COMMERCIAL PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: November 1, 2024 Notification Posted: September 17, 2024

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

No new policies for November 1, 2024

POLICIES REVISED

• Program Summary: Antiemetic Agents

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
50280020000130		Aprepitant Capsule 125 MG	125 MG	2	Capsules	30	DAYS				
50250035100310		Granisetron HCl Tab 1 MG	1 MG	14	Tablets	30	DAYS				
50250065052070		Ondansetron HCl Oral Soln 4 MG/5ML	4 MG/5ML	100	mLs	30	DAYS				
50250065050340		Ondansetron HCl Tab 24 MG	24 MG	1	Tablet	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
50250065050310		Ondansetron HCl Tab 4 MG	4 MG	21	Tablets	30	DAYS				
50250065050320		Ondansetron HCl Tab 8 MG	8 MG	21	Tablets	30	DAYS				
50250065007260		ondansetron orally disintegrating tab	16 MG	1	Tablet	30	DAYS				
502500650072		ondansetron orally disintegrating tab	16 MG; 4 MG; 8 MG	21	Tablets	30	DAYS				
50309902290120	Akynzeo	Netupitant-Palonosetron Cap 300-0.5 MG	300-0.5 MG	2	Capsules	30	DAYS				
502500252003	Anzemet	dolasetron mesylate tab	50 MG	7	Tablets	30	DAYS				
50280020000120	Emend	Aprepitant Capsule 80 MG	80 MG	4	Capsules	30	DAYS				
50280020001930	Emend	Aprepitant For Oral Susp 125 MG (125 MG/5ML)	125 MG/5ML	6	Packs	30	DAYS				
50280020006320	Emend tripack	Aprepitant Capsule Therapy Pack 80 & 125 MG	80 & 125 MG	2	Packs	30	DAYS				
50250035005920	Sancuso	Granisetron TD Patch 3.1 MG/24HR (Contains 34.3 MG)	3.1 MG/24HR	2	Patches	30	DAYS				
5028005020B720	Varubi	Rolapitant HCl Tab Therapy Pack 2 x 90 MG (Base Equiv)	90 MG	4	Tablets	30	DAYS				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Target Agent(s)	Prerequisite Agent(s)
Sancuso (granisetron) **Ondansetron ODT 16 mg**	Any ONE of the following generic oral 5HT-3 agents granisetron tablet ondansetron tablet ondansetron solution ondansetron ODT

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 document.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Akynzeo, Emend, Varubi QL	**Quantity limit for Akynzeo, Emend, or Varubi** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The patient has cancer chemotherapy related nausea and vomiting, and the patient will be receiving chemotherapy more than 7 days per month **OR** 3. There is support for the use of the requested agent for the requested diagnosis and quantity **Length of Approval:** 12 months
Anzemet, granisetron, ondansetron/ondansetron ODT QL	**Quantity limit for Anzemet, granisetron, or ondansetron/ondansetron ODT** 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. There is support for the use of the requested agent for the requested diagnosis and quantity **Length of Approval**: 12 months
Sancuso QL	**Quantity limit for Sancuso** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The patient has cancer chemotherapy related nausea and vomiting and will be receiving chemotherapy more than 14 days per month **OR** 3. There is support for the use of the requested agent for the requested diagnosis and quantity **Length of Approval:** 12 months

• Program Summary: Calcitonin Gene-Related Peptide (CGRP)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs Wher Exclusions Exist	Age Limit	Effective Date	Term Date
67701060707220	Nurtec	Rimegepant Sulfate Tab Disint 75 MG	75 MG	16	Tablets	30	DAYS				
67701010000310	Qulipta	Atogepant Tab	10 MG	30	Tablets	30	DAYS				
67701010000320	Qulipta	Atogepant Tab	30 MG	30	Tablets	30	DAYS				
67701010000330	Qulipta	Atogepant Tab	60 MG	30	Tablets	30	DAYS				
67701080000340	Ubrelvy	Ubrogepant Tab 100 MG	100 MG	16	Tablets	30	DAYS				
67701080000320	Ubrelvy	Ubrogepant Tab 50 MG	50 MG	16	Tablets	30	DAYS				
6770202010D540	Aimovig	Erenumab-aooe Subcutaneous Soln Auto-Injector 140 MG/ML	140 MG/ML	1	Injection Device	28	DAYS				
6770202010D520	Aimovig	Erenumab-aooe Subcutaneous Soln Auto-Injector 70 MG/ML	70 MG/ML	1	Injection Device	28	DAYS				
6770203530D520	Emgality	Galcanezumab-gnlm Subcutaneous Soln Auto-Injector 120 MG/ML	120 MG/ML	1	Injection Device	28	DAYS				
6770203530E515	Emgality	Galcanezumab-gnlm Subcutaneous Soln Prefilled Syr 100 MG/ML	100 MG/ML	9	Syringes	180	DAYS				
6770203530E520	Emgality	Galcanezumab-gnlm Subcutaneous Soln Prefilled Syr 120 MG/ML	120 MG/ML	1	Syringe	28	DAYS				
6770203020D520	Ajovy	Fremanezumab-vfrm Subcutaneous Soln Auto-inj 225 MG/1.5ML	225 MG/1.5ML	3	Injection Devices	84	DAYS				
6770203020E520	Ajovy	Fremanezumab-vfrm Subcutaneous Soln Pref Syr 225 MG/1.5ML	225 MG/1.5ML	3	Syringes	84	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Indication	Preferred Agent(s)	Non-Preferred Agent(s)	Stand Alone Target Agent(s)
Chronic Migraine Prophylaxis	Aimovig, AJOVY, Emgality, QULIPTA		
Episodic Migraine Prophylaxis	Aimovig, AJOVY, Emgality, Nurtec, QULIPTA		
Episodic Cluster Headaches	Emgality		
Acute Migraine Treatment	Nurtec, UBRELVY		Zavzpret

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 being used for migraine prophylaxis AND ALL of the following:
        1. ONE of the following:
            A. The patient has at least 15 headache days per month of migraine-like or tension-like headache for a minimum of 3 months (chronic migraine) AND ALL of the following:
                1. The patient has at least 8 migraine headache days per month for a minimum of 3 months **AND**
                2. The patient will NOT be using the requested agent in combination with another prophylactic use CGRP **AND**
                3. The requested agent and strength are FDA labeled for chronic migraine prophylaxis **OR**
            B. The patient has 4-14 monthly migraine headache days (episodic migraine) AND ALL of the following:
                1. The patient has experienced at least moderate disability due to migraines as indicated by ONE of the following:
                    A. Migraine Disability Assessment (MIDAS) score greater than or equal to 11 **OR**
                    B. Headache Impact Test (HIT-6) greater than 50 **AND**
                2. The patient will NOT be using the requested agent in combination with another prophylactic use CGRP agent **AND**
                3. The requested agent and strength are FDA labeled for episodic migraine prophylaxis **AND**
        2. If the client has a preferred agent, then ONE of the following:
            A. The requested agent is a preferred agent or a stand-alone agent for the requested indication **OR**
            B. The requested agent is a non-preferred agent and ONE of the following:
                1. The patient has tried and had an inadequate response to ONE preferred agent for the requested indication **OR**
                2. The patient has tried has an intolerance or hypersensitivity to ONE preferred agent for the requested indication **OR**
                3. The patient has an FDA labeled contraindication to ALL preferred agent(s) 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 ALL preferred agents for the requested indication 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. Medication overuse headache has been ruled out **OR**

B. The requested agent is being used for the treatment of episodic cluster headache AND ALL of the following:
1. The patient has had at least 5 cluster headache attacks **AND**
2. The patient has at least two cluster periods lasting 7-365 days **AND**
3. The patient's cluster periods are separated by a pain-free remission period of greater than or equal to 3 months **AND**
4. ONE of the following:
    A. The patient has tried and had an inadequate response to verapamil, melatonin, corticosteroids, topiramate, OR lithium **OR**
    B. The patient has an intolerance or hypersensitivity to verapamil, melatonin, corticosteroid, topiramate, OR lithium **OR**
    C. The patient has an FDA labeled contraindication to verapamil, melatonin, corticosteroid, topiramate, AND lithium **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 verapamil, melatonin, corticosteroids, topiramate, OR lithium 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. Medication overuse headache has been ruled out **AND**
6. The requested agent and strength are FDA labeled for episodic cluster headache treatment **OR**

C. The requested agent is being used for acute migraine treatment AND ALL of the following:
1. ONE of the following:
    A. The patient has tried and had an inadequate response to at least one triptan agent **OR**
    B. The patient has an intolerance or hypersensitivity to a triptan agent **OR**
    C. The patient has an FDA labeled contraindication to ALL triptan agents **OR**
    D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
        1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
        2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**

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

E. The prescriber has provided documentation that ALL triptan 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. The patient will NOT be using the requested agent in combination with another acute migraine therapy (i.e., 5HT-1F, acute use CGRP, triptan, ergotamine) **AND**
3. If the client has a preferred agent, then ONE of the following:
   A. The requested agent is a preferred agent or a stand-alone agent for the requested indication **OR**
   B. The requested agent is a non-preferred agent and ONE of the following:
      1. The patient has tried and had an inadequate response to ONE preferred agent for the requested indication **OR**
      2. The patient has tried has an intolerance or hypersensitivity to ONE preferred agent for the requested indication **OR**
      3. The patient has an FDA labeled contraindication to ALL preferred agent(s) 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 ALL preferred agents for the requested indication 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. Medication overuse headache has been ruled out **AND**
5. The requested agent and strength are FDA labeled for acute migraine treatment **OR**

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

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

2. If the patient has an FDA labeled indication, then ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
   B. There is support for using the requested agent for the patient's age for the requested indication **AND**
3. The patient does not have any FDA labeled contraindications to the requested agent

Compendia Allowed: AHFS, or DrugDex 1 or 2a level of evidence
Length of Approval: Cluster headache treatment - 6 months; migraine prophylaxis - 6 months; all other indications - 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 approved for the requested agent previously through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**
2. ONE of the following:
   A. BOTH of the following:

	1. ONE of the following: A. The requested agent is being used for migraine prophylaxis AND ALL of the following: 1. The patient has had improvement in migraine prevention (e.g., reduced migraine headache days, reduced migraine frequency, reduced use of acute abortive migraine medication) with the requested agent **AND** 2. The patient will NOT be using the requested agent in combination with another prophylactic use CGRP for the requested indication **AND** 3. ONE of the following: A. BOTH of the following: 1. The patient has at least 15 days per month of migraine-like or tension-like headache days (chronic migraine) **AND** 2. The requested agent and strength are FDA labeled for chronic migraine **OR** B. BOTH of the following: 1. The patient has 4-14 monthly migraine days (episodic migraine) **AND** 2. The requested agent and strength are FDA labeled for episodic migraine **OR** B. The requested agent is being used for episodic cluster headache treatment AND BOTH of the following: 1. The patient has had improvement in cluster headaches management with the requested agent **AND** 2. The requested agent and strength are FDA labeled for episodic cluster headache treatment **OR** C. The requested agent is being used for acute migraine treatment AND ALL of the following: 1. The patient has had improvement in acute migraine management with the requested agent **AND** 2. The patient will NOT be using the requested agent in combination with another acute migraine therapy (i.e., 5HT-1F, acute use CGRP, triptan, ergotamine) for the requested indication **AND** 3. The requested agent and strength are FDA labeled for acute migraine treatment **AND** 2. Medication overuse headache has been ruled out **OR** B. The requested agent is being used for an indication other than migraine prophylaxis, episodic cluster headache treatment, or acute migraine treatment AND has had clinical benefit with the requested agent **AND** 3. The patient does not have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months 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 Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND**

