COMMERCIAL PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

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

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

• Program Summary: Joenja (leniolisib)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	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** 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** 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:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	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. The patient has failed at least two prior lines of systemic therapy **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**

Module	Clinical Criteria for Approval
	B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., 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** 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 Agents

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

Antiemetic Step Therapy with Quantity Limit

TARGET AGENT(S)
Sancuso® (granisetron)
Zuplenz® (ondansetron)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL
Target Agent(s) will be approved when ONE of the following is met:

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

   OR
2. The patient's medication history includes use of ONE generic oral 5HT-3 antiemetic agent (e.g., granisetron, ondansetron)
   OR
3. BOTH of the following:
   A. The prescriber has stated that the patient has tried at least ONE generic oral 5HT-3 antiemetic agent
   AND
   B. Generic oral 5HT-3 antiemetic agents were discontinued due to lack of effectiveness or an adverse event

   OR
4. The patient has an intolerance or hypersensitivity to ONE generic oral 5HT-3 antiemetic agent (e.g., granisetron, ondansetron)
   OR
5. The patient has an FDA labeled contraindication to ALL generic oral 5HT-3 antiemetic agents
   OR
6. The prescriber has provided documentation that ALL generic oral 5HT-3 antiemetic agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

Length of Approval: 12 months

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

Antiemetic Agents Quantity Limit

TARGET AGENT(S)
Akynzeo® (netupitant/palonosetron)
Anzemet® (dolasetron)
Emend® (aprepitant)[c]
granisetron[b]
ondansetron ODT[b]
Sancuso® (granisetron)
Varubi® (rolapitant)
Zofran® (ondansetron)[a]
Zuplenz® (ondansetron)

a - generic available and included in quantity limit program
b - available as generic onl
c - Emend 40 mg capsules are not included in this program due to use for postoperative nausea and vomiting only

QUANTITY LIMIT TARGET AGENT(S) - RECOMMENDED LIMITS
(Limits allow for at least 7 days of cancer chemotherapy or radiotherapy)

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
Akynzeo (netupitant/palonosetron)			
300 mg / 0.5 mg capsule	50309902290120	M, N, O, or Y	2 capsules/30 days
Anzemet (dolasetron)			
50 mg tablet	50250025200320	M, N, O, or Y	7 tablets/30 days
100 mg tablet	50250025200330	M, N, O, or Y	7 tablets/30 days
Emend (aprepitant)[c]			
80 mg capsule[a]	50280020000120	M, N, O, or Y	4 capsules/30 days
125 mg capsule[a]	50280020000130	M, N, O, or Y	2 capsules/30 days
Emend Therapy Pack (1x125 mg capsule, 2x80 mg capsules)[a]	50280020006320	M, N, O, or Y	6 capsules (2 therapy packs)/30 days
125mg/5mL oral suspension	50280020001930	M, N, O, or Y	6 single-use kits/30 days
granisetron[b]			
1 mg tablet	50250035100310	M, N, O, or Y	14 tablets/30 days
ondansetron ODT[b]			
4 mg orally disintegrating tablet	50250065007220	M, N, O, or Y	21 tablets/30 days
8 mg orally disintegrating tablet	50250065007240	M, N, O, or Y	21 tablets/30 days
Sancuso (granisetron)			
3.1 mg/24 hours patch	50250035005920	M, N, O, or Y	2 patches/30 days
Varubi (rolapitant)			
90 mg tablet	5028005020B720	M, N, O, or Y	4 tablets/30 days
Zofran (ondansetron)[a]			
4 mg tablet	50250065050310	M, N, O, or Y	21 tablets/30 days
8 mg tablet	50250065050320	M, N, O, or Y	21 tablets/30 days
24 mg tablet[b]	50250065050340	M, N, O, or Y	1 tablet/30 days
4 mg/5 mL oral solution	50250065052070	M, N, O, or Y	
Zuplenz (ondansetron)			
4 mg oral soluble film	50250065008220	M, N, O, or Y	20 films (2 boxes of 10)/30 days
8 mg oral soluble film	50250065008240	M, N, O, or Y	20 films (2 boxes of 10)/30 days

a - generic available and included in quantity limit program
b - available as generic only
c - Emend 40 mg capsules are not included in this program due to use for postoperative nausea and vomiting only

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Quantity limit for **Anzemet, granisetron, Zofran/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

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

Quantity limit for **Akynzeo**, **Emend/aprepitant, 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

• Program Summary: Camzyos

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	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	Capsule	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**

Module	Clinical Criteria for Approval
	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 has tried and had an inadequate response to a beta blocker **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 has tried and had an inadequate response to a calcium channel blocker **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

Module	Clinical Criteria for Approval
	age for the requested indication **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. **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 Pruritus

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☐ Quantity Limit ☐ Step Therapy ☐ Coverage / 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 has tried and had an inadequate response to a 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 ability in performing daily activities or cause physical or mental harm

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 has tried and had an inadequate response to a standard cholestasis pruritus treatment agent (i.e., ursodiol, cholestyramine, naltrexone, or rifampicin)

    OR

    B. The patient has an intolerance or hypersensitivity to therapy with a standard cholestasis pruritus treatment agent (i.e., ursodiol, cholestyramine, naltrexone, or rifampicin)

    OR

    C. The patient has an FDA labeled contraindication to ALL standard cholestasis pruritus treatment agents (i.e., ursodiol, cholestyramine, naltrexone, 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, naltrexone, and rifampicin) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

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: Compound Medications Coverage Exception / Formulary Exception

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

This program applies to all BCBS MN closed plans.

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Compounded Medications will be approved when ALL of the following are met:

1. The product contains at least one non-formulary prescription ingredient
   AND
2. The non-formulary prescription ingredient(s) is/are not excluded from coverage on the pharmacy benefit
   AND
3. The non-formulary prescription ingredient(s) is/are FDA approved for medical use in the United States
   AND
4. ALL non-formulary prescription ingredients in the compounded product are being used for an FDA approved indication (including the final route of administration)
   AND
5. The compounded medication is not a copy of a commercially available FDA-approved drug product UNLESS that commercially available product is the subject of a drug shortage making it unavailable for dispensing
   AND
6. If the compounded product is similar to a commercially available product, but differs in dosage, dosage form, and/or omission of dye, sweetener, flavoring, or preservative, then the requested medication is being compounded to meet a specific patient need for which an FDA approved product is not available (e.g., compounding of liquid formulations for patients unable to swallow; compounding for patients with sensitivities to dyes, preservatives or fillers; compounding of therapeutic strengths not commercially available when the dose is not above FDA labeled maximum dose)
   AND
7. ONE of the following:
   A. The patient has tried and failed at least three (or as many as available, if fewer than three) formulary alternatives for the diagnosis being treated with the requested agent
      OR
   B. The prescriber has indicated that available formulary alternatives are contraindicated, likely to be less effective, or likely to cause an adverse reaction or harm for the patient
      OR
   C. The prescriber has attested that the patient has been stabilized on the requested agent for a minimum of 90 days and that switching could potentially cause harm or a health risk

If the compound contains more than one non-formulary prescription ingredient listed above ALL criteria must be met for each individual ingredient. If any component does not meet the criteria, the entire compound will not be covered.

Length of Approval: 12 months for compounds containing only non-controlled substances
6 months for compounds containing at least one controlled substance

• Program Summary: Constipation Agents

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	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				02-01-2017	

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

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Through Preferred	**TARGET AGENT(S)** **Preferred Agent(s)** **Movantik** (naloxegol) **Symproic** (naldemedine)

Module	Clinical Criteria for Approval
	Trulance (plecanatide) **Nonpreferred Agent(s)** **Amitiza** (lubiprostone)* **Ibsrela** (tenapanor) **Linzess** (linaclotide) **Motegrity** (prucalopride) **Relistor** (methylnaltrexone) **Zelnorm** (tegaserod) *-generic available **Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of irritable bowel syndrome with constipation (IBS-C) AND ALL of the following: 1. The patient has had IBS-C symptoms for greater than or equal to 3 months **AND** 2. ONE of the following: A. The requested agent is Trulance (plecanatide), Linzess (linaclotide) OR Ibsrela (tenapanor) **OR** B. The requested agent is Amitiza (lubiprostone) OR Zelnorm (tegaserod) AND ONE of the following: 1. The patient's sex is female **OR** 2. The prescriber has provided information that the requested agent is medically appropriate for the patient's sex and the intended diagnosis **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to at least 2 standard laxative therapy classes (e.g., bulk-forming, stimulant, enema, osmotic, or stool softener) **OR** B. The patient has an intolerance or hypersensitivity to at least 2 standard laxative therapy classes **OR** C. The patient has an FDA labeled contraindication to ALL standard laxative therapy classes **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL standard laxative therapy classes cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has a diagnosis of chronic idiopathic constipation (CIC) AND ALL of the following: 1. The patient has had CIC symptoms for greater than or equal to 3 months **AND** 2. The requested agent is Amitiza (lubiprostone), Linzess (linaclotide), Motegrity (prucalopride), or Trulance (plecanatide) **AND**

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

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

Module	Clinical Criteria for Approval
	5. The prescriber has provided documentation that Symproic (naldemedine) and Movantik (naloxegol) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 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: Factor VIII and von Willebrand Factor

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
851000102521	Advate ; Kovaltry	antihemophilic factor recomb (rahf-pfm) for inj	1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 4000 UNIT; 500 UNIT	Dependent on patient weight and number of doses			
851000104021	Adynovate	antihemophilic factor recomb pegylated for inj	1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 500 UNIT; 750 UNIT	Dependent on patient weight and number of doses			
851000105564	Afstyla	antihemophilic fact rcmb single chain for inj kit	1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 2500 UNIT; 3000 UNIT; 500 UNIT	Dependent on patient weight and number of doses			
851000151021	Alphanate ; Humate-p	antihemophilic factor/vwf (human) for inj	1000 UNIT; 1000-2400 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 250-600 UNIT; 500 UNIT; 500-1200 UNIT	Dependent on patient weight and number of doses			
851000103121	Altuviiio	antihemophilic fact rcmb fc-vwf-xten-ehtl for inj	1000 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 4000 UNIT; 500 UNIT	Dependent on patient weight and number of doses			
851000103021	Eloctate	antihemophilic factor rcmb (bdd-rfviiifc) for inj	1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 4000 UNIT; 500 UNIT; 5000 UNIT; 6000 UNIT; 750 UNIT	Dependent on patient weight and number of doses			
851000103521	Esperoct	antihemophilic factor recomb	1000 UNIT; 1500 UNIT;	Dependent on patient weight and number of doses			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		glycopeg-exei for inj	2000 UNIT; 3000 UNIT; 500 UNIT				
851000100021	Hemofil m ; Koate ; Koate-dvi	antihemophilic factor (human) for inj	1000 UNIT; 1700 UNIT; 250 UNIT; 500 UNIT	Dependent on patient weight and number of doses			
851000104121	Jivi	antihemophil fact rcmb(bdd-rfviii peg-aucl) for inj ; antihemophil fact rcmb(bdd-rfviii peg-aucl)for inj	1000 UNIT; 2000 UNIT; 3000 UNIT; 500 UNIT	Dependent on patient weight and number of doses			
851000102064	Kogenate fs	antihemophilic factor recomb (rfviii) for inj kit	1000 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 500 UNIT	Dependent on patient weight and number of doses			
851000103321	Novoeight	antihemophilic fact rcmb (bd trunc-rfviii) for inj	1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 500 UNIT	Dependent on patient weight and number of doses			
851000102264	Nuwiq	antihemophil fact rcmb (bdd-rfviii,sim) for inj kit ; antihemophil fact rcmb(bdd-rfviii,sim) for inj kit	1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 2500 UNIT; 3000 UNIT; 4000 UNIT; 500 UNIT	Dependent on patient weight and number of doses			
851000102221	Nuwiq	antihemophilic fact rcmb (bdd-rfviii,sim) for inj ; antihemophilic factor rcmb (bdd-rfviii,sim) for inj	1000 UNIT; 1500 UNIT; 2000 UNIT; 250 UNIT; 2500 UNIT; 3000 UNIT; 4000 UNIT; 500 UNIT	Dependent on patient weight and number of doses			
851000102021	Recombinate	antihemophilic factor recomb (rfviii) for inj	1241 -1800 UNIT; 1801 -2400 UNIT; 220 -400 UNIT; 401 -800 UNIT; 801 -1240 UNIT	Dependent on patient weight and number of doses			
851000702021	Vonvendi	von willebrand factor (recombinant) for inj	1300 UNIT; 650 UNIT	Dependent on patient weight and number of doses			
851000151064	Wilate	antihemophilic	1000-1000 UNIT;	Dependent on patient weight and number			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		factor/vwf (human) for inj	500-500 UNIT	of doses			
851000102664	Xyntha ; Xyntha solofuse	antihemophil fact rcmb (bdd-rfviii,mor) for inj kit ; antihemophil fact rcmb(bdd-rfviii,mor) for inj kit	1000 UNIT; 2000 UNIT; 250 UNIT; 3000 UNIT; 500 UNIT	Dependent on patient weight and number of doses			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Effective until 10/31/24 for:** **Those with an original PA date prior to 11/1/23 seeking reauthorization AND that have not started a new plan year** **Preferred and Non-Preferred Agents to be determined by client**

