COMMERCIAL PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: February 1, 2024 Notification Posted: December 15, 2023

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

No new policies for February 1, 2024

POLICIES REVISED

• Program Summary: Bempedoic Acid

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
39380020000320	Nexletol	Bempedoic Acid Tab 180 MG	180 MG	30	Tablets	30	DAYS				
39991002200320	Nexlizet	Bempedoic Acid-Ezetimibe Tab 180-10 MG	180-10 MG	30	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. 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 **OR** 2. History of myocardial infarction **OR**

Module	Clinical Criteria for Approval
	3. Stable or unstable angina **OR** 4. Coronary or other arterial revascularization **OR** 5. Stroke **OR** 6. Transient ischemic attack **OR** 7. Peripheral arterial disease, including aortic aneurysm, presumed to be of atherosclerotic origin **OR** 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:** AHFS, DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following 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:** AHFS, DrugDex 1 or 2a level of evidence **Length of approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
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:

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	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			
30042010100870	Binosto	Alendronate Sodium Effervescent Tab 70 MG	70 MG	4	Tablets	28	DAYS			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
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:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
52450045000120	Amitiza	Lubiprostone Cap 24 MCG	24 MCG	60	Capsules	30	DAYS			02-01-2017	

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
52450045000110	Amitiza	Lubiprostone Cap 8 MCG	8 MCG	120	Capsules	30	DAYS			02-01-2017	
525570500001	Linzess	linaclotide cap	145 MCG; 290 MCG; 72 MCG	30	Capsules	30	DAYS			02-01-2017	
525600602003	Motegrity	prucalopride succinate tab	1 MG; 2 MG	30	Tablets	30	DAYS			07-01-2019	
525800603003	Movantik	naloxegol oxalate tab	12.5 MG; 25 MG	30	Tablets	30	DAYS			01-01-2020	
52580050102020	Relistor	methylnaltrexone bromide inj	12 MG/0.6ML	30	Syringes	30	DAYS	65649055103 ; 65649055107		01-01-2020	
52580050102020	Relistor	methylnaltrexone bromide inj	12 MG/0.6ML	60	Vials	30	DAYS	65649055102		01-01-2020	
52580050102015	Relistor	Methylnaltrexone Bromide Inj 8 MG/0.4ML (20 MG/ML)	8 MG/0.4ML	30	Syringes	30	DAYS			01-01-2020	
525800501003	Relistor	methylnaltrexone bromide tab	150 MG	90	Tablets	30	DAYS			01-01-2020	
525800572003	Symproic	naldemedine tosylate tab	0.2 MG	30	Tablets	30	DAYS			01-01-2020	
525430600003	Trulance	plecanatide tab	3 MG	30	Tablets	30	DAYS			08-01-2017	
52555060200320	Zelnorm	Tegaserod Maleate Tab 6 MG (Base Equivalent)	6 MG	60	Tablets	30	DAYS			10-01-2019	
52558580100320	Ibsrela	Tenapanor HCl Tab	50 MG	60	Tablets	30	DAYS			03-18-2022	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Through Preferred	**TARGET AGENT(S)** **Preferred Agent(s)** **Movantik** (naloxegol) **Symproic** (naldemedine) **Trulance** (plecanatide) **Nonpreferred Agent(s)** **Amitiza** (lubiprostone)* **Ibsrela** (tenapanor) **Linzess** (linaclotide) **Motegrity** (prucalopride) **Relistor** (methylnaltrexone) **Zelnorm** (tegaserod) *-generic available

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 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 has tried and had an inadequate response to at least 2 standard laxative therapy classes (e.g., bulk-forming, stimulant, enema, osmotic, or stool softener) **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 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 has tried and had an inadequate response to at least 2 standard laxative therapy classes (e.g., bulk-forming, stimulant, enema, osmotic, or stool softener) **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

Module	Clinical Criteria for Approval
	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 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** 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 has tried and had an inadequate response to at least 2 standard laxative therapy classes (e.g., stimulant, enema, osmotic, or stool softener, but not including fiber or bulking agents) **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**

Module	Clinical Criteria for Approval

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 has tried and had an inadequate response to at least 2 standard laxative therapy classes (e.g., bulk-forming, stimulant, enema, osmotic, or stool softener) **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:
   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 has tried and had an inadequate response to the generic equivalent that is not expected to occur with the brand agent **OR**
   B. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**
   C. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent for the requested indication **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

Module	Clinical Criteria for Approval
	cause harm **OR** E. The prescriber has provided documentation that the generic equivalent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. ONE of the following: A. The request is for Symproic (naldemedine), Trulance (plecanatide), Movantik (naloxegol), OR Relistor (methylnaltrexone) injection **OR** B. The request is for Linzess (linactolide) for use in pediatric functional constipation **OR** C. The requested agent is for use in IBS-C or CIC AND ONE of the following: 1. The patient has tried and had an inadequate response to Trulance (plecanatide) **OR** 2. The patient has an intolerance or hypersensitivity to Trulance (plecanatide) that is not expected to occur with the requested agent **OR** 3. The patient has an FDA labeled contraindication to Trulance (plecanatide) that is not expected to occur with the requested agent for the requested indication **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that Trulance (plecanatide) 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 requested agent is for use in OIC AND ONE of the following: 1. The patient has tried and had an inadequate response to Symproic (naldemedine) and Movantik (naloxegol) **OR** 2. The patient has an intolerance or hypersensitivity to Symproic (naldemedine) and Movantik (naloxegol) that is not expected to occur with the requested agent **OR** 3. The patient has an FDA labeled contraindication to Symproic (naldemedine) and Movantik (naloxegol) that is not expected to occur with the requested agent **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that Symproic (naldemedine) and Movantik (naloxegol) 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**

Module	Clinical Criteria for Approval
	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: 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** 3. 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: Coverage Exception with Quantity Limit - Commercial

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

This program should not be used as formulary exception criteria. Ascensia products are the preferred glucose test strip products. This criterion does not apply to FocusRx or KeyRx (see appropriate program).

Objective

These criteria apply to any request for agents that are included in the clients Lockout/Excluded Agents list and is not otherwise excluded from coverage under the member's pharmacy benefit.

EXCEPTION CRITERIA FOR APPROVAL

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

1. The request is NOT for a drug/drug class/medical condition that is restricted to coverage under the medical benefit (Medical Benefit Agents are pharmacy benefit exclusions and non-reviewable; they should be directed to the plan)

Examples of Agents Restricted to Coverage on the Medical Benefit
Insulin Pumps and Insulin Pump Supplies
Route of Administration which is excluded from coverage under the pharmacy benefit

AND

2. ONE of the following:
   - A. ALL of the following:
     - i. The requested agent is in an Affordable Care Act (ACA) Preventive Care category
       AND
     - ii. The member's benefit includes ACA Preventive Care for the category requested
       AND
     - iii. ONE of the following:
       - a. The requested agent is a contraception agent **AND** the following:
         1. The prescriber has provided information stating that the requested contraceptive agent is medically necessary
            AND
         2. The requested agent is being used for contraception

       OR

       - b. BOTH of the following:
         1. If the requested agent is a brand product with an available formulary generic equivalent, then ONE of the following:
            - A. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent
              OR
            - B. The patient has an intolerance or hypersensitivity to a formulary generic equivalent agent that is not expected to occur with the requested agent
              OR
            - C. The patient has an FDA labeled contraindication to ALL formulary generic equivalent agent(s) that is not expected to occur with the requested agent

            AND
         2. ONE of the following:
            - A. The requested agent is an aspirin agent **AND** ALL of the following:
              - i. The requested agent is the 81 mg strength aspirin
                AND
              - ii. The prescriber has provided information stating that the requested aspirin agent is medically necessary
                AND
              - iii. The patient is pregnant, at high risk of preeclampsia, and using the requested agent after 12 weeks of gestation

OR

B. The requested agent is a bowel prep agent **AND** ALL of the following:
   i. The prescriber has provided information stating that the requested bowel prep agent is medically necessary
   AND
   ii. The prescriber has indicated the requested agent will be used for the preparation of colorectal cancer screening using fecal occult blood testing, sigmoidoscopy, or colonoscopy
   AND
   iii. The patient is 45 years of age or over

OR

C. The requested agent is a breast cancer primary prevention agent **AND** ALL of the following:
   i. The prescriber has provided information stating that the requested breast cancer primary prevention agent is medically necessary
   AND
   ii. The requested agent is tamoxifen, raloxifene, or aromatase inhibitor (anastrozole, exemestane, letrozole)
   AND
   iii. The patient is 35 years of age or over
   AND
   iv. The agent is requested for the primary prevention of breast cancer

OR

D. The requested agent is a fluoride supplement **AND** BOTH of the following:
   i. The prescriber has provided information stating that the requested fluoride supplement is medically necessary
   AND
   ii. The patient is 6 months to 16 years of age

OR

E. The requested agent is a folic acid agent **AND** ALL of the following:
   i. The prescriber has provided information stating that the requested folic acid supplement is medically necessary
   AND
   ii. The requested folic acid supplement contains 0.4-0.8 mg of folic acid
   AND
   iii. The requested folic acid supplement is to be used in support of pregnancy

OR

F. The requested agent is an HIV infection pre-exposure prophylaxis (PrEP) agent being used for PrEP **AND** ALL of the following:
   i. The prescriber has provided information stating that the requested PrEP agent is medically necessary compared to other available PrEP agents
   AND
   ii. ONE of the following:
      a. The requested PrEP agent is ONE of the following:
         1. Tenofovir disoproxil fumarate and emtricitabine combination ingredient agent
         OR
         2. Tenofovir disoproxil fumarate single ingredient agent
         OR
         3. Tenofovir alafenamide and emtricitabine combination ingredient agent

OR

b. The prescriber has provided information stating that a tenofovir disoproxil fumarate and emtricitabine combination ingredient agent, tenofovir disoproxil fumarate single ingredient agent, or tenofovir alafenamide and emtricitabine combination ingredient agent is contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

AND

iii. The patient is at high risk of HIV infection

AND

iv. The patient has recently tested negative for HIV

OR

G. The requested agent is an infant eye ointment **AND** ALL of the following:

i. The prescriber has provided information stating that the requested infant eye ointment is medically necessary

AND

ii. The patient is 3 months of age or younger

AND

iii. The requested agent is requested for the prevention of gonococcal ophthalmia neonatorum

OR

H. The requested agent is an iron supplement **AND** ALL of the following:

i. The prescriber has provided information stating that the requested iron supplement is medically necessary

AND

ii. The patient is under 12 months of age

AND

iii. The patient is at increased risk for iron deficiency anemia

OR

I. The requested agent is a statin **AND** ALL of the following:

i. The prescriber has provided information stating that the requested statin is medically necessary

AND

ii. The requested agent is for use in ONE of the following low to moderate daily statin regimen (with up to the highest dosage strength as noted):

a. Atorvastatin 10-20 mg per day (20 mg tablet) **OR**
b. Fluvastatin 20-80 mg per day (40 mg capsule) **OR**
c. Fluvastatin ER 80 mg per day (80 mg tablet) **OR**
d. Lovastatin 20-40 mg per day (40 mg tablet) **OR**
e. Lovastatin ER 20-40 mg per day (40 mg tablet) **OR**
f. Pitavastatin 1-4 mg per day (4 mg tablet) **OR**
g. Pravastatin 10-80 mg per day (80 mg tablet) **OR**
h. Rosuvastatin 5-10 mg per day (10 mg tablet) **OR**
i. Simvastatin 10-40 mg per day (40 mg tablet, 40 mg/5 mL suspension)

AND

iii. The requested statin is for use in the primary prevention of cardiovascular disease (CVD)

AND

iv. The patient is 40-75 years of age (inclusive)

AND

v. The patient has at least one of the following risk factors:

a. Dyslipidemia **OR**
b. Diabetes **OR**
c. Hypertension **OR**
d. Smoking

AND

vi. The patient has a calculated 10-year risk of a cardiovascular event of 10% or greater per the American College of Cardiology and American Heart Association's Atherosclerotic Cardiovascular Disease (ASCVD) calculator

OR

J. The requested agent is a tobacco cessation agent **AND** BOTH of the following:
   i. The patient is a non-pregnant adult
   AND
   ii. The prescriber has provided information stating that the requested tobacco cessation agent is medically necessary

OR

K. The requested agent is a vaccine **AND** BOTH of the following:
   i. The prescriber has provided information stating that the requested vaccine is medically necessary
   AND
   ii. The requested vaccine will be used per the recommendations of the Advisory Committee on Immunization Practices/CDC

OR

B. ALL of the following:
   i. ONE of the following:
      a. The requested agent is in an ACA Preventive Care category AND did NOT meet the preventive service requirements
      OR
      b. BOTH of the following:
         1. ONE of the following:
            A. The requested agent is NOT in an ACA Preventive Care category
            OR
            B. The member's benefit does NOT include ACA Preventive Care for the category requested