	2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. ALL of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. If the requested agent is being used for treatment of acute migraine, then ONE of the following: A. The patient is currently being treated with a migraine prophylactic medication (i.e., anticonvulsants [i.e., divalproex, valproate, topiramate], beta blockers [i.e., atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [i.e., amitriptyline, venlafaxine], candesartan, prophylactic use CGRP [e.g., Aimovig, AJOVY, Emgality, Nurtec, QULIPTA, Vyepti], onabotulinum toxin A [Botox]) **OR** B. The patient has an intolerance or hypersensitivity to therapy with migraine prophylactic medication (i.e., anticonvulsants [i.e., divalproex, valproate, topiramate], beta blockers [i.e., atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [i.e., amitriptyline, venlafaxine], candesartan, prophylactic use CGRP [e.g., Aimovig, AJOVY, Emgality, Nurtec, QULIPTA, Vyepti], OR onabotulinum toxin A [Botox]) **OR** C. The patient has an FDA labeled contraindication to ALL migraine prophylactic medications (i.e., anticonvulsants [i.e., divalproex, valproate, topiramate], beta blockers [i.e., atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [i.e., amitriptyline, venlafaxine], candesartan, prophylactic use CGRP [e.g., Aimovig, AJOVY, Emgality, Nurtec, QULIPTA, Vyepti], AND onabotulinum toxin A [Botox]) **OR** D. There is support that the patient's migraine is manageable with acute therapy alone **AND** 3. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months. NOTE: For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of approval up to 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	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
Camzyos	Mavacamten Cap	2.5 MG	30	Capsules	30	DAYS					
Camzyos	Mavacamten Cap	5 MG	30	Capsules	30	DAYS					
Camzyos	Mavacamten Cap	10 MG	30	Capsules	30	DAYS					
Camzyos	Mavacamten Cap	15 MG	30	Capsules	30	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

PA

Initial Evaluation

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

1. ONE of the following:
   - A. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**
   - B. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR**
   - C. The patient has a diagnosis of symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) AND ALL of the following:
     1. The patient has a left ventricular ejection fraction (LVEF) of greater than or equal to 55% **AND**
     2. The patient has a left ventricular outflow tract (LVOT) peak gradient greater than or equal to 50 mmHg at rest or with provocation (Valsalva or post-exercise) **AND**
     3. The patient does not have a known infiltrative or storage disorder causing cardiac hypertrophy that mimics obstructive HCM (e.g., Fabry disease, amyloidosis, 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 labeled 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. There is support for 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., cardiologist), 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. **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 [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. Patient has a left ventricular ejection fraction (LVEF) of greater than or equal to 50% **AND** 4. 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** 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. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months

• Program Summary: Cholestasis Pruritus

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
	523500600001	Bylvay	odevixibat cap	1200 MCG; 400 MCG	M; N; O; Y				
	523500600068	Bylvay (pellets)	odevixibat pellets cap sprinkle	200 MCG; 600 MCG	M; N; O; Y				
	523500501020	Livmarli	maralixibat chloride oral soln	9.5 MG/ML	M; N; O; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. BOTH of the following: 1. The patient has a diagnosis of progressive familial intrahepatic cholestasis (PFIC) with pruritus (medical records required) **AND** 2. 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) **OR** B. The patient has a diagnosis of Alagille syndrome with pruritus (medical records required) **OR** C. The patient has another FDA labeled indication for the requested agent and route of administration **OR** D. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested 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: 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 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. If the requested agent is Bylvay, then BOTH of the following: A. The patient's INR is less than 1.4 **AND** B. The patient has an ALT and total bilirubin that is less than 10-times the upper limit of normal **AND**

	5. If the requested agent is Livmarli, then BOTH of the following: A. The patient does NOT have decompensated cirrhosis **AND** B. The patient has NOT had surgical interruption of the enterohepatic circulation of bile acid **AND** 6. The patient has a serum bile acid concentration above the upper limit of normal **AND** 7. ONE of the following: A. The patient has NOT had a liver transplant **OR** B. The patient has had a liver transplant and there is support for using the requested agent post liver transplant **AND** 8. 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** 9. The patient will NOT be using the requested agent in combination with another Ileal Bile Acid Transport (IBAT) inhibitor agent **AND** 10. 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 [Note: patients not previously approved for the requested agent will require initial evaluation review] **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 **AND** 5. The requested quantity (dose) is within FDA labeled dosing for the requested indication **Length of Approval:** 12 months

• Program Summary: Compounded Medications

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

CLINICAL CRITERIA FOR APPROVAL

Module	Clinical 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** **FlexRx/GenRx Closed: Follow FE/CE process for determining benefit coverage.** **HIM:**

Excluded from Coverage on the Pharmacy Benefit
Alcohol Swabs
Blood Component (not including Hemophilia Factor)
Bulk Powders* (Defined as those products containing the third-party restriction code of B (BULK CHEMICALS) in the product file in RxClaim)
Clinic Packs* (Y in the Clinic Pack field)
Cosmetic Alteration*
Diagnostic Agents (not including glucose test strips)
Dietary and Herbal Supplements
General Anesthetic
Infertility Agents* For the treatment of infertility
Institutional Packs* Those that contain any one of the following modifier codes in the product file in RXClaims MODIFIER AAAD31 INSTITUTIONAL/HOSP. PACK MODIFIER BBAD9A INSTITUTIONAL MODIFIER TTAAJQ INSTITUTIONAL MODIFIER TTAA5V INSTITUTIONAL USE ONLY MODIFIER AAAB9A HOSPITAL PACK MODIFIER AAADQQ HUD (HOSPITAL UNIT DOSE) MODIFER AAAD6T HOSPITAL USE ONLY
Investigative, experimental, or not medically necessary
Medical Devices and Supplies (not including spacers, lancets, needles, syringes) (Defined by GPI 97**********)
Medical devices approved through a different FDA-approval process than drugs (Defined by one of the following: 1) Drug Application File Marketing Category 15 – Premarket Application 2) Drug Application File Marketing Category 16 – Premarket Notification)
Non-FDA Approved Agents* (Refer to all tiers on Formulary ID 220 or reject messaging of 'Non-FDA Approved Drug')
Over-The-Counter Medications* (specific OTC medications are covered if group purchases OTC benefit) (not including glucose test strips, insulin, or ACA required drugs)
Repackagers (not including Veterans Administration and Department of Defense Claims)* (Defined as indicated as Y in Repkg code field in the product file in RxClaim)
Self-Administered Contraceptives* (2510**********, 2540**********, 2596**********, 2597**********, 2599**********, 260000301003**) (ONLY when not covered in BET AND is being requested exclusively for the use of pregnancy prevention)
Sexual Dysfunction Agents* (Addyi, Viagra, Cialis, Levitra, Staxyn, Caverject, Edex, Muse) for treatment of sexual dysfunction

Surgical Supplies/Medical Devices/Ostomy (not including spacers, lancets, needles, syringes) (Defined as indicated by the third-party restriction code 3 (SURGICAL SUPPLY/MEDICAL DEVICE/OSTOMY) in the product file in RxClaim)
Syringes other than insulin syringes
Weight Loss Agents* (GPI: 6120**********, 6125**********) for the treatment of weight loss

KeyRx and FocusRx:

Excluded from Coverage on the Pharmacy Benefit
AHFS (devices and pharmaceutical aids, not including needles, syringes, lancets) (Defined as those products containing the AHFS code 940000000 (DEVICES) and/ or 960000000 (PHARMACEUTICAL AIDS) in the product file in RxClaim)
Brand for Generic* generic equivalents of the following brand products- Advair Diskus, Nuvaring, Restasis (for FocusRx), Soolantra, Vagifem, and Vascepa
Bulk Powders* (Defined as those products containing the third-party restriction code of B (BULK CHEMICALS) in the product file in RxClaim)
Clinic Packs* (Y in the Clinic Pack field)
Cosmetic Alteration* (Defined as those products containing the third-party restriction code of C (COSMETIC ALTERATION DRUGS) in the product file in RxClaim)
Diagnostic Agents (not including glucose test strips) (Defined as those products containing the third-party restriction code of 5 (DIAGNOSTIC AGENT) in the product file in RxClaim)
Drugs That Are Not Covered Exclusion (not including glucose test strips, insulin, AuviQ 0.1 mg, ACA required drugs, lancets, syringes, CGM/sensor/transmitter/receiver) [See MN NDC Lock Out List NetResults]
General Anesthetic (Defined as those products containing the third-party restriction code of 6 (GENERAL ANESTHETIC) in the product file in RxClaim)
Infertility Agents* (Defined as those products containing the third-party restriction code 7 (FERTILITY DRUGS) in the product file in RxClaim) (only when not covered in BET AND is being requested for treatment of infertility)
Injectable drugs not on covered drug list, not including the drugs on the following list: *BCBSMN* Tier 40 Reviewable Drugs List KeyRx/FocusRx (Defined as those products included on Tier 40 of FID 33102 with any reject message other than "NOT ON DRUG LIST, CHECK MEDICAL BENEFIT. CALL NUMBER ON THE BACK OF YOUR CARD FOR MORE INFORMATION".)
Institutional Packs* Those that contain any one of the following modifier codes in the product file in RXClaims MODIFIER AAAD31 INSTITUTIONAL/HOSP. PACK MODIFIER BBAD9A INSTITUTIONAL MODIFIER TTAAJQ INSTITUTIONAL MODIFIER TTAA5V INSTITUTIONAL USE ONLY

MODIFIER AAAB9A HOSPITAL PACK MODIFIER AAADQQ HUD (HOSPITAL UNIT DOSE) MODIFER AAAD6T HOSPITAL USE ONLY
Investigative, experimental, or not medically necessary
Medical Devices and Supplies (not including spacers, lancets, needles, syringes) (Defined by GPI 97**********)
Medical devices approved through a different FDA-approval process than drugs (Defined by one of the following: 1) Drug Application File Marketing Category 15 – Premarket Application 2) Drug Application File Marketing Category 16 – Premarket Notification)
Non-FDA Approved Agents* (Refer all tiers on Formulary ID 220 or reject messaging of 'Non-FDA Approved Drug')
Over-The-Counter Medications* (not including glucose test strips, insulin, ACA required drugs, lancets, syringes) (Defined as indicated by O or P in the Rx-OTC indicator code field in the Product file in RxClaim)
Repackagers (not including Veterans Administration and Department of Defense Claims)* (Defined as indicated as Y in Repkg code field in the product file in RxClaim)
Self-Administered Contraceptives* (2510**********, 2540**********, 2596**********, 2597**********, 2599**********, 260000301003**) (ONLY when not covered in BET AND is being requested exclusively for the use of pregnancy prevention)
Sexual Dysfunction Agents* (Defined as those products (e.g., Addyi, Viagra, Cialis 10 mg and 20 mg, Levitra, Staxyn, Caverject, Edex, Muse) containing the third-party restriction V (IMPOTENCE AGENTS) in the product file in RxClaim (only when not covered in BET AND is being requested for treatment of sexual dysfunction)
Surgical Supplies/Medical Devices/Ostomy (not including spacers, lancets, needles, syringes) (Defined as indicated by the third-party restriction code 3 (SURGICAL SUPPLY/MEDICAL DEVICE/OSTOMY) in the product file in RxClaim)
Universal Product Code (UPC), Health Related Item Code (HRI) (not including glucose test strips) (UPCs will be defined as those products designated as product type 1 in the product file in RxClaim. HRIs will be defined as those products designated as product type 2 in the product file in RxClaim.)
Weight Loss Agents* (Defined as those products containing the third-party restriction code 8 (ANOREXIC, ANTI-OBESITY) in the product file in RxClaim) (only when not covered in BET AND is being requested for treatment of weight loss)