Preferred Agents for Hemophilia A	Non-Preferred Agents for Hemophilia A
Advate Adynovate Afstyla Eloctate Esperoct Jivi Kogenate FS Kovaltry NovoEight Nuwiq Recombinate Vonvendi Wilate Xyntha/Xyntha solofuse Alphanate Altuviiio Hemofil-M Humate-P Koāte	None

Preferred Agents for von Willebrand disease	Non-Preferred Agents for von Willebrand disease
Vonvendi Wilate Alphanate Humate-P	None

Module	Clinical Criteria for Approval

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 hemophilia A (also known as Factor VIII deficiency or classic hemophilia) AND ONE of the following:
      1. The patient is currently experiencing a bleed AND BOTH of the following:
         A. The patient is out of medication **AND**
         B. The patient needs to receive a ONE TIME emergency supply of medication **OR**
      2. BOTH of the following:
         A. The requested agent is being used for ONE of the following:
            1. Prophylaxis AND the patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **OR**
            2. As a component of Immune Tolerance Therapy (ITT)/Immune Tolerance Induction (ITI) AND BOTH of the following:
               A. The patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **AND**
               B. ONE of the following: (medical records required)
                  1. The patient has NOT had more than 33 months of ITT/ITI therapy **OR**
                  2. Information has been provided supporting the continued use of ITT/ITI therapy (i.e., the patient has had a greater than or equal to 20% decrease in inhibitor level over the last 6 months and needs further treatment to eradicate inhibitors) **OR**
            3. On-demand use for bleeds **OR**
            4. Peri-operative management of bleeding **AND**
         B. If the client has a preferred agent(s), then ONE of the following:
            1. The requested agent is a preferred agent **OR**
            2. The patient has tried and had an inadequate response to ALL of the preferred agent(s) for the requested indication **OR**
            3. The patient has an intolerance or hypersensitivity to ALL of the preferred agent(s) for the requested indication **OR**
            4. The patient has an FDA labeled contraindication to ALL preferred agents for the requested indication **OR**
            5. The patient is currently being treated with the requested agent as indicated by ALL of the following:
               A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
               B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
               C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

Module	Clinical Criteria for Approval
	6. The prescriber has provided documentation the preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has a diagnosis of von Willebrand disease (VWD) AND ALL of the following: 1. ONE of the following: A. The patient is currently experiencing a bleed AND BOTH of the following: 1. The patient is out of medication **AND** 2. The patient needs to receive a ONE TIME emergency supply of medication **OR** B. The patient has type 1, 2A, 2M or 2N VWD AND ONE of the following: 1. The patient has tried and had an inadequate response to desmopressin (e.g., DDAVP injection, Stimate nasal spray) **OR** 2. The patient did not respond to a DDAVP trial with 1 and 4 hour post infusion bloodwork **OR** 3. The patient has an intolerance or hypersensitivity to desmopressin **OR** 4. The patient has an FDA labeled contraindication to desmopressin **OR** 5. The prescriber has provided information supporting why the patient cannot use desmopressin (e.g., shortage in marketplace) **OR** 6. 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** 7. The prescriber has provided documentation desmopressin (e.g., DDAVP injection, Stimate nasal spray) 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 type 2B or 3 VWD **AND** 2. The requested agent will be used for ONE of the following: A. Prophylaxis AND ONE of the following: 1. The requested agent is Vonvendi AND ONE of the following: A. The patient has severe Type 3 VWD **OR** B. The patient has another subtype of VWD AND the subtype is FDA approved for prophylaxis use **OR** 2. The requested agent is NOT Vonvendi **OR** B. On-demand use for bleeds **OR** C. Peri-operative management of bleeding **AND** 3. If the client has a preferred agent(s), then ONE of the following: A. The requested agent is a preferred agent **OR** B. The patient has tried and had an inadequate response to ALL of the preferred agent(s) for the requested indication **OR** C. The patient has an intolerance or hypersensitivity to ALL of the preferred agent(s) for the requested indication **OR** D. The patient has an FDA labeled contraindication to ALL preferred agents for the

Module	Clinical Criteria for Approval
	requested indication **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 the preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. If the patient has an FDA approved indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following: A. The patient will NOT be using the requested agent in combination with a nonsteroidal anti-inflammatory agent (NSAID) (e.g., aspirin, ibuprofen) other than cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib) NOTE: for the purposes of this criteria COX-2 inhibitors will be accepted for concomitant use **OR** B. The prescriber has provided information in support of using an NSAID for this patient **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 6. The prescriber must provide the actual prescribed dose with ALL of the following: A. Patient's weight **AND** B. Intended use/regimen: (e.g., prophylaxis, ITT/ITI, on-demand, peri-operative) **AND** C. If the patient has a diagnosis of hemophilia A BOTH of the following: 1. Severity of the factor deficiency (i.e., severe is less than 1% factor activity, moderate is greater than or equal to 1 to less than or equal to 5% factor activity, mild is greater than 5 to 40% factor activity) **AND** 2. Inhibitor status **AND** 7. ONE of the following: A. The patient will NOT be using the requested agent in combination with another agent in the same category (e.g., Factor VIII agents, Factor VIII and von Willebrand Factor combination agents) included in this program **OR** B. Information has been provided supporting the use of more than one unique agent in the same category (medical records required) **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** One time emergency use: up to 2 weeks Peri-operative dosing: 1 time per request On-demand: up to 3 months Prophylaxis: up to 6 months ITT/ITI: up to 6 months NOTE: If Quantity Limit applies, please see Quantity Limit criteria

Module	Clinical Criteria for Approval
	Renewal Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (if current request is for ONE TIME emergency use or if patient ONLY has previous approval(s) for emergency use, must use Initial Evaluation) **AND** 2. If the patient is using the requested agent for prophylaxis, then ONE of the following: A. The patient has a diagnosis of hemophilia A AND the patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **OR** B. The patient has another diagnosis **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following: A. The patient will NOT be using the requested agent in combination with a nonsteroidal anti-inflammatory agent (NSAID) (e.g., aspirin, ibuprofen) other than cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib) NOTE: for the purposes of this criteria COX-2 inhibitors will be accepted for concomitant use **OR** B. The prescriber has provided information in support of using an NSAID for this patient **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 6. The prescriber must provide the actual prescribed dose with ALL of the following: A. Patient's weight **AND** B. Intended use/regimen: (e.g., prophylaxis, ITT/ITI, on-demand, peri-operative) **AND** C. If the patient has a diagnosis of hemophilia A BOTH of the following: 1. Severity of the factor deficiency (i.e., severe is less than 1% factor activity, moderate is greater than or equal to 1 to less than or equal to 5% factor activity, mild is greater than 5 to 40% factor activity) **AND** 2. Inhibitor status **AND** 7. ONE of the following: A. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have greater than 5 on-demand doses on hand **OR** B. The prescriber has provided information in support of the patient having more than 5 on-demand doses on hand **AND** 8. ONE of the following: A. The patient will NOT be using the requested agent in combination with another agent in the same category (e.g., Factor VIII agents, Factor VIII and von Willebrand Factor combination agents) included in this program **OR** B. Information has been provided supporting the use of more than one unique agent in the same category (medical records required) **AND** 9. If the patient is using Immune Tolerance Therapy (ITT)/Immune Tolerance Induction (ITI), then ONE of the following: A. The patient has NOT had more than 33 months of ITT/ITI therapy **OR** B. Information has been provided supporting the continued use of ITT/ITI therapy (i.e., the patient has had a greater than or equal to 20% decrease in inhibitor level over the last 6 months and needs further treatment to eradicate inhibitors) (medical records required) **Length of Approval:** Peri-operative: 1 time per request On-demand: up to 3 months Prophylaxis: up to 12 months ITT/ITI: up to 6 months, or up to a total of 33 months of ITT/ITI therapy, or requested duration, whichever is shortest

Module	Clinical Criteria for Approval

NOTE: If Quantity Limit applies, please see Quantity Limit criteria

Initial Evaluation

Effective 11/1/23 for:
Those who were approved through criteria after 11/1/23
Those who have started a new plan year since last authorization

Preferred and Non-Preferred Agents to be determined by client

Preferred Agents for Hemophilia A	Non-Preferred Agents for Hemophilia A
Advate Adynovate Afstyla Eloctate Esperoct Jivi Kogenate FS Kovaltry NovoEight Nuwiq Recombinate Vonvendi Wilate Xyntha/Xyntha solofuse Alphanate Altuviiio Hemofil-M Humate-P Koāte	None

Preferred Agents for von Willebrand disease	Non-Preferred Agents for von Willebrand disease
Vonvendi Wilate Alphanate Humate-P	None

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 hemophilia A (also known as Factor VIII deficiency or classic hemophilia) AND ONE of the following:

Module	Clinical Criteria for Approval
	1. The patient is currently experiencing a bleed AND BOTH of the following: A. The patient is out of medication **AND** B. The patient needs to receive a ONE TIME emergency supply of medication **OR** 2. Both ALL of the following: A. The requested agent is FDA approved or compendia supported for a diagnosis of hemophilia A **AND** B. The requested agent is being used for ONE of the following: 1. Prophylaxis AND the patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **OR** 2. As a component of Immune Tolerance Therapy (ITT)/Immune Tolerance Induction (ITI) AND BOTH of the following: A. The patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **AND** B. ONE of the following: (medical records required) 1. The patient has NOT had more than 33 months of ITT/ITI therapy **OR** 2. Information has been provided supporting the continued use of ITT/ITI therapy (i.e., the patient has had a greater than or equal to 20% decrease in inhibitor level over the last 6 months and needs further treatment to eradicate inhibitors) **OR** 3. On-demand use for bleeds **OR** 4. Peri-operative management of bleeding **AND** C. If the client has a preferred agent(s), then ONE of the following: 1. The requested agent is a preferred agent **OR** 2. The patient has tried and had an inadequate response to ALL of the preferred agent(s) for the requested indication **OR** 3. The patient has an intolerance or hypersensitivity to ALL of the preferred agent(s) for the requested indication **OR** 4. The patient has an FDA labeled contraindication to ALL preferred agents for the requested indication **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 the preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has a diagnosis of von Willebrand disease (VWD) AND ALL of the following: 1. The requested agent is FDA approved or compendia supported for a diagnosis of von Willebrand disease **AND** 2. ONE of the following: A. The patient is currently experiencing a bleed AND BOTH of the following:

Module	Clinical Criteria for Approval
	1. The patient is out of medication **AND** 2. The patient needs to receive a ONE TIME emergency supply of medication **OR** B. The patient has type 1, 2A, 2M or 2N VWD AND ONE of the following: 1. The patient has tried and had an inadequate response to desmopressin (e.g., DDAVP injection, Stimate nasal spray) **OR** 2. The patient did not respond to a DDAVP trial with 1 and 4 hour post infusion bloodwork **OR** 3. The patient has an intolerance or hypersensitivity to desmopressin **OR** 4. The patient has an FDA labeled contraindication to desmopressin **OR** 5. The prescriber has provided information supporting why the patient cannot use desmopressin (e.g., shortage in marketplace) **OR** 6. 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** 7. The prescriber has provided documentation desmopressin (e.g., DDAVP injection, Stimate nasal spray) 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 type 2B or 3 VWD **AND** 3. The requested agent will be used for ONE of the following: A. Prophylaxis AND ONE of the following: 1. The requested agent is Vonvendi AND ONE of the following: A. The patient has severe Type 3 VWD **OR** B. The patient has another subtype of VWD AND the subtype is FDA approved for prophylaxis use **OR** 2. The requested agent is NOT Vonvendi **OR** B. On-demand use for bleeds **OR** C. Peri-operative management of bleeding **AND** 4. If the client has a preferred agent(s), then ONE of the following: A. The requested agent is a preferred agent **OR** B. The patient has tried and had an inadequate response to ALL of the preferred agent(s) for the requested indication **OR** C. The patient has an intolerance or hypersensitivity to ALL of the preferred agent(s) for the requested indication **OR** D. The patient has an FDA labeled contraindication to ALL preferred agents for the requested indication **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

Module	Clinical Criteria for Approval
	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 the preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. If the patient has an FDA approved indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following: A. The patient will NOT be using the requested agent in combination with a nonsteroidal anti-inflammatory agent (NSAID) (e.g., aspirin, ibuprofen) other than cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib) NOTE: for the purposes of this criteria COX-2 inhibitors will be accepted for concomitant use **OR** B. The prescriber has provided information in support of using an NSAID for this patient **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 6. The prescriber must provide the actual prescribed dose with ALL of the following: A. Patient's weight **AND** B. Intended use/regimen: (e.g., prophylaxis, ITT/ITI, on-demand, peri-operative) **AND** C. If the patient has a diagnosis of hemophilia A BOTH of the following: 1. Severity of the factor deficiency (i.e., severe is less than 1% factor activity, moderate is greater than or equal to 1 to less than or equal to 5% factor activity, mild is greater than 5 to 40% factor activity) **AND** 2. Inhibitor status **AND** 7. ONE of the following: A. The patient will NOT be using the requested agent in combination with another agent in the same category (e.g., Factor VIII agents, Factor VIII and von Willebrand Factor combination agents) included in this program **OR** B. Information has been provided supporting the use of more than one unique agent in the same category (medical records required) **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** One time emergency use: up to 2 weeks Peri-operative dosing: 1 time per request On-demand: up to 3 months Prophylaxis: up to 6 months ITT/ITI: up to 6 months NOTE: If Quantity Limit applies, please see Quantity Limit criteria **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (if current request is for ONE TIME emergency use or if patient ONLY has previous approval(s) for emergency use, must use Initial Evaluation) **AND** 2. If the patient is using the requested agent for prophylaxis, then ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient has a diagnosis of hemophilia A AND the patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **OR** B. The patient has another diagnosis **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following: A. The patient will NOT be using the requested agent in combination with a nonsteroidal anti-inflammatory agent (NSAID) (e.g., aspirin, ibuprofen) other than cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib) NOTE: for the purposes of this criteria COX-2 inhibitors will be accepted for concomitant use **OR** B. The prescriber has provided information in support of using an NSAID for this patient **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 6. The prescriber must provide the actual prescribed dose with ALL of the following: A. Patient's weight **AND** B. Intended use/regimen: (e.g., prophylaxis, ITT/ITI, on-demand, peri-operative) **AND** C. If the patient has a diagnosis of hemophilia A BOTH of the following: 1. Severity of the factor deficiency (i.e., severe is less than 1% factor activity, moderate is greater than or equal to 1 to less than or equal to 5% factor activity, mild is greater than 5 to 40% factor activity) **AND** 2. Inhibitor status **AND** 7. ONE of the following: A. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have greater than 5 on-demand doses on hand **OR** B. The prescriber has provided information in support of the patient having more than 5 on-demand doses on hand **AND** 8. ONE of the following: A. The patient will NOT be using the requested agent in combination with another agent in the same category (e.g., Factor VIII agents, Factor VIII and von Willebrand Factor combination agents) included in this program **OR** B. Information has been provided supporting the use of more than one unique agent in the same category (medical records required) **AND** 9. If the patient is using Immune Tolerance Therapy (ITT)/Immune Tolerance Induction (ITI), then ONE of the following: A. The patient has NOT had more than 33 months of ITT/ITI therapy **OR** B. Information has been provided supporting the continued use of ITT/ITI therapy (i.e., the patient has had a greater than or equal to 20% decrease in inhibitor level over the last 6 months and needs further treatment to eradicate inhibitors) (medical records required) **Length of Approval:** Peri-operative: 1 time per request On-demand: up to 3 months Prophylaxis: up to 12 months ITT/ITI: up to 6 months, or up to a total of 33 months of ITT/ITI therapy, or requested duration, whichever is shortest NOTE: If Quantity Limit applies, please see Quantity Limit criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

Module	Clinical Criteria for Approval
	the following: A. The requested dose is within the FDA labeled dosing **AND** B. The requested quantity (number of doses) is appropriate based on intended use (e.g., prophylaxis, ITT/ITI, on-demand, peri-operative) **OR** 2. The prescriber has provided clinical reasoning for exceeding the defined program quantity limit (dose and/or number of doses) (medical records required) **Length of Approval:** Peri-operative: 1 time per request; On-demand: up to 3 months; Prophylaxis: up to 12 months; ITT/ITI: up to 6 months, or up to a total of 33 months of ITT/ITI therapy, or requested duration, whichever is shortest

• Program Summary: Furoscix (furosemide)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	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** 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**

Module	Clinical Criteria for Approval
	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: Gattex (teduglutide)

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

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	525330700064	Gattex	teduglutide (rdna) for inj kit	5 MG	M; N; O; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of short bowel syndrome (SBS) and ALL of the following: 1. The patient has less than 200 cm of functional small intestine **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to maximal use of TWO anti-diarrheal agents (e.g., loperamide, diphenoxylate) used concomitantly with oral rehydration solution **OR** B. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** C. The prescriber has provided documentation that anti-diarrheal agents (e.g. loperamide, diphenoxylate) used concomitantly with oral rehydration solution cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The patient is currently receiving parenteral nutrition/intravenous fluids (PN/IV) at least 3 days per week **AND** 4. ONE of the following: A. The patient is a pediatric patient at least 1 year of age AND BOTH of the following: 1. A fecal occult blood test has been performed within 6 months prior to initiating treatment with the requested agent **AND** 2. ONE of the following: A. There was no unexplained blood in the stool **OR** B. There was unexplained blood in the stool AND a colonoscopy or a sigmoidoscopy was performed **OR** B. The patient is an adult AND BOTH of the following: 1. The patient has had a colonoscopy within 6 months of initiating treatment with the requested agent **AND** 2. If polyps were present at this colonoscopy, the polyps were removed **OR** B. The patient has another FDA approved indication for the requested agent **AND**

Module	Clinical Criteria for Approval
	2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication **Length of Approval:** 6 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. 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., gastroenterologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. If the patient is using parenteral nutrition/intravenous fluids (PN/IV), the patient has had at least a 20% reduction in PN/IV fluids from baseline prior to therapy with the requested agent **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 6. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication **Length of Approval:** 12 months

● Program Summary Gonadotropin Hormones

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

TARGET AGENT(S)

Preferred Agents	Non-Preferred Agents
Follistim AQ® (follitropin beta)	Gonal-F® Kit (follitropin alfa) Gonal-F® RFF (follitropin alfa) Gonal-F® RFF Pen (follitropin alfa)
Ovidrel® (choriogonadotropin alfa) Pregnyl® (chorionic gonadotropin) (50090-5923-**, 00052-0315-**)	Chorionic gonadotropin (63323-0030-**) Novarel® (chorionic gonadotropin) (55566-1501-**, 55566-1502-**)
Ganirelix Acetate[a]	Cetrotide® (cetrorelix acetate)
Menopur® (menotropin)	NA

[a] Generic available and included as preferred in this program

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
Cetrotide (cetrorelix acetate) injection[a]			
0.25 mg kit	30090025106420	M, N, O, or Y	5 kits per 30 days
Follistim AQ (follitropin beta) injection			
300 unit/0.36 mL cartridge	30062030102020	M, N, O, or Y	6.3 mL (15 cartridges) per 30 days
600 unit/0.72 mL cartridge	30062030102030	M, N, O, or Y	6.24 mL (8 cartridges) per 30 days
900 unit/1.08 mL cartridge	30062030102040	M, N, O, or Y	5.85 mL (5 cartridges) per 30 days
Ganirelix Acetate injection[a]			
250 mcg/0.5 mL prefilled syringe	3009004010E520	M, N, O, or Y	2.5 mL (5 syringes) per 30 days
Gonal-F (follitropin alfa) injection			
75 unit RFF pre-filled syringe	30062030052115	M, N, O, or Y	20 syringes per 30 days
300 unit/0.5 mL Rediject multi-dose delivery system	3006203005D220	M, N, O, or Y	7.5 mL (15 pens) per 30 days
450 unit/0.75 mL Rediject multi-dose delivery system	3006203005D225	M, N, O, or Y	7.5 mL (10 pens) per 30 days
450 unit multi-dose pre-filled syringe multi-dose delivery system	30062030052140	M, N, O. or Y	10 syringes per 30 days
900 unit/1.5 mL Rediject multi-dose delivery system	3006203005D240	M, N, O, or Y	7.5 mL (5 pens) per 30 days
1050 unit multi-dose pre-filled syringe	30062030052150	M, N, O, or Y	4 syringes per 30 days
Menopur (menotropins) injection			
75 unit vial	30062050002175	M, N, O, or Y	60 vials per 30 days
Novarel (chorionic gonadotropin) injection			
5,000 unit vial	30062020002130	M, N, O, or Y	4 vials per 30 days
10,000 unit vial	30062020002140	M, N, O, or Y	2 vials per 30 days
Ovidrel (choriogonadotropin alfa) injection			
250 mcg/0.5 mL pre-filled syringe	30062022052220	M, N, O, or Y	1 mL (2 syringes) per 30 days
Pregnyl (chorionic gonadotropin) injection			
10,000 unit multi-dose vial[a]	30062020002140	M, N, O, or Y	2 vials per 30 days

[a] generic available

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Follicle Stimulating Hormone Evaluation

Follistim AQ and Gonal-F will be approved when ALL of the following are met:

1. The patient's benefit plan covers agents for infertility
   AND
2. ONE of the following:
   A. The requested agent will be used for ovulation induction AND ONE of the following:
      i. 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

      a. Information has been provided that indicates the patient has been treated with the requested agent within the past 90 days
         OR

b. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed

OR

ii. ALL of the following:
   a. ONE of the following:
      1. The patient has tried and had an inadequate response to clomiphene citrate
         OR
      2. The patient has an intolerance or hypersensitivity to clomiphene citrate
         OR
      3. The patient has an FDA labeled contraindication to clomiphene citrate
         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 clomiphene citrate 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 is NOT pregnant
      AND
   c. The patient does NOT have primary ovarian failure
      AND
   d. The patient will receive human chorionic gonadotropin (hCG) following completion of the requested agent unless there are risks present for ovarian hyperstimulation syndrome (OHSS)
      AND
   e. ONE of the following:
      1. The requested agent is a preferred agent
         OR
      2. The patient has tried and had an inadequate response to ONE of the preferred agent(s)
         OR
      3. The patient has an intolerance or hypersensitivity to ONE of the preferred agent(s) that is NOT expected to occur with the requested agent
         OR
      4. The patient has an FDA labeled contraindication to ALL of the preferred agent(s) 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 ALL of the preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

OR

B. The requested agent will be used for the development of multiple follicles as part of an assisted reproductive technology (ART) [e.g., invitro fertilization (IVF), gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), tubal embryo transfer (TET), cryopreservation, intracytoplasmic sperm injection (ICSI)] AND ONE of the following:

i. 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

a. Information has been provided that indicates the patient has been treated with the requested agent within the past 90 days

OR

b. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed

OR

ii. ALL of the following:

a. The patient is NOT pregnant

AND

b. The patient does NOT have primary ovarian failure

AND

c. The patient will receive human chorionic gonadotropin (hCG) following completion of the requested agent unless there are risks present for ovarian hyperstimulation syndrome (OHSS)

AND

d. ONE of the following:

1. The requested agent is a preferred agent

OR

2. The patient has tried and had an inadequate response to ONE of the preferred agent(s)

OR

3. The patient has an intolerance or hypersensitivity to ONE of the preferred agent(s) that is NOT expected to occur with the requested agent

OR

4. The patient has an FDA labeled contraindication to ALL of the preferred agent(s) 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 ALL of the preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

OR

C. The requested agent will be used for hypogonadotropic hypogonadism AND ALL of the following:
   i. The requested agent is Follistim AQ or Gonal-F
   AND
   ii. The patient does not have primary testicular failure
   AND
   iii. The requested agent will be used in combination with human chorionic gonadotropin (hCG)
   AND
   iv. The requested agent will not be started until the patient's serum testosterone level is at normal levels
   AND
   v. ONE of the following:
      a. The requested agent is a preferred agent
      OR
      b. The patient has tried and had an inadequate response to ONE of the preferred agent(s)
      OR
      c. The patient has an intolerance or hypersensitivity to ONE of the preferred agent(s) that is NOT expected to occur with the requested agent
      OR
      d. The patient has an FDA labeled contraindication to ALL of the preferred agent(s) 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 ALL of the preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

AND

3. The patient has undergone a complete medical and endocrinologic evaluation
AND
4. The fertility status of the patient's partner has been evaluated (if applicable)
AND
5. The patient does NOT have any FDA labeled contraindications to the requested agent
AND
6. ONE of the following:
   A. The requested quantity (dose) does NOT exceed the program quantity limit
   OR
   B. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
      AND

ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
AND
iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

OR

C. ALL of the following:
i. The requested quantity (dose) is greater than the program quantity limit
AND
ii. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
AND
iii. The prescriber has provided information in support of therapy with a higher dose for the requested indication

Length of Approval: 3 months for ART or ovulation induction
6 months for hypogonadotropic hypogonadism

Human Chorionic Gonadotropin Evaluation
Novarel, Ovidrel, Pregnyl, or **Chorionic Gonadotropin** will be approved when ALL of the following are met:

1. ONE of the following:
A. The requested agent will be used for a diagnosis of cryptorchidism AND ALL of the following:
i. The requested agent is Novarel, Pregnyl, or hCG
AND
ii. The diagnosis is not due to an anatomical obstruction
AND
iii. The patient is prepubertal
AND
iv. ONE of the following:
a. The patient has had surgery to correct the cryptorchidism
OR
b. The patient will have surgery to correct the cryptorchidism after using the requested agent
OR
c. The patient is unable to have surgery to correct the cryptorchidism

OR

B. The requested agent will be used for a diagnosis of hypogonadotropic hypogonadism AND BOTH of the following:
i. The requested agent is Novarel, Pregnyl, or hCG
AND
ii. ONE of the following:
a. The patient is not currently receiving treatment for the diagnosis AND has ONE of the following pretreatment levels:
1. Total serum testosterone level that is below the testing laboratory's normal range or is less than 300 ng/dL
OR
2. Free serum testosterone level that is below the testing laboratory's normal range

OR

b. The patient is currently receiving treatment for the diagnosis AND has ONE of the following current levels:
1. Total serum testosterone level that is within OR below the testing laboratory's normal range OR is less than 300 ng/dL
OR
2. Free serum testosterone level is within OR below the testing laboratory's normal range

OR

C. The requested agent will be used for the development of multiple follicles as part of an assisted reproductive technology (ART) [e.g., invitro fertilization (IVF), gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), tubal embryo transfer (TET), cryopreservation, intracytoplasmic sperm injection (ICSI)] OR for ovulation induction AND BOTH of the following:
   i. The patient's benefit plan covers agents for infertility
   AND
   ii. 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
Ovidrel (chorionic gonadotropin)
Pregnyl (chorionic gonadotropin)

         1. Information has been provided that indicates the patient has been treated with the requested agent within the past 90 days
         OR
         2. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed

      OR

      b. ALL of the following:
         1. The patient is NOT pregnant
         AND
         2. The patient does NOT have primary ovarian failure
         AND
         3. The patient will receive follicle stimulating hormone (FSH) OR clomiphene before the requested agent unless there are risks present for ovarian hyperstimulation syndrome (OHSS)
         AND
         4. The patient has undergone a complete medical and endocrinologic evaluation
         AND
         5. The fertility status of the patient's partner has been evaluated (if applicable)
         AND
         6. ONE of the following:
            A. The requested agent is a preferred agent
            OR
            B. The patient has tried and had an inadequate response to ONE of the preferred agent(s)
            OR
            C. The patient has an intolerance or hypersensitivity to ONE preferred agent(s) that is NOT expected to occur with the requested agent
            OR
            D. The patient has an FDA labeled contraindication to ALL of the preferred agent(s) 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:
               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

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

AND

2. The patient does NOT have any FDA labeled contraindications to the requested agent
   AND
3. ONE of the following:
   A. The requested quantity (dose) does NOT exceed the program quantity limit
      OR
   B. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
         AND
      ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
         AND
      iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
      OR
   C. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
         AND
      ii. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
         AND
      iii. The prescriber has provided information in support of therapy with a higher dose for the requested indication

Length of Approval: 3 months for ovulation induction or ART
6 months for hypogonadotropic hypogonadism
3 months for cryptorchidism

Gonadotropin Releasing Hormone (GnRH) Analogs Evaluation

Cetrotide or **Ganirelix acetate** will be approved when ALL of the following are met:

1. The patient's benefit plan covers agents for infertility
   AND
2. 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 the requested agent within the past 90 days
         OR
      ii. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed
      OR
   B. ALL of the following:
      i. The patient is undergoing ovarian stimulation
         AND
      ii. The patient is NOT pregnant
         AND
      iii. The patient has undergone a complete medical and endocrinologic evaluation

AND

iv. The fertility status of the patient's partner has been evaluated (if applicable)
AND

v. The patient will receive human chorionic gonadotropin (hCG) following completion of the requested agent unless there are risks present for ovarian hyper-stimulation syndrome (OHSS)
AND

vi. ONE of the following:
   a. The requested agent is a preferred agent
   OR
   b. The patient has tried and had an inadequate response to ONE of the preferred agent(s)
   OR
   c. The patient has an intolerance or hypersensitivity to ONE of the preferred agent(s) that is NOT expected to occur with the requested agent
   OR
   d. The patient has an FDA labeled contraindication to ALL of the preferred agent(s) 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 ALL of the preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

AND

3. The patient does NOT have any FDA labeled contraindications to the requested agent
AND
4. ONE of the following:
   A. The requested quantity (dose) does NOT exceed the program quantity limit
   OR
   B. ALL of the following:
      i. The requested quantity (dose) is greater than the program limit
      AND
      ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
      AND
      iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

   OR
   C. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
      AND
      ii. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
      AND
      iii. The prescriber has provided information in support of therapy with a higher dose for the requested indication

Length of Approval: 3 months

Menotropins

Menopur will be approved when ALL of the following are met:

1. The patient's benefit plan covers agents for infertility
   AND
2. 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 the requested agent within the past 90 days
      OR
      ii. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed

   OR

   B. ALL of the following:
      i. The requested agent will be used for the development of multiple follicles as part of an assisted reproductive technology (ART) [e.g., invitro fertilization (IVF), gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), tubal embryo transfer (TET), cryopreservation, intracytoplasmic sperm injection (ICSI)
      AND
      ii. The patient is NOT pregnant
      AND
      iii. The patient does NOT have primary ovarian failure
      AND
      iv. The patient will receive human chorionic gonadotropin (hCG) following completion of the requested agent unless there are risks present for ovarian hyperstimulation syndrome (OHSS)
      AND
      v. The patient has undergone a complete medical and endocrinologic evaluation
      AND
      vi. The fertility status of the patient's partner has been evaluated (if applicable)

   AND
3. The patient does NOT have any FDA labeled contraindications to the requested agent
   AND
4. ONE of the following:
   A. The requested quantity (dose) does NOT exceed the program quantity limit
   OR
   B. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
      AND
      ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
      AND
      iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

   OR

   C. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
      AND
      ii. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication

AND

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

Length of Approval: 3 months

● Program Summary: Hepatitis C Direct Acting Antivirals

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

Hepatitis C Direct Acting Antivirals Prior Authorization with Quantity Limit – Through Preferred Oral Agent(s)

TARGET AGENT(S)

Preferred Agent(s)a,c	Non-Preferred Agent(s)c,d
Genotype 1 **Epclusa**® (sofosbuvir/velpatasvir) **Harvoni**® (ledipasvir/sofosbuvir) **Ledipasvir/Sofosbuvir** **Sofosbuvir/Velpatasvir** **Mavyret**® (glecaprevir/pibrentasvir) **Vosevi**® (sofosbuvir/velpatasvir/voxilaprevir)	**Genotype 1** **Sovaldi**® (sofosbuvir)b **Viekira PAK**® (ombitasvir/paritaprevir/ritonavir + dasabuvir) **Zepatier**® (elbasvir/grazoprevir)
Genotype 2 **Epclusa**® (sofosbuvir/velpatasvir) **Sofosbuvir/Velpatasvir** **Mavyret**® (glecaprevir/pibrentasvir) **Vosevi**® (sofosbuvir/velpatasvir/voxilaprevir)	**Genotype 2** **Sovaldi**® (sofosbuvir)b
Genotype 3 **Epclusa**® (sofosbuvir/velpatasvir) **Sofosbuvir/Velpatasvir** **Mavyret**® (glecaprevir/pibrentasvir) **Vosevi**® (sofosbuvir/velpatasvir/voxilaprevir)	**Genotype 3** **Sovaldi**® (sofosbuvir)b
Genotype 4 **Epclusa**® (sofosbuvir/velpatasvir) **Harvoni**® (ledipasvir/sofosbuvir) **Ledipasvir/Sofosbuvir** **Sofosbuvir/Velpatasvir** **Mavyret**® (glecaprevir/pibrentasvir) **Vosevi**® (sofosbuvir/velpatasvir/voxilaprevir)	**Genotype 4** **Sovaldi**® (sofosbuvir)b **Zepatier**® (elbasvir/grazoprevir)
Genotype 5 **Epclusa**® (sofosbuvir/velpatasvir) **Harvoni**® (ledipasvir/sofosbuvir) **Ledipasvir/Sofosbuvir** **Sofosbuvir/Velpatasvir** **Mavyret**® (glecaprevir/pibrentasvir) **Vosevi**® (sofosbuvir/velpatasvir/voxilaprevir)	**Genotype 5**
Genotype 6	**Genotype 6**

