MHCP PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: November 1, 2023 Notification Posted: October 17, 2023

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

• Program Summary: Joenja (leniolisib)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
99391540600320	Joenja	leniolisib phosphate tab	70 MG	60	Tablets	30	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** Joenja 1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**

Module	Clinical Criteria for Approval
	2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. BOTH of the following: 1. The patient has a diagnosis of activated phosphoinositide 3-kinase (PI3K) delta syndrome (APDS) **AND** 2. The patient has a variant in either PIK3CD or PIK3R1 **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 agent **AND** 3. The patient's weight is 45 kg or greater **AND** 4. The prescriber has assessed the patient's baseline (prior to therapy with the requested agent) lymphoproliferation (nodal and/or extranodal) and immunophenotype (as measured by the percentage of naive B cells out of total B cells) **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., geneticist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent (e.g., improvement in lymphoproliferation, normalization of immunophenotype) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., geneticist, immunologist) 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) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND**

Module	Clinical Criteria for Approval
	B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval:** Initial 3 months; Renewal 12 months

• Program Summary: Rezurock (belumosudil)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
99398510500320	Rezurock	Belumosudil Mesylate Tab	200 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. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy**: Rezurock 1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. BOTH of the following: 1. The patient has chronic graft-versus-host disease (chronic GVHD) **AND** 2. ONE of the following: A. The patient's medication history includes therapy with at least two prior lines of systemic therapy AND ONE of the following: 1. The patient has had an inadequate response to at least two prior lines of systemic therapy **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over at least two prior lines of systemic therapy **OR** B. The patient has an intolerance or hypersensitivity to therapy with at least two prior lines of systemic therapy **OR** C. The patient has an FDA labeled contraindication to ALL lines of systemic therapy **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND**

Module	Clinical Criteria for Approval
	2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that systemic 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** 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, oncologist) or has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to therapy with 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 Review 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., hematologist, oncologist) or has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months Note: If Quantity Limit applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

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

POLICIES REVISED

• Program Summary: Antiemetic

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
50280020000130		Aprepitant Capsule 125 MG	125 MG	2	Capsules	30	DAYS					
50250025200330		Dolasetron Mesylate Tab 100 MG		7	Tablets	30	DAYS					
50250035100310		Granisetron HCl Tab 1 MG	1 MG	14	Tablets	30	DAYS					
50250065052070		Ondansetron HCl Oral Soln 4 MG/5ML	4 MG/5ML	100	mLs	30	DAYS					
50250065050340		Ondansetron HCl Tab 24 MG	24 MG	1	Tablet	30	DAYS					
50250065050320		Ondansetron HCl Tab 8 MG	8; 8 MG	21	Tablets	30	DAYS					
50250065007220		Ondansetron Orally Disintegrating Tab 4 MG	4 MG	21	Tablets	30	DAYS					
50250065007240		Ondansetron Orally Disintegrating Tab 8 MG	8 MG	21	Tablets	30	DAYS					
50309902290120	Akynzeo	Netupitant-Palonosetron Cap 300-0.5 MG	300-0.5 MG	2	Capsules	30	DAYS					
50250025200320	Anzemet	Dolasetron Mesylate Tab 50 MG	50 MG	7	Tablets	30	DAYS					
50280020000120	Emend	Aprepitant Capsule 80 MG	80 MG	4	Capsules	30	DAYS					
50280020001930	Emend	Aprepitant For Oral Susp 125 MG (125 MG/5ML)	125 MG/5ML	6	Kits	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
50280020006320	Emend tripack	Aprepitant Capsule Therapy Pack 80 & 125 MG	80 & 125 MG	2	Packs	30	DAYS					
50250035005920	Sancuso	Granisetron TD Patch 3.1 MG/24HR (Contains 34.3 MG)	3.1 MG/24HR	2	Patches	30	DAYS					
5028005020B720	Varubi	Rolapitant HCl Tab Therapy Pack 2 x 90 MG (Base Equiv)	90 MG	4	Tablets	30	DAYS					
50250065050310	Zofran	Ondansetron HCl Tab 4 MG	4; 4 MG	21	Tablets	30	DAYS					
50250065008220	Zuplenz	Ondansetron Oral Soluble Film 4 MG	4 MG	20	Films	30	DAYS					
50250065008240	Zuplenz	Ondansetron Oral Soluble Film 8 MG	8 MG	20	Films	30	DAYS					

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Akynzeo, Emend, Varubi Standalone QL	**Quantity limit for Akynzeo, Emend, or Varubi** 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 patient has cancer chemotherapy related nausea and vomiting and the patient will be receiving chemotherapy more than 7 days per month **OR** 3. The prescriber has provided information supporting the use of the requested agent for the requested diagnosis and quantity **Length of Approval:** 12 months
Anzemet, granisetron, ondansetron/ ondansetron ODT. Zuplenz Standalone QL	**Quantity limit for Anzemet, granisetron, ondansetron/ondansetron ODT, or Zuplenz** 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 patient has cancer chemotherapy related nausea and vomiting and will be receiving chemotherapy more than 7 days per month **OR** 3. The patient has delayed emesis in highly emetogenic chemotherapy **OR** 4. The patient has hyperemesis gravidarum **OR** 5. The patient has radiation therapy induced nausea and vomiting for radiation treatment that extends beyond 7 days per month **OR** 6. The prescriber has provided information supporting the use of the requested agent for the requested diagnosis and quantity **Length of Approval**: 12 months

Module	Clinical Criteria for Approval
Sancuso Standalone QL	**Quantity limit for Sancuso** 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 patient has cancer chemotherapy related nausea and vomiting and will be receiving chemotherapy more than 14 days per month **OR** 3. The prescriber has provided information supporting the use of the requested agent for the requested diagnosis and quantity **Length of Approval:** 12 months

• Program Summary: Camzyos

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
40190050000110	Camzyos	Mavacamten Cap	2.5 MG	30	Capsules	30	DAYS					
40190050000120	Camzyos	Mavacamten Cap	5 MG	30	Capsules	30	DAYS					
40190050000130	Camzyos	Mavacamten Cap	10 MG	30	Capsules	30	DAYS					
40190050000140	Camzyos	Mavacamten Cap	15 MG	30	Capsules	30	DAYS					