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 labeled 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. There is support that ALL 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	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
52450045000120	Amitiza	Lubiprostone Cap 24 MCG	24 MCG	60	Capsules	30	DAYS				
52450045000110	Amitiza	Lubiprostone Cap 8 MCG	8 MCG	120	Capsules	30	DAYS				
525570500001	Linzess	linaclotide cap	145 MCG; 290 MCG; 72 MCG	30	Capsules	30	DAYS				
525600602003	Motegrity	prucalopride succinate tab	1 MG; 2 MG	30	Tablets	30	DAYS				
525800603003	Movantik	naloxegol oxalate tab	12.5 MG; 25 MG	30	Tablets	30	DAYS				
52580050102020	Relistor	methylnaltrexone bromide inj	12 MG/0.6ML	60	Vials	30	DAYS	65649055102			
52580050102020	Relistor	methylnaltrexone bromide inj	12 MG/0.6ML	30	Syringes	30	DAYS	65649055103; 65649055107			
52580050102015	Relistor	Methylnaltrexone Bromide Inj 8 MG/0.4ML (20 MG/ML)	8 MG/0.4ML	30	Syringes	30	DAYS				
525800501003	Relistor	methylnaltrexone bromide tab	150 MG	90	Tablets	30	DAYS				
525800572003	Symproic	naldemedine tosylate tab	0.2 MG	30	Tablets	30	DAYS				
525430600003	Trulance	plecanatide tab	3 MG	30	Tablets	30	DAYS				
52558580100320	Ibsrela	Tenapanor HCl Tab	50 MG	60	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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

1. The patient has had CIC symptoms for greater than or equal to 3 months **AND**
2. The requested agent is Amitiza (lubiprostone), Linzess (linaclotide), Motegrity (prucalopride), or Trulance (plecanatide) **AND**
3. ONE of the following:
    A. The patient has tried and had an inadequate response to at least 2 standard laxative therapy classes (e.g., bulk-forming, stimulant, enema, osmotic, or stool softener) **OR**
    B. The patient has an intolerance or hypersensitivity to at least 2 standard laxative therapy classes **OR**
    C. The patient has an FDA labeled contraindication to ALL standard laxative therapy classes **OR**
    D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
        1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
        2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
        3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
    E. The prescriber has provided documentation that ALL standard laxative therapy classes cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

C. The patient has a diagnosis of opioid-induced constipation (OIC) AND ALL of the following:
1. ONE of the following:
    A. BOTH of the following:
        1. ONE of the following:
            A. The requested agent is Symproic (naldemedine), Movantik (naloxegol), OR Relistor (methylnaltrexone) tablet **OR**
            B. The requested agent is Amitiza (lubiprostone), AND the patient is not currently receiving a diphenylheptane opioid (e.g., methadone) **AND**
        2. ONE of the following:
            A. The patient has chronic non-cancer pain **OR**
            B. The patient has chronic pain related to prior cancer or its treatment **OR**
            C. The patient has active cancer pain **OR**
    B. The requested agent is Linzess (linaclotide) AND the patient has active cancer pain **OR**
    C. The request is for Relistor (methylnaltrexone) injection, and the patient is receiving palliative care AND ONE of the following:
        1. The patient has advanced illness **OR**
        2. The patient has pain caused by active cancer **AND**
2. The patient has chronic use of an opioid agent in the past 30 days **AND**
3. ONE of the following:
    A. The patient has tried and had an inadequate response to at least 2 standard laxative therapy classes (e.g., stimulant, enema, osmotic, or stool softener, but not including fiber or bulking agents) **OR**
    B. The patient has an intolerance or hypersensitivity to at least 2 standard laxative therapy classes **OR**
    C. The patient has an FDA labeled contraindication to ALL standard laxative therapy classes **OR**
    D. The patient is currently being treated with the requested agent as indicated by ALL of the following:

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

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

D. The patient has a diagnosis of pediatric functional constipation and ONE of the following:
1. The patient has tried and had an inadequate response to at least 2 standard laxative therapy classes (e.g., bulk-forming, stimulant, enema, osmotic, or stool softener) **OR**
2. The patient has an intolerance or hypersensitivity to at least 2 standard laxative therapy classes **OR**
3. The patient has an FDA labeled contraindication to ALL standard laxative therapy classes **OR**
4. The patient is currently being treated with the requested agent as indicated by ALL of the following:
A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
5. The prescriber has provided documentation that ALL standard laxative therapy classes (e.g., bulk-forming, stimulant, enema, osmotic, or stool softener) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

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

Brand	**Generic**
Amitiza	lubiprostone

A. The patient has tried and had an inadequate response to the generic equivalent that is not expected to occur with the brand agent **OR**
B. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**
C. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent for the requested indication **OR**
D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

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

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

Length of Approval: 12 months

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

	Renewal Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for 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 (i.e., Amitiza/lubiprostone, Ibsrela, Linzess, Motegrity, Movantik, Relistor, Symproic, Trulance) **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
Universal 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. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

● Program Summary: Enspryng (satralizumab-mwge)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
9940507040E520	Enspryng	Satralizumab-mwge Subcutaneous Soln Pref Syringe	120 MG/ML	1	Syringe	28	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) **AND** 2. The patient is anti-aquaporin-4 (AQP4) antibody positive **AND** 3. The diagnosis was confirmed by at least ONE of the following: A. Optic neuritis **OR** B. Acute myelitis **OR** C. Area postrema syndrome (episode of otherwise unexplained hiccups or nausea and vomiting) **OR** D. Acute brainstem syndrome **OR** E. Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions **OR** F. Symptomatic cerebral syndrome with NMOSD-typical brain lesions **AND** 4. The patient has had at least 1 discrete clinical attack of CNS symptoms **AND** 5. Alternative diagnoses (e.g., multiple sclerosis, ischemic optic neuropathy) have been ruled out **AND** 6. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 8. The prescriber has screened the patient for hepatitis B viral (HBV) infection AND BOTH of the following: A. The patient does NOT have an active HBV infection **AND** B. If the patient has had a previous HBV infection or is a carrier for HBV infection the prescriber has consulted with a gastroenterologist or a hepatologist before initiating and during treatment with the requested agent **AND** 9. The patient does NOT have active or untreated tuberculosis **AND** 10. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 11. The patient will not be using the requested agent in combination with rituximab, Soliris, Uplizna, or Ultomiris for the requested indication **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met:

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

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Universal 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. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why 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 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 labeled indication for the requested agent **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for 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) is within FDA labeled dosing 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 [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. 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** 3. The patient has had clinical benefit with the requested agent **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. The requested quantity (dose) is within FDA labeled dosing for the requested indication **Length of Approval:** 12 months

● Program Summary: Gonadotropin Hormones

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
30090025106420	Cetrotide	Cetrorelix Acetate For Inj Kit 0.25 MG	0.25 MG	5	Kits	30	DAYS				
30062030102020	Follistim aq	Follitropin Beta Inj 300 Unit/0.36ML	300 UNT/0.36 ML	15	Cartridges	30	DAYS				
30062030102030	Follistim aq	Follitropin Beta Inj 600 Unit/0.72ML	600 UNT/0.72 ML	8	Cartridges	30	DAYS				
30062030102040	Follistim aq	Follitropin Beta Inj 900 Unit/1.08ML	900 UNT/1.08 ML	5	Cartridges	30	DAYS				
3009004010E520	Ganirelix	Ganirelix Acetate Soln Prefilled Syringe 250 MCG/0.5ML	250 MCG/0.5 ML	5	Syringes	30	DAYS				
30062030052150	Gonal-f	Follitropin Alfa For Inj 1050 Unit	1050 UNIT	4	Syringes	30	DAYS				
30062030052140	Gonal-f	Follitropin Alfa For Inj 450 Unit	450 UNIT	10	Syringes	30	DAYS				
30062030052115	Gonal-f rff	Follitropin Alfa For	75 UNIT	20	Syringes	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		Subcutaneous Inj 75 Unit									
3006203005D220	Gonal-f rff rediject	Follitropin Alfa Subcutaneous Soln Pen-inj	300 UNIT/0.5 ML	15	Pens	30	DAYS				
3006203005D225	Gonal-f rff rediject	Follitropin Alfa Subcutaneous Soln Pen-inj	450 UNT/0.75 ML	10	Pens	30	DAYS				
3006203005D240	Gonal-f rff rediject	Follitropin Alfa Subcutaneous Soln Pen-inj	900 UNIT/1.5 ML	5	Pens	30	DAYS				
30062050002175	Menopur	Menotropins For Subcutaneous Inj 75 Unit	75 UNIT	60	Vials	30	DAYS				
30062020002130	Novarel	Chorionic Gonadotropin For IM Inj 5000 Unit	5000 UNIT	4	Vials	30	DAYS				
30062020002140	Novarel; Pregnyl; Pregnyl w/diluent benzyl	Chorionic Gonadotropin For IM Inj 10000 Unit	10000 UNIT	2	Vials	30	DAYS				
30062022052220	Ovidrel	Choriogonadotropin Alfa Inj 250 MCG/0.5ML	250 MCG/0.5 ML	2	Syringes	30	DAYS				
		Inj Unit									

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Follicle Stimulating Hormone	**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: 1. 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. 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** 2. 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:

Preferred Target Agents	**Non-Preferred Target Agents**
Follistim AQ (follitropin beta)	Gonal F Kit (follitropin alfa) Gonal F RFF (follitropin alfa) Gonal F RFF Pen (follitropin alfa)

   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:
    1. 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. 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**
    2. 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:

Preferred Target Agents	**Non-Preferred Target Agents**
Follistim AQ (follitropin beta)	Gonal F Kit (follitropin alfa) Gonal F RFF (follitropin alfa) Gonal F RFF Pen (follitropin alfa)

            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**

C. The requested agent will be used for hypogonadotropic hypogonadism AND ALL of the following:

1. The requested agent is Follistim AQ or Gonal-F **AND**
2. The patient does not have primary testicular failure **AND**
3. The requested agent will be used in combination with human chorionic gonadotropin (hCG) **AND**
4. The requested agent will not be started until the patient's serum testosterone level is at normal levels **AND**
5. ONE of the following:

Preferred Target Agents	Non-Preferred Target Agents
Follistim AQ (follitropin beta)	Gonal F Kit (follitropin alfa) Gonal F RFF (follitropin alfa) Gonal F RFF Pen (follitropin alfa)

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 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

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

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

Gonadotropin Releasing Hormone (GnRH) Analogs

Gonadotropin Releasing Hormone (GnRH) Analogs Evaluation

Cetrotide and 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

1. 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 undergoing ovarian stimulation **AND**
2. The patient is NOT pregnant **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 will receive human chorionic gonadotropin (hCG) following completion of the requested agent unless there are risks present for ovarian hyper-stimulation syndrome (OHSS) **AND**
6. ONE of the following:

Preferred Target Agents	Non-Preferred Target Agents
Ganirelix acetate* *generic available and included as preferred in this program	Cetrotide (cetrorelix acetate)

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

Length of Approval: 3 months

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

Human Chorionic Gonadotropin Evaluation	**Human Chorionic Gonadotropin Evaluation** **Novarel, Ovidrel, Pregnyl, and Chorionic gonadotropin** will be approved when BOTH 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: 1. The requested agent is Novarel, Pregnyl, or hCG **AND** 2. The diagnosis is not due to an anatomical obstruction **AND**