Epclusa® (sofosbuvir/velpatasvir) **Harvoni**® (ledipasvir/sofosbuvir) **Ledipasvir/Sofosbuvir** **Sofosbuvir/Velpatasvir** **Mavyret**® (glecaprevir/pibrentasvir) **Vosevi**® (sofosbuvir/velpatasvir/voxilaprevir)	

a - Preferred agents will require prior authorization. The prior authorization for a specific agent will be based the Food and Drug Administration (FDA) approved product labeling for the patient's specific factors (e.g., age, genotype, cirrhosis status, treatment naïve vs. experienced, previous treatment)

b - Sovaldi is non-preferred for patients without hepatocellular carcinoma.

c – HCV/HIV-1 co-infection, follow recommendations in table above

d – Offer only those preferred agents that are indicated for the patient's specific factors (e.g., age, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment)

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
Epclusa (sofosbuvir/velpatasvir)			
150 mg sofosbuvir/37.5 mg velpatasvir packet with oral pellets	12359902653020	M, N, O, or Y	1 packet
200 mg sofosbuvir/50 mg packet with oral pellets	12359902653030	M, N, O, or Y	1 packet
200 mg sofosbuvir/50 mg velpatasvir tablets	12359902650320	M. N, O, or Y	1 tablet
400 mg sofosbuvir/100 mg velpatasvir tablets	12359902650330	M, N, O, or Y	1 tablet
Harvoni (ledipasvir/sofosbuvir)			
33.75 mg/150 mg packet with oral pellets	12359902403006	M, N, O, or Y	1 packet
45 mg/200 mg tablets	12359902400310	M, N, O, or Y	1 tablet
45 mg/200 mg packet with oral pellets	12359902403010	M, N, O, or Y	1 packet
90 mg ledipasvir/ 400 mg sofosbuvir tablets	12359902400320	M, N, O, or Y	1 tablet
Ledipasvir/sofosbuvir			
90 mg ledipasvir/ 400 mg sofosbuvir tablets	12359902400320	M, N, O, or Y	1 tablet
Mavyret (glecaprevir/pibrentasvir)			
50 mg glecaprevir/20 mg pibrentasvir packets	12359902353020	M, N, O, or Y	5 packets
100 mg glecaprevir/40 mg pibrentasvir tablets	12359902350320	M, N, O, or Y	3 tablets
Sofosbuvir/velpatasvir			
400 mg sofosbuvir/ 100 mg velpatasvir tablets	12359902650330	M, N, O, or Y	1 tablet
Sovaldi (sofosbuvir)			
150 mg packet with oral pellets	12353080003015	M, N, O, or Y	1 packet
200 mg tablets	12353080000310	M, N, O, or Y	1 tablet
200 mg packet with oral pellets	12353080003020	M, N, O, or Y	1 packet
400 mg tablets	12353080000320	M, N, O, or Y	1 tablet
Viekira PAK (ombitasvir/paritaprevir/ritonavir + dasabuvir)			
12.5/75/50 mg ombitasvir/ paritaprevir/ritonavir + 250 mg dasabuvir tablets	1235990460B720	M, N, O, or Y	1 pack (112 tablets)/28 days
Vosevi (sofosbuvir/velpatasvir/voxilaprevir)			
400 mg sofosbuvir/100 mg velpatasvir/100 mg voxilaprevir tablets	12359903800330	M, N, O, or Y	1 tablet
Zepatier (elbasvir/grazoprevir)			
50 mg elbasvir/100 mg grazoprevir tablets	12359902300320	M, N, O, or Y	1 tablet

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Epclusa and Sofosbuvir/Velpatasvir Evaluation

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

1. ONE of the following is met:
    A. There is documentation that the patient is currently using the requested agent in the past 30 days
    OR
    B. The patient is new to therapy and ALL of the below:
        i. The patient has a diagnosis of hepatitis C genotype 1, 2, 3, 4, 5, or 6
        AND
        ii. ONE of the following:
            a. The patient is treatment naïve
            OR
            b. The patient was previously treated (i.e., treatment experienced) with ONLY peg-interferon and ribavirin with or without an HCV protease inhibitor
            OR
            c. The patient has decompensated cirrhosis
        AND
        iii. 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 supporting the use of the requested agent for the patient's age for the requested indication
        AND
        iv. The prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection
        AND
        v. If the screening for HBV was positive for current or prior HBV infection, the prescriber will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent
        AND
        vi. ONE of the following:
            a. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist, or infectious disease) or has consulted with a specialist in the area of the patient's diagnosis
            OR
            b. ALL of the following:
                1. The patient is treatment is treatment naïve
                AND
                2. The patient does NOT have cirrhosis or has compensated cirrhosis
                AND
                3. The requested agent is supported in AASLD guidelines for simplified treatment
                AND
                4. The patient meets all of the qualifications for AASLD guidelines simplified treatment (please see Patient Who Qualify for simplified Treatment tables below)
                AND

Patients Without Cirrhosis Who Qualify for Simplified Treatment
• Hepatitis B surface antigen (HBsAg) negative • NOT currently pregnant • No known or suspected hepatocellular carcinoma • No prior liver transplantation
Patients With Compensated Cirrhosis Who Qualify for Simplified Treatment
• Patient has NOT had current or prior episode of decompensated cirrhosis, defined as Child-Turcotte-Pugh (CTP) score greater than or equal to 7 (ascites, hepatic encephalopathy, total bilirubin greater than 2.0 mg/dL, albumin less than or equal to 3.5 g/dL, or INR greater than or equal to 1.7) • Does NOT have end-stage renal disease (i.e., eGFR less than 30 mL/min/m^2) • HBsAg negative • NOT currently pregnant • No known or suspected hepatocellular carcinoma • No prior liver transplantation

2. The patient does NOT have any FDA labeled contraindications to the requested agent
   AND
3. The patient meets all requirements and will use the requested agent in a treatment regimen noted in Table 1 (FDA labeling) or 2 (AASLD/IDSA guidelines for decompensated cirrhosis)
   AND
4. BOTH of the following:
   A. The requested length of therapy does NOT exceed the length of therapy noted in Table 1 (FDA labeling) or 2 (AASLD/IDSA guidelines for decompensated cirrhosis) for the patient's treatment regimen
      AND
   B. ONE of the following:
      i. The requested quantity (dose) does NOT exceed the program quantity limit
         OR
      ii. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following:
         a. The requested agent is Epclusa 200 mg/50 mg packets AND BOTH of the following:
            1. The requested quantity (dose) does NOT exceed 2 packets per day
               AND
            2. The prescriber has provided information supporting why the patient cannot take 1 tablet of the 400 mg/100 mg tablet
               OR
         b. The requested agent is Epclusa 200 mg/50 mg tablet AND BOTH of the following:
            1. The requested quantity (dose) does NOT exceed 2 tablets per day
               AND
            2. The prescriber has provided information supporting why the patient cannot take 1 tablet of the 400 mg/100mg tablet

Length of Approval: Up to the duration of treatment as determined in Tables 1 or 2

Table 1: Epclusa or Sofosbuvir/Velpatasvir Treatment Recommendations based on FDA labeling

Genotype	Patients 3 years of age and older*	Treatment	Duration
1, 2, 3, 4, 5, or 6	Patients without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh A)	Epclusa, Sofosbuvir/Velpatasvir	12 weeks
	Patients with decompensated cirrhosis (Child-Turcotte-Pugh B and C)	Epclusa + ribavirin, Sofosbuvir/Velpatasvir + ribavirin	12 weeks

* HCV/HIV-1 co-infection, follow recommendation in table above

Table 2: Epclusa or Sofosbuvir/Velpatasvir Decompensated Cirrhosis Treatment Recommendations based on AASLD/IDSA Guidelines for unique populations

Genotype	Patient Population*	Treatment	Duration
1, 2, 3, 4, 5, or 6	Patients with decompensated cirrhosis (Child-Turcotte-Pugh B and C) who are ribavirin ineligible (i.e., patients with history of intolerance, contraindication, or hypersensitivity to ribavirin)	Epclusa, Sofosbuvir/Velpatasvir	24 weeks
1, 2, 3, 4, 5, or 6	Patients with decompensated cirrhosis (Child-Turcotte-Pugh B and C) in whom prior sofosbuvir- or NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir,	Epclusa with weight-based ribavirin (low initial dose of ribavirin [600 mg] is recommended for patients with Child-Turcotte-Pugh class C cirrhosis), Sofosbuvir/Velpatasvir	24 weeks

	velpatasvir) -based treatment failed	with weight-based ribavirin (low initial dose of ribavirin [600 mg] is recommended for patients with Child-Turcotte-Pugh class C cirrhosis)	

* HCV/HIV-1 co-infection, follow recommendations in table above

Harvoni and Ledipasvir/Sofosbuvir Evaluation

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

1. ONE of the following is met:
    A. There is documentation that the patient is currently using the requested agent in the past 30 days
    OR
    B. The patient is new to therapy and ALL of the below:
        i. The patient has a diagnosis of hepatitis C genotype 1, 4, 5, or 6
        AND
        ii. The prescriber has provided the patient's baseline HCV RNA level if the patient has genotype 1
        AND
        iii. ONE of the following:
            a. The patient is treatment naïve
            OR
            b. The patient was previously treated (i.e., treatment experienced) with peg-interferon and ribavirin with or without an HCV protease inhibitor
            OR
            c. The patient has decompensated cirrhosis
            AND
        iv. The prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection
        AND
        v. If the screening for HBV was positive for current or prior HBV infection, the prescriber will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent
        AND
        vi. 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
        vii. ONE of the following:
            a. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist, or infectious disease) or has consulted with a specialist in the area of the patient's diagnosis **OR**
            b. ALL of the following:
                1. The patient is treatment is treatment naïve
                AND
                2. The patient does NOT have cirrhosis or has compensated cirrhosis
                AND
                3. The requested agent is supported in AASLD guidelines for simplified treatment
                AND
                4. The patient meets all of the qualifications for AASLD guidelines simplified treatment (please see Patient Who Qualify for simplified Treatment tables below)
                AND

Patients Without Cirrhosis Who Qualify for Simplified Treatment
• Hepatitis B surface antigen (HBsAg) negative
• NOT currently pregnant
• No known or suspected hepatocellular carcinoma

• No prior liver transplantation
Patients With Compensated Cirrhosis Who Qualify for Simplified Treatment
• Patient has NOT had current or prior episode of decompensated cirrhosis, defined as Child-Turcotte-Pugh (CTP) score greater than or equal to 7 (ascites, hepatic encephalopathy, total bilirubin greater than 2.0 mg/dL, albumin less than or equal to 3.5 g/dL, or INR greater than or equal to 1.7) • Does NOT have end-stage renal disease (i.e., eGFR less than 30 mL/min/m^2) • HBsAg negative • NOT currently pregnant • No known or suspected hepatocellular carcinoma • No prior liver transplantation