         AND

         2. The request is NOT for a drug/drug class/medical condition which are excluded from coverage under the pharmacy benefit

Examples of Agents Excluded from Coverage on the Pharmacy Benefit
Brand for Generic*   Agents with the following reject message: #NDC NOT COVERED, USE XXX#
Bulk Powders*   (Defined as those products containing the third-party restriction code of B (BULK CHEMICALS) in the product file in RxClaim)
Clinic Packs*   (Y in the Clinic Pack field)
Cosmetic Alteration*   (Defined as those products containing the third-party restriction code of C (COSMETIC ALTERATION DRUGS) in the product file in RxClaim)
Infertility Agents*   (Defined as those products containing the third-party restriction code 7 (FERTILITY DRUGS) in the product file in RxClaim) (only when not covered in BET AND is being requested for treatment of infertility)
Institutional Packs*   Those that contain any one of the following modifier codes in the product file in RXClaims   i. MODIFIER AAAD31 INSTITUTIONAL/HOSP. PACK

ii. MODIFIER BBAD9A INSTITUTIONAL iii. MODIFIER TTAAJQ INSTITUTIONAL iv. MODIFIER TTAA5V INSTITUTIONAL USE ONLY v. MODIFIER AAAB9A HOSPITAL PACK vi. MODIFIER AAADQQ HUD (HOSPITAL UNIT DOSE) vii. MODIFER AAAD6T HOSPITAL USE ONLY
Non-FDA Approved Agents* (Refer to all tiers on Formulary ID 220 or reject messaging of 'Non-FDA Approved Drug')
Repackagers (not including Veterans Administration and Department of Defense Claims)* (Defined as indicated as Y in Repkg code field in the product file in RxClaim)
Over-The-Counter Medications* (not including glucose test strips, insulin, ACA required drugs, lancets, syringes) (Defined as indicated by O or P in the Rx-OTC indicator code field in the Product file in RxClaim)
Sexual Dysfunction Agents* (Defined as those products (e.g., Addyi, Viagra, Cialis 10 mg and 20 mg, Levitra, Staxyn, Caverject, Edex, Muse) containing the third-party restriction V (IMPOTENCE AGENTS) in the product file in RxClaim (only when not covered in BET AND is being requested for treatment of sexual dysfunction))
Weight Loss Agents* (Defined as those products containing the third-party restriction code 8 (ANOREXIC, ANTI-OBESITY) in the product file in RxClaim) (only when not covered in BET AND is being requested for treatment of weight loss)
Other

*Category specific denial reasons apply

AND

ii. ONE of the following:
   a. The requested agent is a CGM/Sensor/Transmitter/Receiver AND ONE of the following:
      1. Patient has a visual impairment
         OR
      2. Patient uses an insulin pump that is only compatible with one specific CGM/sensor/transmitter/receiver
         OR
      3. Patient has a physical or a mental disability

   OR

   b. The requested agent is a glucose cartridge, test strip, or all-in-one glucose meter system AND ONE of the following:
      1. Patient has visual impairment
         OR
      2. Patient uses an insulin pump OR continuous glucose monitor that is not accommodated with a preferred glucose cartridge, test strip, or all-in-one glucose meter system
         OR
      3. Patient has a physical or a mental disability

   OR

   c. The requested agent is a rapid, regular, Humalog 50/50, Mix, or NPH insulin agent and ONE of the following:
      1. BOTH of the following:
         A. The requested agent is a rapid insulin
            AND
         B. There is information that the patient is currently using an insulin pump that has an incompatibility with the preferred rapid insulin agent that is not expected to occur with the requested agent

      OR

      2. The request is for Humalog Mix 50/50 AND ONE of the following:
         A. The patient is currently using Humalog Mix 50/50 AND the prescriber states the patient is at risk if switched to a different insulin

OR

B. The patient has tried and failed a preferred insulin mix (e.g., Novolin, Novolog)

OR

3. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to the preferred insulin agents (e.g., Novolin, Novolog) of the same type (rapid or regular, mix or NPH) that is not expected to occur with the requested agent

OR

4. There is information that the patient has a physical or a mental disability that would prevent him/her from using a preferred insulin agent

OR

5. The patient is pregnant

OR

d. The requested agent is a long-acting insulin agent and the following:
    1. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to the preferred insulin agents (e.g., Semglee, Insulin glargine-yfgn) of the same type (long-acting) that is not expected to occur with the requested agent

OR

e. The requested agent is Cialis/tadalafil 2.5 and 5 mg AND BOTH of the following:
    1. The requested agent is be used for a diagnosis of benign prostatic hyperplasia

    AND

    2. The requested quantity is equal to or less than 30 tablets per month

OR

f. The requested agent is a Self-Administered Contraceptive Agent AND the agent is being prescribed for an allowable diagnosis **OR**

Allowable Diagnoses
Acne vulgaris
Amenorrhea
Dysfunctional uterine bleeding
Dysmenorrhea
Endometriosis
Fibroid Uterus
Hyperandrogenism
Irregular menses (menorrhagia, oligomenorrhea, and hypermenorrhea)
Menstrual migraine
Perimenopausal symptoms
Polycystic ovarian syndrome
Premenstrual dysphoric disorder (PMDD)
Premenstrual syndrome
Treatment to reduce the risk of osteoporosis, ovarian cancer, colorectal cancer, and endometrial cancer, especially in women with a family history of these disorders

g. The requested agent is Auvi-Q 0.1 mg AND the patient weighs 7.5 to 15 kg (16.5 to 33 pounds)

OR

h. The requested agent is an HIV infection post-exposure prophylaxis (PEP) agent being used for PEP for a member with a Fully Insured plan and ALL of the following:
    1. ONE of the following:
        A. The requested PEP agent is ONE of the following (agent AND strength must match):
            i. Emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada)

            OR

            ii. Tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread)

            OR

iii. Emtricitabine 200 mg single ingredient agent (Emtriva)
OR
iv. Raltegravir 400 mg single ingredient agent (Isentress)
OR
v. Dolutegravir 50 mg single ingredient agent (Tivicay)
OR
vi. Darunavir 800 mg single ingredient agent (Prezista)
OR
vii. Ritonavir 100 mg single ingredient agent (Norvir)

OR

B. The prescriber has provided information stating that emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada), tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread), emtricitabine 200 mg single ingredient agent (Emtriva), raltegravir 400 mg single ingredient agent (Isentress), dolutegravir 50 mg single ingredient agent (Tivicay), darunavir 800 mg single ingredient agent (Prezista), or ritonavir 100 mg single ingredient agent (Norvir) is contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

AND

2. The patient is at high risk of HIV infection
AND
3. The patient is initiating or has initiated PEP within 72 hours of suspected exposure to HIV

OR

i. BOTH of the following:
1. The requested agent is for ONE of the following:
A. Weight loss agent that will not be used for weight loss
OR
B. Infertility agent that will not be used for infertility
OR
C. Coverage Delay Agent

AND

2. BOTH of the following:
A. ONE of the following:
i. The patient has an FDA labeled indication for the requested agent
OR
ii. The patient has an indication supported in AHFS, DrugDex with 1 or 2a level of evidence, or NCCN with 1 or 2a level of evidence (for oncology agents also accept NCCN Compendium™ level of evidence 2B, DrugDex 2B, Wolters Kluwer Lexi-Drugs level A, and Clinical Pharmacology) for the requested agent
OR
iii. The patient has a diagnosis of Gender Identity Disorder (GID) or gender dysphoria and clinical guidelines support therapy with the requested agent

AND

B. ONE of the following:
i. The requested agent has formulary alternatives (any formulary tier) for the diagnosis being treated by the requested agent AND BOTH of the following:
a. If the requested agent is a brand product with an available formulary generic equivalent AND ONE of the following:

1. The patient has tried and failed one or more available formulary generic equivalents to the requested agent
OR
2. The prescriber has provided information stating that ALL available formulary (any formulary tier) generic equivalents to the requested agent are contraindicated, are likely to be less effective, or will cause an adverse reaction or other harm for the patient

AND

b. ONE of the following:
1. The patient has tried and failed at least three formulary alternatives (any formulary tier), if available, for the diagnosis being treated with the requested agent
OR
2. The prescriber has provided information stating that ALL available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

OR

ii. The requested agent does NOT have formulary (any formulary tier) alternatives for the diagnosis being treated with the requested agent
OR
iii. The prescriber stated that the patient is currently stabilized on for a minimum of 90 days the requested agent and switching could potentially cause harm or a health risk (starting on samples is not approvable)

AND

iii. If the requested agent is a biologic immunomodulator agent, Otezla, or Zeposia, the patient will NOT be using the requested agent in combination with another biologic immunomodulator agent, Otezla, or Zeposia
AND

3. ONE of the following:
A. The requested agent is not subject to an existing quantity limit program
OR
B. The requested agent is subject to an existing quantity limit program and ONE of the following:
i. The requested quantity (dose) does NOT exceed the program quantity limit
OR
ii. Information has been provided that fulfills the criteria listed under the "Allowed exceptions/diagnoses" (if applicable)
OR
iii. The requested quantity (dose) is greater than the program quantity limit and ONE of the following:
a. BOTH of the following:
1. The requested agent does not have a maximum FDA labeled dose for the requested indication
AND
2. The prescriber has provided information in support of 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. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

OR

c. BOTH of the following:
1. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
   AND
2. The prescriber has provided information in support of therapy with a higher dose for the requested indication

ACA Length of Approval:

- Aspirin 81 mg:
  - Preeclampsia in pregnancy: 9 months
- Infant eye appointment: 3 months
- All other indications: 12 months
- Apply $0 copay if ACA criteria met

HIV PEP Length of Approval:

- 12 months
- Apply $0 copay if HIV PEP criteria met

Coverage Exception Length of Approval: 12 months

• Program Summary: Coverage Exception with Quantity Limit – Health Insurance Marketplace (HIM)

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

This program applies to individual and small group plans, on- and off-Exchange, that are fully insured and non-grandfathered.

Please note, this program applies to clinical appropriateness. Please see the Clinical Review process flows for determination of exigency as defined per the regulation.

These criteria apply to any request for medication that is not included on the Essential Health Benefit covered drug list.

Objective

These criteria apply to any request for agents that are included on the covered agents list and can be used to treat a medical condition/disease state that is not otherwise excluded from coverage under the pharmacy benefit.

EXCEPTION CRITERIA FOR APPROVAL

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

1. The request is NOT for a drug/drug class/medical condition that is restricted to coverage under the medical benefit (Medical Benefit Agents are pharmacy benefit exclusions and non-reviewable; they should be directed to the plan)

Examples of Agents Restricted to Coverage on the Medical Benefit
Insulin Pumps and Insulin Pump Supplies
Route of Administration which is excluded from coverage under the pharmacy benefit

   AND
2. ONE of the following:
   A. ALL of the following:
      i. The requested agent is in an Affordable Care Act (ACA) Preventive Care category
         AND
      ii. The member's benefit includes ACA Preventive Care for the category requested

AND

iii. ONE of the following:
- a. The requested agent is a contraception agent **AND** BOTH of the following:
  1. The prescriber has provided information stating that the requested contraceptive agent is medically necessary
     AND
  2. The requested agent is being used for contraception

  OR
- b. BOTH of the following:
  1. If the requested agent is a brand product with an available formulary generic equivalent, then ONE of the following:
     - A. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent
       OR
     - B. The patient has an intolerance or hypersensitivity to a formulary generic equivalent agent that is not expected to occur with the requested agent
       OR
     - C. The patient has an FDA labeled contraindication to ALL formulary generic equivalent agent(s) that is not expected to occur with the requested agent

     AND
  2. ONE of the following:
     - A. The requested agent is an aspirin agent **AND** ALL of the following:
       - i. The requested agent is the 81 mg strength aspirin
         AND
       - ii. The prescriber has provided information stating that the requested aspirin agent is medically necessary
         AND
       - iii. The patient is pregnant, at high risk of preeclampsia, and using the requested agent after 12 weeks of gestation

       OR
     - B. The requested agent is a bowel prep agent **AND** ALL of the following:
       - i. The prescriber has provided information stating that the requested bowel prep agent is medically necessary
         AND
       - ii. The prescriber has indicated the requested agent will be used for the preparation of colorectal cancer screening using fecal occult blood testing, sigmoidoscopy, or colonoscopy
         AND
       - iii. The patient is 45 years of age or over

       OR
     - C. The requested agent is a breast cancer primary prevention agent **AND** ALL of the following:
       - i. The prescriber has provided information stating that the requested breast cancer primary prevention agent is medically necessary
         AND
       - ii. The requested agent is tamoxifen, raloxifene, or aromatase inhibitor (anastrozole, exemestane, letrozole)
         AND
       - iii. The patient is 35 years of age or over
         AND
       - iv. The agent is requested for the primary prevention of breast cancer

