15 mg tablet[a]	65100075100325	6 tablets	NA
15 mg tablet	6510007510A540	6 tablets	NA
20 mg tablet[a]	65100075100330	6 tablets	NA
30 mg tablet[a]	65100075100340	6 tablets	NA
30 mg tablet	6510007510A560	6 tablets	NA
5 mg/5 mL solution[a]	65100075102005	180 mL	NA
20 mg/mL concentrate[a]	65100075101320	9 mL	NA
Opana (oxymorphone)[a]			
5 mg tablet	65100080100305	6 tablets	NA
10 mg tablet	65100080100310	6 tablets	NA
Nucynta (tapentadol)			
50 mg tablet	65100091100320	6 tablets	NA
75 mg tablet	65100091100330	6 tablets	NA
100 mg tablet	65100091100340	6 tablets	NA
Qdolo, Ultram, Tramadol			
50 mg tablet[a]	65100095100320	8 tablets	≥18 years

100 mg tablet	65100095100340	4 tablets	≥18 years
5 mg/mL solution	65100095102005	80 mL	≥18 years
OPIOID IR COMBINATION INGREDIENT AGENT(S)			
Apadaz, Benzhydrocodone/acetaminophen			
4.08/325 mg tablet	65990002020310	12 tablets	NA
6.12/325 mg tablet	65990002020320	12 tablets	NA
8.16/325 mg tablet	65990002020330	12 tablets	NA
Tylenol w/Codeine (acetaminophen/codeine)[a]			
120 mg/12 mg/5 mL solution	65991002052020	90 mL	≥18 years
300 mg/15 mg tablet	65991002050310	12 tablets	≥18 years
300 mg/30 mg tablet	65991002050315	12 tablets	≥18 years
300 mg/60 mg tablet	65991002050320	6 tablets	≥18 years
Fioricet w/Codeine (butalbital/acetaminophen/caffeine/codeine)[a]			
50 mg/300 mg/40 mg/30 mg capsule	65991004100113	6 capsules	≥18 years
50 mg/325 mg/40 mg/30 mg capsule	65991004100115	6 capsules	≥18 years
Fiorinal w/Codeine (butalbital/aspirin/caffeine/codeine)[a]			
50 mg/325 mg/40 mg/30 mg capsule	65991004300115	6 capsules	≥18 years
Trezix, Acetaminophen/caffeine/dihydrocodeine			
320.5 mg/30 mg/16 mg capsule	65991303050115	10 capsules	≥18 years
325 mg/30 mg/16 mg tablet	65991303050320	10 tablets	≥18 years
Lortab, Norco, Hydrocodone/acetaminophen			
5 mg/300 mg tablet[a]	65991702100309	8 tablets	NA
5 mg/325 mg tablet[a]	65991702100356	8 tablets	NA
7.5 mg/300 mg tablet[a]	65991702100322	6 tablets	NA
7.5 mg/325 mg tablet[a]	65991702100358	6 tablets	NA
10 mg/300 mg tablet[a]	65991702100375	6 tablets	NA
10 mg/325 mg tablet[a]	65991702100305	6 tablets	NA
7.5 mg/325 mg/15 mL solution[a]	65991702102015	90 mL	NA
10 mg/300 mg/15 mL solution	65991702102024	67.5 mL	NA
Hydrocodone/Ibuprofen			
5 mg/200 mg tablet	65991702500315	5 tablets	NA
7.5 mg/200 mg tablet[a]	65991702500320	5 tablets	NA
10 mg/200 mg tablet[a]	65991702500330	5 tablets	NA
Percocet, Prolate, Oxycodone/acetaminophen, Nalocet, Primlev			
2.5 mg/300 mg tablet	65990002200303	12 tablets	NA
2.5 mg/325 mg tablet[a]	65990002200305	12 tablets	NA
5 mg/300 mg tablet	65990002200308	12 tablets	NA
5 mg/325 mg tablet[a]	65990002200310	12 tablets	NA
7.5 mg/300 mg tablet	65990002200325	8 tablets	NA
7.5 mg/325 mg tablet[a]	65990002200327	8 tablets	NA
10 mg/300 mg tablet	65990002200333	6 tablets	NA
10 mg/325 mg tablet[a]	65990002200335	6 tablets	NA
10 mg/300 mg/5 mL solution	65990002202020	30 mL	NA
Oxycodone/Ibuprofen			
5 mg/400 mg tablet	65990002260320	4 tablets	NA
pentazocine/naloxone[a]			
50 mg/0.5 mg tablet	65200040300310	12 tablets	NA
Ultracet (tramadol/acetaminophen)[a]			
37.5 mg/325 mg tablet	65995002200320	8 tablets	≥18 years

OPIOID ER AGENT(S)			
Brand (generic)	**GPI**	**Daily Quantity Limit**	**Age Limit**
Belbuca (buprenorphine)			
75 mcg buccal film	65200010108210	2 films	NA
150 mcg buccal film	65200010108220	2 films	NA
300 mcg buccal film	65200010108230	2 films	NA
450 mcg buccal film	65200010108240	2 films	NA
600 mcg buccal film	65200010108250	2 films	NA

OPIOID ER AGENT(S)			
Brand (generic)	**GPI**	**Daily Quantity Limit**	**Age Limit**
750 mcg buccal film	65200010108260	2 films	NA
900 mcg buccal film	65200010108270	2 films	NA
Butrans (buprenorphine)[a]			
5 mcg/hour transdermal system	65200010008820	1 system/week	NA
7.5 mcg/hour transdermal system	65200010008825	1 system/week	NA
10 mcg/hour transdermal system	65200010008830	1 system/week	NA
15 mcg/hour transdermal system	65200010008835	1 system/week	NA
20 mcg/hour transdermal system	65200010008840	1 system/week	NA
ConZip, Tramadol ER			
100 mg extended-release capsule	65100095107070	1 capsule	≥ 18 years
200 mg extended-release capsule	65100095107080	1 capsule	≥ 18 years
300 mg extended-release capsule	65100095107090	1 capsule	≥ 18 years
fentanyl transdermal patch[a]			
12 mcg/hr transdermal patch	65100025008610	15 patches/month	NA
25 mcg/hr transdermal patch	65100025008620	15 patches/month	NA
37.5 mcg/hr transdermal patch	65100025008626	15 patches/month	NA
50 mcg/hr transdermal patch	65100025008630	15 patches/month	NA
62.5 mcg/hr transdermal patch	65100025008635	15 patches/month	NA
75 mcg/hr transdermal patch	65100025008640	15 patches/month	NA
87.5 mcg/hr transdermal patch	65100025008645	15 patches/month	NA
100 mcg/hr transdermal patch	65100025008650	15 patches/month	NA
Hydrocodone ER Abuse Deterrent			
10 mg sustained-release capsule	65100030106910	2 capsules	NA
15 mg sustained-release capsule	65100030106915	2 capsules	NA
20 mg sustained-release capsule	65100030106920	2 capsules	NA
30 mg sustained-release capsule	65100030106930	2 capsules	NA
40 mg sustained-release capsule	65100030106940	2 capsules	NA
50 mg sustained-release capsule	65100030106950	2 capsules	
hydromorphone ER[a]			
8 mg extended-release tablet	65100035107521	1 tablet	NA
12 mg extended-release tablet	65100035107531	1 tablet	NA
16 mg extended-release tablet	65100035107541	1 tablet	NA
32 mg extended-release tablet	65100035107556	1 tablet	NA
Hysingla ER (hydrocodone ER)[a]			
20 mg extended-release tablet	6510003010A810	1 tablet	NA
30 mg extended-release tablet	6510003010A820	1 tablet	NA
40 mg extended-release tablet	6510003010A830	1 tablet	NA
60 mg extended-release tablet	6510003010A840	1 tablet	NA
80 mg extended-release tablet	6510003010A850	1 tablet	NA
100 mg extended-release tablet	6510003010A860	1 tablet	NA
120 mg extended-release tablet	6510003010A870	1 tablet	NA
Morphine Sulfate ER			
30 mg extended-release capsule	65100055207020	1 capsule	NA
45 mg extended-release capsule	65100055207025	1 capsule	NA
60 mg extended-release capsule	65100055207030	1 capsule	NA
75 mg extended-release capsule	65100055207035	1 capsule	NA
90 mg extended-release capsule	65100055207040	1 capsule	NA
120 mg extended-release capsule	65100055207050	1 capsule	NA