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. 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. ALL of the following: 1. The patient has a diagnosis of symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) **AND** 2. The requested agent will be used to improve functional capacity and symptoms **AND** 3. The patient does not have a known infiltrative or storage disorder causing cardiac hypertrophy that mimics obstructive HCM, such as Fabry disease, amyloidosis, or Noonan syndrome with left ventricular hypertrophy **AND** 4. ONE of the following: A. The patient's medication history includes therapy with a beta blocker AND ONE of the following: 1. The patient has had an inadequate response to a beta blocker **OR**

Module	Clinical Criteria for Approval
	2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over beta blockers **OR** B. The patient has an intolerance or hypersensitivity to therapy with beta blockers **OR** C. The patient has an FDA labeled contraindication to ALL beta blockers **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 beta blockers cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 5. ONE of the following A. The patient's medication history includes therapy with a calcium channel blocker AND ONE of the following: 1. The patient has had an inadequate response to a calcium channel blocker **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over calcium channel blockers **OR** B. The patient has an intolerance or hypersensitivity to therapy with calcium channel blockers **OR** C. The patient has an FDA labeled contraindication to ALL calcium channel blockers **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 calcium channel blockers 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 and route of administration **AND** 2. ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**

Module	Clinical Criteria for Approval
	3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The prescriber is enrolled in the Camzyos Risk Evaluation and Mitigation Strategy (REMS) program **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 had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The prescriber is enrolled in the Camzyos Risk Evaluation and Mitigation Strategy (REMS) program **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

● Program Summary: Cholestasis Pruiritis

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

TARGET AGENT(S)

Bylvay™ (odevixibat)
Livmarli™ (maralixibat)

Brand (generic)	GPI	Multisource Code
Bylvay (odevixibat)		
200 mcg capsule (pellets)	52350060006810	M, N, O, or Y
600 mcg capsule (pellets)	52350060006830	M, N, O, or Y
400 mcg capsule	52350060000120	M, N, O, or Y
1200 mcg capsule	52350060000140	M, N, O, or Y
Livmarli (maralixibat)		
9.5 mg/mL oral solution	52350050102020	M, N, O, or Y

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL
Initial Evaluation

Bylvay (odevixibat) will be approved when ALL of the following are met:

1. ONE of the following:
    A. The patient has a diagnosis of progressive familial intrahepatic cholestasis (PFIC) with pruritus (medical records required) AND BOTH of the following:
        i. The patient is 3 months of age or older
        AND
        ii. The patient is starting therapy with the requested agent or has already begun therapy as a pediatric patient
    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. ONE of the following:
    A. The patient's medication history includes standard cholestasis pruritus treatment agent (i.e., ursodiol, cholestyramine, or rifampicin) AND ONE of the following:
        i. The patient has had an inadequate response to standard cholestasis pruritus treatment agent (i.e., ursodiol, cholestyramine, or rifampicin)
        OR
        ii. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over standard cholestasis pruritus treatment agent (i.e., ursodiol, cholestyramine, or rifampicin)
    OR
    B. The patient has an intolerance or hypersensitivity to therapy with a standard cholestasis pruritus treatment agent (i.e., ursodiol, cholestyramine, or rifampicin)
    OR
    C. The patient has an FDA labeled contraindication to ALL standard cholestasis pruritus treatment agents (i.e., ursodiol, cholestyramine, and rifampicin)
    OR
    D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
        i. A statement by the prescriber that the patient is currently taking the requested agent
        AND
        ii. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent

AND

iii. 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 cholestasis pruritus treatment agents (i.e., ursodiol, cholestyramine, and rifampicin) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional

AND

3. The patient does NOT have a diagnosis of PFIC2 with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3)

AND

4. The patient's INR is less than 1.4

AND

5. The patient has an ALT and total bilirubin that is less than 10-times the upper limit of normal (ULN)

AND

6. ONE of the following:
   A. The patient has NOT had a liver transplant

   OR

   B. The patient has had a liver transplant and the prescriber has provided information in support of using the requested agent post liver transplant

AND

7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

AND

8. The patient will NOT be using the requested agent in combination with another Ileal Bile Acid Transport (IBAT) inhibitor agent (e.g., Livmarli)

AND

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

Compendia Allowed: AHFS, or DrugDex 1 or 2a level of evidence
Length of Approval: 12 months

Livmarli (maralixibat) will be approved when ALL of the following are met:

1. ONE of the following:
   A. The patient has a diagnosis of Alagille syndrome with pruritus (medical records required)

   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 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 required indication

AND

3. ONE of the following:
   A. The patient's medication history includes standard cholestasis pruritus treatment agent (i.e., ursodiol, cholestyramine, or rifampicin) AND ONE of the following:
      i. The patient has had an inadequate response to standard cholestasis pruritus treatment agent (i.e., ursodiol, cholestyramine, or rifampicin)

      OR

      ii. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over standard cholestasis pruritus treatment agent (i.e., ursodiol, cholestyramine, or rifampicin)

OR

B. The patient has an intolerance or hypersensitivity to therapy with a standard cholestasis pruritus treatment agent (i.e., ursodiol, cholestyramine, or rifampicin)
OR
C. The patient has an FDA labeled contraindication to ALL standard cholestasis pruritus treatment agents (i.e., ursodiol, cholestyramine, and rifampicin)
OR
D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    i. A statement by the prescriber that the patient is currently taking the requested agent
    AND
    ii. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
    AND
    iii. 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 cholestasis pruritus treatment agents (i.e., ursodiol, cholestyramine, and rifampicin) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional

AND

4. The patient does NOT have decompensated cirrhosis
AND
5. That patient has NOT had surgical interruption of the enterohepatic circulation of bile acid
AND
6. ONE of the following:
    A. The patient has NOT had a liver transplant
    OR
    B. The patient has had a liver transplant and the prescriber has provided information in support of using the requested agent post liver transplant

AND

7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis
AND
8. The patient will NOT be using the requested agent in combination with another Ileal Bile Acid Transport (IBAT) inhibitor agent (e.g., Bylvay)
AND
9. The requested quantity (dose) is within FDA labeled dosing for the requested indication

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

Length of Approval: 12 months

Renewal Evaluation

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

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process
AND
2. The patient has had clinical benefit with the requested agent
AND
3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist) 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 Ileal Bile Acid Transport (IBAT) inhibitor agent (e.g., Bylvay, Livmarli)