       OR
     - D. The requested agent is a fluoride supplement **AND** BOTH of the following:

i. The prescriber has provided information stating that the requested fluoride supplement is medically necessary
AND
ii. The patient is 6 months to 16 years of age

OR

E. The requested agent is a folic acid agent **AND** ALL of the following:
i. The prescriber has provided information stating that the requested folic acid supplement is medically necessary
AND
ii. The requested folic acid supplement contains 0.4-0.8 mg of folic acid
AND
iii. The requested folic acid supplement is to be used in support of pregnancy

OR

F. The requested agent is an HIV infection pre-exposure prophylaxis (PrEP) agent being used for PrEP **AND** ALL of the following:
i. The prescriber has provided information stating that the requested PrEP agent is medically necessary compared to other available PrEP agents
AND
ii. ONE of the following:
a. The requested PrEP agent is ONE of the following:
1. Tenofovir disoproxil fumarate and emtricitabine combination ingredient agent
OR
2. Tenofovir disoproxil fumarate single ingredient agent
OR
3. Tenofovir alafenamide and emtricitabine combination ingredient agent

OR

b. The prescriber has provided information stating that a tenofovir disoproxil fumarate and emtricitabine combination ingredient agent, tenofovir disoproxil fumarate single ingredient agent, or tenofovir alafenamide and emtricitabine combination ingredient agent is contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

AND
iii. The patient is at high risk of HIV infection
AND
iv. The patient has recently tested negative for HIV

OR

G. The requested agent is an infant eye ointment **AND** ALL of the following:
i. The prescriber has provided information stating that the requested infant eye ointment is medically necessary
AND
ii. The patient is 3 months of age or younger
AND
iii. The requested agent is requested for the prevention of gonococcal ophthalmia neonatorum

OR

H. The requested agent is an iron supplement **AND** ALL of the following:

i. The prescriber has provided information stating that the requested iron supplement is medically necessary
AND
ii. The patient is under 12 months of age
AND
iii. The patient is at increased risk for iron deficiency anemia

OR

I. The requested agent is a statin **AND** ALL of the following:
i. The prescriber has provided information stating that the requested statin is medically necessary
AND
ii. The requested agent is for use in ONE of the following low to moderate daily statin regimen (with up to the highest dosage strength as noted):
a. Atorvastatin 10-20 mg per day (20 mg tablet) **OR**
b. Fluvastatin 20-80 mg per day (40 mg capsule) **OR**
c. Fluvastatin ER 80 mg per day (80 mg tablet) **OR**
d. Lovastatin 20-40 mg per day (40 mg tablet) **OR**
e. Lovastatin ER 20-40 mg per day (40 mg tablet) **OR**
f. Pitavastatin 1-4 mg per day (4 mg tablet) **OR**
g. Pravastatin 10-80 mg per day (80 mg tablet) **OR**
h. Rosuvastatin 5-10 mg per day (10 mg tablet) **OR**
i. Simvastatin 10-40 mg per day (40 mg tablet, 40 mg/5 mL suspension)
AND
iii. The requested statin is for use in the primary prevention of cardiovascular disease (CVD)
AND
iv. The patient is 40-75 years of age (inclusive)
AND
v. The patient has at least one of the following risk factors:
a. Dyslipidemia **OR**
b. Diabetes **OR**
c. Hypertension **OR**
d. Smoking
AND
vi. The patient has a calculated 10-year risk of a cardiovascular event of 10% or greater per the American College of Cardiology and American Heart Association's Atherosclerotic Cardiovascular Disease (ASCVD) calculator

OR

J. The requested agent is a tobacco cessation agent **AND** BOTH of the following:
i. The patient is a non-pregnant adult
AND
ii. The prescriber has provided information stating that the requested tobacco cessation agent is medically necessary

OR

K. The requested agent is a vaccine **AND** BOTH of the following:
i. The prescriber has provided information stating that the requested vaccine is medically necessary
AND
ii. The requested vaccine will be used per the recommendations of the Advisory Committee on Immunization Practices/CDC

OR

B. ALL of the following:
   i. ONE of the following:
      a. The requested agent is in an ACA Preventive Care category AND did NOT meet the preventive service requirements
      OR
      b. BOTH of the following:
         1. ONE of the following:
            A. The requested agent is NOT in an ACA Preventive Care category
            OR
            B. The member's benefit does NOT include ACA Preventive Care for the category requested
         AND
         2. ONE of the following:
            A. The request is for a drug that is part of BCBS MN's "Drugs that are not covered" exclusion program AND BOTH of the following:
               i. The patient has an FDA labeled indication for the requested agent or an indication supported in AHFS, DrugDex with 1 or 2a level of evidence, or NCCN with 1 or 2a level of evidence (for oncology agents also accept NCCN Compendium™ level of evidence 2B, DrugDex 2B, Wolters Kluwer Lexi-Drugs level A, and Clinical Pharmacology) for the requested agent
               AND
               ii. The patient has tried and failed ALL formulary alternatives for the diagnosis being treated with the requested agent
            OR
            B. The request is NOT for a drug/drug class/medical condition which are excluded from coverage under the pharmacy benefit

Excluded from Coverage on the Pharmacy Benefit
Alcohol Swabs
Blood Component (not including Hemophilia Factor)
Bulk Powders* (Defined as those products containing the third-party restriction code of B (BULK CHEMICALS) in the product file in RxClaim)
Clinic Packs* (Y in the Clinic Pack field)
Cosmetic Alteration*
Diagnostic Agents (not including glucose test strips)
Dietary and Herbal Supplements
General Anesthetic
Infertility Agents* For the treatment of infertility
Institutional Packs* Those that contain any one of the following modifier codes in the product file in RXClaims i. MODIFIER AAAD31 INSTITUTIONAL/HOSP. PACK ii. MODIFIER BBAD9A INSTITUTIONAL iii. MODIFIER TTAAJQ INSTITUTIONAL iv. MODIFIER TTAA5V INSTITUTIONAL USE ONLY v. MODIFIER AAAB9A HOSPITAL PACK vi. MODIFIER AAADQQ HUD (HOSPITAL UNIT DOSE) vii. MODIFER AAAD6T HOSPITAL USE ONLY
Investigative, experimental, or not medically necessary

Medical Devices and Supplies (not including spacers, lancets, needles, syringes, continuous glucose monitor/sensor/transmitter/receiver) (Defined by GPI 97**********)
Medical devices approved through a different FDA-approval process than drugs (Defined by one of the following: 1) Drug Application File Marketing Category 15 – Premarket Application 2) Drug Application File Marketing Category 16 – Premarket Notification)
Non-FDA Approved Agents* (Refer to all tiers on Formulary ID 220 or reject messaging of 'Non-FDA Approved Drug')
Over-The-Counter Medications* (specific OTC medications are covered if group purchases OTC benefit) (not including glucose test strips, insulin, or ACA required drugs)
Repackagers (not including Veterans Administration and Department of Defense Claims)* (Defined as indicated as Y in Repkg code field in the product file in RxClaim)
Self-Administered Contraceptives* (2510**********, 2540**********, 2596**********, 2597**********, 2599**********, 260000301003**) (ONLY when not covered in BET AND is being requested exclusively for the use of pregnancy prevention)
Sexual Dysfunction Agents* (Addyi, Viagra, Cialis, Levitra, Staxyn, Caverject, Edex, Muse) for treatment of sexual dysfunction
Surgical Supplies/Medical Devices/Ostomy (not including spacers, lancets, needles, syringes, continuous glucose monitor/sensor/transmitter/receiver) (Defined as indicated by the third-party restriction code 3 (SURGICAL SUPPLY/MEDICAL DEVICE/OSTOMY) in the product file in RxClaim)
Syringes other than insulin syringes
Weight Loss Agents* (GPI: 6120**********, 6125**********) for the treatment of weight loss

*Category specific denial reasons apply

AND

ii. ONE of the following:
   a. The requested agent is a CGM/Sensor/Transmitter/Receiver AND ONE of the following:
      1. Patient has a visual impairment
         OR
      2. Patient uses an insulin pump that is only compatible with one specific CGM/sensor/transmitter/receiver
         OR
      3. Patient has a physical or a mental disability

   OR

   b. The requested agent is a glucose cartridge, test strip, or all-in-one glucose meter system AND ONE of the following:
      1. Patient has visual impairment
         OR
      2. Patient uses an insulin pump OR continuous glucose monitor that is not accommodated with a preferred glucose cartridge, test strip, or all-in-one glucose meter system
         OR
      3. Patient has a physical or a mental disability

   OR

   c. The requested agent is a rapid, regular, Humalog 50/50, Mix, or NPH insulin agent and ONE of the following:
      1. BOTH of the following:
         A. The requested agent is a rapid insulin
            AND

B. There is information that the patient is currently using an insulin pump that has an incompatibility with the preferred rapid insulin agent that is not expected to occur with the requested agent

OR

2. The request is for Humalog Mix 50/50 AND ONE of the following:
   A. The patient is currently using Humalog Mix 50/50 AND the prescriber states the patient is at risk if switched to a different insulin
      OR
   B. The patient has tried and failed a preferred insulin mix (e.g., Novolin, Novolog)

OR

3. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to the preferred insulin agents (e.g., Novolin, Novolog) of the same type (rapid or regular, mix or NPH) that is not expected to occur with the requested agent

OR

4. There is information that the patient has a physical or a mental disability that would prevent him/her from using a preferred insulin agent

OR

5. The patient is pregnant

OR

d. The requested agent is a long-acting insulin agent and the following:
   1. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to the preferred insulin agents of the same type (long-acting) that is not expected to occur with the requested agent

OR

e. The requested agent is part of the Brand for Generic strategy (i.e., Agents with the following reject message: #NDC NOT COVERED, USE XXX#) AND BOTH of the following:
   1. The prescriber has provided information stating that the available formulary (any formulary tier) brand equivalents to the requested agent are contraindicated, are likely to be less effective, or will cause an adverse reaction or other harm for the patient

      AND

   2. ONE of the following:
      A. The patient has tried and failed at least three formulary alternatives (any formulary tier), if available, for the diagnosis being treated with the requested agent
         OR
      B. The prescriber has provided information stating that ALL available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient
         OR
      C. The prescriber stated that the patient is currently stabilized on for a minimum of 90 days the requested agent and switching could potentially cause harm or a health risk (starting on samples is not approvable)

OR

f. The requested agent is Procysbi AND the patient has tried and had an inadequate response to therapy with Cystagon in combination with a GI protectant (e.g., proton pump inhibitor, histamine-2 receptor antagonists)

OR

g. The requested agent is a Self-Administered Contraceptive Agent (e.g., 2510**********, 2540**********, 2596**********, 2597**********, 2599**********, 260000301003**) AND the agent is being prescribed for an allowable diagnosis

Allowable Diagnoses
Acne vulgaris
Amenorrhea
Dysfunctional uterine bleeding
Dysmenorrhea
Endometriosis
Fibroid Uterus
Hyperandrogenism
Irregular menses (menorrhagia, oligomenorrhea, and hypermenorrhea)
Menstrual migraine
Perimenopausal symptoms
Polycystic ovarian syndrome
Premenstrual dysphoric disorder (PMDD)
Premenstrual syndrome
Treatment to reduce the risk of osteoporosis, ovarian cancer, colorectal cancer, and endometrial cancer, especially in women with a family history of these disorders

OR

h. The requested agent is Auvi-Q 0.1 mg AND the patient weighs 7.5 to 15 kg (16.5 to 33 pounds)
OR

i. The requested agent is an HIV infection post-exposure prophylaxis (PEP) agent being used for PEP and ALL of the following:
    1. The prescriber has provided information stating that the requested PEP agent is medically necessary compared to other available PEP agents
    AND
    2. ONE of the following:
        A. The requested PEP agent is ONE of the following (agent AND strength must match):
            i. Emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada)
            OR
            ii. Tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread)
            OR
            iii. Emtricitabine 200 mg single ingredient agent (Emtriva)
            OR
            iv. Raltegravir 400 mg single ingredient agent (Isentress)
            OR
            v. Dolutegravir 50 mg single ingredient agent (Tivicay)
            OR
            vi. Darunavir 800 mg single ingredient agent (Prezista)
            OR
            vii. Ritonavir 100 mg single ingredient agent (Norvir)
        OR
        B. The prescriber has provided information stating that emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada), tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread), emtricitabine 200 mg single ingredient agent (Emtriva), raltegravir 400 mg single ingredient agent (Isentress), dolutegravir 50 mg single ingredient agent (Tivicay), darunavir 800 mg single ingredient agent (Prezista),

or ritonavir 100 mg single ingredient agent (Norvir) is contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

AND

3. The patient is at high risk of HIV infection

AND

4. The patient is initiating or has initiated PEP within 72 hours of suspected exposure to HIV

OR

j. ONE of the following:
    1. The requested medication is an antipsychotic prescribed to treat emotional disturbance or mental illness AND the following:
        A. The prescriber has indicated at least three formulary drugs (or as many as available, if fewer than three) have been considered and they have determined that the medication prescribed will best treat the patient's condition