OPIOID ER AGENT(S)			
Brand (generic)	**GPI**	**Daily Quantity Limit**	**Age Limit**
MS Contin (morphine sulfate ER)[a]			
15 mg extended-release tablet	65100055100415	3 tablets	NA
30 mg extended-release tablet	65100055100432	3 tablets	NA
60 mg extended-release tablet	65100055100445	3 tablets	NA
100 mg extended-release tablet	65100055100460	3 tablets	NA
200 mg extended-release tablet	65100055100480	3 tablets	NA
Nucynta ER (tapentadol ER)			
50 mg extended-release tablet	65100091107420	2 tablets	NA
100 mg extended-release tablet	65100091107430	2 tablets	NA
150 mg extended-release tablet	65100091107440	2 tablets	NA
200 mg extended-release tablet	65100091107450	2 tablets	NA
250 mg extended-release tablet	65100091107460	2 tablets	NA
OxyContin, Oxycodone ER			
10 mg extended-release tablet	6510007510A710	2 tablets	NA
15 mg extended-release tablet	6510007510A715	2 tablets	NA
20 mg extended-release tablet	6510007510A720	2 tablets	NA
30 mg extended-release tablet	6510007510A730	2 tablets	NA
40 mg extended-release tablet	6510007510A740	2 tablets	NA
60 mg extended-release tablet	6510007510A760	4 tablets	NA
80 mg extended-release tablet	6510007510A780	4 tablets	NA
Oxymorphone SR			
5 mg extended-release tablet	65100080107405	2 tablets	NA
7.5 mg extended-release tablet	65100080107407	2 tablets	NA
10 mg extended-release tablet	65100080107410	2 tablets	NA
15 mg extended-release tablet	65100080107415	2 tablets	NA
20 mg extended-release tablet	65100080107420	2 tablets	NA
30 mg extended-release tablet	65100080107430	2 tablets	NA
40 mg extended-release tablet	65100080107440	2 tablets	NA
tramadol ER[a]			
100 mg extended-release tablet	65100095107520	1 tablet	≥ 18 years
100 mg sustained-release tablet	65100095107560	1 tablet	≥ 18 years
200 mg extended-release tablet	65100095107530	1 tablet	≥ 18 years
200 mg sustained-release tablet	65100095107570	1 tablet	≥ 18 years
300 mg extended-release tablet	65100095107540	1 tablet	≥ 18 years
300 mg sustained-release tablet	65100095107580	1 tablet	≥ 18 years
Xtampza ER (oxycodone ER)			
9 mg capsule	6510007500A310	2 capsules	NA
13.5 mg capsule	6510007500A315	2 capsules	NA
18 mg capsule	6510007500A320	2 capsules	NA
27 mg capsule	6510007500A330	2 capsules	NA
36 mg capsule	6510007500A340	8 capsules	NA

a - generic available

b - all target agents are subject to a ≤ 7 days of therapy if no prior opioid or oncology claims are found in the past 120 days

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

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

1. The request exceeds the 7 day supply limit and ALL of the following:
    A. If the requested agent contains acetaminophen, then the requested dose of acetaminophen does NOT exceed 4 g/day
    AND
    B. If the requested agent contains tramadol, dihydrocodeine, OR codeine, then ONE of the following:
        i. The patient is 12 to less than 18 years of age AND the requested agent will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy
        OR
        ii. The patient is 18 years of age or over
    AND
    C. ONE of the following:
        i. The patient is not concurrently using buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment
        OR
        ii. The prescriber has provided information in support of use of opioids with buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment
    AND
    D. ONE of the following:
        i. There is information that the patient is NOT new to opioid therapy in the past 120 days
        OR
        ii. The prescriber states the patient is NOT new to opioid therapy AND is at risk if therapy is changed
        OR
        iii. There is information that the patient has taken an oncology agent in the past 120 days
        OR
        iv. ONE of the following:
            a. The patient has a diagnosis of chronic cancer pain due to an active malignancy
            OR
            b. The patient is eligible for hospice OR palliative care
            OR
            c. The patient has a diagnosis of sickle cell disease
            OR
            d. The patient is undergoing treatment of non-cancer pain and ALL of the following:
                1. The prescriber has provided information in support of use of opioids for an extended duration (>7 days)
                AND
                2. A formal, consultative evaluation which includes BOTH of the following was conducted:
                    A. Diagnosis
                    AND
                    B. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy
                AND
                3. A patient-specific pain management plan is on file for the patient
                AND
                4. The prescriber has reviewed the patient's records in the state's prescription drug monitoring program (PDMP) **AND** has determined that the opioid dosages and combinations of opioids and other controlled substances within the patient's records do NOT indicate the patient is at high risk for overdose
    AND
    E. If the requested quantity (dose) exceeds the program quantity daily limit or the program maximum daily dose, then BOTH of the following:
        i. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
        AND

ii. The prescriber has provided information in support of therapy with a higher dose for the requested indication

OR

2. The request does NOT exceed the 7 day supply limit AND ALL of the following:
   A. The requested dose exceeds the program quantity daily limit
      AND
   B. The requested dose is less than or equal to the program maximum daily dose (maximum mg allowed with highest dosage strength)
      AND
   C. If the requested agent contains acetaminophen, then the requested dose of acetaminophen does NOT exceed 4 g/day
      AND
   D. If the requested agent contains tramadol, dihydrocodeine, OR codeine, then ONE of the following:
      i. The patient is 12 to less than 18 years of age AND the requested agent will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy
         OR
      ii. The patient is 18 years of age or over
      AND
   E. ONE of the following:
      i. The patient is not concurrently using buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment
         OR
      ii. The prescriber has provided information in support of use of opioids with buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment
      AND
   F. BOTH of the following:
      i. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
         AND
      ii. The prescriber has provided information in support of therapy with a higher dose for the requested indication

OR

3. The request does NOT exceed the 7 day supply limit AND ALL of the following:
   A. The requested dose exceeds the program maximum daily dose (maximum mg allowed with highest dosage strength)
      AND
   B. If the requested agent contains acetaminophen, then the requested dose of acetaminophen does NOT exceed 4 g/day
      AND
   C. If the requested agent contains tramadol, dihydrocodeine, OR codeine, then ONE of the following:
      i. The patient is 12 to less than 18 years of age AND the requested agent will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy
         OR
      ii. The patient is 18 years of age or over
      AND
   D. ONE of the following:
      i. The patient is not concurrently using buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment
         OR
      ii. The prescriber has provided information in support of use of opioids with buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment
      AND
   E. ONE of the following:
      i. The patient has a diagnosis of active cancer pain due to an active malignancy
         OR
      ii. The patient is eligible for hospice OR palliative care