2. The patient does NOT have any FDA labeled contraindications to the requested agent
   AND
3. The patient meets all requirements and will use the requested agent in a treatment regimen noted in Table 3 (FDA labeling) or 4 (AASLD/IDSA guidelines for decompensated cirrhosis)
   AND
4. BOTH of the following:
   A. The requested length of therapy does NOT exceed the length of therapy noted in Table 3 (FDA labeling) or 4 (AASLD/IDSA guidelines for decompensated cirrhosis) for the patient's treatment regimen
      AND
   B. ONE of the following:
      i. The requested quantity (dose) does NOT exceed the program quantity limit
         OR
      ii. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following:
         a. The requested agent is Harvoni 45 mg/200 mg oral pellets AND BOTH of the following:
            1. The requested quantity (dose) does NOT exceed 2 packets daily
               AND
            2. The prescriber has provided information stating why the patient cannot take 1 tablet of Harvoni 90 mg/400 mg strength
               OR
         b. The requested agent is Harvoni 45 mg/200 mg tablet AND BOTH of the following:
            1. The requested quantity (dose) does NOT exceed 2 tablets daily
               AND
            2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

Length of Approval: Up to the duration of treatment as determined in Tables 3 or 4

Table 3: Harvoni or Ledipasvir/Sofosbuvir Treatment Recommendations based on FDA labeling

Genotype	Patients 3 years of age and older*	Treatment	Treatment Duration
1	Treatment-naïve with initial viral load of less than 6 M IU/mL and without cirrhosis, HIV infection, history of liver transplantation and/or are not black or African-American	Harvoni, Ledipasvir/Sofosbuvir	8 weeks* **NOTE: approve 8 weeks length of therapy ONLY if prescriber is requesting 8 weeks of therapy**
	Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh A)	Harvoni, Ledipasvir/Sofosbuvir	12 weeks
	Treatment-experienced (i.e., patients who have failed therapy with either peg-interferon + ribavirin ± an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir]) without cirrhosis	Harvoni, Ledipasvir/Sofosbuvir	12 weeks

	Treatment-experienced (i.e., patients who have failed therapy with either peg-interferon + ribavirin ± an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir]) with compensated cirrhosis (Child-Turcotte-Pugh A) and eligible for ribavirin	Harvoni + ribavirin, Ledipasvir/Sofosbuvir + ribavirin	12 weeks
	Treatment-experienced (i.e., patients who have failed therapy with either peg-interferon + ribavirin ± an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir]) with compensated cirrhosis (Child-Turcotte-Pugh A) and ineligible for ribavirin (i.e., patients with a history of intolerance, contraindication, or hypersensitivity to ribavirin)	Harvoni, Ledipasvir/Sofosbuvir	24 weeks
	Treatment-naïve and treatment-experienced (i.e., patients who have failed therapy with either peg-interferon + ribavirin ± an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir]) with decompensated cirrhosis (Child-Turcotte-Pugh B or C)	Harvoni + ribavirin, Ledipasvir/Sofosbuvir + ribavirin	12 weeks
1 or 4	Treatment-naïve and treatment-experienced (i.e., patients who have failed therapy with either peg-interferon + ribavirin ± an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir]) liver transplant recipients without cirrhosis, or with compensated cirrhosis (Child-Turcotte-Pugh A)	Harvoni + ribavirin, Ledipasvir/Sofosbuvir + ribavirin	12 weeks
4, 5, or 6	Treatment-naïve and treatment-experienced (i.e., patients who have failed therapy with either peg-interferon + ribavirin ± an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir]) without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh A)	Harvoni, Ledipasvir/Sofosbuvir	12 weeks

* - HCV/HIV-1 co-infection, follow recommendation in table above

Table 4: Harvoni or Ledipasvir/Sofosbuvir Decompensated Cirrhosis Treatment Recommendations based on AASLD Guidelines for unique populations

Genotype	Patients 3 years of age and older*	Treatment	Duration
1, 4, 5, or 6	Patients with decompensated cirrhosis (Child-Turcotte-Pugh B or C) AND are ribavirin ineligible (i.e., patients with history of intolerance, contraindication, or hypersensitivity to ribavirin)	Harvoni, Ledipasvir/Sofosbuvir	24 weeks
1, 4, 5, or 6	Patients with decompensated cirrhosis (Child-Turcotte-Pugh B or C) previously treated with sofosbuvir-based treatment failure	Harvoni + low initial dose of ribavirin (600 mg); increase as tolerated, Ledipasvir/Sofosbuvir + low initial dose of	24 weeks

		ribavirin (600 mg); increase as tolerated	

* - HCV/HIV-1 co-infection, follow recommendation in table above

Mavyret Evaluation

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

1. ONE of the following is met:
    A. There is documentation that the patient is currently using the requested agent in the past 30 days
    OR
    B. The patient is new to therapy and ALL of the below:
        i. The patient has a diagnosis of hepatitis C genotype 1, 2, 3, 4, 5, or 6
        AND
        ii. 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 supporting the use of the requested agent for the patient's age for the requested indication
        AND
        iii. The prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection
        AND
        iv. If the screening for HBV was positive for current or prior HBV infection, the prescriber will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent
        AND
        v. ONE of the following:
            a. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist, or infectious disease) or has consulted with a specialist in the area of the patient's diagnosis
            OR
            b. ALL of the following:
                1. The patient is treatment naïve
                AND
                2. The patient does NOT have cirrhosis or has compensated cirrhosis
                AND
                3. The requested agent is supported in AASLD guidelines for simplified treatment
                AND
                4. The patient meets all of the qualifications for AASLD guidelines simplified treatment (please see Patients Who Qualify for Simplified Treatment tables below)
                AND

Patients Without Cirrhosis Who Qualify for Simplified Treatment
• Hepatitis B surface antigen (HBsAg) negative
• NOT currently pregnant
• No known or suspected hepatocellular carcinoma
• No prior liver transplantation
Patients With Compensated Cirrhosis Who Qualify for Simplified Treatment
• Patient has NOT had current or prior episode of decompensated cirrhosis, defined as Child-Turcotte-Pugh (CTP) score greater than or equal to 7 (ascites, hepatic encephalopathy, total bilirubin greater than 2.0 mg/dL, albumin less than or equal to 3.5 g/dL, or INR greater than or equal to 1.7)
• Does NOT have end-stage renal disease (i.e., eGFR less than 30 mL/min/m^2)
• HBsAg negative
• NOT currently pregnant
• No known or suspected hepatocellular carcinoma
• No prior liver transplantation

        vi. The patient has not been previously treated with the requested agent

AND

2. The patient does NOT have any FDA labeled contraindications to the requested agent
   AND
3. The patient meets all requirements and will use the requested agent will in a treatment regimen noted in Table 5 (FDA labeling)
   AND
4. BOTH of the following:
   A. The requested length of therapy does NOT exceed the length of therapy noted in Table 5 (FDA labeling) for the patient's treatment regimen
      AND
   B. ONE of the following:
      i. The requested quantity (dose) does NOT exceed the program quantity limit
         OR
      ii. The requested quantity (dose) exceeds the program quantity limit AND ALL of the following:
         a. The requested agent is Mavyret 50 mg/20 mg packets
            AND
         b. The requested quantity (dose) does NOT exceed 6 packets per day
            AND
         c. The prescriber has provided information supporting why the patient cannot take 3 tablets of the 100 mg/40 mg tablet

Length of Approval: Up to the duration of treatment as determined in Table 5

Table 5: **Mavyret Treatment Recommendations based on FDA labeling**

Genotype	Patient Population - adults and pediatric patients 3 years of age and older*†	Treatment	Duration	
			No Cirrhosis	Compensated Cirrhosis (Child-Turcotte-Pugh A)
1, 2, 3, 4, 5, or 6	Liver or kidney transplant recipients	Mavyret	12 weeks	12 weeks
1	Liver or kidney transplant recipients who are treatment experienced with an NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir) but without prior treatment with an NS3/4A protease inhibitor (PI)	Mavyret	16 weeks	16 weeks
3	Liver or kidney transplant recipients who are treatment experienced with PRS (i.e., Prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor)	Mavyret	16 weeks	16 weeks
1, 2, 3, 4, 5, or 6	Treatment naïve	Mavyret	8 weeks	8 weeks
1	Treatment experienced with an NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir) but without prior treatment with an NS3/4A protease inhibitor (PI)	Mavyret	16 weeks	16 weeks
1	Treatment experienced with an NS3/4A protease inhibitor (e.g., simeprevir, boceprevir, telaprevir) but without prior treatment with an NS5A inhibitor	Mavyret	12 weeks	12 weeks

1, 2, 4, 5, or 6	Treatment experienced with PRS (i.e., Prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor)	Mavyret	8 weeks	12 weeks
3	Treatment experienced with PRS (i.e., Prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor)	Mavyret	16 weeks	16 weeks

* HCV/HIV-1 co-infection, follow recommendation in table above

† Patients with any degree of kidney impairment (including those on hemodialysis), follow recommendation in table above

Sovaldi Evaluation

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

1. ONE of the following:
    A. There is documentation that the patient is currently using the requested agent in the past 30 days
    OR
    B. The patient is new to therapy and ALL of the below:
        i. ONE of the following:
            a. The patient is a pediatric patient with a diagnosis of hepatocellular carcinoma secondary to chronic hepatitis C genotype 2 or 3 AND if the patient has an FDA approved indication, ONE of the following:
                1. The patient's age is within FDA labeling for the requested agent for the requested indication
                OR
                2. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication
                OR
            b. The patient is a pediatric patient with a diagnosis of hepatitis C genotype 2 or 3 AND ALL of the following:
                1. If the patient has an FDA approved indication, ONE of the following:
                    A. The patient's age is within FDA labeling for the requested agent for the requested indication
                    OR
                    B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication
                AND
                2. ONE of the following:
                    A. The patient has an intolerance or hypersensitivity to BOTH Epclusa and Mavyret
                    OR
                    B. The patient has an FDA labeled contraindication to BOTH Epclusa and Mavyret
                    OR
                    C. The prescriber has provided information supporting the use of the requested agent over BOTH Epclusa and Mavyret (e.g., the patient is currently taking the requested agent)
                    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 BOTH Epclusa and Mavyret cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

AND

3. ONE of the following:
   A. The patient is treatment naïve
   OR
   B. The patient was previously treated (i.e., treatment experienced) with ONLY peg-interferon and ribavirin

OR

c. The patient is an adult and has a diagnosis of hepatocellular carcinoma secondary to chronic hepatitis C genotype 1, 2, 3, or 4
OR
d. The patient is an adult with a diagnosis of hepatitis C genotype 1, 2, 3, or 4 AND BOTH of the following:
   1. ONE of the following:
      A. The patient is treatment naïve
      OR
      B. The patient was previously treated (i.e., treatment experienced) with ONLY peg-interferon and ribavirin

   AND

   2. If the client has preferred agent(s) for the patient's specific factors (e.g., age, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment), then ONE of the following:
      A. Information has been provided that indicates the patient has been treated with the requested non-preferred agent in the past 30 days
      OR
      B. The patient has an intolerance or hypersensitivity to ALL preferred agent(s) for the patient's specific factors (e.g., age, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment)
      OR
      C. The patient has an FDA labeled contraindication to ALL preferred agent(s) for the patient's specific factors (e.g., age, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment)
      OR
      D. The prescriber has provided clinical information supporting the use of the non-preferred agent over the preferred agent(s)
      OR
      E. 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

F. The prescriber has provided documentation that ALL preferred agent(s) for the patient's specific factors (e.g., age, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment) 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

ii. The prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection
AND
iii. If the HBV screening was positive for current or prior HBV infection, the prescriber will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent
AND
iv. ONE of the following:
a. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist, infectious disease) or has consulted with a specialist in the area of the patient's diagnosis
OR
b. ALL of the following:
1. The patient is treatment naïve
AND
2. The patient does NOT have cirrhosis or has compensated cirrhosis
AND
3. The requested agent is supported in AASLD guidelines for simplified treatment
AND
4. The patient meets all the qualifications for AASLD guidelines simplified treatment (please see Patients Who Qualify for Simplified Treatment tables below)
AND