    OR

    2. The requested agent is Supprelin or Vantas and is being requested for a diagnosis of Gender Identity Disorder (GID) or gender dysphoria

    OR

    3. BOTH of the following:
        A. ONE of the following:
            i. The patient has an FDA labeled indication for the requested agent

            OR

            ii. The patient has an indication supported in AHFS, DrugDex with 1 or 2a level of evidence, or NCCN with 1 or 2a level of evidence (for oncology agents also accept NCCN Compendium™ level of evidence 2B, DrugDex 2B, Wolters Kluwer Lexi-Drugs level A, and Clinical Pharmacology) for the requested agent

            OR

            iii. The patient has a diagnosis of Gender Identity Disorder (GID) or gender dysphoria and clinical guidelines support therapy with the requested agent

        AND

        B. ONE of the following:
            i. The requested agent has formulary alternatives (any formulary tier) for the diagnosis being treated by the requested agent AND BOTH of the following:
                a. If the requested agent is a brand product with an available formulary generic equivalent AND ONE of the following:
                    1. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent

                    OR

                    2. The prescriber has provided information stating that ALL available formulary (any formulary tier) generic equivalents to the requested agent are contraindicated, are likely to be less effective, or will cause an adverse reaction or other harm for the patient

                AND

                b. ONE of the following:
                    1. The patient has tried and failed at least three formulary alternatives (any formulary tier), if

available, for the diagnosis being treated with the requested agent

OR

2. The prescriber has provided information stating that ALL available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

OR

ii. The requested agent does NOT have formulary (any formulary tier) alternatives for the diagnosis being treated with the requested agent

OR

iii. The prescriber stated that the patient is currently stabilized on for a minimum of 90 days the requested agent and switching could potentially cause harm or a health risk (starting on samples is not approvable)

AND

iii. If the request is for Restasis or Xiidra and the patient has met the additional clinical review criteria

AND

iv. If the requested agent is a biologic immunomodulator agent, Otezla, or Zeposia, the patient will NOT be using the requested agent in combination with another biologic immunomodulator agent, Otezla, or Zeposia

AND

3. ONE of the following:
   A. The requested agent is not subject to an existing quantity limit program

   OR

   B. The requested agent is subject to an existing quantity limit program and ONE of the following:
      i. The requested quantity (dose) does NOT exceed the program quantity limit

      OR

      ii. Information has been provided that fulfills the criteria listed under the "Allowed exceptions/diagnoses" (if applicable)

      OR

      iii. The requested quantity (dose) is greater than the program quantity limit and ONE of the following:
         a. BOTH of the following:
            1. The requested agent does not have a maximum FDA labeled dose for the requested indication

            AND

            2. The prescriber has provided information in support of 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. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

         OR

         c. BOTH of the following:
            1. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication

            AND

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

ACA Length of Approval:

- Aspirin 81 mg:
  - Preeclampsia in pregnancy: 9 months
- Infant eye appointment: 3 months
- All other indications: 12 months
- Apply $0 copay if ACA criteria met

HIV PEP Length of Approval:

- 12 months
- Apply $0 copay if HIV PEP criteria is met

Coverage Exception Length of Approval: 12 months

• Program Summary: Coverage Exception with Quantity Limit – NetResults (KeyRx and FocusRx)

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

Objective

These criteria apply to any request for agents that are included on the covered agents list and can be used to treat a medical condition/disease state that is not otherwise excluded from coverage under the pharmacy benefit.

EXCEPTION CRITERIA FOR APPROVAL

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

1. The request is NOT for a drug/drug class/medical condition that is restricted to coverage under the medical benefit (Medical Benefit Agents are pharmacy benefit exclusions and non-reviewable; they should be directed to the plan)

Examples of Agents Restricted to Coverage on the Medical Benefit
Insulin Pumps and Insulin Pump Supplies
Route of Administration which is excluded from coverage under the pharmacy benefit (Injectable drugs included on Tier 40 of FID 33102 that reject "NOT ON DRUG LIST, CHECK MEDICAL BENEFIT. CALL NUMBER ON THE BACK OF YOUR CARD FOR MORE INFORMATION" [Excluding drugs on the following list: BCBSMN Tier 40 Reviewable Drugs List KeyRx/FocusRx])

AND

2. ONE of the following:
   - A. ALL of the following:
     - i. The requested agent is in an Affordable Care Act (ACA) Preventive Care category
       AND
     - ii. The member's benefit includes ACA Preventive Care for the category requested
       AND
     - iii. ONE of the following:
       - a. The requested agent is a contraception agent **AND** BOTH of the following:
         1. The prescriber has provided information stating that the requested contraceptive agent is medically necessary
            AND
         2. The requested agent is being used for contraception

       OR

       - b. BOTH of the following:
         1. If the requested agent is a brand product with an available formulary generic equivalent, then ONE of the following:
            - A. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent
              OR
            - B. The patient has an intolerance or hypersensitivity to a formulary generic equivalent agent that is not expected to occur with the requested agent

OR

C. The patient has an FDA labeled contraindication to ALL formulary generic equivalent agent(s) that is not expected to occur with the requested agent

AND

2. ONE of the following:
   A. The requested agent is an aspirin agent **AND** ALL of the following:
      i. The requested agent is the 81 mg strength aspirin
      AND
      ii. The prescriber has provided information stating that the requested aspirin agent is medically necessary
      AND
      iii. The patient is pregnant, at high risk of preeclampsia, and using the requested agent after 12 weeks of gestation

   OR

   B. The requested agent is a bowel prep agent **AND** ALL of the following:
      i. The prescriber has provided information stating that the requested bowel prep agent is medically necessary
      AND
      ii. The prescriber has indicated the requested agent will be used for the preparation of colorectal cancer screening using fecal occult blood testing, sigmoidoscopy, or colonoscopy
      AND
      iii. The patient is 45 years of age or over

   OR

   C. The requested agent is a breast cancer primary prevention agent **AND** ALL of the following:
      i. The prescriber has provided information stating that the requested breast cancer primary prevention agent is medically necessary
      AND
      ii. The requested agent is tamoxifen, raloxifene, or aromatase inhibitor (anastrozole, exemestane, letrozole)
      AND
      iii. The patient is 35 years of age or over
      AND
      iv. The agent is requested for the primary prevention of breast cancer

   OR

   D. The requested agent is a fluoride supplement **AND** BOTH of the following:
      i. The prescriber has provided information stating that the requested fluoride supplement is medically necessary
      AND
      ii. The patient is 6 months to 16 years of age

   OR

   E. The requested agent is a folic acid agent **AND** ALL of the following:
      i. The prescriber has provided information stating that the requested folic acid supplement is medically necessary
      AND
      ii. The requested folic acid supplement contains 0.4-0.8 mg of folic acid
      AND
      iii. The requested folic acid supplement is to be used in support of pregnancy

   OR

   F. The requested agent is an HIV infection pre-exposure prophylaxis (PrEP) agent being used for PrEP **AND** ALL of the following:

i. The prescriber has provided information stating that the requested PrEP agent is medically necessary compared to other available PrEP agents
AND
ii. ONE of the following:
a. The requested PrEP agent is ONE of the following:
1. Tenofovir disoproxil fumarate and emtricitabine combination ingredient agent
OR
2. Tenofovir disoproxil fumarate single ingredient agent
OR
3. Tenofovir alafenamide and emtricitabine combination ingredient agent
OR
b. The prescriber has provided information stating that a tenofovir disoproxil fumarate and emtricitabine combination ingredient agent, tenofovir disoproxil fumarate single ingredient agent, or tenofovir alafenamide and emtricitabine combination ingredient agent is contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient
AND
iii. The patient is at high risk of HIV infection
AND
iv. The patient has recently tested negative for HIV

OR

G. The requested agent is an infant eye ointment **AND** ALL of the following:
i. The prescriber has provided information stating that the requested infant eye ointment is medically necessary
AND
ii. The patient is 3 months of age or younger
AND
iii. The requested agent is requested for the prevention of gonococcal ophthalmia neonatorum

OR

H. The requested agent is an iron supplement **AND** ALL of the following:
i. The prescriber has provided information stating that the requested iron supplement is medically necessary
AND
ii. The patient is under 12 months of age
AND
iii. The patient is at increased risk for iron deficiency anemia

OR

I. The requested agent is a statin **AND** ALL of the following:
i. The prescriber has provided information stating that the requested statin is medically necessary
AND
ii. The requested agent is for use in ONE of the following low to moderate daily statin regimen (with up to the highest dosage strength as noted):
a. Atorvastatin 10-20 mg per day (20 mg tablet) **OR**
b. Fluvastatin 20-80 mg per day (40 mg capsule) **OR**
c. Fluvastatin ER 80 mg per day (80 mg tablet) **OR**

d. Lovastatin 20-40 mg per day (40 mg tablet) **OR**
e. Lovastatin ER 20-40 mg per day (40 mg tablet) **OR**
f. Pitavastatin 1-4 mg per day (4 mg tablet) **OR**
g. Pravastatin 10-80 mg per day (80 mg tablet) **OR**
h. Rosuvastatin 5-10 mg per day (10 mg tablet)**OR**
i. Simvastatin 10-40 mg per day (40 mg tablet, 40 mg/5 mL suspension)

AND

iii. The requested statin is for use in the primary prevention of cardiovascular disease (CVD)

AND

iv. The patient is 40-75 years of age (inclusive)

AND

v. The patient has at least one of the following risk factors:
a. Dyslipidemia **OR**
b. Diabetes **OR**
c. Hypertension **OR**
d. Smoking

AND

vi. The patient has a calculated 10-year risk of a cardiovascular event of 10% or greater per the American College of Cardiology and American Heart Association's Atherosclerotic Cardiovascular Disease (ASCVD) calculator

OR

J. The requested agent is a tobacco cessation agent **AND** BOTH of the following:
i. The patient is a non-pregnant adult

AND

ii. The prescriber has provided information stating that the requested tobacco cessation agent is medically necessary

OR

K. The requested agent is a vaccine **AND** BOTH of the following:
i. The prescriber has provided information stating that the requested vaccine is medically necessary

AND

ii. The requested vaccine will be used per the recommendations of the Advisory Committee on Immunization Practices/CDC

OR

B. ALL of the following:
i. ONE of the following:
a. The requested agent is in an ACA Preventive Care category AND did NOT meet the preventive service requirements

OR

b. BOTH of the following:
1. ONE of the following:
A. The requested agent is NOT in an ACA Preventive Care category

OR

B. The member's benefit does NOT include ACA Preventive Care for the category requested

AND

2. The request is NOT for a drug/drug class/medical condition which are excluded from coverage under the pharmacy benefit

Excluded from Coverage on the Pharmacy Benefit
AHFS (devices and pharmaceutical aids, not including needles, syringes, lancets, CGM/sensor/transmitter/receiver) (Defined as those products containing the AHFS code 940000000 (DEVICES) and/ or 960000000 (PHARMACEUTICAL AIDS) in the product file in RxClaim)
Brand for Generic* Agents with the following reject message: #NDC NOT COVERED, USE XXX#
Bulk Powders* (Defined as those products containing the third-party restriction code of B (BULK CHEMICALS) in the product file in RxClaim)
Clinic Packs* (Y in the Clinic Pack field)
Cosmetic Alteration* (Defined as those products containing the third-party restriction code of C (COSMETIC ALTERATION DRUGS) in the product file in RxClaim)
Diagnostic Agents (not including glucose test strips) (Defined as those products containing the third-party restriction code of 5 (DIAGNOSTIC AGENT) in the product file in RxClaim)
Drugs That Are Not Covered Exclusion (not including glucose test strips, insulin, AuviQ 0.1 mg, ACA required drugs, lancets, syringes, CGM/sensor/transmitter/receiver) [See MN NDC Lock Out List NetResults]
General Anesthetics (Defined as those products containing the third-party restriction code of 6 (GENERAL ANESTHETIC) in the product file in RxClaim)
Infertility Agents* (Defined as those products containing the third-party restriction code 7 (FERTILITY DRUGS) in the product file in RxClaim) (only when not covered in BET AND is being requested for treatment of infertility)
Injectable drugs not on covered drug list, not including the drugs on the following list: BCBSMN Tier 40 Reviewable Drugs List KeyRx/FocusRx (Defined as those products included on Tier 40 of FID 33102 with any reject message other than "NOT ON DRUG LIST, CHECK MEDICAL BENEFIT. CALL NUMBER ON THE BACK OF YOUR CARD FOR MORE INFORMATION".)
Institutional Packs* Those that contain any one of the following modifier codes in the product file in RXClaims i. MODIFIER AAAD31 INSTITUTIONAL/HOSP. PACK ii. MODIFIER BBAD9A INSTITUTIONAL iii. MODIFIER TTAAJQ INSTITUTIONAL iv. MODIFIER TTAA5V INSTITUTIONAL USE ONLY v. MODIFIER AAAB9A HOSPITAL PACK vi. MODIFIER AAADQQ HUD (HOSPITAL UNIT DOSE) vii. MODIFER AAAD6T HOSPITAL USE ONLY
Investigative, experimental, or not medically necessary
Medical Devices and Supplies (not including spacers, lancets, needles, syringes, continuous glucose monitor/sensor/transmitter/receiver) (Defined by GPI 97**********)
Medical devices approved through a different FDA-approval process than drugs (Defined by one of the following: 1) Drug Application File Marketing Category 15 – Premarket Application 2) Drug Application File Marketing Category 16 – Premarket Notification)
Non-FDA Approved Agents* (Refer all tiers on Formulary ID 220 or reject messaging of 'Non-FDA Approved Drug')
Over-The-Counter Medications* (not including glucose test strips, insulin, ACA required drugs, lancets, syringes) (Defined as indicated by O or P in the Rx-OTC indicator code field in the Product file in RxClaim)
Repackagers (not including Veterans Administration and Department of Defense Claims)*