OR

iii. The patient has a diagnosis of sickle cell disease

OR

iv. The patient is undergoing treatment of chronic non-cancer pain and ALL of the following:

a. A formal, consultative evaluation which includes BOTH of the following has been conducted:

1. Diagnosis

AND

2. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy

AND

b. A patient-specific pain management plan is on file for the patient

AND

c. The prescriber has reviewed the patient's records in the state's prescription drug monitoring program (PDMP) **AND** has determined that the opioid dosages and combinations of opioids and other controlled substances within the patient's records do NOT indicate the patient is at high risk for overdose

AND

F. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit

AND

G. The prescriber has provided information in support of therapy with a higher dose for the requested indication

OR

4. The request does NOT exceed the 7 day supply limit, the program quantity daily limit or the program maximum daily dose AND the requested agent contains tramadol, dihydrocodeine, OR codeine, then ONE of the following:

A. The patient is 12 to less than 18 years of age AND the requested agent will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy

OR

B. The patient is 18 years of age or over

OR

5. If the request is for an oral liquid form of a medication, then BOTH of the following:

a. The patient has an FDA approved indication **AND**

b. The patient uses an enteral tube for feeding or medication administration

Length of Approval: 1 month for new to therapy overrides and dose titration requests
Up to 6 months for all other requests

NOTE: If other programs (e.g., MED, Concurrent Opioids) also applies, please refer to program specific documents.

Opioid IR Program Maximum Daily Dose

Agent(s)	Program Maximum Daily Dose
butorphanol	0.25 mL
Codeine	360 mg
Dilaudid (hydromorphone)	48 mg
Levorphanol	12 mg
Meperidine	600 mg
Dolophine, Methadose (methadone) Tablet, solution, concentrate	30 mg
Methadose (methadone) Soluble tablet	120 mg
Morphine	180 mg
Oxaydo, Roxicodone (oxycodone)	180 mg
Opana (oxymorphone)	60 mg
Nucynta (tapentadol)	600 mg
Qdolo, Ultram, Tramadol	400 mg

Opioid ER Program Maximum Daily Dose

Agent(s)	Program Maximum Daily Dose
Belbuca (buprenorphine buccal film)	1800 mcg

Butrans (buprenorphine transdermal system)	20 mcg/hr system/week
ConZip, Tramadol SR (tramadol ER)	300 mg
fentanyl transdermal patch	100 mcg/hr patch/2 days
hydrocodone ER abuse deterrent	100 mg
Hysingla (hydrocodone ER)	120 mg
Morphine Sulfate ER	120 mg
MS Contin (morphine sulfate ER)	600 mg
Nucynta ER (tapentadol ER)	500 mg
OxyContin (oxycodone ER)	160 mg
Oxymorphone ER	80 mg
tramadol ER	300 mg
Ultram ER (tramadol ER)	300 mg
Xtampza ER (oxycodone ER)	288 mg

• Program Summary: Parathyroid Hormone Analog for Osteoporosis

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

Prior authorization applies to Teriparatide and Tymlos only. Quantity limits apply to Teriparatide, Tymlos, and Forteo.

For Medicaid, the preferred product is the MN Medicaid Preferred Drug List (PDL) preferred drug: Forteo.

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
3004407000D221		Teriparatide (Recombinant) Soln Pen-inj 620 MCG/2.48ML	620 MCG/2.48ML	1	Pen	28	DAYS			
3004407000D220	Forteo	Teriparatide (Recombinant) Soln Pen-inj 600 MCG/2.4ML	600 MCG/2.4ML	1	Pen	28	DAYS			
3004400500D230	Tymlos	Abaloparatide Subcutaneous Soln Pen-injector 3120 MCG/1.56ML	3120 MCG/1.56ML	1	Pen	30	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Teriparatide through preferred	**For Medicaid, the preferred product is the MN Medicaid Preferred Drug List (PDL) preferred drug: Forteo** **Non-Preferred Agent(s) Teriparatide** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of osteoporosis AND ALL of the following: 1. ONE of the following: A. The patient's sex is male and ONE of the following: 1. The patient's age is 50 years or over **OR** 2. The prescriber has provided information that the requested agent is medically appropriate for the patient's age and sex **OR** B. The patient's sex is female and ONE of the following: 1. The patient is postmenopausal **OR**

Module	Clinical Criteria for Approval
	2. The prescriber has provided information that the requested agent is medically appropriate for the patient's sex and menopause status **AND** 2. The patient's diagnosis was confirmed by ONE of the following: A. A fragility fracture in the hip or spine **OR** B. A T-score of -2.5 or lower **OR** C. A T-score of -1.0 to -2.5 and ONE of the following: 1. A fragility fracture of a proximal humerus, pelvis, or distal forearm **OR** 2. A FRAX 10-year probability for major osteoporotic fracture of greater than or equal to 20% **OR** 3. A FRAX 10-year probability of hip fracture of greater than or equal to 3% **AND** 3. ONE of the following: A. The patient is at a very high fracture risk as defined by ONE of the following: 1. Patient had a recent fracture (within the past 12 months) **OR** 2. Patient had fractures while on FDA approved osteoporosis therapy **OR** 3. Patient has had multiple fractures **OR** 4. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) **OR** 5. Patient has a very low T-score (less than -3.0) **OR** 6. Patient is at high risk for falls or has a history of injurious falls **OR** 7. Patient has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm **OR** B. ONE of the following: 1. The patient's medication history includes a bisphosphonate AND ONE of the following: A. The patient has had an inadequate response to bisphosphonate therapy (medical records required) **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over bisphosphonates **OR** 2. The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required) **OR** 3. The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required) **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 bisphosphonates 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 glucocorticoid-induced osteoporosis AND ALL of the following: 1. The patient is either initiating or currently taking glucocorticoids in a daily dosage equivalent to 5 mg or higher of prednisone **AND**

Module	Clinical Criteria for Approval
	2. The patient's expected current course of therapy of glucocorticoids is for a period of at least 3 months **AND** 3. The patient's diagnosis was confirmed by ONE of the following: A. A fragility fracture in the hip or spine **OR** B. A T-score of -2.5 or lower **OR** C. A T-score of -1.0 to -2.5 and ONE of the following: 1. A fragility fracture of a proximal humerus, pelvis, or distal forearm **OR** 2. A FRAX 10-year probability for major osteoporotic fracture of greater than or equal to 20% **OR** 3. A FRAX 10-year probability of hip fracture of greater than or equal to 3% **AND** 4. ONE of the following: A. The patient is at a very high fracture risk as defined by ONE of the following: 1. Patient had a recent fracture (within the past 12 months) **OR** 2. Patient had fractures while on FDA approved osteoporosis therapy **OR** 3. Patient has had multiple fractures **OR** 4. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) **OR** 5. Patient has a very low T-score (less than -3.0) **OR** 6. Patient is at high risk for falls or has a history of injurious falls **OR** 7. Patient has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm **OR** B. ONE of the following: 1. The patient's medication history includes a bisphosphonate AND ONE of the following: A. The patient has had an inadequate response to bisphosphonate therapy (medical records required) **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over bisphosphonates **OR** 2. The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required) **OR** 3. The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required) **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 bisphosphonates cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. ONE of the following: A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR** B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following:

Module	Clinical Criteria for Approval
	1. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following: A. ONE of the following: 1. Evidence of a paid claim(s) **OR** 2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND** B. ONE of the following: 1. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR** 3. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** 4. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The patient will NOT be using the requested agent in combination with a bisphosphonate, denosumab (e.g., Prolia, Xgeva), romosozumab-aqqg or another parathyroid hormone analog (e.g., abaloparatide) **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. ONE of the following: A. The patient has never received treatment with a parathyroid hormone analog (Teriparatide, Forteo, and Tymlos) **OR** B. The patient has been previously treated with parathyroid hormone analog(s) AND the total duration of treatment with Forteo (teriparatide), Teriparatide, and Tymlos (abaloparatide) has NOT exceeded 24 months in lifetime **Length of approval:** up to a total of 2 years of treatment in lifetime between Teriparatide and Tymlos (abaloparatide). Only one parathyroid hormone analog will be approved for use at a time. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Tymlos through preferred	**For Medicaid, the preferred product is the MN Medicaid Preferred Drug List (PDL) preferred drug: Forteo** **Non-Preferred Agent(s) Tymlos** will be approved when ALL of the following are met: 1. The patient has a diagnosis of osteoporosis AND ALL of the following: A. ONE of the following: 1. The patient's sex is male and ONE of the following: A. The patient's age is 50 years or over **OR**

Module	Clinical Criteria for Approval
	B. The prescriber has provided information that the requested agent is medically appropriate for the patient's age and sex **OR** 2. The patient's sex is female and ONE of the following: A. The patient is postmenopausal **OR** B. The prescriber has provided information that the requested agent is medically appropriate for the patient's sex and menopause status **AND** B. The patient's diagnosis was confirmed by ONE of the following: 1. A fragility fracture in the hip or spine **OR** 2. A T-score of -2.5 or lower **OR** 3. A T-score of -1.0 to -2.5 and ONE of the following: A. A fragility fracture of a proximal humerus, pelvis, or distal forearm **OR** B. a FRAX 10-year probability for major osteoporotic fracture of greater than or equal to 20% **OR** C. a FRAX 10-year probability of hip fracture of greater than or equal to 3% **AND** C. ONE of the following: 1. The patient is at a very high fracture risk as defined by ONE of the following: A. Patient had a recent fracture (within the past 12 months) **OR** B. Patient had fractures while on FDA approved osteoporosis therapy **OR** C. Patient has had multiple fractures **OR** D. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) **OR** E. Patient a very low T-score (less than -3.0) **OR** F. Patient is at high risk for falls or has a history of injurious falls **OR** G. Patient has a very high fracture probability by FRAX (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm **OR** 2. ONE of the following: A. The patient's medication history includes a bisphosphonate AND ONE of the following: 1. The patient has had an inadequate response to bisphosphonate therapy (medical records required) **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over bisphosphonates **OR** B. The patient has an intolerance or hypersensitivity to bisphosphonate (medical records required) **OR** C. The patient has an FDA labeled contraindication to ALL bisphosphonates (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 ALL bisphosphonates cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. ONE of the following: A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR**

Module	Clinical Criteria for Approval
	B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following: 1. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following: A. ONE of the following: 1. Evidence of a paid claim(s) **OR** 2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND** B. ONE of the following: 1. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR** 3. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** 4. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The patient will NOT be using the requested agent in combination with a bisphosphonate, denosumab (e.g., Prolia, Xgeva), romosozumab-aqqg, or another parathyroid hormone analog (e.g., teriparatide) therapy **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. The total duration of treatment with Forteo (teriparatide), Teriparatide, and Tymlos (abaloparatide) has NOT exceeded 2 years in lifetime **Length of approval:** For those who have had less than 2 years of treatment in lifetime between Teriparatide, and Tymlos (abaloparatide), approve for the remainder of the 2 years of therapy remaining. Only one parathyroid hormone analog will be approved for use at a time. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Forteo, Teriparatide	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **Length of approval:** up to a total of 2 years of treatment in lifetime between Teriparatide and Tymlos (abaloparatide); Approve for up to 2 years for new Forteo starts or patients new to the plan's Prior Authorization process. Approve for 1 year if patient has already had 2 years of Forteo in lifetime and is at high risk. Only one parathyroid hormone analog will be approved for use at a time.
QL with PA Tymlos through preferred	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **Length of approval:** For those who have had less than 2 years of treatment in lifetime between Teriparatide and Tymlos (abaloparatide), approve for the remainder of the 2 years of therapy remaining. Only one parathyroid hormone analog will be approved for use at a time.

• Program Summary: Phenylketonuria

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

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

INITIAL EVALUATION

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

1. The patient has a diagnosis of phenylketonuria (PKU) **AND**
2. If the patient has an FDA approved indication, then ONE of the following:
    A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
    B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**
3. ONE of the following:
    A. BOTH of the following:
        1. Phenylalanine levels cannot be maintained within the recommended maintenance range with dietary intervention (phenylalanine-restriction) despite strict compliance **AND**
        2. The Phe-restricted diet will continue while being treated with the requested agent **OR**
    B. If the requested agent is Palynziq, the patient's current phenylalanine level is less than 360 micromol/L (6 mg/dL) **AND**
4. If the requested agent is Kuvan or sapropterin, then ONE of the following:
    A. The patient is less than 12 years of age AND has a baseline (prior to therapy for the requested indication) blood Phe level greater than 360 micromol/L (6 mg/dL) **OR**
    B. The patient is 12 years of age or over AND has a baseline (prior to therapy for the requested indication) blood Phe level greater than 600 micromol/L (10 mg/dL) **OR**
    C. The patient is planning on becoming pregnant OR is currently pregnant AND has a baseline (prior to therapy for the requested indication) Phe level greater than 360 micromol/L (6 mg/dL) **AND**
5. If the requested agent is Palynziq, the patient has a baseline (prior to therapy for the requested indication) blood Phe level greater than 600 micromol/L (10 mg/dL) **AND**
6. If the request is for a brand agent, then ONE of the following:
    A. The patient's medication history includes generic sapropterin AND ONE of the following:
        1. The patient has had an inadequate response to generic sapropterin despite monitored adherence to treatment **OR**
        2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over generic sapropterin **OR**
    B. The patient has an intolerance or hypersensitivity to generic sapropterin that is not expected to occur with the brand agent **OR**
    C. The patient has an FDA labeled contraindication to generic sapropterin that is not expected to occur with the brand agent **OR**
    D. The prescriber has provided information to support the use of the requested brand agent over generic sapropterin (e.g., presence of two null mutations in trans) **OR**
    E. The patient is currently being treated with the requested agent as indicated by ALL of the following:
        1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
        2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
        3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
    F. The prescriber has provided documentation that generic sapropterin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
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**
8. The patient will NOT be using the requested agent in combination with another targeted agent included in this program **AND**
9. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**

10. The requested quantity (dose) is within FDA labeled dosing for the requested indication

Length of Approval:

Kuvan (sapropterin): Approve for 2 months if initial dose is 5 mg/kg/day to less than 20 mg/kg/day, and for 1 month if initial dose is 20 mg/kg/day

