

Pharmacy Medical Necessity Guidelines: Medications for the Treatment of Hepatitis C

Effective: February 15, 2021

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p>Commercial Products</p> <input type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input type="checkbox"/> Tufts Health Freedom Plan products – small group plans <ul style="list-style-type: none"> CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization <p>Tufts Health Public Plans Products</p> <input type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan		<p>Fax Numbers:</p> <p>RXUM: 617-673-0988</p>	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

The hepatitis C medications bolded in the table below are preferred. See information in the Limitations section for more details.

Drug	FDA-approved Indication	FDA-approved Duration
Daklinza (daclatasvir)	Adults with chronic HCV genotype 1 or 3 infection	<ul style="list-style-type: none"> Genotype 1 <ul style="list-style-type: none"> Without cirrhosis or compensated cirrhosis: 12 weeks in combination with Sovaldi® Decompensated cirrhosis or post-transplant: 12 weeks in combination with Sovaldi® and RBV Genotype 3 <ul style="list-style-type: none"> Without cirrhosis: 12 weeks in combination with Sovaldi® Compensated cirrhosis, decompensated cirrhosis, or post-transplant: 12 weeks in combination with Sovaldi® and RBV
Epclusa (sofosbuvir/velpatasvir)	<ul style="list-style-type: none"> Adults and pediatric patients 6 years of age and older weighing at least 17 kg with chronic HCV genotype 1-6 infection <ul style="list-style-type: none"> Without cirrhosis or with cirrhosis (compensated or decompensated) With decompensated cirrhosis for use in combination with ribavirin 	<ul style="list-style-type: none"> Treatment-naïve and treatment-experienced, without cirrhosis or compensated cirrhosis: 12 weeks Treatment-naïve and treatment-experienced, decompensated cirrhosis: 12 weeks in combination with RBV
Harvoni (ledipasvir/sofosbuvir)	<ul style="list-style-type: none"> Adults and pediatric patients at least 3 years of age with chronic HCV infection <ul style="list-style-type: none"> Genotype 1, 4, 5, or 6 without cirrhosis or 	<ul style="list-style-type: none"> Genotype 1 <ul style="list-style-type: none"> Treatment-naïve without cirrhosis or compensated cirrhosis: 12 weeks Treatment-experienced without cirrhosis: 12 weeks

Drug	FDA-approved Indication	FDA-approved Duration
	<ul style="list-style-type: none"> with compensated cirrhosis ○ Genotype 1 with decompensated cirrhosis, in combination with ribavirin ○ Genotype 1 or 4 who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin 	<ul style="list-style-type: none"> ○ Treatment-experienced with compensated cirrhosis: 24 weeks ○ Treatment-naïve and -experienced with decompensated cirrhosis: 12 weeks in combination with RBV (adults only) • Genotype 4, 5, or 6 without cirrhosis or compensated cirrhosis: 12 weeks • Adults genotype 1 or 4 post liver-transplant without cirrhosis or compensated cirrhosis: 12 weeks in combination with RBV
Mavyret (glecaprevir/pibrentasvir)	<ul style="list-style-type: none"> • Adults and pediatric patients (12 years and older or weighing at least 45 kg) with chronic HCV infection genotype 1, 2, 3, 4, 5, or 6 without cirrhosis and with compensated cirrhosis • Adults and pediatric patients (12 years and older or weighing at least 45 kg) with chronic HCV infection genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both 	<ul style="list-style-type: none"> • Genotypes 1, 2, 3, 4, 5, or 6 treatment-naïve <ul style="list-style-type: none"> ○ No cirrhosis: 8 weeks ○ Compensated cirrhosis: 12 weeks • Genotype 1 in NS5A inhibitor treatment-experienced: 16 weeks • Genotype 1 in NS3/4A protease inhibitor treatment-experienced: 12 weeks • Genotype 1, 2, 4, 5, or 6 in interferon, pegylated interferon, ribavirin, and/or sofosbuvir treatment-experienced: <ul style="list-style-type: none"> ○ No cirrhosis: 8 weeks ○ Compensated cirrhosis: 12 weeks • Genotype 3 in interferon, pegylated interferon, ribavirin, and/or sofosbuvir treatment-experienced: 16 weeks
Olysio (simeprevir)	Adults with chronic HCV infection genotype 1 or 4 infection without cirrhosis or with compensated cirrhosis	<ul style="list-style-type: none"> • Genotype 1 <ul style="list-style-type: none"> ○ Without cirrhosis: 12 weeks in combination with Sovaldi® OR 12 weeks in combination with Peginterferon alfa and RBV ○ Compensated cirrhosis: 24 weeks in combination with Sovaldi® OR 12 weeks in combination with peginterferon alfa and RBV • Genotype 4: 12 weeks in combination with peginterferon alfa and RBV
Sovaldi (sofosbuvir)	<ul style="list-style-type: none"> • Adults with chronic HCV infection genotype 1, 2, 3, or 4 without cirrhosis or with compensated cirrhosis • Pediatrics 3 years of age and older with chronic HCV infection genotype 2 or 3 without cirrhosis or with compensated cirrhosis 	<ul style="list-style-type: none"> • Genotypes 1 or 4 treatment-naïve: 12 weeks in combination with peginterferon alfa and RBV (adults only) • Genotype 2: 12 weeks in combination with RBV • Genotype 3: 24 weeks in combination with RBV
Technivie (ombitasvir/pa ritaprevir/ritonavir)	Adults with chronic HCV genotype 4 infection without cirrhosis or with compensated cirrhosis	<ul style="list-style-type: none"> • 12 weeks in combination with RBV
Viekira Pak/Viekira XR (dasabuvir/ombitasvir)	Adults with chronic HCV genotype 1 without cirrhosis or with compensated cirrhosis	<ul style="list-style-type: none"> • Genotype 1a <ul style="list-style-type: none"> ○ Without cirrhosis: 12 weeks in combination with RBV