3. The patient is prepubertal **AND**
4. 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:
1. The requested agent is Novarel, Pregnyl, or hCG **AND**
2. 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:
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
Ovidrel (chorionic gonadotropin) Pregnyl (chorionic gonadotropin)

        1. 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 partner been evaluated (if applicable) **AND**

6. ONE of the following:

Preferred Target Agents	Non-Preferred Target Agents
Ovidrel (chorionic gonadotropin) Pregnyl (chorionic gonadotropin)	Chorionic gonadotropin Novarel (chorionic gonadotropin)

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:
    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**

2. The patient does NOT have any FDA labeled contraindications to the requested agent

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

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

Menotropins

Menotropins Evaluation

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

1. 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 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** 2. The patient is NOT pregnant **AND** 3. The patient does NOT have primary ovarian failure **AND** 4. 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** 5. The patient has undergone a complete medical and endocrinologic evaluation **AND** 6. 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 **Length of Approval:** 3 months NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Universal 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. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months

• Program Summary: Hepatitis C Direct Acting Antivirals

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
123599026530	Epclusa	sofosbuvir-velpatasvir pellet pack	150-37.5 MG; 200-50 MG	28	Packets	28	DAYS				
123599026503	Epclusa	sofosbuvir-velpatasvir tab	200-50 MG; 400-100 MG	28	Tablets	28	DAYS				
123599024030	Harvoni	ledipasvir-sofosbuvir pellet pack	33.75-150 MG; 45-200 MG	28	Packets	28	DAYS				
123599024003	Harvoni	ledipasvir-sofosbuvir tab	45-200 MG; 90-400 MG	28	Tablets	28	DAYS				
123599023530	Mavyret	glecaprevir-pibrentasvir pellet pack	50-20 MG	150	Packets	30	DAYS				
123599023503	Mavyret	glecaprevir-pibrentasvir tab	100-40 MG	90	Tablets	30	DAYS				
123530800030	Sovaldi	sofosbuvir pellet pack	150 MG; 200 MG	28	Packs	28	DAYS				
123530800003	Sovaldi	sofosbuvir tab	200 MG; 400 MG	30	Tablets	30	DAYS				
1235990460B7	Viekira pak	ombitas-paritapre-riton & dasab tab pak	12.5-75-50 & 250 MG	1	Pack	28	DAYS				
123599038003	Vosevi	sofosbuvir-velpatasvir-voxilaprevir tab	400-100-100 MG	30	Tablets	30	DAYS				
123599023003	Zepatier	elbasvir-grazoprevir tab	50-100 MG	30	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval	
Epclusa and Sofosbuvir/Velpatasvir	**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	**Genotype 3**

Epclusa (sofosbuvir/velpatasvir) **Sofosbuvir/Velpatasvir** **Mavyret** (glecaprevir/pibrentasvir) **Vosevi** (sofosbuvir/velpatasvir/voxilaprevir)	**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 **Epclusa** (sofosbuvir/velpatasvir) **Harvoni** (ledipasvir/sofosbuvir) **Ledipasvir/Sofosbuvir** **Sofosbuvir/Velpatasvir** **Mavyret** (glecaprevir/pibrentasvir) **Vosevi** (sofosbuvir/velpatasvir/voxilaprevir)	**Genotype 6**

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)

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:
        1. The patient has a diagnosis of hepatitis C genotype 1, 2, 3, 4, 5, or 6 **AND**
        2. 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**
        3. If the patient has an FDA labeled indication, then ONE of the following:

A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
B. There is support for the use of the requested agent for the patient's age for the requested indication **AND**

4. The prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection **AND**
5. 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**
6. 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 Eligible for Simplified HCV Treatment

Adults with chronic HCV infection, including persons living with HIV:
• Infected with any genotype
• Have NOT previously received HCV treatment
• Without cirrhosis OR with compensated cirrhosis (Child-Pugh A) as determined by:
  ○ Liver stiffness > 12.5 kPa by FibroScan
  ○ FIB-4 > 3.25
  ○ Noninvasive serologic test
  ○ Liver biopsy
  ○ Live nodularity or splenomegaly on imaging
  ○ Platelet count < 150,000/mm^3

Patients Excluded from Simplified HCV Treatment
Adults with chronic HCV infection: • Previously received HCV treatment • Hepatitis B surface antigen-positive • Compensated cirrhosis (Child-Pugh A) with end-stage renal disease (i.e., eGFR less than 30 mL/min/m^2) • Current or prior decompensated cirrhosis, defined by Child-Pugh score greater than or equal to 7 • Current pregnancy • Known or suspected hepatocellular carcinoma • 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. 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 regiment

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

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

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
1, 2, 3, 4, 5, or 6	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, velpatasvir) - based treatment failed	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 with weight-based ribavirin (low initial dose of ribavirin [600 mg] is recommended for patients	24 weeks

<table>
<tr><td></td><td>
<table>
<tr><td></td><td></td><td>with Child-Turcotte-Pugh class C cirrhosis)</td><td></td></tr>
</table>
*HCV/HIV-1 co-infection, follow recommendation in table above
</td></tr>
<tr><td>Harvoni and Ledipasvir/Sofosbuvir</td><td>
<table>
<tr><th>Preferred Agent(s) - a,c</th><th>Non-Preferred Agent(s) - c,d</th></tr>
<tr><td>Genotype 1

Epclusa (sofosbuvir/velpatasvir
Harvoni (ledipasvir/sofosbuvir)
Ledipasvir/Sofosbuvir
Sofosbuvir/Velpatasvir
Mavyret (glecaprevir/pibrentasvir)
Vosevi (sofosbuvir/velpatasvir/voxilaprevir)</td><td>Genotype 1

Sovaldi (sofosbuvir) -b
Viekira PAK (ombitasvir/paritaprevir/ritonavir + dasabuvir)
Zepatier (elbasvir/grazoprevir)</td></tr>
<tr><td>Genotype 2

Epclusa (sofosbuvir/velpatasvir)
Sofosbuvir/Velpatasvir
Mavyret (glecaprevir/pibrentasvir)
Vosevi (sofosbuvir/velpatasvir/voxilaprevir)</td><td>Genotype 2

Sovaldi (sofosbuvir) -b</td></tr>
<tr><td>Genotype 3

Epclusa (sofosbuvir/velpatasvir)
Sofosbuvir/Velpatasvir
Mavyret (glecaprevir/pibrentasvir)
Vosevi (sofosbuvir/velpatasvir/voxilaprevir)</td><td>Genotype 3

Sovaldi (sofosbuvir) -b</td></tr>
<tr><td>Genotype 4

Epclusa (sofosbuvir/velpatasvir)
Harvoni (ledipasvir/sofosbuvir)
Ledipasvir/Sofosbuvir
Sofosbuvir/Velpatasvir
Mavyret (glecaprevir/pibrentasvir)
Vosevi (sofosbuvir/velpatasvir/voxilaprevir)</td><td>Genotype 4

Sovaldi (sofosbuvir) -b
Zepatier (elbasvir/grazoprevir)</td></tr>
<tr><td>Genotype 5

Epclusa (sofosbuvir/velpatasvir)
Harvoni (ledipasvir/sofosbuvir)
Ledipasvir/Sofosbuvir
Sofosbuvir/Velpatasvir
Mavyret (glecaprevir/pibrentasvir)
Vosevi (sofosbuvir/velpatasvir/voxilaprevir)</td><td>Genotype 5</td></tr>
<tr><td>Genotype 6

Epclusa (sofosbuvir/velpatasvir)
Harvoni (ledipasvir/sofosbuvir)
Ledipasvir/Sofosbuvir
Sofosbuvir/Velpatasvir
Mavyret (glecaprevir/pibrentasvir)
Vosevi (sofosbuvir/velpatasvir/voxilaprevir)</td><td>Genotype 6</td></tr>
</table>
</td></tr>
</table>

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)

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:
        1. The patient has a diagnosis of hepatitis C genotype 1, 4, 5, or 6 **AND**
        2. The prescriber has provided the patient's baseline HCV RNA level if the patient has genotype 1 **AND**
        3. 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**
        4. The prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection **AND**
        5. 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**
        6. If the patient has an FDA labeled indication, then ONE of the following:
            A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
            B. There is support for using the requested agent for the patient's age for the requested indication **AND**
        7. 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 Eligible for Simplified HCV Treatment
Adults with chronic HCV infection, including persons living with HIV: • Infected with any genotype • Have NOT previously received HCV treatment

- Without cirrhosis OR with compensated cirrhosis (Child-Pugh A) as determined by:
    - Liver stiffness > 12.5 kPa by FibroScan
    - FIB-4 > 3.25
    - Noninvasive serologic test
    - Liver biopsy
    - Live nodularity or splenomegaly on imaging
    - Platelet count < 150,000/mm^3

Patients Excluded from Simplified HCV Treatment

Adults with chronic HCV infection:

- Previously received HCV treatment
- Hepatitis B surface antigen-positive
- Compensated cirrhosis (Child-Pugh A) with end-stage renal disease (i.e., eGFR less than 30 mL/min/m^2)
- Current or prior decompensated cirrhosis, defined by Child-Pugh score greater than or equal to 7
- Current pregnancy
- Known or suspected hepatocellular carcinoma
- 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. 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

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

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

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

Genotype	Patients 3 years of age and older*	Treatment	Duration
1	Treatment-naive 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**
1	Treatment-naive without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh A)	Harvoni, Ledipasvir/Sofosbuvir	12 weeks
1	Treatment-experienced (i.e., patients who have	Harvoni, Ledipasvir/Sofosbuvir	12 weeks

		failed therapy with either peg-interferon + ribavirin +/- an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir]) without cirrhosis		
	1	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
	1	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
	1	Treatment-naive 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-naive and treatment-experienced (i.e., patients who have failed therapy with either peg-interferon + ribavirin +/- an HCV protease inhibitor [e.g., boceprevir,	Harvoni + ribavirin, Ledipasvir/Sofosbuvir + ribavirin	12 weeks

	paritaprevir, simeprevir, telaprevir]) liver transplant recipients without cirrhosis, or with compensated cirrhosis (Child-Turcotte-Pugh A)		
4, 5, or 6	Treatment-naive 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 ribavirin (600 mg); increase as tolerated	24 weeks

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

Mavyret

Preferred Agent(s) - a,c	Non-Preferred Agent(s) - c,d
Genotype 1 **Epclusa** (sofosbuvir/velpatasvir) **Harvoni** (ledipasvir/sofosbuvir) **Ledipasvir/Sofosbuvir**	**Genotype 1** **Sovaldi** (sofosbuvir) -b **Viekira PAK** (ombitasvir/paritaprevir/ritonavir +

Sofosbuvir/Velpatasvir **Mavyret** (glecaprevir/pibrentasvir) **Vosevi** (sofosbuvir/velpatasvir/voxilaprevir)	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 **Epclusa** (sofosbuvir/velpatasvir) **Harvoni** (ledipasvir/sofosbuvir) **Ledipasvir/Sofosbuvir** **Sofosbuvir/Velpatasvir** **Mavyret** (glecaprevir/pibrentasvir) **Vosevi** (sofosbuvir/velpatasvir/voxilaprevir)	**Genotype 6**

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)

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:

1. The patient has a diagnosis of hepatitis C genotype 1, 2, 3, 4, 5, or 6 **AND**
2. If the patient has an FDA labeled indication, then ONE of the following:
    A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
    B. There is support for using the requested agent for the patient's age for the requested indication **AND**
3. The prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection **AND**
4. 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**
5. 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 Patients Who Qualify for Simplified Treatment tables below) **AND**

Patients Eligible for Simplified HCV Treatment

Adults with chronic HCV infection, including persons living with HIV:
 	
