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

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

RXUM: 617-673-0988

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

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Hepatitis C medications covered on the formulary are included in the table below. All medications require prior authorization. See information in the Limitations section for more details. Requests for non-covered Hepatitis C medications will be reviewed with the Non-Covered with Suggested Alternatives Medical Necessity Guideline.

Drug	FDA-Approved Indication
Epclusa (sofosbuvir/ velpatasvir)	• Adults and pediatric patients 6 years of age and older weighing at least 17 kg with chronic HCV genotype 1-6 infection o Without cirrhosis or with cirrhosis (compensated or decompensated) o With decompensated cirrhosis for use in combination with ribavirin
Harvoni (ledipasvir/ sofosbuvir)	• Adults and pediatric patients at least 3 years of age with chronic HCV infection o Genotype 1, 4, 5, or 6 without cirrhosis or with compensated cirrhosis o Genotype 1 with decompensated cirrhosis, in combination with ribavirin o Genotype 1 or 4 who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin
Vosevi (sofosbuvir/ velpatasvir/ voxilaprevir)	• Adult patients with chronic HCV infection without cirrhosis or with compensated cirrhosis who have: o Genotype 1-6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor o Genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A 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.

American Association for The Study of Liver Diseases (AASLD) Guidelines

AASLD Recommendations for Covered Hepatitis C Medications in Treatment-Naïve Patients

GT 1	GT2	GT3	GT4	GT5	GT6
Harvoni 8 wks	Epclusa 12 wks				
Epclusa 12 wks			Harvoni 12 wks		
Harvoni 12 wks					

AASLD Recommendations for Covered Hepatitis C Medications in Treatment-Experienced Patients

GT 1	**PEG/RBV, Olysio/PEG/RBV**	**Sovaldi/Olysio, Sovaldi/PEG±RBV**	**NS5A-Inhibitor**
	Epclusa 12 wks		
	Harvoni 12 wks	Vosevi 12 wks	
GT2	**PEG/RBV, Sovaldi/RBV**		
	Epclusa 12 wks		
GT3	**PEG/RBV**	**DAA (including NS5A Inhibitors)**	
	Epclusa 12 wks		
	Vosevi 12 wks		
GT4-6	**PEG/RBV**	**DAA (Including NS5A Inhibitors**	
	Epclusa 12 wks	Vosevi 12 wks	
	Harvoni 12 wks		

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 coinfected 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 coinfected 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

Tufts Health Plan may authorize coverage of Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/ sofosbuvir), or Vosevi (sofosbuvir/velpatasvir/voxilaprevir) for Members when all of the following criteria are met:

REQUIRED DOCUMENTATION FOR ALL REQUESTS

1. Documented diagnosis of chronic hepatitis C with confirmation of genotype

AND

2. The prescription is written by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist

AND

3. Documentation of at least one of the following:
    a. Member is at least 18 years of age if the request is for Vosevi
    b. Member is at least 6 years of age or weighing at least 17 kg if request is for Epclusa
    c. Member is at least 3 years of age if the request is for Harvoni

AND

4. Documentation of the presence or absence of cirrhosis

AND

5. Documentation of hepatitis C viral load within 6 months prior to initiation of treatment

AND

6. Documentation the prescriber has assessed the Member for substance use disorder and, if present, the Member is receiving appropriate counseling services or treatment for substance use disorder as an adjunct to HCV treatment

AND

7. Documented attestation from the prescriber that the Member has been assessed for potential non-adherence

Treatment-naive or treatment-experienced but NS5A inhibitor-naïve (Epclusa, Harvoni)

1. Documentation of at least one of the following:
    a. Member is treatment-naïve
    b. Member is treatment-experienced but NS5A-inhibitor naïve

AND

2. Documentation of the presence or absence of cirrhosis

AND

3. If the request is for Harvoni (ledipasvir/sofobuvir), documentation the Member has genotype 1, 4, 5, or 6 infection

NS5A inhibitor-experienced or treatment-experienced with sofosbuvir without an NS5A inhibitor) (Vosevi)

1. Documentation of at least one of the following:
    a. Previous treatment with an NS5A inhibitor
    b. Previous treatment with Sovaldi (sofosbuvir) without an NS5A inhibitor

AND

2. Documentation the Member is without decompensated cirrhosis

AND

3. If previous treatment with Sovaldi (sofosbuvir) without an NS5A inhibitor, documentation the Member has genotype 1a or 3 infection

***Comparison of Scoring Systems for Histological Stage (Fibrosis)**

METAVIR	Batt-Ludwig	Knodell	Ishak
0	**0**	**0**	**0**
1	**1**	**1**	**1**
1	**1**	**1**	**2**
2	**2**	**-**	**3**
3	**3**	**3**	**4**
4	**4**	**4**	**5**
4	**4**	**4**	**6**

LIMITATIONS

- Vosevi (sofosbuvir/velpatasvir/voxilaprevir) will not be authorized for initial treatment.
- Members with genotype 1 who are treatment-naïve, without cirrhosis, and who have a baseline viral load <6 million IU/mL will only be approved for treatment with Harvoni (ledipasvir/sofosbuvir) for 8 weeks. No other medication or regimen for the treatment of Hepatitis C will be authorized for these Members unless documentation of clinical inappropriateness with or contraindications to Harvoni (ledipasvir/sofosbuvir) 8 weeks is provided.
- Epclusa (velpatasvir/sofosbuvir) will be authorized for 12 weeks based on package labeling.
    - Requests for 24 weeks can be approved in Members with decompensated cirrhosis who have a contraindication to ribavirin.
- Harvoni (ledipasvir/sofosbuvir) will be authorized for 8, 12 or 24 weeks based on package labeling and current treatment guidelines.
- Vosevi (sofosbuvir/velpatasvir/voxilaprevir) will be authorized for 12 weeks based on package labeling.
- Any alternative treatment requests will require detailed clinical documentation of need for alternative treatment and will be considered on a case by case basis.

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 Hepatitits 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. Epclusa (sofosbuvir/velpatasvir) [prescribing information]. Foster City, CA: Gilead Sciences, Inc.; July 2020.
3. Harvoni (ledipasvir/sofosbuvir) [prescribing information]. Mississauga, Ontario, Canada: Gilead Sciences Inc.; September 2019.

4. Vosevi (sofosbuvir/velpatasvir/voxilaprevir) [prescribing information]. Foster City, CA: Gilead Sciences, Inc.; November 2017.

APPROVAL HISTORY

December 12, 2017: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. February 13, 2018: Added the Limitation requests for 24 weeks of Epclusa can be approved in Members with decompensated cirrhosis who have a contraindication to ribavirin.
2. April 9, 2019: Removed documentation of stage of fibrosis.
3. August 13, 2019: No changes
4. November 12, 2019: Updated Harvoni age requirements to pediatric patients at least 3 years of age based on updated package labeling.
5. September 15, 2020: No changes
6. February 9, 2021: Updated age requirements for Epclusa based on expanded indication in patients at least 6 years of age or weighing at least 17 kg.

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.

Provider Services