(Defined as indicated as Y in Repkg code field in the product file in RxClaim)
RX drugs with OTC Equivalents (Excluded categories listed below) (Defined by an RX NDC (Rx-OTC indicator R or S) with an OTC NDC (RX-OTC indicator O or P) within the same GPI 14 in the product file in RxClaim. Rx drugs with OTC alternatives where the Rx drug category will be excluded: 1. Omega-3 Fatty Acids (GPI 395000********) 2. Non-Sedating Antihistamines (GPI 415500********) 3. Topical Antivirals (GPI 903500********))
Self-Administered Contraceptives* (2510**********, 2540**********, 2596**********, 2597**********, 2599**********, 260000301003**) (ONLY when not covered in BET AND is being requested exclusively for the use of pregnancy prevention)
Sexual Dysfunction Agents* (Defined as those products (e.g., Addyi, Viagra, Cialis 10 mg and 20 mg, Levitra, Staxyn, Caverject, Edex, Muse) containing the third-party restriction V (IMPOTENCE AGENTS) in the product file in RxClaim (only when not covered in BET AND is being requested for treatment of sexual dysfunction)
Surgical Supplies/Medical Devices/Ostomy (not including spacers, lancets, needles, syringes, continuous glucose monitor/sensor/transmitter/receiver) (Defined as indicated by the third-party restriction code 3 (SURGICAL SUPPLY/MEDICAL DEVICE/OSTOMY) in the product file in RxClaim)
Universal Product Code (UPC), Health Related Item Code (HRI) (not including glucose test strips) (UPCs will be defined as those products designated as product type 1 in the product file in RxClaim. HRIs will be defined as those products designated as product type 2 in the product file in RxClaim.)
Weight Loss Agents* (Defined as those products containing the third-party restriction code 8 (ANOREXIC, ANTI-OBESITY) in the product file in RxClaim) (only when not covered in BET AND is being requested for treatment of weight loss)

*Category specific denial reasons apply

AND

ii. ONE of the following:
   a. The requested agent is a CGM/Sensor/Transmitter/Receiver AND ONE of the following:
      1. Patient has a visual impairment
         OR
      2. Patient uses an insulin pump that is only compatible with one specific CGM/sensor/transmitter/receiver
         OR
      3. Patient has a physical or a mental disability

   OR

   b. The requested agent is a glucose cartridge, test strip, or all-in-one glucose meter system AND ONE of the following:
      1. Patient has visual impairment
         OR
      2. Patient uses an insulin pump OR continuous glucose monitor that is not accommodated with a preferred glucose cartridge, test strip, or all-in-one glucose meter system
         OR
      3. Patient has a physical or a mental disability

   OR

   c. The requested agent is a rapid, regular, Humalog 50/50, Mix, or NPH insulin agent and ONE of the following:
      1. BOTH of the following:
         A. The requested agent is a rapid insulin
            AND

B. There is information that the patient is currently using an insulin pump that has an incompatibility with the preferred rapid insulin agent that is not expected to occur with the requested agent

OR

2. The request is for Humalog Mix 50/50 AND ONE of the following:
   A. The patient is currently using Humalog Mix 50/50 AND the prescriber states the patient is at risk if switched to a different insulin
   OR
   B. The patient has tried and failed a preferred insulin mix (e.g., Novolin, Novolog)

OR

3. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to the preferred insulin agents (e.g., Novolin, Novolog) of the same type (rapid or regular, mix or NPH) that is not expected to occur with the requested agent

OR

4. There is information that the patient has a physical or a mental disability that would prevent him/her from using a preferred insulin agent

OR

5. The patient is pregnant

OR

d. The requested agent is a long-acting insulin agent and the following:
   1. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to the preferred insulin agents of the same type (long-acting) that is not expected to occur with the requested agent

OR

e. The requested agent is Supprelin or Vantas and is being requested for a diagnosis of Gender Identity Disorder (GID) or gender dysphoria

OR

f. The requested agent is a Self-Administered Contraceptive Agent (e.g., 2510**********, 2540**********, 2596**********, 2597**********, 2599**********, 260000301003**) AND the agent is being prescribed for an allowable diagnosis

Allowable Diagnoses
Acne vulgaris
Amenorrhea
Dysfunctional uterine bleeding
Dysmenorrhea
Endometriosis
Fibroid Uterus
Hyperandrogenism
Irregular menses (menorrhagia, oligomenorrhea, and hypermenorrhea)
Menstrual migraine
Perimenopausal symptoms
Polycystic ovarian syndrome
Premenstrual dysphoric disorder (PMDD)
Premenstrual syndrome
Treatment to reduce the risk of osteoporosis, ovarian cancer, colorectal cancer, and endometrial cancer, especially in women with a family history of these disorders

OR

g. The requested agent is Auvi-Q 0.1 mg AND the patient weighs 7.5 to 15 kg (16.5 to 33 pounds)

OR

h. The requested agent is an HIV infection post-exposure prophylaxis (PEP) agent being used for PEP for a member with a Fully Insured plan and ALL of the following:

1. The prescriber has provided information stating that the requested PEP agent is medically necessary compared to other available PEP agents
   AND
2. ONE of the following:
   A. The requested PEP agent is ONE of the following (agent AND strength must match):
      i. Emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada)
         OR
      ii. Tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread)
         OR
      iii. Emtricitabine 200 mg single ingredient agent (Emtriva)
         OR
      iv. Raltegravir 400 mg single ingredient agent (Isentress)
         OR
      v. Dolutegravir 50 mg single ingredient agent (Tivicay)
         OR
      vi. Darunavir 800 mg single ingredient agent (Prezista)
         OR
      vii. Ritonavir 100 mg single ingredient agent (Norvir)
      OR
   B. The prescriber has provided information stating that emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada), tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread), emtricitabine 200 mg single ingredient agent (Emtriva), raltegravir 400 mg single ingredient agent (Isentress), dolutegravir 50 mg single ingredient agent (Tivicay), darunavir 800 mg single ingredient agent (Prezista), or ritonavir 100 mg single ingredient agent (Norvir) is contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient
   AND
3. The patient is at high risk of HIV infection
   AND
4. The patient is initiating or has initiated PEP within 72 hours of suspected exposure to HIV

OR

i. BOTH of the following:
   1. If the requested agent is part of a drug class listed below then ONE of the following:

Prescription drugs with OTC alternatives (partial category lockout)
• Artificial Tears/Dry Eye Therapy (GPI 8672**********, 8673**********) • Topical Acne (GPI 9005**********) • Topical Antifungals; Combination products (GPI 901599********) • Ophthalmic Antiallergic Agents (GPI 868020********) • Prenatal vitamins (GPI 7851**********) • Ulcer drugs/H2 Antagonists/Proton Pump Inhibitors (GPI 4920**********, 4927**********) • Nasal steroids (GPI 4220**********)

      A. The patient has tried and failed the OTC alternative for the requested diagnosis
         OR

B. The prescriber has provided information stating that OTC equivalents are contraindicated, are likely to be less effective, or will cause an adverse reaction or other harm for the patient

AND

2. ONE of the following:
   A. The requested medication is an antipsychotic prescribed to treat emotional disturbance or mental illness AND the following:
      i. The prescriber has indicated at least three formulary drugs (or as many as available, if fewer than three) have been considered and they have determined that the medication prescribed will best treat the patient's condition

      OR

   B. BOTH of the following:
      i. ONE of the following:
         a. The patient has an FDA labeled indication for the requested agent

            OR

         b. The patient has an indication supported in AHFS, DrugDex with 1 or 2a level of evidence, or NCCN with 1 or 2a level of evidence (for oncology agents also accept NCCN Compendium™ level of evidence 2B, DrugDex 2B, Wolters Kluwer Lexi-Drugs level A, and Clinical Pharmacology) for the requested agent

            OR

         c. The patient has a diagnosis of Gender Identity Disorder (GID) or gender dysphoria and clinical guidelines support therapy with the requested agent

      AND

      ii. ONE of the following:
         a. The requested agent has formulary alternatives (any formulary tier) for the diagnosis being treated by the requested agent AND BOTH of the following:
            1. If the requested agent is a brand product with an available formulary generic equivalent AND ONE of the following:
               A. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent

               OR

               B. The prescriber has provided information stating that ALL available formulary (any formulary tier) generic equivalents to the requested agent are contraindicated, are likely to be less effective, or will cause an adverse reaction or other harm for the patient

            AND

            2. ONE of the following:
               A. The patient has tried and failed at least three formulary alternatives (any formulary tier), if available, for the diagnosis being treated with the requested agent

               OR

B. The prescriber has provided information stating that ALL available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

OR

b. The requested agent does NOT have formulary (any formulary tier) alternatives for the diagnosis being treated with the requested agent

OR

c. The prescriber stated that the patient is currently stabilized on for a minimum of 90 days the requested agent and switching could potentially cause harm or a health risk (starting on samples is not approvable)

AND

iii. If the requested agent is a biologic immunomodulator agent, Otezla, or Zeposia, the patient will NOT be using the requested agent in combination with another biologic immunomodulator agent, Otezla, or Zeposia

AND

3. ONE of the following:
   A. The requested agent is not subject to an existing quantity limit program

   OR

   B. The requested agent is subject to an existing quantity limit program and ONE of the following:
      i. The requested quantity (dose) does NOT exceed the program quantity limit

      OR

      ii. Information has been provided that fulfills the criteria listed under the "Allowed exceptions/diagnoses" (if applicable)

      OR

      iii. The requested quantity (dose) is greater than the program quantity limit and ONE of the following:
         a. BOTH of the following:
            1. The requested agent does not have a maximum FDA labeled dose for the requested indication

            AND

            2. The prescriber has provided information in support of 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. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

         OR

         c. BOTH of the following:
            1. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication

            AND

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

ACA Length of Approval:

- Aspirin 81 mg:
  - Preeclampsia in pregnancy: 9 months
- Infant eye appointment: 3 months
- All other indications: 12 months
- Apply $0 copay if ACA criteria met

HIV PEP Length of Approval:

- 12 months
- Apply $0 copay if HIV PEP criteria is met

Coverage Exception Length of Approval: 12 months

• Program Summary: Elagolix/Relugolix

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	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 has tried and had an inadequate response to at least ONE hormonal contraceptive

Module	Clinical Criteria for Approval
	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 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 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

Module	Clinical Criteria for Approval
	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 has tried and had an inadequate response to at least ONE hormonal contraceptive used in the treatment of 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 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**

Module	Clinical Criteria for Approval
	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 has tried and had an inadequate response to ONE hormonal contraceptive therapy used in the treatment of the requested indication **OR** B. The patient has an intolerance or hypersensitivity to hormonal contraceptive therapy 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 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:

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	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 prescriber has provided information that the patient has tried and failed a 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**

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

POLICY AGENT SUMMARY QUANTITY LIMITS

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

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) as confirmed by flow cytometry with at least 2 independent flow cytometry reagents on at least 2 cell lineages (e.g., RBCs and WBCs) demonstrating that the patient's peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI) – linked proteins (lab tests required) **OR** B. The patient has another FDA 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**

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

POLICY AGENT SUMMARY QUANTITY LIMITS

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	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**

Module	Clinical Criteria for Approval
	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** 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: Formulary Exception with Quantity Limit

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

APPLICATION

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

This criteria only applies to FlexRx Closed and GenRx Closed products which are non-formulary.