AND

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

Length of Approval: 12 months

• Program Summary: Constipation Agents

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
52450045000120	Amitiza	Lubiprostone Cap 24 MCG	24 MCG	60	Capsules	30	DAYS					
52450045000110	Amitiza	Lubiprostone Cap 8 MCG	8 MCG	120	Capsules	30	DAYS					
52580050102020	Relistor	methylnaltrexone bromide inj	12 MG/0.6 ML	30	Syringes	30	DAYS			65649055103; 65649055107		
52580050102020	Relistor	methylnaltrexone bromide inj	12 MG/0.6 ML	60	Vials	30	DAYS	Quantity Limit allows for dosing for individuals at least 90th percentile weight		65649055102		
52580050102015	Relistor	Methylnaltrexone Bromide Inj 8 MG/0.4ML (20 MG/ML)	8 MG/0.4 ML	30	Syringes	30	DAYS					
52555060200320	Zelnorm	Tegaserod Maleate Tab 6 MG (Base Equivalent)	6 MG	60	Tablets	30	DAYS					
52557050000120	Linzess	Linaclotide Cap 145 MCG	145 MCG	30	Capsules	30	DAYS					
52557050000140	Linzess	Linaclotide Cap 290 MCG	290 MCG	30	Capsules	30	DAYS					
52557050000110	Linzess	Linaclotide Cap 72 MCG	72 MCG	30	Capsules	30	DAYS					
52558580100320	Ibsrela	Tenapanor HCl Tab	50 MG	60	Tablets	30	DAYS					
52560060200320	Motegrity	Prucalopride Succinate Tab 1 MG (Base Equivalent)	1 MG	30	Tablets	30	DAYS					
52560060200330	Motegrity	Prucalopride Succinate Tab 2 MG (Base Equivalent)	2 MG	30	Tablets	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
52580060300320	Movantik	Naloxegol Oxalate Tab 12.5 MG (Base Equivalent)	12.5 MG	30	Tablets	30	DAYS					
52580060300330	Movantik	Naloxegol Oxalate Tab 25 MG (Base Equivalent)	25 MG	30	Tablets	30	DAYS					
52580050100320	Relistor	Methylnaltrexone Bromide Tab 150 MG	150 MG	90	Tablets	30	DAYS					
52580057200320	Symproic	Naldemedine Tosylate Tab 0.2 MG (Base Equivalent)	0.2 MG	30	Tablets	30	DAYS					
52543060000320	Trulance	Plecanatide Tab 3 MG	3 MG	30	Tablets	30	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Through Preferred	**TARGET AGENT(S)** **Preferred Agent(s)** **Amitiza®** (lubiprostone)* **Linzess®** (linaclotide) **Nonpreferred Agent(s)** **Ibsrela®** (tenapanor) **Motegrity®** (prucalopride) **Movantik®** (naloxegol) **Relistor®** (methylnaltrexone) **Symproic®** (naldemedine) **Trulance®** (plecanatide) **Zelnorm™** (tegaserod) *-generic available **Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of irritable bowel syndrome with constipation (IBS-C) AND ALL of the following: 1. The patient has had IBS-C symptoms for greater than or equal to 3 months **AND** 2. ONE of the following: A. The requested agent is Trulance (plecanatide), Linzess (linaclotide) OR Ibsrela (tenapanor) **OR** B. The requested agent is Amitiza, Lubiprostone OR Zelnorm (tegaserod) AND ONE of the following: 1. The patient's sex is female **OR**

Module	Clinical Criteria for Approval
	2. The prescriber has provided information that the requested agent is medically appropriate for the patient's sex and the intended diagnosis **AND** 3. ONE of the following: A. The patient's medication history includes at least 2 standard laxative therapy classes (e.g., bulk-forming, stimulant, enema, osmotic, or stool softener) AND ONE of the following: 1. The patient has had an inadequate response to at least 2 standard laxative therapy classes **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over at least 2 standard laxative therapy classes **OR** B. The patient has an intolerance or hypersensitivity to at least 2 standard laxative therapy classes **OR** C. The patient has an FDA labeled contraindication to ALL standard laxative therapy classes **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL standard laxative therapy classes (e.g., bulk-forming, stimulant, enema, osmotic, or stool softener) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has a diagnosis of chronic idiopathic constipation (CIC) AND ALL of the following: 1. The patient has had CIC symptoms for greater than or equal to 3 months **AND** 2. The requested agent is Amitiza, Lubiprostone, Linzess (linaclotide), Motegrity (prucalopride), or Trulance (plecanatide) **AND** 3. ONE of the following: A. The patient's medication history includes at least 2 standard laxative therapy classes (e.g., bulk-forming, stimulant, enema, osmotic, or stool softener) AND ONE of the following: 1. The patient has had an inadequate response to at least 2 standard laxative therapy classes **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over at least 2 standard laxative therapy classes **OR** B. The patient has an intolerance or hypersensitivity to at least 2 standard laxative therapy classes **OR** C. The patient has an FDA labeled contraindication to ALL standard laxative therapy classes **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**

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

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

Module	Clinical Criteria for Approval
	F. The prescriber has provided documentation that Linzess (linaclotide) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The requested agent is for use in CIC or OIC AND ONE of the following: 1. The requested agent is Lubiprostone **OR** 2. The patient's medication history includes Lubiprostone AND ONE of the following: A. The patient has had an inadequate response to Lubiprostone **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over Lubiprostone **OR** 3. The patient has an intolerance or hypersensitivity to Lubiprostone that is not expected to occur with the requested agent **OR** 4. The patient has an FDA labeled contraindication to Lubiprostone that is not expected to occur with the requested agent **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that Lubiprostone cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 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. **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) is greater than the program quantity limit **AND** 2. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 3. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** 3. ALL of the following: 1. The requested quantity (dose) is greater than the program quantity limit **AND** 2. The requested quantity (dose) is greater than 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: Furoscix (furosemide)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
3720003000F720	Furoscix	Furosemide Subcutaneous Cartridge Kit	80 MG/10ML	8	Kits	180	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of New York Heart Association (NYHA) Class II or Class III chronic heart failure with congestion due to fluid overload **AND** 2. The patient has ONE of the following: A. An estimated creatinine clearance of >30 mL/min **OR** B. An estimated glomerular filtration rate of >20 mL/min/1.73m^2 **AND** 3. The requested agent will NOT be used in emergency situations **AND** 4. BOTH of the following: A. ONE of the following: 1. The patient is currently treated with a loop diuretic (e.g., bumetanide, furosemide, torsemide) equivalent to a total daily oral furosemide dose of at least 40-160 mg for 4 weeks **OR**