Patients Without Cirrhosis Who Qualify for Simplified Treatment
• Hepatitis B surface antigen (HBsAg) negative • NOT currently pregnant • No known or suspected hepatocellular carcinoma • No prior liver transplantation
Patients With Compensated Cirrhosis Who Qualify for Simplified Treatment
• Patient has NOT had current or prior episode of decompensated cirrhosis, defined as Child-Turcotte-Pugh (CTP) score greater than or equal to 7 (ascites, hepatic encephalopathy, total bilirubin greater than 2.0 mg/dL, albumin less than or equal to 3.5 g/dL, or INR greater than or equal to 1.7) • Does NOT have end-stage renal disease (i.e., eGFR less than 30 mL/min/m^2) • HBsAg negative • NOT currently pregnant • No known or suspected hepatocellular carcinoma • No prior liver transplantation

2. The patient does NOT have any FDA labeled contraindications to the requested agent
AND
3. The patient meets all requirements and will use the requested agent in a treatment regimen noted in Table 6 or 7 (FDA labeling)
AND

4. BOTH of the following:
    A. The requested length of therapy does NOT exceed the length of therapy noted in Table 6 or 7 (FDA labeling) for the patient's treatment regimen
    AND
    B. ONE of the following:
        i. The requested quantity (dose) does NOT exceed the program quantity limit
        OR
        ii. The requested agent is Sovaldi 200 mg oral pellets AND BOTH of the following:
            a. The requested quantity (dose) does NOT exceed 2 packets daily
            AND
            b. The prescriber has provided information stating why the patient cannot take 1 tablet of Sovaldi 400 mg strength
        OR
        iii. The requested agent is Sovaldi 200 mg tablets AND BOTH of the following:
            a. The requested quantity (dose) does NOT exceed 2 tablets daily
            AND
            b. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

Length of Approval: Up to the duration of treatment as determined in Table 6 or 7

Table 6: Sovaldi Treatment Recommendations in Adult Patients with Genotype 1, 2, 3, or 4 Based on FDA Labeling

Genotype	Patient population*	Treatment	Duration
1 or 4	Treatment naïve without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh A)	Sovaldi + Peg-interferon alfa + ribavirin	12 weeks
1	Treatment naïve without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh A) and are interferon ineligible defined as one or more of the following: • Intolerance to interferon • Autoimmune hepatitis and other autoimmune disorders • Hypersensitivity to PEG interferon or any of its components • Decompensated hepatic disease • Major uncontrolled depressive illness • A baseline neutrophil count below 1500/µL • A baseline platelet count below 90,000/µL • A baseline hemoglobin below 10 g/dL • A history of preexisting cardiac disease)	Sovaldi + ribavirin	24 weeks
2	Treatment naïve or treatment	Sovaldi + ribavirin	12 weeks

	experienced (i.e., patients who have failed an interferon based regimen with or without ribavirin) without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh A)		
3	Treatment naïve or treatment experienced (i.e., patients who have failed an interferon based regimen with or without ribavirin) without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh A)	Sovaldi + ribavirin	24 weeks
1-4	With hepatocellular carcinoma awaiting liver transplantation	Sovaldi + ribavirin	Up to 48 weeks

* HCV/HIV-1 co-infection, follow recommendation in table above

Table 7: Sovaldi and Ribavirin with or without Peg-interferon Treatment Recommendations for Pediatric Patients 3 Years of Age and Older Based on FDA Labeling

Genotype	Patient population*	Treatment	Duration
2	Treatment-naïve and treatment experienced (i.e., patients who have failed an interferon-based regimen with or without ribavirin) without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh A)	Sovaldi + ribavirin	12 weeks
3	Treatment-naïve and treatment experienced (i.e., patients who have failed an interferon-based regimen with or without ribavirin) without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh A)	Sovaldi + ribavirin	24 weeks
2 or 3	Pediatric patients with hepatocellular carcinoma awaiting liver transplantation	Sovaldi + ribavirin	48 weeks

* HCV/HIV-1 co-infection, follow recommendation in table above

Viekira Pak Evaluation

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

1. ONE of the following is met:
    A. There is documentation that the patient is currently using the requested agent in the past 30 days
    OR
    B. The patient is new to therapy and ALL of the below:
        i. The patient has a diagnosis of hepatitis C genotype 1
        AND
        ii. The prescriber has provided the patient's subtype
        AND
        iii. ONE of the following:

a. The patient is treatment naïve
OR
b. The patient was previously treated (i.e., treatment experienced) with ONLY peg-interferon and ribavirin

AND

iv. 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 supporting the use of the requested agent for the patient's age for the requested indication

AND

v. The prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection
AND

vi. If the screening for HBV was positive for current or prior HBV infection, the prescriber will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent
AND

vii. ONE of the following:
a. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist, or infectious disease) or has consulted with a specialist in the area of the patient's diagnosis
OR
b. ALL of the following:
1. The patient is treatment naïve
AND
2. The patient does NOT have cirrhosis or has compensated cirrhosis
AND
3. The requested agent is supported in AASLD guidelines for simplified treatment
AND
4. The patient meets all the qualifications for AASLD guidelines simplified treatment (please see Patients Who Qualify for Simplified Treatment tables below)
AND

Patients Without Cirrhosis Who Qualify for Simplified Treatment
• Hepatitis B surface antigen (HBsAg) negative • NOT currently pregnant • No known or suspected hepatocellular carcinoma • No prior liver transplantation
Patients With Compensated Cirrhosis Who Qualify for Simplified Treatment
• Patient has NOT had current or prior episode of decompensated cirrhosis, defined as Child-Turcotte-Pugh (CTP) score greater than or equal to 7 (ascites, hepatic encephalopathy, total bilirubin greater than 2.0 mg/dL, albumin less than or equal to 3.5 g/dL, or INR greater than or equal to 1.7) • Does NOT have end-stage renal disease (i.e., eGFR less than 30 mL/min/m^2) • HBsAg negative • NOT currently pregnant • No known or suspected hepatocellular carcinoma • No prior liver transplantation

viii. If the client has preferred agents for the patient's specific factors (e.g., age, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment), then ONE of the following:
a. Information has been provided that indicates the patient has been treated with the requested non-preferred agent in the past 30 days
OR
b. The patient has an intolerance or hypersensitivity to ALL preferred agent(s) for the patient's specific factors (e.g., age, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment)

OR

c. The patient has an FDA labeled contraindication to ALL preferred agent(s) for the patient's specific factors (e.g., age, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment)
OR

d. The prescriber has provided clinical information supporting the use of the non-preferred agent over the preferred agent(s)
OR

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

f. The prescriber has provided documentation that ALL preferred agent(s) for the patient's specific factors (e.g., age and/or weight, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

AND

2. The patient does NOT have any FDA contraindications to the requested agent
AND
3. The patient meets all requirements and will use the requested agent will be used in a treatment regimen noted in Table 8 (FDA labeling)
AND
4. BOTH of the following:
    A. The requested length of therapy does NOT exceed the length of therapy noted in Table 8 (FDA labeling) for the patient's treatment regimen
    AND
    B. The requested quantity (dose) does NOT exceed the program quantity limit

Length of Approval: Up to the duration as determined in Table 8

Table 8: Viekira PAK Treatment Recommendations based on FDA labeling

Genotype	Patient Population*	Treatment	Duration
1a	Without cirrhosis	Viekira PAK + ribavirin	12 weeks
	With compensated cirrhosis	Viekira PAK + ribavirin	24 weeks
1b	With or without compensated cirrhosis	Viekira PAK	12 weeks
1a or 1b	Post liver transplant with normal hepatic function (i.e. Metavir less than or equal to 2)	Viekira PAK + ribavirin	24 weeks

* HCV/HIV-1 co-infection, follow recommendation in table above

Vosevi Evaluation

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

1. ONE of the following is met:
    A. There is documentation that the patient is currently using the requested agent in the past 30 days
    OR

B. The patient is new to therapy and ALL of the below:
   i. The patient has a diagnosis of hepatitis C genotype 1, 2, 3, 4, 5, or 6
   AND
   ii. If genotype 1, the prescriber has provided the patient's subtype
   AND
   iii. The patient is NOT treatment naïve
   AND
   iv. The patient has NOT been previously treated with the requested agent
   AND
   v. 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 supporting the use of the requested agent for the patient's age for the requested indication
   AND
   vi. The prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection
   AND
   vii. If the screening for HBV was positive for current or prior HBV infection, the prescriber will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent
   AND
   viii. ONE of the following:
      a. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist, or infectious disease) or has consulted with a specialist in the area of the patient's diagnosis
      OR
      b. ALL of the following:
         1. The patient is treatment naïve
         AND
         2. The patient does NOT have cirrhosis or has compensated cirrhosis
         AND
         3. The requested agent is supported in AASLD guidelines for simplified treatment
         AND
         4. The patient meets all the qualifications for AASLD guidelines simplified treatment (please see Patients Who Qualify for Simplified Treatment tables below)
         AND

Patients Without Cirrhosis Who Qualify for Simplified Treatment
• Hepatitis B surface antigen (HBsAg) negative • NOT currently pregnant • No known or suspected hepatocellular carcinoma • No prior liver transplantation
Patients With Compensated Cirrhosis Who Qualify for Simplified Treatment
• Patient has NOT had current or prior episode of decompensated cirrhosis, defined as Child-Turcotte-Pugh (CTP) score greater than or equal to 7 (ascites, hepatic encephalopathy, total bilirubin greater than 2.0 mg/dL, albumin less than or equal to 3.5 g/dL, or INR greater than or equal to 1.7) • Does NOT have end-stage renal disease (i.e., eGFR less than 30 mL/min/m^2) • HBsAg negative • NOT currently pregnant • No known or suspected hepatocellular carcinoma • No prior liver transplantation

2. The patient does NOT have any FDA labeled contraindications to the requested agent
   AND
3. The patient meets all requirements and will use the requested agent in a treatment regimen noted in Table 9
   AND

4. BOTH of the following:
    A. The requested length of therapy does NOT exceed the length of therapy noted in Table 9 (FDA labeling) for the patient's regimen
    AND
    B. The requested quantity (dose) does NOT exceed the program quantity limit

Length of Approval: Up to the duration of treatment as determined in Table 9

Table 9: **Vosevi Treatment Recommendations based on FDA labeling**

Genotype	Patient Population*	Patients Previously Treated with an HCV Regimen Containing:	Treatment Duration
1,2,3,4,5, or 6	Without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh A)	An NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir)	12 weeks
1a or 3	Without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh A)	Sofosbuvir without an NS5A inhibitor†	12 weeks

* – HCV/HIV-1 co-infection, follow recommendation in table above
† - Sofosbuvir with or without any of the following: peginterferon alfa/ribavirin, ribavirin, HCV NS3/4A protease inhibitor (simeprevir)