• Infected with any genotype
• Have NOT previously received HCV treatment
• Without cirrhosis OR with compensated cirrhosis (Child-Pugh A) as determined by:
  ○ Liver stiffness > 12.5 kPa by FibroScan
  ○ FIB-4 > 3.25
  ○ Noninvasive serologic test
  ○ Liver biopsy
  ○ Live nodularity or splenomegaly on imaging
  ○ Platelet count < 150,000/mm^3

Patients Excluded from Simplified HCV Treatment
Adults with chronic HCV infection: • Previously received HCV treatment • Hepatitis B surface antigen-positive • Compensated cirrhosis (Child-Pugh A) with end-stage renal disease (i.e., eGFR less than 30 mL/min/m^2) • Current or prior decompensated cirrhosis, defined by Child-Pugh score greater than or equal to 7 • Current pregnancy • Known or suspected hepatocellular carcinoma

- Prior liver transplantation

6. 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. The requested length of therapy does NOT exceed the length of therapy noted in Table 5 (FDA labeling) for the patient's treatment regimen

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

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

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**	**Duration - 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	Mavyret	16 weeks	16 weeks

	HCV NS3/4A PI or NS5A inhibitor)			
1, 2, 3, 4, 5, or 6	Treatment naive	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 recommendations in the table above + Patients with any degree of kidney impairment (including those on hemodialysis), follow recommendations in the table above
Sovaldi	

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 **Epclusa** (sofosbuvir/velpatasvir) **Harvoni** (ledipasvir/sofosbuvir) **Ledipasvir/Sofosbuvir** **Sofosbuvir/Velpatasvir** **Mavyret** (glecaprevir/pibrentasvir) **Vosevi** (sofosbuvir/velpatasvir/voxilaprevir)	**Genotype 6**

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)

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:
        1. 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 labeled indication, ONE of the following:
                1. The patient's age is within FDA labeling for the requested agent for the requested indication **OR**
                2. There is support for 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 labeled indication, then ONE of the following:
                    A. The patient's age is within FDA labeling for the requested agent for the requested indication **OR**
                    B. There is support for 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. There is support for 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:
                        1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
                        2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
                        3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
                    E. The prescriber has provided documentation that BOTH 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. 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 **OR**
    C. The patient has an FDA labeled contraindication to ALL preferred agent(s) for the patient's specific factors **OR**
    D. There is support for 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, 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 prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection **AND**
3. 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**
4. 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 Eligible for Simplified HCV Treatment

Adults with chronic HCV infection, including persons living with HIV:
• Infected with any genotype
• Have NOT previously received HCV treatment
• Without cirrhosis OR with compensated cirrhosis (Child-Pugh A) as determined by:
  ○ Liver stiffness > 12.5 kPa by FibroScan
  ○ FIB-4 > 3.25
  ○ Noninvasive serologic test
  ○ Liver biopsy
  ○ Live nodularity or splenomegaly on imaging
  ○ Platelet count < 150,000/mm^3

Patients Excluded from Simplified HCV Treatment
Adults with chronic HCV infection: • Previously received HCV treatment • Hepatitis B surface antigen-positive • Compensated cirrhosis (Child-Pugh A) with end-stage renal disease (i.e., eGFR less than 30 mL/min/m^2) • Current or prior decompensated cirrhosis, defined by Child-Pugh score greater than or equal to 7 • Current pregnancy • Known or suspected hepatocellular carcinoma • 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 will in a treatment regimen noted in Table 6 or 7 (FDA labeling) **AND**
4. 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

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

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

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	Sovaldi + ribavirin	24 weeks

	• A baseline platelet count below 90,000/µL • A baseline hemoglobin below 10 g/dL • A history of preexisting cardiac disease)		
2	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	12 weeks
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 recommendations 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)	Sovaldi + ribavirin	12 weeks

	without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh A)		
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 recommendations in table above

Viekira Pak

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 **Epclusa** (sofosbuvir/velpatasvir) **Harvoni** (ledipasvir/sofosbuvir) **Ledipasvir/Sofosbuvir** **Sofosbuvir/Velpatasvir** **Mavyret** (glecaprevir/pibrentasvir) **Vosevi** (sofosbuvir/velpatasvir/voxilaprevir)	**Genotype 6**

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)

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:
        1. The patient has a diagnosis of hepatitis C genotype 1 **AND**
        2. The prescriber has provided the patient's subtype **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 **AND**
        4. If the patient has an FDA labeled indication, then ONE of the following:
            A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
            B. There is support for the use of the requested agent for the patient's age for the requested indication **AND**
        5. The prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection **AND**
        6. 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**
        7. 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 naive **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 Eligible for Simplified HCV Treatment

Adults with chronic HCV infection, including persons living with HIV:
• Infected with any genotype
• Have NOT previously received HCV treatment
• Without cirrhosis OR with compensated cirrhosis (Child-Pugh A) as determined by:
  ○ Liver stiffness > 12.5 kPa by FibroScan
  ○ FIB-4 > 3.25
  ○ Noninvasive serologic test
  ○ Liver biopsy
  ○ Live nodularity or splenomegaly on imaging
  ○ Platelet count < 150,000/mm^3

Patients Excluded from Simplified HCV Treatment
Adults with chronic HCV infection: • Previously received HCV treatment • Hepatitis B surface antigen-positive • Compensated cirrhosis (Child-Pugh A) with end-stage renal disease (i.e., eGFR less than 30 mL/min/m^2) • Current or prior decompensated cirrhosis, defined by Child-Pugh score greater than or equal to 7 • Current pregnancy • Known or suspected hepatocellular carcinoma • Prior liver transplantation

8. 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. 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 **OR**
   C. The patient has an FDA labeled contraindication to ALL preferred agent(s) for the patient's specific factors **OR**
   D. There is support for 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. The requested length of therapy does NOT exceed the length of therapy noted in Table 8 (FDA labeling) for the patient's treatment regimen

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

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

Table 8: Viekira PAK Treatment Recommendations based on FDA labeling:

Genotype	Patient Population*	Treatment	Duration
1a	Without cirrhosis	Viekira PAK + ribavirin	12 weeks
1a	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 recommendations in table above

Vosevi

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 **Epclusa** (sofosbuvir/velpatasvir) **Harvoni** (ledipasvir/sofosbuvir) **Ledipasvir/Sofosbuvir** **Sofosbuvir/Velpatasvir** **Mavyret** (glecaprevir/pibrentasvir) **Vosevi** (sofosbuvir/velpatasvir/voxilaprevir)	**Genotype 6**

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)

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:
        1. The patient has a diagnosis of hepatitis C genotype 1, 2, 3, 4, 5, or 6 **AND**
        2. If genotype 1, the prescriber has provided the patient's subtype **AND**
        3. The patient is NOT treatment naïve **AND**
        4. The patient has NOT been previously treated with the requested agent **AND**
        5. If the patient has an FDA labeled indication, then ONE of the following:
            A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**

B. There is support for the use of the requested agent for the patient's age for the requested indication **AND**

6. The prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection **AND**
7. 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**
8. 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 Eligible for Simplified HCV Treatment

Adults with chronic HCV infection, including persons living with HIV:
 	
• Infected with any genotype
• Have NOT previously received HCV treatment
• Without cirrhosis OR with compensated cirrhosis (Child-Pugh A) as determined by:
  ○ Liver stiffness > 12.5 kPa by FibroScan
  ○ FIB-4 > 3.25
  ○ Noninvasive serologic test
  ○ Liver biopsy
  ○ Live nodularity or splenomegaly on imaging
  ○ Platelet count < 150,000/mm^3

Patients Excluded from Simplified HCV Treatment
Adults with chronic HCV infection: • Previously received HCV treatment • Hepatitis B surface antigen-positive • Compensated cirrhosis (Child-Pugh A) with end-stage renal disease (i.e., eGFR less than 30 mL/min/m^2) • Current or prior decompensated cirrhosis, defined by Child-Pugh score greater than or equal to • Current pregnancy • Known or suspected hepatocellular carcinoma • 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.

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

Table 9: Vosevi Treatment Recommendations based on FDA labeling

Genotype	Patient Population*	Patients Previously Treated with an HCV Regimen containing:	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 recommendations in table above
+ - Sofosbuvir with or without any of the following: peginterferon alfa/ribavirin, ribavirin, HCV NS3/4A protease inhibitor (simeprevir)

Zepatier

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**	**Genotype 4** **Sovaldi** (sofosbuvir) -b **Zepatier** (elbasvir/grazoprevir)

Mavyret (glecaprevir/pibrentasvir) **Vosevi** (sofosbuvir/velpatasvir/voxilaprevir)	
Genotype 5 **Epclusa** (sofosbuvir/velpatasvir) **Harvoni** (ledipasvir/sofosbuvir) **Ledipasvir/Sofosbuvir** **Sofosbuvir/Velpatasvir** **Mavyret** (glecaprevir/pibrentasvir) **Vosevi** (sofosbuvir/velpatasvir/voxilaprevir)	**Genotype 5**
Genotype 6 **Epclusa** (sofosbuvir/velpatasvir) **Harvoni** (ledipasvir/sofosbuvir) **Ledipasvir/Sofosbuvir** **Sofosbuvir/Velpatasvir** **Mavyret** (glecaprevir/pibrentasvir) **Vosevi** (sofosbuvir/velpatasvir/voxilaprevir)	**Genotype 6**

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)

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:
        1. The patient has a diagnosis of hepatitis C genotype 1 or 4 **AND**
        2. 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**
        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 with or without an HCV protease inhibitor **AND**
        4. If the patient has an FDA labeled indication, then ONE of the following:
            A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
            B. There is support for the use of the requested agent for the patient's age for the requested indication **AND**
        5. The prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection **AND**
        6. 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**

7. 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 Eligible for Simplified HCV Treatment

Adults with chronic HCV infection, including persons living with HIV:
 	
• Infected with any genotype
• Have NOT previously received HCV treatment
• Without cirrhosis OR with compensated cirrhosis (Child-Pugh A) as determined by:
  ○ Liver stiffness > 12.5 kPa by FibroScan
  ○ FIB-4 > 3.25
  ○ Noninvasive serologic test
  ○ Liver biopsy
  ○ Live nodularity or splenomegaly on imaging
  ○ Platelet count < 150,000/mm^3

Patients Excluded from Simplified HCV Treatment
Adults with chronic HCV infection: • Previously received HCV treatment • Hepatitis B surface antigen-positive • Compensated cirrhosis (Child-Pugh A) with end-stage renal disease (i.e., eGFR less than 30 mL/min/m^2) • Current or prior decompensated cirrhosis, defined by Child-Pugh score greater than or equal to 7 • Current pregnancy • Known or suspected hepatocellular carcinoma • Prior liver transplantation

8. 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 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 **OR**
    C. The patient has an FDA labeled contraindication to ALL preferred agent(s) for the patient's specific factors **OR**
    D. There is support for 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

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

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
1a	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
4	PegIFN/RBV-experienced	Zepatier + ribavirin	16 weeks

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

ZZZ New to Market Hepatitis C Agents

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 **Epclusa** (sofosbuvir/velpatasvir) **Harvoni** (ledipasvir/sofosbuvir) **Ledipasvir/Sofosbuvir** **Sofosbuvir/Velpatasvir** **Mavyret** (glecaprevir/pibrentasvir) **Vosevi** (sofosbuvir/velpatasvir/voxilaprevir)	**Genotype 6**

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)