Module	Clinical Criteria for Approval
	2. The patient has an intolerance or hypersensitivity to another loop diuretic (e.g., bumetanide, furosemide, torsemide) equivalent to a total daily oral furosemide dose of at least 40-160 mg **OR** 3. The patient has an FDA labeled contraindication to ALL other loop diuretics (e.g., bumetanide, furosemide, and torsemide) equivalent to a total daily oral furosemide dose of at least 40-160 mg **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 other loop diuretics (e.g., bumetanide, furosemide, and torsemide) equivalent to a total daily oral furosemide dose of at least 40-160 mg cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** B. The patient will NOT be using the requested agent in combination with another loop diuretic agent and will be transitioned back to oral diuretic maintenance therapy after discontinuation of requested agent **AND** 5. 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** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

● Program Summary: Immune Globulins

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

TARGET AGENT(S)
Asceniv™ 10% IVIG
Bivigam® 10% IVIG
Cutaquig 16.5% SCIG
Cuvitru™ 20% SCIG
Flebogamma® 5% DIF IVIG
Flebogamma® 10% DIF IVIG
GamaSTAN® S/D, 15-18% IMIG
Gammagard® S/D 5% IVIG
Gammagard™ Liquid 10% SCIG/IVIG
Gammaked™ Liquid 10% SCIG/IVIG
Gammaplex® 5% Liquid IVIG
Gammaplex® 10% Liquid IVIG
Gamunex®-C 10% SCIG/IVIG
Hizentra® 20% SCIG
HyQvia™ 10% SCIG
Octagam® 5% IVIG
Octagam® 10% IVIG
Panzyga 10% IVIG
Privigen™ 10% IVIG
Xembify 20% SCIG

Brand (generic)	GPI	Multisource Code
Asceniv 10% IVIG		
5 gm/50 mL	19100020802030	M, N, O, or Y
Bivigam 10% IVIG		
5 gm/50 mL	19100020102068	M, N, O, or Y
Cutaquig 16.5% SCIG		
1 gm	19100020572021	M, N, O, or Y
1.65 gm	19100020572025	M, N, O, or Y
2 gm	19100020572030	M, N, O, or Y
3.3 gm	19100020572035	M, N, O, or Y
4 gm	19100020572040	M, N, O, or Y
8 gm	19100020572055	M, N, O, or Y
Cuvitru 20% SCIG		
1 gm/5 mL	19100020202050	M, N, O, or Y
2 gm/10 mL	19100020202054	M, N, O, or Y
4 gm/20 mL	19100020202058	M, N, O, or Y
8 gm/40 mL	19100020202062	M, N, O, or Y
10 gm/50 mL	19100020202065	M, N, O, or Y
Flebogamma 5% DIF IVIG		
0.5 gm/10 mL	19100020102020	M, N, O, or Y
2.5 gm/50 mL	19100020102034	M, N, O, or Y
5 gm/100 mL	19100020102038	M, N, O, or Y
10 gm/200 mL	19100020102042	M, N, O, or Y
20 gm/400 mL	19100020102044	M, N, O, or Y
Flebogamma 10% DIF IVIG		
5 gm/50 mL	19100020102068	M, N, O, or Y
10 gm/100 mL	19100020102072	M, N, O, or Y
20 gm/200 mL	19100020102076	M, N, O, or Y

Brand (generic)	GPI	Multisource Code
GamaSTAN S/D 15-18% IMIG		
2 mL vial	19100020002200	M, N, O, or Y
10 mL vial	19100020002200	M, N, O, or Y
Gammagard S/D 5% IVIG		
5.0 gm	19100020102120	M, N, O, or Y
10.0 gm	19100020102130	M, N, O, or Y
Gammagard Liquid 10% SCIG/IVIG		
1 gm/10 mL	19100020302060	M, N, O, or Y
2.5 gm/25 mL	19100020302064	M, N, O, or Y
5 gm/50 mL	19100020302068	M, N, O, or Y
10 gm/100 mL	19100020302072	M, N, O, or Y
20 gm/200 mL	19100020302076	M, N, O, or Y
30 gm/300 mL	19100020302080	M, N, O, or Y
Gammaked 10% SCIG/IVIG		
1 gm/10 mL	19100020302060	M, N, O, or Y
2.5 gm/25 mL	19100020302064	M, N, O, or Y
5 gm/50 mL	19100020302068	M, N, O, or Y
10 gm/100 mL	19100020302072	M, N, O, or Y
20 gm/200 mL	19100020302076	M, N, O, or Y
Gammaplex 5% Liquid IVIG		
5 gm/100 mL	19100020102038	M, N, O, or Y
10 gm/200 mL	19100020102042	M, N, O, or Y
20 gm/400 mL	19100020102044	M, N, O, or Y
Gammaplex 10% Liquid IVIG		
5 gm/50 mL	19100020102068	M, N, O, or Y
10 gm/100 mL	19100020102072	M, N, O, or Y
20 gm/200 mL	19100020102076	M, N, O, or Y
Gamunex-C 10% SCIG/IVIG		
1 gm/10 mL	19100020302060	M, N, O, or Y
2.5 gm/25 mL	19100020302064	M, N, O, or Y
5 gm/50 mL	19100020302068	M, N, O, or Y
10 gm/100 mL	19100020302072	M, N, O, or Y
20 gm/200 mL	19100020302076	M, N, O, or Y
40 gm/400 mL	19100020302084	M, N, O, or Y
Hizentra 20% SCIG		
1 gm/5 mL	19100020202050	M, N, O, or Y
1 gm/5 mL prefilled syringe	1910002020E520	M, N, O, or Y
2 gm/10 mL	19100020202054	M, N, O, or Y
2 gm/10 mL prefilled syringe	1910002020E530	M, N, O, or Y
4 gm/ 20 mL	19100020202058	M, N, O, or Y
4 gm/20 mL prefilled syringe	1910002020E540	M, N, O, or Y
10 gm/50 mL	19100020202065	M, N, O, or Y
HyQvia 10% SCIG		
2.5 gm/25 mL	19990002356420	M, N, O, or Y
5.0 gm/50 mL	19990002356425	M, N, O, or Y
10.0 gm/100 mL	19990002356430	M, N, O, or Y
20.0 gm/200 mL	19990002356440	M, N, O, or Y
30.0 gm/ 300 mL	19990002356450	M, N, O, or Y
Octagam 5% IVIG		
1 gm/20 mL	19100020102030	M, N, O, or Y
2.5 gm/50 mL	19100020102034	M, N, O, or Y
5 gm/100 mL	19100020102038	M, N, O, or Y