Palynziq (pegvaliase-pqpz): 9 months

RENEWAL EVALUATION

Target Agent(s) will be approved when 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 improvements or stabilization with the requested agent as indicated by ONE of the following:
    A. If the requested agent is Kuvan or sapropterin, then ONE of the following:
        1. The patient's blood Phe levels are being maintained within the acceptable range [less than 12 years of age and for females currently pregnant or planning on becoming pregnant: 120-360 micromol/L (2-6 mg/dL); greater than or equal to 12 years of age: 120-600 micromol/L (2-10 mg/dL)] **OR**
        2. The patient has had at least a 30% decrease in blood Phe level from baseline (prior to therapy for the requested indication) **OR**
    B. If the requested agent is Palynziq, then ONE of the following:
        1. The patient's blood Phe level is less than or equal to 600 micromol/L (10 mg/dL) **OR**
        2. The patient has had at least a 20% decrease in blood Phe level from baseline (prior to therapy for the requested indication) **OR**
        3. The patient has NOT received 16 weeks of therapy at the maximum recommended dose in approved labeling AND the prescriber will evaluate for a dose escalation to induce clinical response **AND**
3. ONE of the following:
    A. The patient is currently on a phenylalanine (Phe) restricted diet and will continue while being treated with the requested agent **OR**
    B. If the requested agent is Palynziq, the patient's phenylalanine level is less than 360 micromol/L (6 mg/dL) **AND**
4. If the request is for a brand agent, then ONE of the following:
    A. The patient's medication history includes generic sapropterin AND ONE of the following:
        1. The patient has had an inadequate response to generic sapropterin despite monitored adherence to treatment **OR**
        2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over generic sapropterin **OR**
    B. The patient has an intolerance or hypersensitivity to generic sapropterin that is not expected to occur with the brand agent **OR**
    C. The patient has an FDA labeled contraindication to generic sapropterin that is not expected to occur with the brand agent **OR**
    D. The prescriber has provided information to support the use of the requested brand agent over generic sapropterin (e.g., presence of two null mutations in trans) **OR**
    E. The patient is currently being treated with the requested agent as indicated by ALL of the following:
        1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
        2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
        3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

	F. The prescriber has provided documentation that generic sapropterin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 5. 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** 6. The patient will NOT be using the requested agent in combination with another targeted agent included in this program **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

• Program Summary: Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
3935002000E5	Repatha	evolocumab subcutaneous soln prefilled syringe	140 MG/ML	2	Syringes	28	DAYS				
3935002000E2	Repatha pushtronex system	evolocumab subcutaneous soln cartridge/infusor	420 MG/3.5ML	2	Cartridges	28	DAYS				
3935002000D5	Repatha sureclick	evolocumab subcutaneous soln auto-injector	140 MG/ML	2	Pens	28	DAYS				
3935001000	Praluent	alirocumab subcutaneous solution auto-injector	150 MG/ML; 75 MG/ML	2	Syringes	28	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. BOTH of the following: 1. ONE of the following: A. The patient has a diagnosis of heterozygous familial hypercholesterolemia (HeFH) AND ONE of the following: 1. Genetic confirmation of <u>one</u> mutant allele at the *LDLR, Apo-B, PCSK9*, or *1/LDLRAP1* gene **OR** 2. History of LDL-C greater than 190 mg/dL (greater than 4.9 mmol/L) (pretreatment) **OR** 3. The patient has clinical manifestations of HeFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthoma, or xanthelasma) **OR** 4. The patient has "definite" or "possible" familial hypercholesterolemia as defined by the Simon Broome criteria **OR**

Module	Clinical Criteria for Approval
	5. The Patient has a Dutch Lipid Clinic Network Criteria score of greater than 5 **OR** 6. The patient has a treated low-density lipoprotein cholesterol (LDL-C) level greater than or equal to 100 mg/dL after treatment with antihyperlipidemic agents but prior to PCSK9 inhibitor therapy **OR** B. The patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) AND ONE of the following: 1. Genetic confirmation of TWO mutant alleles at the *LDLR, Apo-B, PCSK9*, or *LDLRAP1* gene **OR** 2. History of untreated LDL-C greater than 500 mg/dL (greater than 13 mmol/L) or treated LDL-C greater than or equal to 300 mg/dL (greater than or equal to 7.76 mmol/L) **OR** 3. The patient has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas, or xanthelasma) **OR** C. The patient has a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) AND has ONE of the following: 1. Acute coronary syndrome **OR** 2. History of myocardial infarction **OR** 3. Stable or unstable angina **OR** 4. Coronary or other arterial revascularization **OR** 5. History of stroke **OR** 6. History of transient ischemic attack **OR** 7. Peripheral arterial disease, including aortic aneurysm, presumed to be of atherosclerotic origin **OR** D. The patient has a diagnosis of primary hyperlipidemia AND ONE of the following: 1. The patient has a coronary artery calcium or calcification (CAC) score greater than or equal to 300 Agatston units **OR** 2. The patient has an LDL-C level greater than or equal to 220 mg/dL (greater than or equal to 5.7 mmol/L) while receiving maximally tolerated statin and ezetimibe therapy **OR** E. The patient has greater than or equal to 20% 10-year ASCVD risk AND ONE of the following: 1. The patient has greater than or equal to 40% 10-year ASCVD risk AND BOTH of the following: A. LDL-C greater than or equal to 70 mg/dL while on maximally tolerated statin therapy **AND** B. ONE of the following: 1. The patient has extensive or active burden of ASCVD (i.e., polyvascular ASCVD, which affects all 3 vascular beds—coronary, cerebrovascular, and peripheral arterial; clinical peripheral arterial disease in addition to coronary and/or cerebrovascular disease; a clinical ASCVD event with multivessel coronary artery disease defined as greater than or equal to 40% stenosis in greater than or equal to 2 large vessels; or recurrent myocardial infarction within 2 years of the initial event) in the presence of adverse or poorly controlled cardiometabolic risk factors **OR** 2. Extremely high-risk elevations in cardiometabolic factors with less-extensive ASCVD (i.e., diabetes, LDL-C greater than or equal to 100 mg/dL, less than high–intensity statin therapy, chronic kidney disease,

Module	Clinical Criteria for Approval
	poorly controlled hypertension, high-sensitivity C-reactive protein greater than 3 mg/L, or metabolic syndrome, usually occurring with other extremely high–risk or very-high-risk characteristics), usually with other adverse or poorly controlled cardiometabolic risk factors present. **OR** 3. Patients with ASCVD and LDL-C greater than or equal to 220 mg/dL with greater than or equal to 45% 10-year ASCVD risk despite statin therapy **OR** 2. The patient has 30-39% 10-year ASCVD risk AND ALL of the following: A. LDL-C greater than or equal to 100 mg/dL while on maximally tolerated statin therapy **AND** B. Less-extensive clinical ASCVD (i.e., no polyvascular ASCVD, no clinical peripheral arterial disease, a prior ASCVD event greater than or equal to 2 years prior, and no coronary artery bypass grafting) **AND** C. Adverse or poorly controlled cardiometabolic risk factor(s) including age 65 years or older, current smoking, chronic kidney disease, lipoprotein(a) greater than or equal to 37 nmol/L, high-sensitivity C-reactive protein 1–3 mg/L, metabolic syndrome with a history of myocardial infarction, ischemic stroke, or symptomatic peripheral arterial disease, usually in the presence of other adverse or poorly controlled cardiometabolic risk factors **OR** 3. The patient has 20-29% 10-year ASCVD risk AND BOTH of the following: A. LDL-C greater than or equal to 130 mg/dL while on maximally tolerated statins **AND** B. ONE of the following: 1. The patient has less extensive ASCVD and well-controlled cardiometabolic risk factors (i.e., no diabetes, nonsmoker, on high-intensity statin with LDL-C less than 100 mg/dL, blood pressure less than 140/90 mm Hg, and C-reactive protein less than 1 mg/dL) **OR** 2. The use is for primary prevention with LDL-C greater than or equal to 220 mg/dL AND BOTH of the following: A. No clinical ASCVD or CAC less than 100 Agatston units **AND** B. Poorly controlled cardiometabolic risk factor **AND** 2. ONE of the following: A. The patient has been adherent to high-intensity statin therapy (i.e., rosuvastatin greater than or equal to 20 mg daily, atorvastatin greater than or equal to 40 mg daily) for greater than or equal to 8 continuous weeks AND ONE of the following: 1. The patient's LDL-C level after this treatment regimen remains greater than or equal to 70 mg/dL **OR** 2. The patient has not achieved a 50% reduction in LDL-C from baseline after this treatment regimen **OR** 3. If the patient has ASCVD, and ONE of the following: A. The patient's non HDL-C level after this treatment regimen remains greater than or equal to 100 mg/dL **OR**