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:
        1. The patient has an FDA labeled diagnosis for the requested agent **AND**
        2. The requested agent is FDA labeled for treatment of the patient's genotype **AND**
        3. If the patient has an FDA labeled indication, then ONE of the following:
            A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
            B. There is support for the use of the requested agent for the patient's age for the requested indication **AND**
        4. 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**
        5. 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**
        6. 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. 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 **OR**
            D. The patient has an FDA labeled contraindication to ALL preferred agent(s) for the patient's specific factors **OR**
            E. There is support for 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**

Patients Eligible for Simplified HCV Treatment

Adults with chronic HCV infection, including persons living with HIV:

- Infected with any genotype
- Have NOT previously received HCV treatment
- Without cirrhosis OR with compensated cirrhosis (Child-Pugh A) as determined by:
    - Liver stiffness > 12.5 kPa by FibroScan
    - FIB-4 > 3.25
    - Noninvasive serologic test
    - Liver biopsy
    - Live nodularity or splenomegaly on imaging
    - Platelet count < 150,000/mm^3

Patients Excluded from Simplified HCV Treatment

Adults with chronic HCV infection:

- Previously received HCV treatment
- Hepatitis B surface antigen-positive
- Compensated cirrhosis (Child-Pugh A) with end-stage renal disease (i.e., eGFR less than 30 mL/min/m^2)
- Current or prior decompensated cirrhosis, defined by Child-Pugh score greater than or equal to 7
- Current pregnancy
- Known or suspected hepatocellular carcinoma
- 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 11 (FDA labeling) **AND**
4. The requested length of therapy does NOT exceed the length of therapy noted in Table 11 (FDA labeling) for the patient's treatment regimen

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

	NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Table 11: Treatment Recommendations based on FDA labeling**

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

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Epclusa and Sofosbuvir/Velpatasvir	**Quantity Limit for the Target Agent(s)** will be approved when BOTH of the following are met: 1. 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** 2. ONE of the following: A. The requested quantity (dose) does NOT exceed the program quantity limit **OR** B. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: 1. The requested agent is Epclusa 200 mg/50 mg packets AND BOTH of the following: A. The requested quantity (dose) does NOT exceed 2 packets per day **AND** B. There is support for why the patient cannot take 1 tablet of the 400 mg/100 mg tablet **OR** 2. 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. There is support for 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
1, 2, 3, 4, 5, or 6	Patients with decompensated cirrhosis (Child-Turcotte-Pugh B and C)	Epclusa + ribavirin, Sofosbuvir/Velpatasvir + ribavirin	12 weeks

*HCV/HIV-1 co-infection, follow recommendations 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, velpatasvir) -based treatment failed	Epclusa with weight-based ribavirin (low initial dose of ribavirin [600 mg] is recommended for patients with Child-Turcotte-Pugh class C cirrhosis), Sofsobuvir/Velpatasvir with weight-based ribavirin (low initial dose of ribavirin [600 mg] is recommended for patients with Child-Turcotte-Pugh class C cirrhosis)	24 weeks

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

Harvoni and Ledipasvir/Sofosbuvir

Quantity Limit for the Target Agent(s) will be approved when BOTH of the following are met:

1. 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**
2. ONE of the following:
    A. The requested quantity (dose) does NOT exceed the program quantity limit **OR**
    B. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following:
        1. The requested agent is Harvoni 45 mg/200 mg oral pellets AND BOTH of the following:
            A. The requested quantity (dose) does NOT exceed 2 packets daily **AND**
            B. There is support for why the patient cannot take 1 tablet of Harvoni 90 mg/400 mg strength **OR**
        2. The requested agent is Harvoni 45 mg/200 mg tablet 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 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
1	Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh A)	Harvoni, Ledipasvir/Sofosbuvir	12 weeks
1	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
1	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
1	Treatment-experienced (i.e., patients who have failed therapy with either peg-interferon +	Harvoni, Ledipasvir/Sofosbuvir	24 weeks

	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)		
1	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	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 ribavirin (600 mg); increase as tolerated	24 weeks

Mavyret	**Quantity Limit for the Target Agent(s)** will be approved when BOTH of the following are met: 1. 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** 2. ONE of the following: A. The requested quantity (dose) does NOT exceed the program quantity limit **OR**

B. The requested quantity (dose) exceeds the program quantity limit AND ALL of the following:
   1. The requested agent is Mavyret 50 mg/20 mg packets **AND**
   2. The requested quantity (dose) does NOT exceed 6 packets per day **AND**
   3. There is support for 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	Duration - 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	Mavyret	16 weeks	16 weeks

	treatment experience with an HCV NS3/4A PI or NS5A inhibitor)			
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	Mavyret	16 weeks	16 weeks

		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)			

*HCV/HIV-1 co-infection, follow recommendations in the table above
+Patients with any degree of kidney impairment (including those on hemodialysis), follow recommendations in the table above

Sovaldi

Quantity Limit for the Target Agent(s) will be approved when BOTH of the following are met:

1. 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**
2. ONE of the following:
   A. The requested quantity (dose) does NOT exceed the program quantity limit **OR**
   B. The requested agent is Sovaldi 200 mg oral pellets AND BOTH of the following:
      1. The requested quantity (dose) does NOT exceed 2 packets daily **AND**
      2. There is support for why the patient cannot take 1 tablet of Sovaldi 400 mg strength **OR**
   C. The requested agent is Sovaldi 200 mg tablets 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 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:	Sovaldi + ribavirin	24 weeks

	• 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)		
2	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	12 weeks
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 recommendations 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 recommendations in table above

Viekira Pak

Quantity Limit for the Target Agent(s) will be approved when BOTH of the following are met:

1. 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**
2. 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

	1a	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 recommendations in table above

Vosevi

Quantity Limit for the Target Agent(s) will be approved when BOTH of the following are met:

1. The requested length of therapy does NOT exceed the length of therapy noted in Table 9 (FDA labeling) for the patient's regimen **AND**
2. 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:	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 recommendations in table above
+ - Sofosbuvir with or without any of the following: peginterferon alfa/ribavirin, ribavirin, HCV NS3/4A protease inhibitor (simeprevir)

Zepatier

Quantity Limit for the Target Agent(s) will be approved when BOTH of the following are met:

1. 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**
2. 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
1a	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
4	PegIFN/RBV-experienced	Zepatier + ribavirin	16 weeks

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

ZZZ New to Market Hepatitis C Agents

Quantity Limit for the Target Agent(s) will be approved when BOTH of the following are met:

1. 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**
2. ONE of the following:
   A. The requested quantity (dose) does NOT exceed the program quantity limit **OR**
   B. BOTH of the following:
      1. The requested quantity (dose) is greater than the program quantity limit **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 Table 11.

Table 11: Treatment Recommendations based on FDA labeling

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

● Program Summary: Multiple Sclerosis Agents

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
62405530006520		Diroximel Fumarate Capsule DR Starter Bottle 231 MG		106	Capsules	180	DAYS				
624040700003	Aubagio	teriflunomide tab	14 MG; 7 MG	30	Tablets	30	DAYS				
6240306045F830	Avonex	Interferon Beta-1a IM Prefilled Syringe Kit 30 MCG/0.5ML	30 MCG/0.5ML	1	Kit	28	DAYS				
6240306045F530	Avonex pen	Interferon Beta-1a IM Auto-Injector Kit 30 MCG/0.5ML	30 MCG/0.5ML	1	Kit	28	DAYS				
62405550006520	Bafiertam	Monomethyl Fumarate Capsule Delayed Release	95 MG	120	Capsules	30	DAYS				
62403060506420	Betaseron	Interferon Beta-; interferon beta-	0.3 MG	14	Vials	28	DAYS	50419052401; 50419052435			
6240003010E520	Copaxone; Glatopa	Glatiramer Acetate Soln Prefilled Syringe 20 MG/ML	20 MG/ML	30	Syringes	30	DAYS				
6240003010E540	Copaxone; Glatopa	Glatiramer Acetate Soln Prefilled Syringe 40 MG/ML	40 MG/ML	12	Syringes	28	DAYS				
62403060506420	Extavia	Interferon Beta-; interferon beta-	0.3 MG	15	Vials	30	DAYS	00078056912; 00078056961; 00078056999			
624070251001	Gilenya	fingolimod hcl cap	0.25 MG; 0.5 MG	30	Capsules	30	DAYS				
6240506500D520	Kesimpta	Ofatumumab Soln Auto-Injector	20 MG/0.4ML	1	Pen	28	DAYS				
6240101500B744	Mavenclad	Cladribine Tab Therapy Pack 10 MG (10 Tabs)	10 MG	20	Tablets	301	DAYS				
6240101500B718	Mavenclad	Cladribine Tab Therapy Pack 10 MG (4 Tabs)	10 MG	8	Tablets	301	DAYS				
6240101500B722	Mavenclad	Cladribine Tab Therapy Pack 10 MG (5 Tabs)	10 MG	10	Tablets	301	DAYS				
6240101500B726	Mavenclad	Cladribine Tab Therapy Pack 10 MG (6 Tabs)	10 MG	12	Tablets	301	DAYS				
6240101500B732	Mavenclad	Cladribine Tab Therapy Pack 10 MG (7 Tabs)	10 MG	14	Tablets	301	DAYS				
6240101500B736	Mavenclad	Cladribine Tab Therapy Pack 10 MG (8 Tabs)	10 MG	8	Tablets	301	DAYS				
6240101500B740	Mavenclad	Cladribine Tab Therapy Pack 10 MG (9 Tabs)	10 MG	9	Tablets	301	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
62407070200330	Mayzent	Siponimod Fumarate Tab	1 MG	30	Tablets	30	DAYS				
62407070200320	Mayzent	Siponimod Fumarate Tab 0.25 MG (Base Equiv)	0.25 MG	120	Tablets	30	DAYS				
62407070200340	Mayzent	Siponimod Fumarate Tab 2 MG (Base Equiv)	2 MG	30	Tablets	30	DAYS				
6240707020B710	Mayzent starter pack	Siponimod Fumarate Tab	0.25 MG	1	Pack	180	DAYS				
6240707020B720	Mayzent starter pack	Siponimod Fumarate Tab 0.25 MG (12) Starter Pack	0.25 MG	1	Pack	180	DAYS				
6240307530E521	Plegridy	Peginterferon Beta-	125 MCG/0.5ML	2	Syringes	28	DAYS				
6240307530D220	Plegridy	Peginterferon Beta-1a Soln Pen-injector 125 MCG/0.5ML	125 MCG/0.5ML	2	Pens	28	DAYS				
6240307530E520	Plegridy	Peginterferon Beta-1a Soln Prefilled Syringe 125 MCG/0.5ML	125 MCG/0.5ML	2	Syringes	28	DAYS				
6240307530D250	Plegridy starter pack	Peginterferon Beta-1a Soln Pen-inj 63 & 94 MCG/0.5ML Pack	63 & 94 MCG/0.5ML	1	Kit	180	DAYS				
6240307530E550	Plegridy starter pack	Peginterferon Beta-1a Soln Pref Syr 63 & 94 MCG/0.5ML Pack	63 & 94 MCG/0.5ML	1	Kit	180	DAYS				
62407060000320	Ponvory	Ponesimod Tab	20 MG	30	Tablets	30	DAYS				
6240706000B720	Ponvory 14-day starter pa	Ponesimod Tab Starter Pack	2-3-4-5-6-7-8-9 & 10 MG	1	Pack	180	DAYS				
6240306045E520	Rebif	Interferon Beta-1a Soln Pref Syr 22 MCG/0.5ML (12MU/ML)	22 MCG/0.5ML	12	Syringes	28	DAYS				
6240306045E540	Rebif	Interferon Beta-1a Soln Pref Syr 44 MCG/0.5ML (24MU/ML)	44 MCG/0.5ML	12	Syringes	28	DAYS				
6240306045D520	Rebif rebidose	Interferon Beta-1a Soln Auto-Inj 22 MCG/0.5ML (12MU/ML)	22 MCG/0.5ML	12	Syringes	28	DAYS				
6240306045D540	Rebif rebidose	Interferon Beta-1a Soln Auto-inj 44 MCG/0.5ML (24MU/ML)	44 MCG/0.5ML	12	Syringes	28	DAYS				
6240306045D560	Rebif rebidose titration	Interferon Beta-1a Auto-inj 6X8.8	6X8.8 & 6X22 MCG	1	Kit	180	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
		MCG/0.2ML & 6X22 MCG/0.5ML									
6240306045E560	Rebif titration pack	Interferon Beta-1a Pref Syr 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6X8.8 & 6X22 MCG	1	Kit	180	DAYS				
62407025207220	Tascenso odt	Fingolimod Lauryl Sulfate Tablet Disintegrating	0.25 MG	30	Tablets	30	DAYS				
62407025207230	Tascenso odt	Fingolimod Lauryl Sulfate Tablet Disintegrating	0.5 MG	30	Tablets	30	DAYS				
62405525006520	Tecfidera	Dimethyl Fumarate Capsule Delayed Release 120 MG	120 MG	56	Capsules	180	DAYS				
62405525006540	Tecfidera	Dimethyl Fumarate Capsule Delayed Release 240 MG	240 MG	60	Capsules	30	DAYS				
6240552500B320	Tecfidera starter pack	dimethyl fumarate capsule dr starter pack	120 & 240 MG	1	Kit	180	DAYS				
62405530006540	Vumerity	Diroximel Fumarate Capsule Delayed Release 231 MG	231 MG	120	Capsules	30	DAYS				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Preferred Agent(s)	Non-Preferred Agent(s)
Avonex (interferon β-1a) **Betaseron** (interferon β-1b) dimethyl fumarate* fingolimod* glatiramer* **Glatopa** (glatiramer)* **Kesimpta** (ofatumumab) **Mavenclad** (cladribine) **Mayzent** (siponimod) **Plegridy** (peginterferon β-1a) **Rebif** (interferon β-1a) teriflunomide* **Vumerity** (diroximel fumarate) **Zeposia** (ozanimod)***	**Aubagio** (teriflunomide)** **Bafiertam** (monomethyl fumarate) **Copaxone** (glatiramer)** **Extavia** (interferon β-1b) **Gilenya** (fingolimod)** **Ponvory** (ponesimod) **Tascenso ODT** (fingolimod) **Tecfidera** (dimethyl fumarate)**