Brand (generic)	GPI	Multisource Code
10 gm/200 mL	19100020102042	M, N, O, or Y
25 gm/500 mL	19100020102046	M, N, O, or Y
Octagam 10% IVIG		
2 gm/20 mL	19100020102063	M, N, O, or Y
5 gm/50 mL	19100020102068	M, N, O, or Y
10 gm/100 mL	19100020102072	M, N, O, or Y
20 gm/200 mL	19100020102076	M, N, O, or Y
30 gm/300 mL	19100020102080	M, N, O, or Y
Panzyga 10% IVIG		
1 gm/10 mL	19100020602020	M, N, O, or Y
2.5 gm/25 mL	19100020602025	M, N, O, or Y
5 gm/50 mL	19100020602030	M, N, O, or Y
10 gm/100 mL	19100020602035	M, N, O, or Y
20 gm/200 mL	19100020602040	M, N, O, or Y
30 gm/300 mL	19100020602045	M, N, O, or Y
Privigen 10% IVIG		
5 gm/50 mL	19100020102068	M, N, O, or Y
10 gm/100 mL	19100020102072	M, N, O, or Y
20 gm/200 mL	19100020102076	M, N, O, or Y
40 gm/400 mL	19100020102090	M, N, O, or Y
Xembify 20% SCIG		
1 gm/5 mL	19100020642020	M, N, O, or Y
2 gm/10 mL	19100020642025	M, N, O, or Y
4 gm/20 mL	19100020642030	M, N, O, or Y
10 gm/50 mL	19100020642040	M, N, O, or 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 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

        i. Information has been provided that indicates the patient has been treated with multiple doses of the requested agent within the past 120 days
        OR
        ii. The prescriber states the patient has been treated with the requested agent within the past 120 days AND is at risk if therapy is changed

    OR

    B. If requesting IVIG or SCIG, ONE of the following:
        i. The patient has a diagnosis of primary immunodeficiency AND ONE of the following:
            a. The patient has a total IgG less than 200 mg/dL at baseline prior to immune globulin therapy
            OR
            b. The patient has abnormal Bruton tyrosine kinase (BTK) gene/absence of BTK protein
            OR
            c. The patient has an absence of B lymphocytes
            OR
            d. ALL of the following:
                1. ONE of the following:
                    A. The patient has selective IgG subclass deficiency [Defined as deficiency of 1 or more IgG subclasses (e.g., IgG1, IgG2, IgG3, or IgG4) by more than 2 standard

deviations (SD) below age-specific mean, assessed on 2 separate occasions during infection free period]

OR

B. The patient has specific antibody deficiency (SAD) with normal levels of both immunoglobulin and total IgG subclasses

OR

C. The patient has hypogammaglobulinemia defined as total IgG < 700 mg/dL OR more than 2 standard deviations below mean for the patient's age at baseline prior to immune globulin therapy **OR**

D. The patient has another Primary immunodeficiency [e.g., Common variable immunodeficiency (CVID), X-linked immunodeficiency, severe combined immunodeficiency (SCID), combined immunodeficiency syndromes (e.g., Ataxia Telangiectasia (A-T), DiGeorge syndrome, Wiskott-Aldrich Syndrome)]

AND

2. The patient has a lack of response or inability to mount an adequate response to protein and/or polysaccharide antigens (e.g., inability to make IgG antibody against either diphtheria and tetanus toxoids, or pneumococcal polysaccharide vaccine, or both)

AND

3. The patient has evidence of recurrent, persistent, severe, difficult-to-treat infections (e.g., recurring otitis media, bronchiectasis, recurrent infections requiring IV antibiotics) despite aggressive prophylactic management and treatment with antibiotics

OR

ii. The patient has a diagnosis of B-cell Chronic lymphocytic leukemia AND ONE of the following:

a. The patient has hypogammaglobulinemia defined as total IgG < 700 mg/dL OR more than 2 standard deviations below mean for the patient's age at baseline prior to immune globulin therapy

OR

b. The patient has history of recurrent bacterial infections requiring antibiotics and/or hospitalization

OR

iii. The patient has a diagnosis of idiopathic thrombocytopenia purpura (ITP) and ONE of the following:

a. The patient's medication history includes ONE conventional therapy (e.g., corticosteroids) for ITP AND ONE of the following:

1. The patient has had an inadequate response to ONE conventional therapy (e.g., corticosteroids) for ITP

OR

2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional therapy (e.g., corticosteroids) for ITP

OR

b. The patient has an intolerance or hypersensitivity to ONE conventional therapy (e.g., corticosteroids)

OR

c. The patient has an FDA labeled contraindication to ALL conventional therapy (e.g., 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 conventional therapy (e.g., corticosteroids) for ITP 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

iv. The requested agent will be used for the prevention of bacterial infection in HIV-infected children AND ALL of the following:
   a. The patient is < 13 years old
   AND
   b. CD4 count is > 200/µL
   AND
   c. The patient has hypogammaglobulinemia defined as total IgG < 700 mg/dL OR more than 2 standard deviations below mean for the patient's age at baseline prior to immune globulin therapy

OR

v. The patient has a diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) AND ALL of the following:
   a. The patient has progressive symptoms present for at least 2 months
   AND
   b. The patient has progressive or relapsing motor sensory impairment of more than one limb
   AND
   c. The patient has electrodiagnostic findings indicating at least ONE of the following are present:
      1. Motor distal latency prolongation in 2 nerves
      OR
      2. Reduction of motor conduction velocity in 2 nerves
      OR
      3. Prolongation of F-wave latency in 2 nerves
      OR
      4. Absence of F-waves in at least 1 nerve
      OR
      5. Partial motor conduction block of at least 1motor nerve
      OR
      6. Abnormal temporal dispersion in at least 2 nerves
      OR
      7. Distal CMAP duration increase in at least 1 nerve

   AND

   d. The prescriber is a specialist (e.g., neurologist) in the area of the patient's diagnosis or has consulted with a specialist in the area of the patient's diagnosis

OR

vi. The patient has a diagnosis of multifocal motor neuropathy AND BOTH of the following:
   a. The diagnosis was confirmed by ALL of the following:
      1. Weakness with slowly progressive or stepwise progressive course over at least 1 month
      AND
      2. Asymmetric involvement of two or more nerves
      AND
      3. Absence of motor neuron signs and bulbar signs

   AND

   b. The prescriber is a specialist (e.g., neurologist) in the area of the patient's diagnosis or has consulted with a specialist in the area of the patient's diagnosis

OR

vii. The patient has a diagnosis of Kawasaki disease

OR

viii. The patient has a diagnosis of Guillain-Barre syndrome

OR

ix. The requested agent will be used for prevention of infection or graft vs host disease following bone marrow transplantation AND the bone marrow transplant was within the last 100 days