Module	Clinical Criteria for Approval
	B. The patient is at very high risk and the patient's LDL-C level after this treatment regimen remains great than or equal to 55 mg/dL **OR** B. The patient has been determined to be statin intolerant by meeting ONE of the following criteria: 1. The patient experienced statin-related rhabdomyolysis **OR** 2. The patient experienced skeletal-related muscle symptoms (e.g., myopathy [muscle weakness] or myalgia [muscle aches, soreness, stiffness, or tenderness]) and BOTH of the following: A. The skeletal-related muscle symptoms (e.g., myopathy or myalgia) occurred while receiving separate trials of both atorvastatin AND rosuvastatin (as single-entity or as combination products) **AND** B. When receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) the skeletal-related muscle symptoms (e.g., myopathy, myalgia) resolved upon discontinuation of each respective statin therapy (atorvastatin AND rosuvastatin) **OR** 3. The patient experienced elevations in hepatic transaminase while receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) **OR** C. The patient has a hypersensitivity to atorvastatin AND rosuvastatin **OR** D. The patient has an FDA labeled contraindication to atorvastatin AND rosuvastatin **OR** E. The patient's medication history includes use of high intensity atorvastatin or rosuvastatin therapy, or a drug in the same pharmacological class with the same mechanism of action, AND ONE of the following: 1. High intensity atorvastatin or rosuvastatin or a 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 high-intensity rosuvastatin or atorvastatin therapy **OR** F. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** G. The prescriber has provided documentation that atorvastatin AND rosuvastatin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has another FDA approved indication for the requested agent and route of administration **OR** C. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA labeled indication, 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**

Module	Clinical Criteria for Approval
	3. The agent was prescribed by, or in consultation with, a cardiologist, an endocrinologist, and/or a physician who focuses in the treatment of cardiovascular (CV) risk management and/or lipid disorders **AND** 4. The patient will NOT be using the requested agent in combination with another PCSK9 agent for the requested indication **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 12 months 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 therapy for PCSK9 inhibitors through the plan's Prior Authorization process **AND** 2. ONE of the following: A. The request is for a preferred agent **OR** B. The patient's medication history includes a preferred agent AND ONE of the following: 1. The patient has had an inadequate response a preferred agent **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL preferred agents **OR** C. The patient has an intolerance or hypersensitivity to the preferred agent **OR** D. The patient has an FDA labeled contraindication to ALL preferred agents **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 preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The patient has shown clinical benefit with a PCSK9 inhibitor **AND** 4. The patient is currently adherent to therapy with a PCSK9 inhibitor **AND** 5. If the patient has cardiovascular disease OR hyperlipidemia, then ONE of the following: A. The patient is currently adherent to high-intensity statin therapy (i.e., rosuvastatin greater than or equal to 20 mg daily, atorvastatin greater than or equal to 40 mg daily) **OR** B. The patient has been determined to be statin intolerant by meeting ONE of the following criteria: 1. The patient experienced statin-related rhabdomyolysis **OR** 2. The patient experienced skeletal-related muscle symptoms (e.g., myopathy [muscle weakness] or myalgia [muscle aches, soreness, stiffness, or tenderness]) and BOTH of the following: A. The skeletal-related muscle symptoms (e.g., myopathy or myalgia) occurred while receiving separate trials of both atorvastatin AND rosuvastatin (as single-entity or as combination products) **AND** B. When receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) the skeletal-related muscle symptoms (e.g.,

Module	Clinical Criteria for Approval
	myopathy, myalgia) resolved upon discontinuation of each respective statin therapy (atorvastatin AND rosuvastatin) **OR** 3. The patient experienced elevations in hepatic transaminase while receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) **OR** C. The patient has a hypersensitivity to atorvastatin AND rosuvastatin **OR** D. The patient has an FDA labeled contraindication to atorvastatin AND rosuvastatin **OR** E. The patient's medication history includes use of high-intensity rosuvastatin or atorvastatin therapy or a drug in the same pharmacological class with the same mechanism of action AND ONE of the following: 1. High-intensity rosuvastatin or atorvastatin, or a 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 high-intensity rosuvastatin or atorvastatin therapy **OR** F. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** G. The prescriber has provided documentation that atorvastatin and rosuvastatin 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 agent was prescribed by, or in consultation with, a cardiologist, an endocrinologist, and/or a physician who focuses in the treatment of cardiovascular (CV) risk management and/or lipid disorders **AND** 7. The patient will NOT be using the requested agent in combination with another PCSK9 agent for the requested indication **AND** 8. The patient does NOT have any FDA labeled contraindications to the requested agent Length of approval: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Sensipar (cinacalcet)

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
	3090522510	Sensipar	cinacalcet hcl tab	30 MG; 60 MG; 90 MG	M; N; O; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of hypercalcemia due to parathyroid carcinoma **OR** B. The patient has a diagnosis of primary hyperparathyroidism (HPT) and BOTH of the following: 1. The patient has a pretreatment serum calcium level that is above the testing laboratory's upper limit of normal **AND** 2. The patient is unable to undergo parathyroidectomy **OR** C. The patient has a diagnosis of secondary hyperparathyroidism (HPT) due to chronic kidney disease (CKD) AND ALL of the following: 1. The patient is on dialysis **AND** 2. The patient has a pretreatment or current intact PTH (iPTH) level that is >300 pg/mL **AND** 3. ONE of the following: A. The patient's medication history includes a phosphate binder [e.g., calcium acetate, calcium carbonate, Renvela (sevelamer carbonate), Fosrenol (lanthanum carbonate), Renagel (sevelamer hydrochloride)] AND ONE of the following: 1. The patient has had an inadequate response to a phosphate binder **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL phosphate binder agents **OR** B. The patient has an intolerance or hypersensitivity to phosphate binder therapy **OR** C. The patient has an FDA labeled contraindication to ALL phosphate binder 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 phosphate binder 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** 4. ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient's medication history includes a vitamin D analog [e.g., calcitriol, Hectorol (doxecalciferol), Rayaldee (calcifediol), Zemplar (paricalcitol)] AND ONE of the following: 1. The patient has had an inadequate response to a vitamin D analog **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL vitamin D analog agents **OR** B. The patient has an intolerance or hypersensitivity to vitamin D analog therapy **OR** C. The patient has an FDA labeled contraindication to ALL vitamin D analog 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 vitamin D analog agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. The patient has another FDA approved indication for the requested agent **OR** E. The patient has another indication that is supported in compendia for the requested agent **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient will NOT be using the requested agent in combination with another calcium sensing receptor agonist [e.g., Parsabiv (etelcalcetide)] **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months **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 hypercalcemia due to parathyroid carcinoma **OR** B. BOTH of the following: 1. The patient has a diagnosis of primary hyperparathyroidism (HPT) **AND** 2. The patient's serum calcium level has been evaluated to confirm the appropriateness of the current dose **OR** C. The patient has a diagnosis of secondary hyperparathyroidism (HPT) due to chronic kidney disease (CKD) AND BOTH of the following: 1. The patient is on dialysis **AND**

Module	Clinical Criteria for Approval
	2. The patient's intact PTH (iPTH) level has been evaluated to confirm the appropriateness of the current dose **OR** D. The patient has another FDA approved indication for the requested agent **OR** E. The patient has another indication that is supported in compendia for the requested agent **AND** 3. The patient has had clinical benefit with the requested agent **AND** 4. The patient will NOT be using the requested agent in combination with another calcium sensing receptor agonist [e.g., Parsabiv (etelcalcetide)] **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months