*subject to duplicate therapy check only
**generic available
***target in a different program

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

1. ONE of following:
    A. 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**
    C. The patient is currently being treated with the requested agent as indicated by ALL of the following:
        1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
        2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
        3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
    D. The requested agent is a preferred agent **OR**
    E. The patient has highly active MS disease activity AND BOTH of the following:
        1. The patient has greater than or equal to 2 relapses in the previous year **AND**
        2. ONE of the following:
            A. The patient has greater than or equal to 1 gadolinium enhancing lesion on MRI **OR**
            B. The patient has significant increase in T2 lesion load compared with a previous MRI **OR**
    F. The patient has been treated with at least 3 MS agents from different drug classes (see MS disease modifying agents drug class table) **OR**
    G. The requested agent is a non-preferred agent AND ONE of the following:
        1. The patient is 17 years of age or younger AND ONE of the following:
            A. The requested agent does NOT have a corresponding preferred generic strength **OR**
            B. The patient has tried and had an inadequate response to generic fingolimod (medical records required) **OR**
            C. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to generic fingolimod **OR**
            D. The patient has an FDA labeled contraindication to generic fingolimod **OR**
            E. The prescriber has provided documentation that generic fingolimod cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**
        2. The patient is 18 years of age or older AND ONE of the following:
            A. The patient's medication history incudes use of TWO preferred agents **OR**
            B. BOTH of the following:
                1. The prescriber has stated that the patient has tried two preferred agents **AND**
                2. The preferred agents were discontinued due to lack of effectiveness or an adverse event **OR**
            C. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to TWO preferred agents **OR**
            D. The patient has an FDA labeled contraindication to ALL preferred agents **OR**
            E. The prescriber has provided documentation that ALL preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
2. If the requested agent is a brand agent with a generic equivalent (listed below) ONE of the following:

Non-Preferred Agent	**Generic Equivalent**
Aubagio	teriflunomide
Copaxone	Glatopa/glatiramer
Gilenya	fingolimod

Tecfidera	dimethyl fumarate

A. The patient's medication history includes use of the generic equivalent **OR**
B. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
    2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
    3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
C. The patient has an intolerance or hypersensitivity to the generic equivalent agent that is not expected to occur with the requested agent **OR**
D. The patient has an FDA labeled contraindication to the generic equivalent agent that is not expected to occur with the requested agent **OR**
E. The prescriber has provided documentation that ALL generic equivalents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

3. The patient will NOT be taking an additional disease modifying agent (DMA) for the requested indication

Length of Approval: 12 months. NOTE: For agents requiring a starter dose for initial use, the starter dose can be approved for the FDA labeled starting dose and the maintenance dose can be approved for the remainder of 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 Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does not have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months NOTE: For agents requiring a starter dose for initial use, the starter dose can be approved for the FDA labeled starting dose and the maintenance dose can be approved for the remainder of 12 months

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Examples of Contraindicated Concomitant Disease Modifying Agents (DMAs) **Aubagio** (teriflunomide)* **Avonex** (interferon β-1a)

Contraindicated as Concomitant Therapy
Bafiertam (monomethyl fumarate) **Betaseron** (interferon β-1b) **Briumvi** (ublituximab-xiiy) **Copaxone** (glatiramer)* dimethyl fumarate **Extavia** (interferon β-1b) fingolimod **Gilenya** (fingolimod)* **Glatopa** (glatiramer) glatiramer **Kesimpta** (ofatumumab) **Lemtrada** (alemtuzumab) **Mavenclad** (cladribine) **Mayzent** (siponimod) **Ocrevus** (ocrelizumab) **Plegridy** (peginterferon β-1a) **Ponvory** (ponesimod) **Rebif** (interferon β-1a) **Tascenso ODT** (fingolimod) **Tecfidera** (dimethyl fumarate)* teriflunomide **Tysabri** (natalizumab) **Vumerity** (diroximel fumarate) **Zeposia** (ozanimod) * -generic available

• Program Summary: Rivfloza (nedosiran)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
56626050602020	Rivfloza	nedosiran sodium subcutaneous soln	80 MG/0.5ML	2	Vials	30	DAYS				
5662605060E520	Rivfloza	nedosiran sodium subcutaneous soln pref syr	128 MG/0.8ML	1	Syringe	30	DAYS				
5662605060E530	Rivfloza	nedosiran sodium subcutaneous soln pref syr	160 MG/ML	1	Syringe	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 primary hyperoxaluria type 1 (PH1) confirmed by ONE of the following:
    A. Genetic testing of the *AGXT* gene indicates a pathogenic mutation **OR**
    B. Liver biopsy demonstrates absent or significantly reduced alanine: glyoxylate aminotransferase (AGT) activity **AND**
2. The requested agent will be used to lower urinary oxalate levels **AND**
3. The patient has an estimated GFR (eGFR) greater than or equal to 30 mL/min/1.73^2 **AND**
4. If the patient has an FDA labeled indication, then ONE of the following:
    A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
    B. There is support for using the requested agent for the patient's age for the requested indication **AND**
5. ONE of the following:
    A. The patient has tried and had an inadequate response to potassium citrate or sodium citrate **OR**
    B. The patient has an intolerance or hypersensitivity to potassium citrate or sodium citrate therapy **OR**
    C. The patient has an FDA labeled contraindication to BOTH potassium citrate AND sodium citrate **OR**
    D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
        1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
        2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND**
        3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
    E. The prescriber has provided documentation that BOTH potassium citrate AND sodium 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**
6. ONE of the following:
    A. The patient has tried and had an inadequate response to pyridoxine (vitamin B6) for at least 3 months AND ONE of the following:
        1. The patient is unresponsive to pyridoxine (vitamin B6) (unresponsive defined as less than or equal to 30% decrease in urine oxalate after 3 months of treatment with maximally tolerated pyridoxine) **OR**
        2. The patient is responsive to pyridoxine (vitamin B6) (responsive defined as greater than 30% decrease in urine oxalate after 3 months of treatment with maximally tolerated pyridoxine) AND will continue treatment with pyridoxine (vitamin B6) in combination with the requested agent **OR**
    B. The patient has an intolerance or hypersensitivity to pyridoxine (vitamin B6) therapy **OR**
    C. The patient has an FDA labeled contraindication to pyridoxine (vitamin B6) **OR**
    D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
        1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
        2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND**
        3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
    E. The prescriber has provided documentation that pyridoxine (vitamin B6) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
7. The patient has NOT received a liver transplant **AND**
8. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., gastroenterologist, nephrologist) or the prescriber has consulted with a specialist in the area of the patient’s diagnosis **AND**
9. The patient will NOT be using the requested agent in combination with Oxlumo (lumasiran) **AND**
10. The patient does NOT have any FDA labeled contraindications to the requested agent

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 [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**
2. The patient has had clinical benefit with the requested agent (e.g., decrease in urinary oxalate levels) **AND**
3. The patient has an estimated GFR (eGFR) greater than or equal to 30 mL/min/1.73^2 **AND**
4. ONE of the following:
    A. The patient's medication history includes pyridoxine (vitamin B6) AND ONE of the following:
        1. The patient will continue treatment with pyridoxine (vitamin B6) in combination with the requested agent **OR**
        2. The patient was unresponsive to pyridoxine (vitamin B6) (unresponsive defined as less than or equal to 30% decrease in urine oxalate after 3 months of treatment with maximally tolerated pyridoxine) **OR**
    B. The patient has an intolerance or hypersensitivity to pyridoxine (vitamin B6) therapy **OR**
    C. The patient has an FDA labeled contraindication to pyridoxine (vitamin B6) **OR**
    D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
        1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
        2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND**
        3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
    E. The prescriber has provided documentation that pyridoxine (vitamin B6) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
5. The patient has NOT received a liver transplant **AND**
6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
7. The patient will NOT be using the requested agent in combination with Oxlumo (lumasiran) **AND**
8. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 12 months

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

	2. There is support for why 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 6 months (Initial); up to 12 months (Renewal