Drug	FDA-approved Indication	FDA-approved Duration
paritaprevir/ ritonavir)		<ul style="list-style-type: none"> ○ Compensated cirrhosis: 24 weeks in combination with RBV • Genotype 1b: 12 weeks
Vosevi (sofosbuvir/ velpatasvir/ voxilaprevir)	<ul style="list-style-type: none"> • Adults with chronic HCV genotype 1, 2, 3, 4, 5, or 6 with cirrhosis or with compensated cirrhosis in patients who have previously been treated with an HCV regimen containing an NS5A inhibitor • Adults with chronic HCV genotype 1a or 3 infection with cirrhosis or with compensated cirrhosis in patients who have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor 	<ul style="list-style-type: none"> • 12 weeks
Zepatier (elbasvir/ grazoprevir)	Adults with chronic HCV genotype 1 or 4 infection	<ul style="list-style-type: none"> • Genotype 1a: <ul style="list-style-type: none"> ○ Treatment-naïve or -experienced[^] without baseline NS5A polymorphisms: 12 weeks ○ Treatment-naïve or -experienced[^] with baseline NS5A polymorphisms: 16 weeks in combination with RBV ○ Treatment-experienced*: 12 weeks in combination with RBV • Genotype 1b: <ul style="list-style-type: none"> ○ Treatment-naïve or -experienced[^]: 12 weeks ○ Treatment-experienced*: 12 weeks in combination with RBV • Genotype 4: <ul style="list-style-type: none"> ○ Treatment-naïve: 12 weeks ○ Treatment-experienced[^]: 16 weeks in combination with RBV

[^]Peginterferon alfa plus ribavirin.

*Peginterferon alfa plus ribavirin plus HCV NS3/4A protease inhibitor.

HCV=hepatitis C virus, FDA=Food and Drug Administration, RBV=ribavirin

Compensated cirrhosis is defined as Child-Pugh A.

Decompensated cirrhosis is defined as Child-Pugh B or C.

All patients should be tested for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment hepatitis C medications. HBV reactivation has been reported in HCV/HBV coinfecting patients who were undergoing or had completed treatment with HCV direct acting antivirals and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. Monitor HCV/HBV coinfecting patients for hepatitis flare or HBV reactivation during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated.

COVERAGE GUIDELINES

Note: Prescribing physicians for Members with Stage 3 and 4 disease must be on the Rhode Island Medicaid Hepatitis C Preferred Provider List. Interested physicians must submit the Preferred Provider Application available on the EOHHS website and await approval before submitting medication pre-authorization requests. Preferred Providers must assume direct responsibility for care or after consultation and establishing a treatment plan, co-manages the Member with the primary care provider. Members with Stages 0 through 2 disease may be managed by the primary care physician, advanced practice nurse, or physician assistant.

The Plan may authorize coverage of a Hepatitis C medication for Members when **ALL** the following criteria are met:

REQUIRED DOCUMENTATION FOR ALL REQUESTS

1. For Members with Stage 3 or 4 disease, documentation of one of the following (**see Note above**):
 - a. The prescribing physician is on the Preferred Provider List
 - b. The prescription was written in consultation with a Preferred Provider who is co-managing the Member with a primary care provider

AND
2. Documentation of current clinical status, including all of the following:
 - a. Stage of disease and test used to determine disease stage
 - b. Absence or presence of decompensated cirrhosis
 - c. For Members with decompensated cirrhosis, documentation the Member has been referred to a physician with experience in managing such disease (ideally at a center with liver transplant capabilities)