FORMULARY EXCEPTION CRITERIA FOR APPROVAL

A formulary exception will be granted when the following are met:

1. ONE of the following:
    A. ALL of the following:
        i. The requested agent is in an Affordable Care Act (ACA) Preventive Care category
        AND
        ii. The member's benefit includes ACA Preventive Care for the category requested
        AND
        iii. ONE of the following:
            a. The requested agent is a contraception agent **AND** the following:
                1. The prescriber has provided information stating that the requested contraceptive agent is medically necessary
                AND
                2. The requested agent is being used for contraception

            OR

            b. BOTH of the following:
                1. If the requested agent is a brand product with an available formulary generic equivalent ONE of the following:
                    A. The patient has tried and failed one or more available formulary generic equivalent(s) to the requested agent
                    OR
                    B. The patient has an intolerance or hypersensitivity to a formulary generic equivalent agent that is not expected to occur with the requested agent
                    OR
                    C. The patient has an FDA labeled contraindication to ALL formulary generic equivalent agent(s) that is not expected to occur with the requested agent

                AND

                2. ONE of the following:

A. The requested agent is an aspirin agent **AND** ALL of the following:
   i. The requested agent is the 81 mg strength aspirin
   AND
   ii. The prescriber has provided information stating that the requested aspirin agent is medically necessary
   AND
   iii. The patient is pregnant, at high risk of preeclampsia, and using the requested agent after 12 weeks of gestation

OR

B. The requested agent is a bowel prep agent **AND** ALL of the following:
   i. The prescriber has provided information stating that the requested bowel prep agent is medically necessary
   AND
   ii. The prescriber has indicated the requested agent will be used for the preparation of colorectal cancer screening using fecal occult blood testing, sigmoidoscopy, or colonoscopy
   AND
   iii. The patient is 45 years of age or over

OR

C. The requested agent is a breast cancer primary prevention agent **AND** ALL of the following:
   i. The prescriber has provided information stating that the requested breast cancer primary prevention agent is medically necessary
   AND
   ii. The requested agent is tamoxifen, raloxifene, or aromatase inhibitor (anastrozole, exemestane, letrozole)
   AND
   iii. The patient is 35 years of age or over
   AND
   iv. The agent is requested for the primary prevention of breast cancer

OR

D. The requested agent is a fluoride supplement **AND** BOTH of the following:
   i. The prescriber has provided information stating that the requested fluoride supplement is medically necessary
   AND
   ii. The patient is 6 months to 16 years of age

OR

E. The requested agent is a folic acid agent **AND** ALL of the following:
   i. The prescriber has provided information stating that the requested folic acid supplement is medically necessary
   AND
   ii. The requested folic acid supplement contains 0.4-0.8 mg of folic acid
   AND
   iii. The requested folic acid supplement is to be used in support of pregnancy

OR

F. The requested agent is an HIV infection pre-exposure prophylaxis (PrEP) agent being used for PrEP **AND** ALL of the following:
   i. The prescriber has provided information stating that the requested PrEP agent is medically necessary compared to other available PrEP agents
   AND
   ii. The requested agent is being used for PrEP
   AND

iii. ONE of the following:
a. The requested PrEP agent is ONE of the following:
1. Tenofovir disoproxil fumarate and emtricitabine combination ingredient agent
OR
2. Tenofovir disoproxil fumarate single ingredient agent
OR
3. Tenofovir alafenamide and emtricitabine combination ingredient agent
OR
b. The prescriber has provided information stating that a tenofovir disoproxil fumarate and emtricitabine combination ingredient agent, tenofovir disoproxil fumarate single ingredient agent, or tenofovir alafenamide and emtricitabine combination ingredient agent is contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient
AND
iv. The patient is at high risk of HIV infection
AND
v. The patient has recently tested negative for HIV
OR

G. The requested agent is an infant eye ointment **AND** ALL of the following:
i. The prescriber has provided information stating that the requested infant eye ointment is medically necessary
AND
ii. The patient is 3 months of age or younger
AND
iii. The requested agent is requested for the prevention of gonococcal ophthalmia neonatorum
OR

H. The requested agent is an iron supplement **AND** ALL of the following:
i. The prescriber has provided information stating that the requested iron supplement is medically necessary
AND
ii. The patient is under 12 months of age
AND
iii. The patient is at increased risk for iron deficiency anemia
OR

I. The requested agent is a statin **AND** ALL of the following:
i. The prescriber has provided information stating that the requested statin is medically necessary
AND
ii. The requested agent is for use in ONE of the following low to moderate daily statin regimen (with up to the highest dosage strength as noted):
a. Atorvastatin 10-20 mg per day (20 mg tablet) **OR**
b. Fluvastatin 20-80 mg per day (40 mg capsule) **OR**
c. Fluvastatin ER 80 mg per day (80 mg tablet) **OR**
d. Lovastatin 20-40 mg per day (40 mg tablet) **OR**
e. Lovastatin ER 20-40 mg per day (40 mg tablet) **OR**
f. Pitavastatin 1-4 mg per day (4 mg tablet) **OR**
g. Pravastatin 10-80 mg per day (80 mg tablet) **OR**

h. Rosuvastatin 5-10 mg per day (10 mg tablet) **OR**
i. Simvastatin 10-40 mg per day (40 mg tablet, 40 mg/5 mL suspension)

AND

iii. The requested statin is for use in the primary prevention of cardiovascular disease (CVD)

AND

iv. The patient is 40-75 years of age (inclusive)

AND

v. The patient has at least one of the following risk factors:
a. Dyslipidemia **OR**
b. Diabetes **OR**
c. Hypertension **OR**
d. Smoking

AND

vi. The patient has a calculated 10-year risk of a cardiovascular event of 10% or greater per the American College of Cardiology and American Heart Association's Atherosclerotic Cardiovascular Disease (ASCVD) calculator

OR

J. The requested agent is a tobacco cessation agent **AND** BOTH of the following:
i. The patient is a non-pregnant adult

AND

ii. The prescriber has provided information stating that the requested tobacco cessation agent is medically necessary

OR

K. The requested agent is a vaccine **AND** BOTH of the following:
i. The prescriber has provided information stating that the requested vaccine is medically necessary

AND

ii. The requested vaccine will be used per the recommendations of the Advisory Committee on Immunization Practices/CDC

OR

B. ALL of the following:
i. ONE of the following:
a. The requested agent is in an ACA Preventive Care category AND did NOT meet the preventive service requirements

OR

b. BOTH of the following:
1. ONE of the following:
A. The requested agent is NOT in an ACA Preventive Care category

OR

B. The member's benefit does NOT include ACA Preventive Care for the category requested

AND

2. The requested agent is not excluded from coverage under the pharmacy benefit

AND

ii. ONE of the following:
a. The requested agent is Supprelin or Vantas and is being requested for a diagnosis of Gender Identity Disorder (GID) or gender dysphoria AND the following:
1. The patient's current benefit plan covers agents for use in the management for GID or gender dysphoria

OR

b. The requested medication is an antipsychotic prescribed to treat emotional disturbance or mental illness AND the following:
    1. The prescriber has indicated at least three formulary drugs (or as many as available, if fewer than three) have been considered and he/she has determined that the medication prescribed will best treat the patient's condition

OR

c. The requested agent is Omnipod DASH or Omnipod 5

OR

d. If the requested agent is an HIV infection post-exposure prophylaxis (PEP) agent being used for PEP for a member with a Fully Insured plan, then ALL of the following:
    1. The prescriber has provided information stating that the requested PEP agent is medically necessary compared to other available PEP agents

    AND

    2. ONE of the following:
        A. The requested PEP agent is ONE of the following (agent AND strength must match):
            i. Emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada)

            OR

            ii. Tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread)

            OR

            iii. Emtricitabine 200 mg single ingredient agent (Emtriva)

            OR

            iv. Raltegravir 400 mg single ingredient agent (Isentress)

            OR

            v. Dolutegravir 50 mg single ingredient agent (Tivicay)

            OR

            vi. Darunavir 800 mg single ingredient agent (Prezista)

            OR

            vii. Ritonavir 100 mg single ingredient agent (Norvir)

            OR

        B. The prescriber has provided information stating that emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg combination ingredient agent (Truvada), tenofovir disoproxil fumarate 300 mg single ingredient agent (Viread), emtricitabine 200 mg single ingredient agent (Emtriva), raltegravir 400 mg single ingredient agent (Isentress), dolutegravir 50 mg single ingredient agent (Tivicay), darunavir 800 mg single ingredient agent (Prezista), or ritonavir 100 mg single ingredient agent (Norvir) is contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

    AND

    3. The patient is at high risk of HIV infection

    AND

    4. The patient is initiating or has initiated PEP within 72 hours of suspected exposure to HIV

OR

e. BOTH of the following:
    1. The patient has an FDA labeled indication or an indication supported in AHFS, DrugDex with 1 or 2A level of evidence, or NCCN with 1 or 2A level of evidence (for oncology agents also accept NCCN Compendium™ level of evidence 2B, DrugDex 2B, Wolters Kluwer Lexi-Drugs level A, and Clinical Pharmacology) for the requested agent

    AND

2. ONE of the following:
    A. The requested agent has formulary alternatives that can be prescribed in a dose to fit the patient's needs AND ONE of the following:
        i. The patient has tried and failed at least three (or as many as available, if fewer than three) formulary alternatives, if available, for the diagnosis being treated with the requested agent
        OR
        ii. The prescriber has provided information stating that ALL available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient
    OR
    B. The requested agent does NOT have formulary (any formulary tier) alternatives for the diagnosis being treated with the requested agent
    OR
    C. The prescriber stated that the patient is currently stabilized on for a minimum of 90 days the requested agent and switching could potentially cause harm or a health risk (starting on samples is not approvable)

AND

iii. If the requested agent is a biologic immunomodulator agent, Otezla, or Zeposia, the patient will NOT be using the requested agent in combination with another biologic immunomodulator agent, Otezla, or Zeposia

AND

2. ONE of the following:
    A. The requested agent is not subject to an existing quantity limit program
    OR
    B. The requested agent is subject to an existing quantity limit program and ONE of the following:
        i. The requested quantity (dose) does NOT exceed the program quantity limit
        OR
        ii. Information has been provided that fulfills the criteria listed under the "Allowed exceptions/diagnoses" (if applicable)
        OR
        iii. The requested quantity (dose) is greater than the program quantity limit and ONE of the following:
            a. BOTH of the following:
                1. The requested agent does not have a maximum FDA labeled dose for the requested indication
                AND
                2. The prescriber has provided information in support of 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. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

            OR

            c. BOTH of the following:
                1. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
                AND
                2. The prescriber has provided information in support of therapy with a higher dose for the requested indication

ACA Length of Approval:

- Aspirin 81 mg:
  - Preeclampsia in pregnancy: 9 months
- Infant eye appointment: 3 months
- All other indications: 12 months
- Apply $0 copay if ACA criteria met

HIV PEP Length of Approval:

- 12 months
- Apply $0 copay if ACA criteria met

Formulary Exception Length of Approval: 12 months

• Program Summary: Hyftor (sirolimus)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
90784070004020	Hyftor	Sirolimus Gel	0.2 %	7	Tubes	84	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 tuberous sclerosis complex (TSC) confirmed by ONE of the following: A. The patient has two major features OR one major and two minor features of TSC clinical diagnostic criteria (Major features: hypomelanotic macules [greater than or equal to 3, at least 5 mm diameter], angiofibroma [greater than or equal to 3] or fibrous cephalic plaque, ungual fibromas [greater than or equal to 2], shagreen patch, multiple retinal hamartomas, multiple cortical tubers and/or radial migration lines, subependymal nodule [greater than or equal to 2], subependymal giant cell astrocytoma, cardiac rhabdomyoma, lymphangiomyomatosis (LAM)*, angiomyolipomas* [greater than or equal to 2]; note that a combination of LAM and angiomyolipomas, without other features, does not meet the criteria for a definite diagnosis. Minor features: "confetti" skin lesions, dental enamel pits [greater than or equal to 3], intraoral fibromas [greater than or equal to 2], retinal achromic patch, multiple renal cysts, nonrenal hamartomas, sclerotic bone lesions) **OR** B. The patient has a pathogenic variant in the TSC1 gene or TSC2 gene confirmed by genetic testing **AND** 2. The patient has three or more facial angiofibromas **AND** 3. 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** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, geneticist) 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

Module	Clinical Criteria for Approval
	Length of Approval: 12 weeks NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, geneticist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

● Program Summary: Korlym (mifepristone)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
2730405000	Korlym	mifepristone tab	300 MG	120	Tablets	30	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent** will be approved when ALL of the following are met: 1. The patient has a diagnosis of Cushing's syndrome **AND**

Module	Clinical Criteria for Approval
	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. The patient has type 2 diabetes mellitus **OR** B. The patient has glucose intolerance as defined by a 2-hr glucose tolerance test plasma glucose value of 140-199 mg/dL **AND** 4. ONE of the following: A. The patient has had an inadequate response to surgical resection **OR** B. The patient is NOT a candidate for surgical resection **AND** 5. 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** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 7. The requested dose does NOT exceed 20 mg/kg/day **Length of Approval:** 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. The requested dose does NOT exceed 20 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 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:** Initial: 6 months; Renewal: 12 months