• Program Summary: Statin

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
394000301001		fluvastatin sodium cap	20 MG; 40 MG	60	Capsules	30	DAYS				
394000500003		lovastatin tab	10 MG; 20 MG; 40 MG	60	Tablets	30	DAYS				
39400058300320		Pitavastatin Magnesium Tab 1 MG (Base Equiv)		45	Tablets	30	DAYS				
39400065100320		Pravastatin Sodium Tab 10 MG	10 MG	45	Tablets	30	DAYS				
39400065100330		Pravastatin Sodium Tab 20 MG	20 MG	45	Tablets	30	DAYS				
39400065100340		Pravastatin Sodium Tab 40 MG	40 MG	45	Tablets	30	DAYS				
39400065100360		Pravastatin Sodium Tab 80 MG	80 MG	30	Tablets	30	DAYS				
39400075000310		Simvastatin Tab 5 MG	5 MG	45	Tablets	30	DAYS				
39400075000360		Simvastatin Tab 80 MG	80 MG	30	Tablets	30	DAYS				
394000500075	Altoprev	lovastatin tab er	20 MG; 40 MG; 60 MG	30	Tablets	30	DAYS				
39400010101810	Atorvaliq	atorvastatin calcium susp	20 MG/5ML	600	mLs	30	DAYS				
39400060100310	Crestor	Rosuvastatin Calcium Tab 10 MG	10 MG	45	Tablets	30	DAYS				
39400060100320	Crestor	Rosuvastatin Calcium Tab 20 MG	20; 20 MG	45	Tablets	30	DAYS				
39400060100340	Crestor	Rosuvastatin Calcium Tab 40 MG	40; 40 MG	30	Tablets	30	DAYS				
39400060100305	Crestor	Rosuvastatin Calcium Tab 5 MG	5 MG	45	Tablets	30	DAYS				
394000601068	Ezallor sprinkle	rosuvastatin calcium sprinkle cap	10 MG; 20 MG; 40 MG; 5 MG	30	Capsules	30	DAYS				
39400075001810	Flolipid	Simvastatin Susp 20 MG/5ML (4 MG/ML)	20 MG/5ML	150	mLs	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
39400075001820	Flolipid	Simvastatin Susp 40 MG/5ML (8 MG/ML)	40 MG/5ML	300	mLs	30	DAYS				
394000301075	Lescol xl	fluvastatin sodium tab er	80 MG	30	Tablets	30	DAYS				
39400010100310	Lipitor	Atorvastatin Calcium Tab 10 MG (Base Equivalent)	10; 10 MG	45	Tablets	30	DAYS				
39400010100320	Lipitor	Atorvastatin Calcium Tab 20 MG (Base Equivalent)	20; 20 MG	45	Tablets	30	DAYS				
39400010100330	Lipitor	Atorvastatin Calcium Tab 40 MG (Base Equivalent)	40 MG	45	Tablets	30	DAYS				
39400010100350	Lipitor	Atorvastatin Calcium Tab 80 MG (Base Equivalent)	80; 80 MG	30	Tablets	30	DAYS				
39400058100321	Livalo	Pitavastatin Calcium Tab 1 MG	1 MG	45	Tablets	30	DAYS				
39400058100331	Livalo	Pitavastatin Calcium Tab 2 MG	2 MG	45	Tablets	30	DAYS				
39400058100341	Livalo	Pitavastatin Calcium Tab 4 MG	4 MG	30	Tablets	30	DAYS				
399940022703	Roszet	ezetimibe-rosuvastatin calcium tab	10-10 MG; 10-20 MG; 10-40 MG; 10-5 MG	30	Tablets	30	DAYS				
399940023003	Vytorin	ezetimibe-simvastatin tab	10-10 MG; 10-20 MG; 10-40 MG; 10-80 MG	30	Tablets	30	DAYS				
39400075000320	Zocor	Simvastatin Tab 10 MG	10 MG	45	Tablets	30	DAYS				
39400075000330	Zocor	Simvastatin Tab 20 MG	20 MG	60	Tablets	30	DAYS				
39400075000340	Zocor	Simvastatin Tab 40 MG	40 MG	45	Tablets	30	DAYS				
39400058300330	Zypitamag	Pitavastatin Magnesium Tab 2 MG (Base Equiv)	2 MG	45	Tablets	30	DAYS				
39400058300340	Zypitamag	Pitavastatin Magnesium Tab 4 MG (Base Equiv)	4 MG	30	Tablets	30	DAYS				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Step Therapy	

TARGET AGENT(S)	PREREQUISITE AGENT(S)
Altoprev (lovastatin ER) **Atorvaliq** (atorvastatin oral suspension) **Crestor*** (rosuvastatin) **Ezallor Sprinkle** (rosuvastatin) **Flolipid** (simvastatin oral suspension) **Lescol XL*** (fluvastatin ER)	Any generic statin or statin combination

	Lipitor* (atorvastatin) **Livalo*** (pitavastatin) **Pravachol*** (pravastatin) **Roszet, Ezetimibe/Rosuvastatin** **Vytorin*** (ezetimibe/simvastatin) **Zocor*** (simvastatin) **Zypitamag** (pitavastatin)		

*generic available

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

1. The patient's medication history includes use of ONE prerequisite agent **OR**
2. The patient has an intolerance or hypersensitivity to a prerequisite agent **OR**
3. The patient has an FDA labeled contraindication to ALL prerequisite agents **OR**
4. BOTH of the following:
    A. The prescriber has stated that the patient has tried ONE prerequisite agent **AND**
    B. The prerequisite agent was discontinued due to lack of effectiveness or an adverse event **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 prerequisite 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 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. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication

	Length of Approval: up to 12 months

• Program Summary: Zeposia (ozanimod)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
624070502001	Zeposia	ozanimod hcl cap	0.92 MG	30	Capsules	30	DAYS				
6240705020B210	Zeposia 7-day starter pac	Ozanimod Cap Pack 4 x 0.23 MG & 3 x 0.46 MG	4 x 0.23MG & 3 x 0.46MG	7	Capsules	180	DAYS				
6240705020B215	Zeposia starter kit	ozanimod cap pack	0.23MG &0.46MG 0.92MG (21)	28	Capsules	180	DAYS				
6240705020B220	Zeposia starter kit	Ozanimod Cap Pack 4 x 0.23 MG & 3 x 0.46 MG & 30 x 0.92 MG	0.23MG & 0.46MG & 0.92MG	37	Capsules	180	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Zeposia PA with MS Step	**Immunomodulatory Agent Step Table**

Formulary ID	Step 1a	Step 1b (Directed to ONE TNF inhibitor) NOTE please see Step 1a for preferred TNF inhibitors	Step 2 (Directed to ONE Step 1 agent)	Step 3a (Directed to TWO Step 1 agents)	Step 3b (Directed to TWO agents from Step 1 and/or Step 2)	Step 3c (Directed to THREE step 1 agents)
FlexRx, GenRx, KeyRx, BasicRx	SQ: Hadlima, Humira, Simlandi, Skyrizi, Stelara	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Hadlima, Humira, or Simlandi is a required Step 1 agent)	N/A	SQ: Entyvio, Omvoh Oral: Zeposia (Hadlima, Humira,	SQ: Abrilada*, Adalimumab-ryvk*, Amjevita*, Cyltezo*, Hulio*,

					Rinvoq, Simlandi, Skyrizi, Stelara, OR Xeljanz/Xeljanz XR are required Step agents)	Hyrimoz*, Idacio*, Yuflyma*, Yusimry*, Zymfentra Oral: Velsipity *Hadlima, Humira, and Simlandi are required Step 1 agents <u>Note:</u> Branded generic available for Cyltezo, Idacio, Hulio, Hyrimoz, and Yuflyma and are included as a target at the same step level in this program
FocusRx	SQ: Cyltezo, Humira, Skyrizi, Stelara	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Cyltezo, or Humira is a required Step 1 agent)	N/A	SQ: Entyvio, Omvoh Oral: Zeposia (Cyltezo, Humira, Rinvoq, Skyrizi, Stelara, OR Xeljanz/Xeljanz XR are required Step agents)	SQ: Abrilada*, Adalimumab-adbm*, Amjevita*, Hadlima*, Hulio*, Hyrimoz*, Idacio*, Simlandi*, Yuflyma*, Yusimry*, Zymfentra Oral: Velsipity *Cyltezo, and Humira are required Step 1 agents <u>Note:</u> Branded generic

						available for Idacio, Hulio, Hyrimoz, Simlandi, and Yuflyma and are included as a target at the same step level in this program

Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product

Initial Evaluation

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

1. The requested agent is eligible for continuation of therapy AND ONE of following:

Agents Eligible for Continuation of Therapy
Zeposia (ozanimod)

   A. 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**
2. BOTH of the following:
   A. The patient has a diagnosis of multiple sclerosis (MS) **AND**
   B. The patient will NOT be using the requested agent in combination with another MS disease modifying agent (DMA) (Please refer to "Multiple Sclerosis Disease Modifying Agents" contraindicated use table) **OR**
3. The patient has a diagnosis of moderately to severely active ulcerative colitis (UC) AND ALL of the following:
   A. ONE of the following:
      1. The patient is currently being treated with the requested agent as indicated by ALL of the following:
         A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
         B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
         C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
      2. The patient has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC **OR**
      3. The patient has severely active ulcerative colitis **OR**
      4. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of UC **OR**
      5. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of UC **OR**
      6. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of UC **OR**
      7. The prescriber has provided documentation that ALL of the conventional agents (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, steroid

suppositories, sulfasalazine) used in the treatment of UC 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. ONE of the following:
    1. The patient is currently being treated with the requested agent as indicated by ALL of the following:
        A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
        B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
        C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
    2. The patient has tried and had an inadequate response to TWO Step 1a and/or Step 1b immunomodulatory agents (see Immunomodulatory Agent Step table) **OR**
    3. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to at least TWO Step 1a and/or Step 1b immunomodulatory agents **OR**
    4. The patient has an FDA labeled contraindication to ALL Step 1a AND Step1b immunomodulatory agents **OR**
    5. The prescriber has provided documentation that ALL Step 1a AND Step1b immunomodulatory 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**
C. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) (Please refer to "Immunomodulatory Agents NOT to be used Concomitantly" table) **AND**
D. If the patient has an FDA labeled indication, then ONE of the following:
    1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
    2. There is support for using the requested agent for the patient's age for the requested indication **AND**
E. 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**
F. The patient does NOT have any FDA labeled contraindications to the requested agent

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

Length of Approval: 12 months. NOTE: The starter dose can be approved for the FDA labeled starting dose and the maintenance dose can be approved for the remainder of 12 months

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

Renewal Evaluation

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

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**
2. ONE of the following:
    A. BOTH of the following:
        1. The patient has a diagnosis of multiple sclerosis (MS) **AND**

	2. The patient will not be using the requested agent in combination with another MS disease modifying agent (DMA) (Please refer to "Multiple Sclerosis Disease Modifying Agents" contraindicated use table) **OR** B. The patient has a diagnosis of ulcerative colitis AND ALL of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. 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** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (see "Immunomodulatory Agents NOT to be used Concomitantly" table) **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
Zeposia PA through preferred and Zeposia PA with MS step	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months. NOTE: The starter dose can be approved for the FDA labeled starting dose and the maintenance dose can be approved for the remainder of 12 months.

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
MS Disease Modifying Agents
Aubagio (teriflunomide)
Avonex (interferon b-1a)
Bafiertam (monomethyl fumarate)
Betaseron (interferon b-1b)
Briumvi (ublituximab-xiiy)
Copaxone (glatiramer)
dimethyl fumarate
Extavia (interferon b-1b)
fingolimod
Gilenya (fingolimod)
Glatopa (glatiramer)
glatiramer
Kesimpta (ofatumumab)
Mavenclad (cladribine)

Contraindicated as Concomitant Therapy
Mayzent (siponimod) Plegridy (peginterferon b-1a) Ponvory (ponesimod) Rebif (interferon b-1a) Tascenso ODT (fingolimod) Tecfidera (dimethyl fumarate) Vumerity (diroximel fumarate) Zeposia (ozanimod) **Immunomodulatory 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) Bimzelx (bimekizumab-bkzx) 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) Omvoh (mirikizumab-mrkz) Opzelura (ruxolitinib) Orencia (abatacept) Otezla (apremilast) Remicade (infliximab) Renflexis (infliximab-abda) Riabni (rituximab-arrx) Rinvoq (upadacitinib) Rituxan (rituximab) Rituxan Hycela (rituximab/hyaluronidase human)

Contraindicated as Concomitant Therapy
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)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)
Zymfentra (infliximab-dyyb)