● Program Summary: Topical Estrogen

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
24000035008705	Alora; Dotti; Lyllana; Minivelle; Vivelle-dot	Estradiol TD Patch Twice Weekly 0.025 MG/24HR	0.025; 0.025 MG/24HR	8	Patches	28	DAYS			
24000035008720	Alora; Dotti; Lyllana; Minivelle; Vivelle-dot	Estradiol TD Patch Twice Weekly 0.05 MG/24HR	0.05; 0.05 MG/24HR	8	Patches	28	DAYS			
24000035008730	Alora; Dotti; Lyllana; Minivelle; Vivelle-dot	Estradiol TD Patch Twice Weekly 0.075 MG/24HR	0.075; 0.075 MG/24HR	8	Patches	28	DAYS			
24000035008750	Alora; Dotti; Lyllana; Minivelle; Vivelle-dot	Estradiol TD Patch Twice Weekly 0.1 MG/24HR	0.1; 0.1 MG/24HR	8	Patches	28	DAYS			
24000035008810	Climara	Estradiol TD Patch Weekly 0.025 MG/24HR	0.025 MG/24HR	4	Patches	28	DAYS			
24000035008815	Climara	Estradiol TD Patch Weekly 0.0375 MG/24HR (37.5 MCG/24HR)	37.5 MCG/24HR	4	Patches	28	DAYS			
24000035008820	Climara	Estradiol TD Patch Weekly 0.05 MG/24HR	0.05 MG/24HR	4	Patches	28	DAYS			
24000035008824	Climara	Estradiol TD Patch Weekly 0.06 MG/24HR	0.06 MG/24HR	4	Patches	28	DAYS			
24000035008830	Climara	Estradiol TD Patch Weekly 0.075 MG/24HR	0.075 MG/24HR	4	Patches	28	DAYS			
24000035008840	Climara	Estradiol TD Patch Weekly 0.1 MG/24HR	0.1 MG/24HR	4	Patches	28	DAYS			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
24993002588820	Climara pro	Estradiol-Levonorgestrel TD Patch Weekly 0.045-0.015 MG/DAY	0.045-0.015 MG/DAY	4	Patches	28	DAYS			
24993002128720	Combipatch	Estradiol-Norethindrone Ace TD PTTW 0.05-0.14 MG/DAY	0.05-0.14 MG/DAY	8	Patches	28	DAYS			
24993002128730	Combipatch	Estradiol-Norethindrone Ace TD PTTW 0.05-0.25 MG/DAY	0.05-0.25 MG/DAY	8	Patches	28	DAYS			
24000035004035	Divigel	Estradiol TD Gel 0.25 MG/0.25GM (0.1%)	0.25 MG/0.25GM	30	Packets	30	DAYS			
24000035004040	Divigel	Estradiol TD Gel 0.5 MG/0.5GM (0.1%)	0.5 MG/0.5GM	30	Packets	30	DAYS			
24000035004042	Divigel	Estradiol TD Gel 0.75 MG/0.75GM (0.1%)	0.75 MG/0.75GM	30	Packets	30	DAYS			
24000035004045	Divigel	Estradiol TD Gel 1 MG/GM (0.1%)	1 MG/GM	30	Packets	30	DAYS			
24000035004050	Divigel	Estradiol TD Gel 1.25 MG/1.25GM (0.1%)	1.25 MG/1.25GM	30	Packets	30	DAYS			
24000035008710	Dotti; Lyllana; Minivelle; Vivelle-dot	Estradiol TD Patch Twice Weekly 0.0375 MG/24HR	0.0375; 0.0375 MG/24HR	8	Patches	28	DAYS			
24000035004008	Elestrin	Estradiol Gel 0.06% (0.52 MG/0.87 GM Metered-Dose Pump)	0.06 %	1	Pump	30	DAYS			
55350020003705	Estrace	Estradiol Vaginal Cream 0.1 MG/GM	0.1 MG/GM	6	Tubes	365	DAYS			
55350020009020	Estring	Estradiol Vaginal Ring 2 MG (7.5 MCG/24HRS)	2 MG; 7.5 MCG/24HR	1	Ring	90	DAYS			
24000035004010	Estrogel	Estradiol Gel 0.06% (0.75 MG/1.25 GM Metered-Dose Pump)	0.06 %	1	Pump	30	DAYS			
24000035002020	Evamist	Estradiol Transdermal Spray 1.53 MG/SPRAY	1.53 MG/SPRAY	5	Vials	93	DAYS			
55350020109020	Femring	Estradiol Acetate Vaginal Ring 0.05 MG/24HR	0.05 MG/24HR	1	Ring	90	DAYS			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
55350020109030	Femring	Estradiol Acetate Vaginal Ring 0.1 MG/24HR	0.1 MG/24HR	1	Ring	90	DAYS			
55350020009940	Imvexxy maintenance pack	Estradiol Vaginal Insert 10 MCG	10 MCG	8	Units	28	DAYS			
55350020009920	Imvexxy maintenance pack	Estradiol Vaginal Insert 4 MCG	4 MCG	8	Units	28	DAYS			
55350020009930	Imvexxy starter pack	Estradiol Vaginal Insert Starter Pack 10 MCG	10 MCG	18	Units	180	DAYS			
55350020009910	Imvexxy starter pack	Estradiol Vaginal Insert Starter Pack 4 MCG	4 MCG	18	Units	180	DAYS			
24000035008805	Menostar	Estradiol TD Patch Weekly 14 MCG/24HR	14 MCG/24HR	4	Patches	28	DAYS			

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) is greater than the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The patient has a diagnosis of gender dysphoria/gender incongruent **AND** 2. The requested agent is ONE of the following: A. Alora (estradiol) B. Climara (estradiol) C. Divigel (estradiol) D. Elestrin (estradiol) E. Estrogel (estradiol) F. EvaMist (estradiol) G. Menostar (estradiol) H. Minivelle (estradiol) I. Vivelle Dot (estradiol) **OR** B. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **OR** C. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** D. BOTH of the following:

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

• Program Summary: Topical Nonsteroidal Anti-inflammatory Drugs (NSAIDs)

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
90210030302025		Diclofenac Sodium Soln 1.5%	1.5%	2	Bottles	30	DAYS			
90210030304020	Arthritis pain reliever; Aspercreme arthritis pain; CVS diclofenac sodiium; CVS diclofenac sodium; Eq arthritis pain; Eq arthritis pain relieve; Ft arthritis pain; Gnp arthritis pain; Gnp diclofenac sodium; Goodsense arthritis pain; Kls arthritis pain relief; Kls diclofenac sodium; Motrin arthritis pain; Qc diclofenac sodium; Sm arthritis pain; Voltaren; Voltaren arthritis pain	Diclofenac Sodium Gel 1%	1%	10	Tubes	30	DAYS			
90210030205920	Flector	Diclofenac Epolamine Patch 1.3%	1.3%	60	Patches	30	DAYS			
90210030208520	Licart	Diclofenac Epolamine Patch 24HR 1.3%	1.3%	30	Systems	30	DAYS			
90210030302030	Pennsaid	Diclofenac Sodium Soln 2%	2%	2	Bottles	28	DAYS			

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

Module	Clinical Criteria for Approval
	2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **OR** B. BOTH of the following: 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: Urea Cycle Disorders