• Program Summary: Oral Tetracycline Derivatives

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

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	040000401003		minocycline hcl tab	100 MG; 50 MG; 75 MG	M; N; O				
	040000201003	Acticlate; Lymepak; Targadox	doxycycline hyclate tab	100 MG; 150 MG; 20 MG; 50 MG; 75 MG	M; N; O				
	040000200003	Avidoxy	doxycycline monohydrate tab	100 MG; 150 MG; 50 MG; 75 MG	M; N; O				
	040000401075	Coremino; Minolira; Solodyn	minocycline hcl tab er	105 MG; 115 MG; 135 MG; 45 MG; 55 MG; 65 MG; 80 MG; 90 MG	M; N; O; Y				
	040000201006	Doryx; Doryx mpc	doxycycline hyclate tab delayed release	100 MG; 120 MG; 150 MG; 200 MG; 50 MG; 60 MG; 75 MG; 80 MG	M; N; O; Y				
	040000401001	Minocin	minocycline hcl cap	100 MG; 50 MG; 75 MG	M; N; O				
	040000200001	Mondoxyne nl	doxycycline monohydrate cap	100; 100 MG; 150 MG; 50 MG; 75 MG	M; N; O				
	900600250065	Oracea	doxycycline (rosacea) cap delayed release	40 MG	M; N; O				
	040000571003	Seysara	sarecycline hcl tab	100 MG; 150 MG; 60 MG	M; N; O; Y				
	040000201001	Vibramycin	doxycycline hyclate cap	100 MG; 50 MG	M; N; O				
	040000200019	Vibramycin	doxycycline monohydrate for susp	25 MG/5ML	M; N; O				
	040000401070	Ximino	minocycline hcl cap er	135 MG; 45 MG; 90 MG	M; N; O				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Target Agent(s) will be approved when ALL of the following are met: 1. The patient has an 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. If the patient's diagnosis is acne, ONE of the following: A. The patient will be using a benzoyl peroxide agent OR a retinoid agent in combination with the

Module	Clinical Criteria for Approval
	requested agent **OR** B. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to a benzoyl peroxide agent OR a retinoid agent **OR** C. The patient's medication history includes use of a benzoyl peroxide agent OR a retinoid agent in the past 999 days **OR** D. BOTH of the following: 1. The prescriber has stated that the patient has tried a benzoyl peroxide agent OR a retinoid agent **AND** 2. The benzoyl peroxide agent or retinoid agent was discontinued due to lack of effectiveness or an adverse event **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 benzoyl peroxide agents AND ALL retinoid 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. If the patient's diagnosis is acne or rosacea, the patient will NOT be using the requested agent in combination with another tetracycline derivative for the treatment of acne or rosacea **AND** 5. ONE of the following: A. The requested agent is a preferred oral generic doxycycline agent **OR** B. The requested agent is a preferred oral generic minocycline agent **OR** C. BOTH of the following: 1. ONE of the following: A. The patient has tried and had an inadequate response to a preferred oral generic doxycyline agent **OR** B. The patient has an intolerance or hypersensitivity to a preferred oral generic doxycycline agent **OR** C. The patient has an FDA labeled contraindication to ALL preferred oral generic doxycycline 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 preferred oral generic doxycycline agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to a preferred oral generic minocycline agent **OR** B. The patient has an intolerance or hypersensitivity to a preferred oral generic

Module	Clinical Criteria for Approval
	minocycline agent **OR** C. The patient has an FDA labeled contraindication to ALL preferred oral generic minocycline 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 preferred oral generic minocycline agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval:** 12 months

• Program Summary: Parathyroid Hormone Analog for Osteoporosis

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	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
Forteo preferred	**Preferred Agent (Forteo)** will be approved when ALL of the following are met: 1. ONE of the following: A. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** B. The prescriber states that the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR**

Module	Clinical Criteria for Approval
	C. 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** 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 has tried and had an inadequate response to a bisphosphonate (medical records required) **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: 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 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

Module	Clinical Criteria for Approval
	physical or mental harm **OR** D. 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** 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 or the 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 has tried and had an inadequate response to a bisphosphonate (medical records required) **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: 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 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. 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** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**

Module	Clinical Criteria for Approval
	4. 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 ONE of the following: 1. The total duration of treatment with Forteo (teriparatide), Teriparatide, and Tymlos (abaloparatide) has NOT exceeded 24 months in lifetime **OR** 2. BOTH of the following: A. The patient has received 24 months or more of parathyroid hormone analog treatment in their lifetime, and is at high risk for fracture (e.g., shown by T-score, FRAX score, continued use of glucocorticoids at a daily equivalent of 5 mg of prednisone or higher) **AND** B. The patient was previously treated with Forteo **Length of approval:** 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. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Teriparatide through preferred	**Non-Preferred Agent(s) Teriparatide** will be approved when ALL of the following are met: 1. ONE of the following: A. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** B. The prescriber states that the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** C. 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** 2. The prescriber has provided information that the requested agent is medically appropriate for the patient's sex and menopause status **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to BOTH of the preferred agents (Forteo AND Tymlos) **OR** B. The patient has an intolerance or hypersensitivity to BOTH of the preferred agents (Forteo AND Tymlos) that is not expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to BOTH of the preferred agent (Forteo AND Tymlos) that is not expected to occur with the requested 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**

Module	Clinical Criteria for Approval
	E. The prescriber has provided documentation BOTH Forteo AND Tymlos 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'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 has tried and had an inadequate response to a bisphosphonate (medical records required) **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: 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 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** D. The patient has a diagnosis of glucocorticoid-induced osteoporosis AND ALL of the following: 1. ONE of the following: A. The patient has tried and had an inadequate response to a preferred agent (Forteo) **OR**

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	B. The patient has an intolerance or hypersensitivity to the preferred agent (Forteo) that is not expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to the preferred agent (Forteo) that is not expected to occur with the requested 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 the preferred agent (Forteo) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient is either initiating or currently taking glucocorticoids in a daily dosage equivalent to 5 mg or higher of prednisone **AND** 3. The patient's expected current course of therapy of glucocorticoids is for a period of at least 3 months **AND** 4. 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** 5. 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 has tried and had an inadequate response to a bisphosphonate (medical records required) **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: 1. A statement by the prescriber that the patient is currently

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	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 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. 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** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. 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	**Preferred Agent (Tymlos)** will be approved when ALL of the following are met: 1. ONE of the following: A. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** B. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** C. 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** 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**

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	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 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 has tried and had an inadequate response to a bisphosphonate (medical records required) **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: 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 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. 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** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. 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
QL with PA Forteo 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:** 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 Teriparatide 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:** 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.
QL with PA Tymlos	**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:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☐ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	309085651030	Javygtor; Kuvan	sapropterin dihydrochloride powder packet	100 MG; 500 MG	M; N; O; Y				
	309085651003	Javygtor; Kuvan	sapropterin dihydrochloride tab	100 MG	M; N; O; Y				
	3090855040E5	Palynziq	pegvaliase-pqpz subcutaneous soln pref syringe	10 MG/0.5ML; 2.5 MG/0.5ML; 20 MG/ML	M; N; O; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	INITIAL EVALUATION **Target Agent(s)** will be approved when 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 has tried and had an inadequate response to generic sapropterin despite monitored adherence to treatment **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

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	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:

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	A. The patient has tried and had an inadequate response to generic sapropterin despite monitored adherence to treatment **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:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

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

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	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, 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

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	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** B. The patient is at very high risk and the patient's LDL-C level after this treatment regimen remains greater 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 in the past 999 days **OR** F. BOTH of the following: 1. The prescriber has stated that the patient has tried high intensity atorvastatin or rosuvastatin therapy **AND** 2. High intensity atorvastatin or rosuvastatin was discontinued due to lack of effectiveness or an adverse event **OR**

Module	Clinical Criteria for Approval
	G. 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** H. 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** 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 **AND** 6. ONE of the following: A. The request is for a preferred agent **OR** B. The patient has tried and had an inadequate response to the preferred agent **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 the preferred agent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

Module	Clinical Criteria for Approval
	Renewal Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for 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 has tried and had an inadequate response to the preferred agent **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., 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 **OR** F. BOTH of the following: 1. The prescriber has stated that the patient has tried high intensity atorvastatin or rosuvastatin **AND** 2. High intensity atorvastatin or rosuvastatin was discontinued due to lack of effectiveness or an adverse event **OR** G. The patient is currently being treated with the requested agent as indicated by ALL of the following:

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

• Program Summary: Sensipar (cinacalcet)

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

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	3090522510	Sensipar	cinacalcet hcl tab	30 MG; 60 MG; 90 MG	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. 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 has tried and had an inadequate response to a phosphate binder [e.g., calcium acetate, calcium carbonate, Renvela (sevelamer carbonate), Fosrenol (lanthanum carbonate), Renagel (sevelamer hydrochloride)] **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:
        - A. The patient has tried and had an inadequate response to a vitamin D analog [e.g., calcitriol, Hectorol (doxecalciferol), Rayaldee (calcifediol), Zemplar (paricalcitol)] **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 *prerequisite agent may be subject to Step Therapy (ST) program **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** 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: Somatostatin Analogs

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
30170070102030		Octreotide Acetate Inj 1000 MCG/ML (1 MG/ML)	1000 MCG/ML	6	Vials	30	DAYS				
30170070102015		Octreotide Acetate Inj 200 MCG/ML (0.2 MG/ML)	1000 MCG/5ML; 200 MCG/ML	18	Vials	30	DAYS				
3017007010E505		Octreotide Acetate Subcutaneous Soln Pref Syr	50 MCG/ML	90	Syringes	30	DAYS				
3017007010E510		Octreotide Acetate Subcutaneous Soln Pref Syr	100 MCG/ML	90	Syringes	30	DAYS				
3017007010E520		Octreotide Acetate Subcutaneous Soln Pref Syr	500 MCG/ML	90	Syringes	30	DAYS				
30170070106520	Mycapssa	Octreotide Acetate Cap Delayed Release 20 MG	20 MG	120	Capsules	30	DAYS				
30170070102010	Sandostatin	Octreotide Acetate Inj 100 MCG/ML (0.1 MG/ML)	100 MCG/ML	90	Ampules	30	DAYS				
30170070102005	Sandostatin	Octreotide Acetate Inj 50 MCG/ML (0.05 MG/ML)	50 MCG/ML	90	Ampules	30	DAYS				
30170070102020	Sandostatin	Octreotide Acetate Inj 500 MCG/ML (0.5 MG/ML)	500 MCG/ML	90	Ampules	30	DAYS				
30170070106410	Sandostatin lar depot	Octreotide Acetate For IM Inj Kit 10 MG	10 MG	1	Kit	28	DAYS				
30170070106420	Sandostatin lar depot	Octreotide Acetate For IM Inj Kit 20 MG	20 MG	1	Kit	28	DAYS				
30170070106430	Sandostatin lar depot	Octreotide Acetate For IM Inj Kit 30 MG	30 MG	1	Kit	28	DAYS				
30170050102040	Somatuline depot	Lanreotide Acetate Extended Release Inj 120 MG/0.5ML	120 MG/0.5ML	1	Syringe	28	DAYS				
30170050102025	Somatuline depot	Lanreotide Acetate Extended Release Inj 60 MG/0.2ML	60 MG/0.2ML	1	Syringe	28	DAYS				
30170050102030	Somatuline	Lanreotide Acetate	90 MG/0.3ML	1	Syringe	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
	depot	Extended Release Inj 90 MG/0.3ML									
30180060002120	Somavert	Pegvisomant For Inj 10 MG (As Protein)	10 MG	30	Vials	30	DAYS				
30180060002130	Somavert	Pegvisomant For Inj 15 MG (As Protein)	15 MG	30	Vials	30	DAYS				
30180060002140	Somavert	Pegvisomant For Inj 20 MG (As Protein)	20 MG	30	Vials	30	DAYS				
30180060002150	Somavert	Pegvisomant For Inj 25 MG (As Protein)	25 MG	30	Vials	30	DAYS				
30180060002160	Somavert	Pegvisomant For Inj 30 MG (As Protein)	30 MG	30	Vials	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Mycapssa (octreotide)	**Initial Evaluation** **Target agents** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. Information has been provided that indicates the patient has been treated with the requested agent within the past 180 days **OR** 2. The prescriber states the patient has been treated with the requested agent within the past 180 days AND is at risk if therapy is changed **OR** B. The patient has a diagnosis of acromegaly AND BOTH of the following: 1. ONE of the following: A. The patient has responded to and tolerated treatment with octreotide or lanreotide **OR** B. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** C. The prescriber has provided documentation that BOTH octreotide AND lanreotide cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient will NOT be using the requested agent in combination with Signifor LAR (pasireotide) **OR** C. The patient has another FDA approved indication for the requested agent **OR**