Zepatier Evaluation
Target Agent(s) will be approved when ALL of the following are met:
1. ONE of the following is met:
    A. There is documentation that the patient is currently using the requested agent in the past 30 days
    OR
    B. The patient is new to therapy and ALL of the below:
        i. The patient has a diagnosis of hepatitis C genotype 1 or 4
        AND
        ii. BOTH of the following:
            a. If genotype 1, the prescriber has provided the patient's subtype
            AND
            b. If the subtype 1a, the prescriber has tested the patient for NS5A polymorphisms
        AND
        iii. ONE of the following:
            a. The patient is treatment naïve
            OR
            b. The patient was previously treated (i.e., treatment experienced) with ONLY peg-interferon and ribavirin with or without an HCV protease inhibitor
        AND
        iv. 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 supporting the use of the requested agent for the patient's age for the requested indication
        AND
        v. The prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection
        AND
        vi. If the screening for HBV was positive for current or prior HBV infection, the prescriber will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent
        AND
        vii. ONE of the following:

a. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist, or infectious disease) or has consulted with a specialist in the area of the patient's diagnosis
OR
b. ALL of the following:
1. The patient is treatment naïve
AND
2. The patient does NOT have cirrhosis or has compensated cirrhosis
AND
3. The requested agent is supported in AASLD guidelines for simplified treatment
AND
4. The patient meets all the qualifications for AASLD guidelines simplified treatment (please see Patients Who Qualify for Simplified Treatment tables below)
AND

Patients Without Cirrhosis Who Qualify for Simplified Treatment
• Hepatitis B surface antigen (HBsAg) negative • NOT currently pregnant • No known or suspected hepatocellular carcinoma • No prior liver transplantation
Patients With Compensated Cirrhosis Who Qualify for Simplified Treatment
• Patient has NOT had current or prior episode of decompensated cirrhosis, defined as Child-Turcotte-Pugh (CTP) score greater than or equal to 7 (ascites, hepatic encephalopathy, total bilirubin greater than 2.0 mg/dL, albumin less than or equal to 3.5 g/dL, or INR greater than or equal to 1.7) • Does NOT have end-stage renal disease (i.e., eGFR less than 30 mL/min/m^2) • HBsAg negative • NOT currently pregnant • No known or suspected hepatocellular carcinoma • No prior liver transplantation

viii. If the client has preferred agent(s) for the patient's specific factors (e.g., age, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment), then ONE of the following:
a. Information has been provided indicating that the patient has been treated with the requested non-preferred agent in the past 30 days
OR
b. The patient has an intolerance or hypersensitivity to ALL preferred agent(s) for the patient's specific factors (e.g., age, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment)
OR
c. The patient has an FDA labeled contraindication to ALL preferred agent(s) for the patient's specific factors (e.g., age, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment)
OR
d. The prescriber has provided clinical information supporting the use of the requested non-preferred agent over the preferred agent(s)
OR
e. The patient is currently being treated with the requested agent as indicated by ALL of the following:
1. A statement by the prescriber that the patient is currently taking the requested agent
AND
2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
AND
3. The prescriber states that a change in therapy is expected to be ineffective or cause harm

OR

f. The prescriber has provided documentation that ALL preferred agent(s) for the patient's specific factors (e.g., age, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

AND

2. The patient does NOT have any FDA labeled contraindications to the requested agent
   AND
3. The patient meets all requirements and will use the requested agent in a treatment regimen noted in Table 10 (FDA labeling)
   AND
4. BOTH of the following:
   A. The requested length of therapy does NOT exceed the length of therapy noted in Table 10 (FDA labeling) for the patient's treatment regimen
      AND
   B. The requested quantity (dose) does NOT exceed the program quantity limit

Length of Approval: Up to the duration of treatment as determined in Table 10

Table 10: Zepatier Treatment Recommendations based on FDA labeling

Genotype	Patient Population*	Treatment	Duration
1a	Treatment-naïve or PegIFN/RBV-experienced without baseline NS5A polymorphisms at amino acid positions 28, 30, 31, or 93	Zepatier	12 weeks
	Treatment-naïve or PegIFN/RBV-experienced with baseline NS5A polymorphisms at amino acid positions 28, 30, 31, or 93	Zepatier + ribavirin	16 weeks
1b	Treatment-naïve or PegIFN/RBV-experienced	Zepatier	12 weeks
1a or 1b	PegIFN/RBV/protease inhibitor-experienced	Zepatier + ribavirin	12 weeks
4	Treatment-naive	Zepatier	12 weeks
	PegIFN/RBV-experienced	Zepatier + ribavirin	16 weeks

* - HCV/HIV-1 co-infection, follow dosage recommendation in the table above

New to Market Hepatitis C Agents Evaluation

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

1. ONE of the following is met:
   A. There is documentation that the patient is currently using the requested agent in the past 30 days
      OR
   B. The patient is new to therapy and ALL of the below:
      i. The patient has an FDA approved diagnosis for the requested agent
         AND
      ii. The requested agent is FDA approved for treatment of the patient's genotype
         AND
      iii. 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 supporting the use of the requested agent for the patient's age for the requested indication
         AND
      iv. If FDA labeling for the requested agent requires patients are tested for hepatitis B viral (HBV) infection prior to starting treatment with the requested agent BOTH of the following:
         a. The prescriber has screened the patient for current or prior HBV

AND

b. If the HBV screening was positive for current or prior HBV, the prescriber will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent

AND

v. ONE of the following:
   a. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist, or infectious disease) or has consulted with a specialist in the area of the patient's diagnosis
      OR
   b. ALL of the following:
      1. The patient is treatment naïve
         AND
      2. The patient does NOT have cirrhosis or has compensated cirrhosis
         AND
      3. The requested agent is supported in AASLD guidelines for simplified treatment
         AND
      4. The patient meets all the qualifications for AASLD guidelines simplified treatment (please see Patients Who Qualify for Simplified Treatment tables below)
         AND

Patients Without Cirrhosis Who Qualify for Simplified Treatment
• Hepatitis B surface antigen (HBsAg) negative • NOT currently pregnant • No known or suspected hepatocellular carcinoma • No prior liver transplantation
Patients With Compensated Cirrhosis Who Qualify for Simplified Treatment
• Patient has NOT had current or prior episode of decompensated cirrhosis, defined as Child-Turcotte-Pugh (CTP) score greater than or equal to 7 (ascites, hepatic encephalopathy, total bilirubin greater than 2.0 mg/dL, albumin less than or equal to 3.5 g/dL, or INR greater than or equal to 1.7) • Does NOT have end-stage renal disease (i.e., eGFR less than 30 mL/min/m^2) • HBsAg negative • NOT currently pregnant • No known or suspected hepatocellular carcinoma • No prior liver transplantation

vi. If the client has preferred agent(s) for the patient's specific factors (e.g., age, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment), then ONE of the following:
   a. The requested agent is a preferred agent for the patient's specific factors (e.g., age, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment)
      OR
   b. Information has been provided indicating that the patient has been treated with the requested non-preferred agent in the past 30 days
      OR
   c. The patient has an intolerance or hypersensitivity to ALL preferred agent(s) for the patient's specific factors (e.g., age, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment)
      OR
   d. The patient has an FDA labeled contraindication to ALL preferred agent(s) for the patient's specific factors (e.g., age, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment)
      OR
   e. The prescriber has provided clinical information supporting the use of the non-preferred agent over the preferred agent(s)
      OR

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

OR

g. The prescriber has provided documentation that ALL preferred agent(s) for the patient's specific factors (e.g., age, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

AND

2. The patient does NOT have any FDA labeled contraindications to the requested agent
AND
3. The patient meets all requirements and will use the requested agent in a treatment regimen noted in Table 11 (FDA labeling)
AND
4. BOTH of the following:
    A. The requested length of therapy does NOT exceed the length of therapy noted in Table 11 (FDA labeling) for the patient's treatment regimen
    AND
    B. ONE of the following:
        i. The requested quantity (dose) does NOT exceed the program quantity limit
        OR
        ii. BOTH of the following:
            a. The requested quantity (dose) is greater than the program quantity limit
            AND
            b. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

Length of Approval: Up to the duration of treatment as determined in Table 11

Table 11: Treatment Recommendations based on FDA labeling

Agent(s)	FDA approved indication(s)	Genotype	Treatment Regimen	FDA labeled dose	Duration
TBD	TBD	TBD	TBD	TBD	TBD

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

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	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 has tried and had an inadequate response to an oral systemic immunosuppressant (e.g., methotrexate, azathioprine, mycophenolate mofetil, cyclosporine) **OR** B. The patient has an intolerance or hypersensitivity to an oral systemic immunosuppressant **OR** C. The patient has tried and had an inadequate response to BOTH at least a mid-potency topical steroid AND a topical calcineurin inhibitor (e.g.,

Module	Clinical Criteria for Approval
	Elidel/pimecrolimus, Protopic/tacrolimus) **OR** D. The patient has an intolerance or hypersensitivity to BOTH at least a mid-potency topical steroid AND a topical calcineurin inhibitor **OR** E. The patient has an FDA labeled contraindication to ALL oral systemic immunosuppressants, mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors **OR** F. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** G. The prescriber has provided documentation that 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** 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:

Module	Clinical Criteria for Approval
	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, 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: 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:

Module	Clinical Criteria for Approval
	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 has tried and had an inadequate response to ONE 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** 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 has tried and had an inadequate response to at least a mid-potency topical steroid **OR** B. The patient has an intolerance or hypersensitivity to therapy with 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

Module	Clinical Criteria for Approval
	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:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **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**

Module	Clinical Criteria for Approval
	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, ICS/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** 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:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months Note: If Quantity Limit applies, please refer to Quantity Limit criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	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:

Module	Clinical Criteria for Approval
	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:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **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)
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)

Contraindicated as Concomitant Therapy
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: Nocturia - *Discontinued*

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

This program will be discontinued, effective 11/1/2023

• Program Summary: Oxbryta (voxelotor)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
82805080000310	Oxbryta	Voxelotor Tab	300 MG	90	Tablets	30	DAYS					
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

Module	Clinical Criteria for Approval
	age for the requested indication **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to maximally tolerated hydroxyurea **OR** B. The patient has an intolerance or hypersensitivity to hydroxyurea OR C. The patient has an FDA labeled contraindication to hydroxyurea **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 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** 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

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

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

• Program Summary: Rho Kinase Inhibitor

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

Note: The Step Therapy component of this program will be discontinued, effective 11/1/2023.

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
86527040202020	Rhopressa	Netarsudil Dimesylate Ophth Soln 0.02%	0.02 %	2.5	mLs	30	DAYS					
86529902402020	Rocklatan	Netarsudil Dimesylate-Latanoprost Ophth Soln 0.02-0.005%	0.02-0.005 %	2.5	mLs	30	DAYS					

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

Module	Clinical Criteria for Approval
	2. The requested quantity (dose) is greater than the program quantity limit **AND BOTH** of the following: A. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** B. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval**: 12 months

• Program Summary: Sucralfate Suspension

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

TARGET AGENT(S)

Carafate® (sucralfate)

a- Generic equivalent available

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
Carafate (sucralfate)*			
1 g/10 mL oral suspension	49300010001820	M, N, O, or Y	40 mL

* - Generic equivalent available

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

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

1. ONE of the following:
   A. The prescriber has provided information that the use of the tablet formulation is not clinically appropriate for the patient
   OR
   B. The patient's medication history includes use of the tablet formulation in the past 999 days
   OR
   C. BOTH of the following:
      i. The prescriber has stated that the patient has tried the tablet formulation
      AND
      ii. The tablet formulation was discontinued due to lack of effectiveness or an adverse event
   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 the tablet formulation cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

   AND
2. The patient does NOT have any FDA labeled contraindications to the requested agent
   AND
3. ONE of the following:
   A. The requested quantity (dose) does NOT exceed the program quantity limit

OR

B. BOTH of the following:
   i. The requested quantity (dose) is greater than the program quantity limit
   AND
   ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication

OR

C. ALL of the following:
   i. The requested quantity (dose) is greater than the program quantity limit
   AND
   ii. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
   AND
   iii. The prescriber has provided information in support of therapy with a higher dose for the requested indication

Length of Approval: 12 months