AND
3. Documentation of prior chronic hepatitis C virus therapy, if relevant
4. Documentation of hepatitis C genotype
5. Documentation of pretreatment viral load and date of testing. Viral load assessment must be within 90 days of preauthorization request
6. Documentation of treatment plan, including all of the following:
 - a. Medication name, dose and duration
 - b. Agreement to submit post treatment viral load data

LIMITATIONS

- Medication approval will be for a full course of treatment with medication being dispensed in 28 day increments. Evidence of non-compliance may cause cancellation of approved medication refills.
- Approval will be valid for 56-84 days from date of approval.
- The Plan's Medical Director will be responsible for monitoring plan processes to insure compliance with this policy. Documentation must be provided to Rhode Island Medicaid upon request.
- Any requests for a non-FDA-approved treatment will be denied.
- Treatment recommendations:
 - Preferred agents: Mavyret or Vosevi
 - Non-preferred agents: All other agents with the exception of ribavirin
- Non-preferred regimens:
 - Will be approved if a Member is completing a regimen which was initiated prior to July 1, 2018 (current policy implementation)
 - Requests will be reviewed on a case by case basis. The request must include supporting, detailed clinical documentation of need, for an alternative, non-preferred agent.
- When transitioning between publicly funded delivery systems, any authorization granted by the prior delivery system will be honored for the portion of the treatment that remains after the transition.

CODES

None

REFERENCES

1. American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America. HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C. 2018 May 24. URL: https://www.hcvguidelines.org/sites/default/files/full-guidance-pdf/HCVGuidance_May_24_2018b.pdf. Available from Internet. Accessed 2019 October 21.
2. Eplclusa (sofosbuvir/velpatasvir) [prescribing information]. Foster City, CA: Gilead Sciences, Inc.; July 2020.
3. Daklinza (daclatasvir) [prescribing information]. Princeton, NJ; Bristol-Myers Squibb Company.; November 2017.
4. Harvoni (ledipasvir/sofosbuvir) [prescribing information]. Mississauga, Ontario, Canada: Gilead Sciences Inc.; September 2019.
5. Mavyret (glecaprevir/pibrentasvir) [prescribing information]. North Chicago, IL; AbbVie Inc.; June 2019.
6. Olysio (simeprevir) [prescribing information]. Titusvill, NJ: Janssen Therapeutics, Division of Janssen Products, LP.; November 2017.
7. Sovaldi (sofosbuvir) [prescribing information]. Foster City, CA: Gilead Sciences, Inc.; September 2019.

8. Technivie (ombitasvir/paritaprevir/ritonavir) [prescribing information]. North Chicago, IL: AbbVie Inc.; November 2017.
9. Viekira Pak (dasabuvir/ombitasvir/paritaprevir/ritonavir). North Chicago, IL: AbbVie Inc.; November 2017.
10. Viekira XR (dasabuvir/ombitasvir/paritaprevir/ritonavir). North Chicago, IL: AbbVie Inc.; November 2017.
11. Vosevi (sofosbuvir/velpatasvir/voxilaprevir). Foster City, CA: Gilead Sciences, Inc.; November 2017.
12. Zepatier (elbasvir/grazoprevir). Whitehouse Station, NJ: Merck & Co., Inc.; November 2017.

APPROVAL HISTORY

May 9, 2017: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. February 13, 2018: Added newly approved Mavyret and Vosevi to the Medical Necessity Guideline. Updated the Limitations section to reflect preferred products effective March 1, 2018 and process for requests for non-preferred products. June 26, 2018: Updated coverage criteria to allow approval of all stages of disease (Stages 0 -4). Updated prescribing provider requirements to allow for primary care physicians, advanced practice nurses, or physician assistants for Stage 0-2 disease and for Stages 3-4 when co-managed with a Preferred Provider. Removed the signed "Patient Contract" requirement. Removed the Coverage Limitation: EOHHS and the Medicaid Managed Care Organizations will periodically review randomly selected, de-identified prior authorizations to ensure consistent application of this policy for all Medicaid enrollees. Updated the approval duration to be 56-84 days from date of approval. Updated the coverage limitation regarding the Plan's Medical Director responsibilities. Removed the requirement of documentation of the following with regards to the treatment plan: method and frequency of patient monitoring and planned post treatment follow-up. Updated the requirement of documentation of current clinical status to only require documentation of the presence or absence of decompensated cirrhosis and for documentation of stage of disease and test used to determine disease stage
2. July 9, 2019: Updated indication for Mavyret to include pediatric patients age 12 and older or weighing at least 45 kg.
3. November 12, 2019: No coverage changes. Updated FDA approved indications for Harvoni and Sovaldi based on updated package labeling.
4. September 15, 2020: No changes
5. February 9, 2021: No coverage changes. Updated FDA approved indication for Eplclusa based on updated package labeling.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

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