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

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

1) the indication is FDA approved AND

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

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	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 ONE of the following are met: 1. ALL of the following: A. The patient has a diagnosis of hyperammonemia AND ALL of the following: 1. 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** 2. The patient has a normal anion gap **AND** 3. The patient has a normal blood glucose level **AND** B. The patient has a diagnosis of ONE of the following urea cycle disorders confirmed by enzyme analysis OR genetic testing:

Module	Clinical Criteria for Approval
	1. carbamoyl phosphate synthetase I deficiency [CPSID] **OR** 2. ornithine transcarbamylase deficiency [OTCD] **OR** 3. argininosuccinic acid synthetase deficiency [ASSD] **OR** 4. argininosuccinic acid lyase deficiency [ASLD] **OR** 5. arginase deficiency [ARG1D] **AND** C. The requested agent will NOT be used as treatment of acute hyperammonemia **AND** D. 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** E. The patient will be using the requested agent as adjunctive therapy to dietary protein restriction **AND** F. ONE of the following: 1. If the requested agent is Buphenyl, Olpruva, or Pheburane, then ONE of the following: A. The patient has an intolerance or hypersensitivity to generic sodium phenylbutyrate that is not expected to occur with the brand agent **OR** B. The patient has an FDA labeled contraindication to generic sodium phenylbutyrate 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 generic sodium phenylbutyrate **OR** D. BOTH of the following: 1. 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: A. Evidence of a paid claim(s) **OR** B. 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** 2. ONE of the following: A. 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** 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 **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that generic 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** 2. If the requested agent is Ravicti, ONE of the following: A. The patient's medication history includes generic sodium phenylbutyrate AND Pheburane AND ONE of the following: 1. The patient has had an inadequate response to generic sodium phenylbutyrate AND Pheburane **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 generic sodium phenylbutyrate AND Pheburane **OR** B. The patient has an intolerance or hypersensitivity to generic sodium phenylbutyrate AND Pheburane **OR** C. The patient has an FDA labeled contraindication to generic sodium phenylbutyrate AND Pheburane **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that generic 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** G. The prescriber is a specialist in the area of the patient's diagnosis (e.g., metabolic disorders) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** H. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** I. The requested quantity (dose) is within FDA labeled dosing for the requested indication **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Length of Approval:** 12 months **Renewal Evaluation** **Target Agent(s)** will be approved when BOTH of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. ONE of the following: A. ALL of the following: 1. The patient has had clinical benefit with the requested agent (e.g., plasma ammonia level within the normal range) **AND** 2. The requested agent will NOT be used as treatment of acute hyperammonemia **AND** 3. The patient will be using the requested agent as adjunctive therapy to dietary protein restriction **AND** 4. ONE of the following: A. If the requested agent is Buphenyl, Olpruva, 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**

Module	Clinical Criteria for Approval
	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** 5. 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** 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 **OR** B. If the request is for an oral liquid form of a medication, then BOTH of the following: 1. The patient has an FDA approved indication **AND** 2. The patient uses an enteral tube for feeding or medication administration **Length of Approval:** 12 months

• Program Summary: Voxzogo

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
309500800021	Voxzogo	vosoritide for subcutaneous inj	0.4 MG; 0.56 MG; 1.2 MG	30	Vials	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. ALL of the following: 1. The patient has a diagnosis of achondroplasia as confirmed by ONE of the following (medical records required): A. Genetic testing **OR** B. Radiographic findings **AND** 2. The requested agent will be used to increase linear growth **AND** 3. The patient has open epiphyses **AND** 4. The patient is ambulatory and able to stand without assistance **OR** B. The patient has another FDA approved indication for the requested agent and route of administration **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**

Module	Clinical Criteria for Approval
	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., 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 another growth hormone agent for the requested indication **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **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 open epiphyses **AND** 3. The patient has had clinical benefit with the requested agent **AND** 4. 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** 5. The patient will NOT be using the requested agent in combination with another growth hormone agent for the requested indication **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	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: Vtama (tapinarof)

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
	902500750037	Vtama	tapinarof cream	1%	M; N; O; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following A. The patient has a diagnosis of plaque psoriasis AND ALL of the following: 1. The patient's affected body surface area (BSA) is less than or equal to 20% **AND** 2. ONE of the following: 1. The patient's medication history includes therapy with a topical corticosteroid AND ONE of the following: 1. The patient has had an inadequate response to a topical corticosteroid **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over topical corticosteroids **OR** 2. The patient has an intolerance or hypersensitivity to therapy with topical corticosteroids **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: 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** 5. The prescriber has provided documentation that topical corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. ONE of the following: 1. The patient's medication history includes therapy with another topical psoriasis agent with a different mechanism of action (e.g., vitamin D analogs, calcineurin inhibitors, tazarotene) AND ONE of the following: 1. The patient has had an inadequate response to another topical psoriasis agent with a different mechanism of action **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over another topical psoriasis agent with a different mechanism of action **OR**

Module	Clinical Criteria for Approval
	2. The patient has an intolerance or hypersensitivity to another topical psoriasis agent with a different mechanism of action **OR** 3. The patient has an FDA labeled contraindication to ALL other topical psoriasis agents with a different mechanism of action **OR** 4. 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** 5. The prescriber has provided documentation that ALL other topical psoriasis agents with a different mechanism of action cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has another FDA approved indication for the requested agent and route of administration **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months **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., dermatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months

• Program Summary: Wakix (pitolisant)

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
61450070100338	Wakix	Pitolisant HCl Tab 17.8 MG (Base Equivalent)	17.8 MG	60	Tablets	30	DAYS				
61450070100318	Wakix	Pitolisant HCl Tab 4.45 MG (Base Equivalent)	4.45 MG	60	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of excessive daytime sleepiness associated with narcolepsy AND BOTH of the following: 1. ONE of the following: A. The patient's medication history includes armodafinil OR modafinil AND ONE of the following: 1. The patient had an inadequate response to armodafinil OR modafinil **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over armodafinil or modafinil **OR** B. The patient has an intolerance or hypersensitivity to armodafinil OR modafinil **OR** C. The patient has an FDA labeled contraindication to BOTH armodafinil AND modafinil **OR** D. The patient has been prescribed the requested non-controlled agent due to comorbid conditions OR concerns about controlled substance use **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 armodafinil AND modafinil cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. ONE of the following: A. The patient's medication history includes Sunosi AND ONE of the following: 1. The patient had an inadequate response to armodafinil OR modafinil **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 armodafinil or modafinil **OR** B. The patient has an intolerance or hypersensitivity to Sunosi **OR** C. The patient has an FDA labeled contraindication to Sunosi **OR** D. The patient has been prescribed the requested non-controlled agent due to comorbid conditions OR concerns about controlled substance use **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 Sunosi 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 narcolepsy with cataplexy AND ONE of the following: 1. The patient's medication history includes armodafinil OR modafinil AND ONE of the following: A. The patient had an inadequate response to armodafinil OR modafinil **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over armodafinil or modafinil **OR** 2. The patient has an intolerance or hypersensitivity to armodafinil OR modafinil **OR** 3. The patient has an FDA labeled contraindication to BOTH armodafinil AND modafinil **OR** 4. The patient has been prescribed the requested non-controlled agent due to comorbid conditions OR concerns about controlled substance use **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 armodafinil AND modafinil cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, psychiatrist, sleep disorder specialist) 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

Module	Clinical Criteria for Approval
	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 **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, psychiatrist, sleep disorder specialist) 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 **Length of Approval**: 12 months

● Program Summary: Zoryve (roflumilast)

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

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

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

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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

Module	Clinical Criteria for Approval
	E. The prescriber has provided documentation that ALL other topical psoriasis agents with a different mechanism of action cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has another FDA approved indication for the requested agent and route of administration **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months **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., dermatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months