OR

x. The patient has a diagnosis of dermatomyositis and BOTH of the following:
    a. ONE of the following:
        1. The patient's medication history includes ONE conventional therapy [e.g., corticosteroids (e.g., prednisone) or immunosuppressants (e.g., azathioprine, mycophenolate)] for dermatomyositis AND ONE of the following:
            A. The patient has had an inadequate response to ONE conventional therapy [e.g., corticosteroids (e.g., prednisone) or immunosuppressants (e.g., azathioprine, mycophenolate)] for dermatomyositis

            OR

            B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional therapy [e.g., corticosteroids (e.g., prednisone) or immunosuppressants (e.g., azathioprine, mycophenolate)] for dermatomyositis

        OR

        2. The patient has an intolerance or hypersensitivity to ONE conventional therapy [e.g., corticosteroids (e.g., prednisone) or immunosuppressants (e.g., azathioprine, mycophenolate)]

        OR

        3. The patient has an FDA labeled contraindication to ALL conventional therapy [e.g., corticosteroids (e.g., prednisone) and immunosuppressants (e.g., azathioprine, mycophenolate)]

        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 conventional therapy [e.g., corticosteroids (e.g., prednisone) or immunosuppressants (e.g., azathioprine, mycophenolate)] cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

    AND

    b. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, immunologist) or has consulted with a specialist in the area of the patient's diagnosis

xi. The patient has a diagnosis of polymyositis and BOTH of the following:
    a. ONE of the following:
        1. The patient's medication history includes conventional therapy [e.g., corticosteroids (e.g., prednisone) or immunosuppressants (e.g., azathioprine, mycophenolate)] for polymyositis AND ONE of the following:
            A. The patient has had an inadequate response to conventional therapy [e.g., corticosteroids (e.g., prednisone) or immunosuppressants (e.g., azathioprine, mycophenolate)] for polymyositis

            OR

B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional therapy [e.g., corticosteroids (e.g., prednisone) or immunosuppressants (e.g., azathioprine, mycophenolate)] for polymyositis

OR

2. The patient has an intolerance or hypersensitivity ONE conventional therapy [e.g., corticosteroids (e.g., prednisone) or immunosuppressants (e.g., azathioprine, mycophenolate)]

OR

3. The patient has an FDA labeled contraindication to ALL conventional therapy [e.g., corticosteroids (e.g., prednisone) or immunosuppressants (e.g., azathioprine, mycophenolate)]

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 conventional therapy [e.g., corticosteroids (e.g., prednisone) or immunosuppressants (e.g., azathioprine, mycophenolate)] for polymyositis cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

AND

b. The prescriber is a specialist in the area of the patient's diagnosis (e.g., immunologist, rheumatologist) or has consulted with a specialist in the area of the patient's diagnosis

OR

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

OR

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

AND

2. If requesting IMIG, ONE of the following:
   A. The patient has a diagnosis of hepatitis A AND BOTH of the following:
      i. The patient requires pre-exposure or post-exposure prophylaxis (exposure is within the previous 14 days)
      AND
      ii. ONE of the following:
         a. The patient cannot be vaccinated due to age (<12 months)
         OR
         b. The patient has a vaccination allergy OR has refused vaccination
         OR
         c. The patient is an infant born to a mother with acute hepatitis A infection

   OR

   B. The patient has a diagnosis of measles AND ALL of the following:
      i. The patient has been exposed to measles within the past 6 days
      AND
      ii. The patient is unvaccinated
      AND

iii. The patient has NOT previously had measles

OR

C. The patient has a diagnosis of rubella AND BOTH of the following:
   i. The patient is pregnant
   AND
   ii. The patient requires post exposure prophylaxis within 72 hours of exposure to reduce the risk of infection and fetal damage

OR

D. The patient has a diagnosis of varicella AND ALL of the following:
   i. The patient is immunocompromised
   AND
   ii. The patient requires post exposure prophylaxis
   AND
   iii. Varicella zoster immune globulin is not available (cannot obtain vaccine within 96 hours of exposure)

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

3. If the patient has an FDA approved indication, ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
   B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**
4. The patient does NOT have any FDA labeled contraindications to the requested agent
   AND
5. ONE of the following:
   A. The requested dose does not exceed the maximum FDA labeled dose or the compendia supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN 1 or 2a level of evidence) for the requested indication
   OR
   B. The prescriber has provided information in support of therapy with the requested dose for the requested indication

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

Length of Approval:

Indication	Length of Approval
Measles, Rubella, Varicella	One time
Guillain-Barre Syndrome	3 months
Hepatitis A	3 months
Kawasaki disease	3 months
Prevention of infection following bone marrow transplant	3 months
Privigen for CIDP	6 months
All other indications	12 months

Renewal Evaluation

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

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process
   AND
2. ONE of the following:
   A. The patient was previously approved for short term use of the requested agent (i.e., ≤ 6 months) (refer to length of approval table) AND the prescriber has provided information supporting continued use of the requested agent

OR

B. The patient was previously approved for more than 6 months AND ONE of the following:
    i. The patient has had clinical improvement or stabilization with the requested agent (e.g., IgG level has improved from pre-treatment levels with the requested agent, reduction in the number and/or severity of difficult to treat infections, reduction in seizure frequency)
    OR
    ii. The prescriber has provided information in support of continued use of the requested agent

AND

3. The patient does NOT have any FDA labeled contraindications to the requested agent
AND
4. ONE of the following:
    A. The requested dose does not exceed the maximum FDA labeled dose or the compendia supported dose for the requested indication
    OR
    B. The prescriber has provided information in support of the requested dose for the requested indication

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

Length of Approval:

Indication	Length of Approval
Measles, Rubella, Varicella	One time
Guillain-Barre Syndrome	3 months
Hepatitis A	3 months
Kawasaki disease	3 months
Prevention of infection following bone marrow transplant	3 months
Privigen for CIDP	6 months
All other indications	12 months

Primary Humoral Immune Deficiency Testing Table
Serum antibody titers to tetanus and/or diphtheria • Initial serum antibody titer to be collected prior to immunization, and then collected again 3-4 weeks after immunization • Inadequate response is defined as < 4-fold increase in antibody titer and lack of protective antibody level (as defined by laboratory)
Serum antibody titer to pneumococcus • Initial serum antibody titer to be collected prior to immunization and then collected again 3-6 weeks after immunization with polyvalent pneumococcal polysaccharide vaccine (Pneumovax 23) • Inadequate response is defined as failure to increase baseline titer at least 2-fold or failure to generate a protective antibody titer (defined as IgG concentration > 1.3 mcg/mL • Overall failure is failure in 12 or more serotypes (50% or more) in a child under 6 years of age or failure in 7 or more serotypes (30%) in patients age 6 years or older