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td></td><td>D. The patient has another indication that is supported in compendia for the requested agent AND
2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, oncologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND
3. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 6 months

Compendia Allowed: AHFS, NCCN 1 or 2a recommended use, or DrugDex 1 or 2a level of evidence

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

Renewal Evaluation

Target agent will be approved when ALL of the following are met:
1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process AND
2. The patient has had clinical benefit with the requested agent (e.g., decrease in symptom severity/frequency, reduction in tumor size, normalized IGF-1 and/or growth hormone levels) AND
3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, oncologist) 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.</td></tr>
<tr><td>Sandostatin (octreotide)/Octreotide prefilled syringes, vials and ampules</td><td>Initial Evaluation

Target agents will be approved when ALL of the following are met:
1. ONE of the following:
A. The requested agent is eligible for continuation of therapy AND ONE of the following:
<table><tr><th>Agents Eligible for Continuation of Therapy</th></tr><tr><td>All target agents are eligible for continuation of therapy</td></tr></table>1. Information has been provided that indicates the patient has been treated with the requested agent within the past 180 days OR
2. The prescriber states the patient has been treated with the requested agent within the past 180 days AND is at risk if therapy is changed OR
B. The patient has a diagnosis of acromegaly AND BOTH of the following:
1. ONE of the following:
A. The patient had an inadequate response to surgical resection or pituitary radiation therapy as indicated by growth hormone and serum IGF-1 that are above the reference ranges OR
B. The patient is not a candidate for surgical resection OR
C. The requested agent will be used in combination with or following pituitary radiation therapy AND
2. The patient will NOT be using the requested agent in combination with Signifor LAR (pasireotide) OR
C. The patient has flushing and/or diarrhea associated with metastatic carcinoid tumors OR
D. The patient has profuse watery diarrhea associated with Vasoactive Intestinal Peptide (VIP) secreting tumors OR</td></tr>
</table>

Module	Clinical Criteria for Approval

E. The patient has another FDA approved indication for the requested agent and route of administration **OR**

F. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND**

2. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following:

Brand	Generic Equivalent
Sandostatin	octreotide

A. The patient's medication history includes the required generic equivalent as indicated by:
   1. Evidence of a paid claim(s) within the past 999 days **OR**
   2. The prescriber has stated that the patient has tried the generic equivalent AND the generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**

B. The patient has an intolerance or hypersensitivity to the generic equivalent that is NOT expected to occur with the brand agent **OR**

C. The patient has an FDA labeled contraindication to the generic equivalent that is NOT expected to occur with the brand agent **OR**

D. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent **OR**

E. The patient is currently being treated with the requested agent as indicated by ALL of the following:
   1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
   2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
   3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

F. The prescriber has provided documentation that the generic equivalent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, oncologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
4. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 6 months

Compendia Allowed: AHFS, NCCN 1 or 2a recommended use, or DrugDex 1 or 2a level of evidence

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

Renewal Evaluation

Target agent will be approved when ALL of the following are met:
1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND**
2. The patient has had clinical benefit with the requested agent (e.g., decrease in symptom severity/frequency, reduction in tumor size, normalized IGF-1 and/or growth hormone levels) **AND**
3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, oncologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td></td><td>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.</td></tr>
<tr><td>Sandostatin LAR (octreotide)</td><td>Initial Evaluation

Target agents will be approved when ALL of the following are met:
1. ONE of the following:
A. The requested agent is eligible for continuation of therapy AND ONE of the following:
<table><tr><th>Agents Eligible for Continuation of Therapy</th></tr><tr><td>All target agents are eligible for continuation of therapy</td></tr></table>1. Information has been provided that indicates the patient has been treated with the requested agent within the past 180 days OR
2. The prescriber states the patient has been treated with the requested agent within the past 180 days AND is at risk if therapy is changed OR
B. The patient has a diagnosis of acromegaly AND BOTH of the following:
1. ONE of the following:
A. The patient had an inadequate response to surgical resection or pituitary radiation therapy as indicated by growth hormone and serum IGF-1 that are above the reference ranges OR
B. The patient is not a candidate for surgical resection OR
C. The requested agent will be used in combination with or following pituitary radiation therapy AND
2. The patient will NOT be using the requested agent in combination with Signifor LAR (pasireotide) OR
C. The patient has flushing and/or diarrhea associated with metastatic carcinoid tumors OR
D. The patient has profuse watery diarrhea associated with Vasoactive Intestinal Peptide (VIP) secreting tumors OR
E. The patient has another FDA approved indication for the requested agent and route of administration OR
F. The patient has another indication that is supported in compendia for the requested agent and route of administration AND
2. ONE of the following:
A. The patient has responded to and tolerated Sandostatin (octreotide) OR
B. The patient is currently being treated with the requested agent as indicated by ALL of the following:
1. A statement by the prescriber that the patient is currently taking the requested agent AND
2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent AND
3. The prescriber states that a change in therapy is expected to be ineffective or cause harm OR
C. The prescriber has provided documentation that Sandostatin (octreotide) 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 prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, oncologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND</td></tr>
</table>

<table>
<tr><th>Module</th><th>Clinical Criteria for Approval</th></tr>
<tr><td></td><td>4. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 6 months

Compendia Allowed: AHFS, NCCN 1 or 2a recommended use, or DrugDex 1 or 2a level of evidence

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

Renewal Evaluation

Target agent will be approved when ALL of the following are met:
1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process AND
2. The patient has had clinical benefit (e.g., decrease in symptom severity/frequency, reduction in tumor size, normalized IGF-1 and/or growth hormone levels) AND
3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, oncologist) 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.</td></tr>
<tr><td>Somatuline Depot (lanreotide)/Lanreotide</td><td>Initial Evaluation

Target agents will be approved when ALL the following are met:
1. ONE of the following:
A. The requested agent is eligible for continuation of therapy AND ONE of the following:
<table><tr><th>Agents Eligible for Continuation of Therapy</th></tr><tr><td>All target agents are eligible for continuation of therapy</td></tr></table>1. Information has been provided that indicates the patient has been treated with the requested agent within the past 180 days OR
2. The prescriber states the patient has been treated with the requested agent within the past 180 days AND is at risk if therapy is changed OR
B. The patient has a diagnosis of acromegaly AND BOTH of the following:
1. ONE of the following:
A. The patient had an inadequate response to surgical resection or pituitary radiation therapy as indicated by growth hormone and serum IGF-1 that are above the reference ranges OR
B. The patient is not a candidate for surgical resection OR
C. The requested agent will be used in combination with or following pituitary radiation therapy AND
2. The patient will NOT be using the requested agent in combination with Signifor LAR (pasireotide) OR
C. The patient has a diagnosis of gastroenteropancreatic neuroendocrine tumors (GEP-NETs) AND BOTH of the following:
1. The tumors are well differentiated or moderately differentiated AND
2. ONE of the following:
A. The tumors are unresectable locally advanced OR
B. The patient has metastatic disease OR</td></tr>
</table>

Module	Clinical Criteria for Approval
	D. The patient has a diagnosis of carcinoid syndrome (i.e., flushing and/or diarrhea) **OR** E. The patient has another FDA approved indication for the requested agent and route of administration **OR** F. 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 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., endocrinologist, oncologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months **Compendia Allowed:** AHFS, NCCN 1 or 2a recommended use, or DrugDex 1 or 2a level of evidence NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target agent** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit (e.g., decrease in symptom severity/frequency, reduction in tumor size, normalized IGF-1 and/or growth hormone levels) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, oncologist) 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.
somavert (pegvisomant)	**Initial Evaluation** **Target agents** will be approved when ALL the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. Information has been provided that indicates the patient has been treated with the requested agent within the past 180 days **OR** 2. The prescriber states the patient has been treated with the requested agent within the past 180 days AND is at risk if therapy is changed **OR** B. The patient has a diagnosis of acromegaly AND ALL of the following: 1. ONE of the following: A. The patient had an inadequate response to surgical resection or pituitary radiation therapy as indicated by growth hormone and serum IGF-1 that are above the reference ranges **OR**

Module	Clinical Criteria for Approval
	B. The patient is not a candidate for surgical resection **OR** C. The requested agent will be used in combination with or following pituitary radiation therapy **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to Sandostatin LAR (octreotide suspension) or Somatuline Depot (lanreotide) **OR** B. The patient has an intolerance or hypersensitivity to Sandostatin LAR (octreotide suspension) OR Somatuline Depot (lanreotide) **OR** C. The patient has an FDA labeled contraindication to BOTH Sandostatin LAR (octreotide suspension) AND Somatuline Depot (lanreotide) **OR** D. The patient is currently using Sandostatin LAR (octreotide suspension) or Somatuline Depot (lanreotide) and the requested agent will be used as add on (adjunctive) therapy **OR** E. The prescriber has provided information in support of use of the requested agent over BOTH Sandostatin LAR (octreotide suspension) AND Somatuline Depot (lanreotide) **OR** F. The patient has tried Signifor LAR (pasireotide) AND had severe hyperglycemia **OR** G. 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** H. prescriber has provided documentation that BOTH Sandostatin LAR (octreotide suspension) AND Somatuline Depot (lanreotide) 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 Signifor LAR (pasireotide) **OR** C. The patient has another FDA approved indication for the requested agent and route of administration **OR** D. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, oncologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months **Compendia Allowed:** AHFS, NCCN 1 or 2a recommended use, or DrugDex 1 or 2a level of evidence NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target agent** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization

Module	Clinical Criteria for Approval
	process **AND** 2. The patient has had clinical benefit (e.g., decrease in symptom severity/frequency, reduction in tumor size, normalized IGF-1 and/or growth hormone levels) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, oncologist) 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 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: Topical Non-Steroidal Anti-Inflammatory Drug (NSAID)

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

TARGET AGENTS[a]

Flector®, Diclofenac Epolamine Patch
Licart™ (diclofenac topical system)
Pennsaid® 2% (diclofenac solution)[b]
Voltaren Gel® (diclofenac gel 1%)[b]

a – diclofenac solution 1.5% available as generic; included as a prerequisite in the step therapy program
b – generic available; included as a prerequisite in the step therapy program

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Target Agents will be approved when ONE of the following are met:

1. The patient is currently being treated with the requested agent as indicated by ALL of the following:
   A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
   B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent

AND

C. The prescriber states that a change in therapy is expected to be ineffective or cause harm

OR

2. The patient's medication history includes use of a generic topical NSAID (non-steroidal anti-inflammatory drug) agent
OR
3. BOTH of the following:
   A. The prescriber has stated that the patient has tried at least ONE generic topical NSAID agent
   AND
   B. The generic topical NSAID agent was discontinued due to lack of effectiveness or an adverse event
OR
4. The patient has an intolerance or hypersensitivity to a generic topical NSAID agent
OR
5. The patient has an FDA labeled contraindication to ALL generic topical NSAID agents that is not expected to occur with the requested agent
OR
6. The prescriber has provided documentation that ALL generic topical NSAID agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

Length of Approval: 12 months

NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents.

• Program Summary: Voxzogo

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
309500800021	Voxzogo	vosoritide for subcutaneous inj	0.4 MG; 0.56 MG; 1.2 MG	30	Vials	30	DAYS			02-07-2022	

PRIOR AUTHORIZATION WITH QUANTITY LIMIT 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:

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

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	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: A. The patient has tried and had an inadequate response to a topical corticosteroid **OR** B. The patient has an intolerance or hypersensitivity to therapy with topical corticosteroids **OR** C. The patient has an FDA labeled contraindication to ALL topical corticosteroids **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on 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 has tried and had an inadequate response to another topical psoriasis agent with a different mechanism of action (e.g., vitamin D analogs, calcineurin inhibitors, tazarotene) **OR** B. The patient has an intolerance or hypersensitivity to another topical psoriasis agent with a different mechanism of action **OR** C. The patient has an FDA labeled contraindication to ALL other topical psoriasis agents with a different mechanism of action **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be

Module	Clinical Criteria for Approval
	ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL other topical psoriasis agents with a different mechanism of action cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The 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: Zoryve (roflumilast)

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

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

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

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**

Module	Clinical Criteria for Approval
	2. ONE of the following: A. The patient has tried and had an inadequate response to a topical corticosteroid **OR** B. The patient has an intolerance or hypersensitivity to therapy with topical corticosteroids **OR** C. The patient has an FDA labeled contraindication to ALL topical corticosteroids **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that topical corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to another topical psoriasis agent with a different mechanism of action (e.g., vitamin D analogs, calcineurin inhibitors, tazarotene) **OR** B. The patient has an intolerance or hypersensitivity to another topical psoriasis agent with a different mechanism of action **OR** C. The patient has an FDA labeled contraindication to ALL other topical psoriasis agents with a different mechanism of action **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL other topical psoriasis agents with a different mechanism of action cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The 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

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., 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