• Program Summary: Interleukin-4 (IL-4) Inhibitor

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
9027302000D215	Dupixent	Dupilumab Subcutaneous Soln Pen-injector	200 MG/1.14ML	2	Pens	28	DAYS					
9027302000D220	Dupixent	Dupilumab Subcutaneous Soln Pen-injector 300 MG/2ML	300 MG/2ML	4	Pens	28	DAYS					
9027302000E510	Dupixent	Dupilumab Subcutaneous Soln Prefilled Syringe	100 MG/0.67ML	2	Syringes	28	DAYS					
9027302000E515	Dupixent	Dupilumab Subcutaneous Soln Prefilled Syringe 200 MG/1.14ML	200 MG/1.14ML	2	Syringes	28	DAYS					
9027302000E520	Dupixent	Dupilumab Subcutaneous Soln Prefilled Syringe 300 MG/2ML	300 MG/2ML	4	Syringes	28	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy**: All target agents are eligible for continuation of therapy 1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. The patient has a diagnosis of moderate-to-severe atopic dermatitis AND ALL of the following: 1. ONE of the following: A. The patient has at least 10% body surface area involvement **OR** B. The patient has involvement of the palms and/or soles of the feet **AND** 2. ONE of the following: A. The patient's medication history includes use of an oral systemic immunosuppressant (e.g., methotrexate, azathioprine, mycophenolate mofetil, cyclosporine) OR BOTH at least a mid- potency topical steroid AND a topical

Module	Clinical Criteria for Approval
	calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) AND ONE of the following: 1. The patient has had an inadequate response to an oral systemic immunosuppressant (e.g., methotrexate, azathioprine, mycophenolate mofetil, cyclosporine) **OR** 2. The patient has had an inadequate response to BOTH at least a mid-potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) **OR** 3. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over an oral systemic immunosuppressant (e.g., methotrexate, azathioprine, mycophenolate mofetil, cyclosporine) AND BOTH at least a mid- potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) **OR** B. The patient has an intolerance or hypersensitivity to an oral systemic immunosuppressant (e.g., methotrexate, azathioprine, mycophenolate mofetil, cyclosporine) **OR** C. The patient has an intolerance or hypersensitivity to BOTH at least a mid-potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) **OR** D. The patient has an FDA labeled contraindication to ALL oral systemic immunosuppressants, mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that ALL oral systemic immunosuppressants, mid-, high-, and super-potency topical steroids, AND topical calcineurin inhibitors cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The prescriber has assessed the patient's baseline (prior to therapy with the requested agent) pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **AND** 4. The patient will be using standard maintenance therapy (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** C. The patient has a diagnosis of moderate to severe asthma AND ALL of the following: 1. ONE of the following: A. The patient has eosinophilic type asthma AND ONE of the following: 1. The patient has a baseline (prior to therapy with the requested agent) blood eosinophilic count of 150 cells/microliter or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **OR** 2. The patient has a fraction of exhaled nitric oxide (FeNO) of 20 parts per billion or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **OR** 3. The patient has sputum eosinophils 2% or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **OR** B. The patient has oral corticosteroid dependent type asthma **AND**

Module	Clinical Criteria for Approval
	2. The patient has a history of uncontrolled asthma while on asthma control therapy as demonstrated by ONE of the following: A. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months **OR** B. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months **OR** C. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered **OR** D. The patient has baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted **AND** 3. ONE of the following: A. The patient is NOT currently being treated with the requested agent AND is currently treated with a maximally tolerated inhaled corticosteroid **OR** B. The patient is currently being treated with the requested agent AND ONE of the following: 1. Is currently treated with an inhaled corticosteroid that is adequately dosed to control symptoms **OR** 2. Is currently treated with a maximally tolerated inhaled corticosteroid **OR** C. The patient has an intolerance or hypersensitivity to inhaled corticosteroid therapy **OR** D. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids **AND** 4. ONE of the following: A. The patient is currently being treated with ONE of the following: 1. A long-acting beta-2 agonist (LABA) **OR** 2. A leukotriene receptor antagonist (LTRA) **OR** 3. Long-acting muscarinic antagonist (LAMA) **OR** 4. Theophylline **OR** B. The patient has an intolerance or hypersensitivity to therapy with a LABA, LTRA, LAMA, or theophylline **OR** C. The patient has an FDA labeled contraindication to ALL LABA, LTRA, LAMA, AND theophylline therapies **AND** 5. The patient will continue asthma control therapy (e.g., ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **OR** D. The patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND ALL of the following: 1. The patient has at least TWO of the following symptoms consistent with chronic rhinosinusitis (CRS): A. Nasal discharge (rhinorrhea or post-nasal drainage) B. Nasal obstruction or congestion C. Loss or decreased sense of smell (hyposmia) D. Facial pressure or pain **AND** 2. The patient has had symptoms consistent with chronic rhinosinusitis (CRS) for at least 12 consecutive weeks **AND** 3. There is information indicating the patient's diagnosis was confirmed by ONE of the following: A. Anterior rhinoscopy or endoscopy **OR** B. Computed tomography (CT) of the sinuses **AND** 4. ONE of the following: A. ONE of the following: 1. The patient had an inadequate response to sinonasal surgery **OR** 2. The patient is NOT a candidate for sinonasal surgery **OR** B. ONE of the following:

Module	Clinical Criteria for Approval
	1. The patient has tried and had an inadequate response to oral systemic corticosteroids **OR** 2. The patient has an intolerance or hypersensitivity to therapy with oral systemic corticosteroids **OR** 3. The patient has an FDA labeled contraindication to ALL oral systemic corticosteroids **AND** 5. ONE of the following: A. The patient has tried and had an inadequate response to intranasal corticosteroids (e.g., fluticasone, Sinuva) **OR** B. The patient has an intolerance or hypersensitivity to therapy with intranasal corticosteroids (e.g., fluticasone, Sinuva) **OR** C. The patient has an FDA labeled contraindication to ALL intranasal corticosteroids **AND** 6. BOTH of the following: A. The patient is currently treated with standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) **AND** B. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **OR** E. The patient has a diagnosis of eosinophilic esophagitis (EoE) AND BOTH of the following: 1. The patient's diagnosis was confirmed by ALL of the following: A. Chronic symptoms of esophageal dysfunction **AND** B. Greater than or equal to 15 eosinophils per high-power field on esophageal biopsy **AND** C. Other causes that may be responsible for or contributing to symptoms and esophageal eosinophilia have been ruled out **AND** 2. ONE of the following: A. The patient's medication history includes use of ONE standard corticosteroid therapy for EoE (i.e., budesonide suspension, fluticasone MDI swallowed) AND ONE of the following: 1. The patient has had an inadequate response to ONE standard corticosteroid therapy for EoE (i.e., budesonide suspension, fluticasone MDI swallowed) **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over standard corticosteroid therapy for EoE (i.e., budesonide suspension, fluticasone MDI swallowed) **OR** B. The patient has an intolerance or hypersensitivity to standard corticosteroid therapy for EoE **OR** C. The patient has an FDA labeled contraindication to standard corticosteroid therapy for EoE **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 corticosteroid therapy for EoE 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**

Module	Clinical Criteria for Approval
	F. The patient has a diagnosis of prurigo nodularis (PN) and BOTH of the following: 1. The patient has ALL of the following features associated with PN: A. Presence of firm, nodular lesions B. Pruritus that has lasted for at least 6 weeks C. History and/or signs of repeated scratching, picking, or rubbing **AND** 2. ONE of the following: A. The patient's medication history includes use of at least a mid- potency topical steroid AND ONE of the following: 1. The patient has had an inadequate response to at least a mid- potency topical steroid **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over at least a mid- potency topical steroid **OR** B. The patient has an intolerance or hypersensitivity to at least a mid- potency topical steroid **OR** C. The patient has an FDA labeled contraindication to ALL mid-, high-, and super-potency topical steroids **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 mid-, high-, and super-potency topical steroids 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** G. The patient has another FDA approved indication for the requested agent and route of administration **OR** H. 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., atopic dermatitis -dermatologist, allergist, immunologist; asthma -allergist, immunologist, pulmonologist; CRSwNP -otolaryngologist, allergist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia

Module	Clinical Criteria for Approval
	Length of Approval: 6 months **Note:** Please approve initial loading dose for asthma, atopic dermatitis, and prurigo nodularis only 300 mg strength requested: 600 mg (two 300 mg injections) followed by maintenance dose 200 mg strength requested: 400 mg (two 200 mg injections) followed by maintenance dose Note: If Quantity Limit applies, please refer to Quantity Limit criteria **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. ONE of the following: A. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND BOTH of the following: 1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following: A. Affected body surface area **OR** B. Flares **OR** C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **AND** 2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has a diagnosis of moderate to severe asthma AND BOTH of the following: 1. The patient has had improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following: A. The patient has had an increase in percent predicted Forced Expiratory Volume (FEV_1) **OR** B. The patient has had a decrease in the dose of inhaled corticosteroids required to control the patient's asthma **OR** C. The patient has had a decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma **OR** D. The patient has had a decrease in number of hospitalizations, need for mechanical ventilation, or visits to urgent care or emergency room due to exacerbations of asthma **AND** 2. The patient is currently treated and is compliant with asthma control therapy [e.g., inhaled corticosteroids, long-acting beta-2 agonist (LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), theophylline] **OR** C. The patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **OR** D. The patient has a diagnosis other than moderate-to-severe atopic dermatitis (AD), moderate to severe asthma, or chronic rhinosinusitis with nasal polyposis (CRSwNP) AND has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., atopic dermatitis -dermatologist, allergist, immunologist; asthma -allergist, immunologist, pulmonologist; CRSwNP -otolaryngologist, allergist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**

Module	Clinical Criteria for Approval
	B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 5. The patient does NOT have an FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 12 months Note: If Quantity Limit applies, please refer to Quantity Limit criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limits for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose, or the compendia supported 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 **Compendia Allowed:** CMS Approved Compendia **Length of Approval**: 6 months for Initial; 12 months for Renewal

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly
Abrilada (adalimumab-afzb) Actemra (tocilizumab) Adalimumab Adbry (tralokinumab-ldrm) Amjevita (adalimumab-atto) Arcalyst (rilonacept) Avsola (infliximab-axxq) Benlysta (belimumab) Cibinqo (abrocitinib) Cimzia (certolizumab) Cinqair (reslizumab) Cosentyx (secukinumab) Cyltezo (adalimumab-adbm) Dupixent (dupilumab) Enbrel (etanercept) Entyvio (vedolizumab) Fasenra (benralizumab) Hadlima (adalimumab-bwwd)

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

• Program Summary: Oxbryta (voxelotor)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

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

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of sickle cell disease **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. The patient's medication history includes hydroxyurea AND ONE of the following: 1. The patient has had an inadequate response to maximally tolerated hydroxyurea **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over hydroxyurea **OR** 3. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to hydroxyurea **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that hydroxyurea cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. ONE of the following: A. The patient's baseline (before treatment with the requested agent) hemoglobin is greater than or equal to 5.5 and less than or equal to 10.5 g/dL **OR** B. The patient's baseline (before treatment with the requested agent) hemoglobin is below the lab reference range for the patient's age and gender **AND** 5. ONE of the following: A. The patient will NOT be using the requested agent in combination with Adakveo (crizanlizumab-tmca) OR Endari (L-glutamine) for the requested indication **OR**

Module	Clinical Criteria for Approval
	B. Information has been provided supporting the use of the requested agent in combination with Adakveo (crizanlizumab-tmca) or Endari (L-glutamine) for the requested indication **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Initial Approval:** 6 months NOTE if Quantity Limit applies, please refer to Quantity Limit criteria **Renewal Evaluation** **Target Agent(s)** will be approved when 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 indicated by one of the following: A. The patient had an increase in hemoglobin level of greater than 1 g/dL from baseline (before treatment with the requested agent) **OR** B. The patient has a hemoglobin level within the normal range for age and gender **OR** C. Information has been provided supporting continuation with the requested agent (medical records required) **AND** 3. ONE of the following: A. The patient will NOT be using the requested agent in combination with Adakveo (crizanlizumab-tmca) OR Endari (L-glutamine) for the requested indication **OR** B. Information supporting the use of the requested agent in combination with Adakveo (crizanlizumab-tmca) or Endari (L-glutamine) for the requested indication **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Renewal Approval:** 12 months NOTE if Quantity Limit applies, please refer to Quantity Limit criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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