TUFTS Health Plan

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

Effective: January 1, 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

This pharmacy medical necessity guideline applies to the following:

Tufts Health Plan Commercial Plans

☐ Tufts Health Plan Commercial Plans – large group plans

☐ Tufts Health Plan Commercial Plans – small group and individual plans

Tufts Health Public Plans

☐ Tufts Health Direct – Health Connector

☒ Tufts Health Together – A MassHealth Plan

☐ Tufts Health RITogether – A RIte Care + Rhody Health Partners Plan

Tufts Health Freedom Plan products

☐ Tufts Health Freedom Plan - large group plans

☐ Tufts Health Freedom Plan - small group plans

Fax Numbers:

RXUM: 617-673-0988

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 Pharmacy Products Medical Necessity Guideline.

Ledipasvir/sofosbuvir, Mavyret (glecaprevir/pibrentasvir), and sofosbuvir/velpatasvir are the preferred medications for the treatment of hepatitis 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 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.

Drug	FDA-Approved Indication
Preferred Products	

Ledipasvir/ sofosbuvir*	• Adults and pediatric patients 3 years of age and older with chronic HCV infection
	  ○ Genotype 1, 4, 5, or 6 without cirrhosis or with compensated cirrhosis
	  ○ Genotype 1 with decompensated cirrhosis, for use in combination with ribavirin
	  ○ Genotype 1 or 4 who are liver transplant recipients without cirrhosis or with compensated cirrhosis, for use in combination with ribavirin

Mavyret (glecaprevir/ pibrentasvir)	• 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
Sofosbuvir/ velpatasvir*	• Adults with chronic HCV genotype 1-6 infection without cirrhosis or with cirrhosis (compensated or decompensated)
Non-preferred	
Daklinza (daclatasvir)	Adult patients with chronic HCV genotype 1 or 3 infection in combination with sofosbuvir, with or without ribavirin
Sovaldi (sofosbuvir)	• Adult patients with genotype 1, 2, 3, or 4 chronic HCV infection without cirrhosis or with compensated cirrhosis as a component of a combination antiviral treatment regimen.

Drug	FDA-Approved Indication
	• Pediatric patients 3 years of age and older with genotype 2 or 3 chronic HCV infection 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 • Genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor
Zepatier (elbasvir/ grazoprevir)	Adults patients with genotype 1 and 4 chronic HCV infection

*Brand formulations are non-covered.
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.

COVERAGE GUIDELINES

Tufts Health Plan may authorize coverage of Daklinza, ledipasvir/sofosbuvir, Mavyret, sofosbuvir/velpatasvir, Sovaldi, Vosevi, or Zepatier when all of the following criteria are met:

In addition to drug specific criteria listed below, the following is required documentation for all requests

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

AND

2. Documentation of at least one of the following:
    a. Member is at least 18 years of age if the request is for Daklinza, sofosbuvir/velpatasvir, Vosevi, or Zepatier
    b. Member is at least 3 years of age if the request is for ledipasvir/sofosbuvir, Harvoni, or Sovaldi
    c. Member is at least 12 years of age or weighing at least 45 kg for Mavyret

AND

3. Documentation of stage of hepatic fibrosis (e.g., F0-F4) through one of the following:
    a. Liver biopsy confirming a METAVIR score or alternative scoring equivalent*
    b. Transient elastography (Fibroscan) score
    c. APRI score
    d. Radiologic imaging
    e. Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician

AND

4. Documentation of the presence or absence of cirrhosis

PREFERRED PRODUCTS

1. Ledipasvir/sofosbuvir

Treatment-naïve genotype 1

1. Documentation of genotype 1

AND

2. Documentation the Member is treatment-naïve

AND

3. Documentation of one of the following:
    a. Member is ≥3 and <18 years
    b. Member is ≥18 years AND no cirrhosis AND baseline viral load <6 million IU/mL
    c. Member is ≥18 years AND cirrhosis or baseline viral load >6 million IU/mL AND clinical rationale for use instead of sofosbuvir/velpatasvir

Approval duration:

- Member ≥18 years, has no cirrhosis and a baseline viral load <6 million IU/mL: 8 weeks unless documentation of HIV co-infection, African American, presence of IL28B polymorphism CT or TT which will all be authorized for 12 weeks
- Member ≥18 years and has cirrhosis or baseline viral load >6 million IU/mL: 12 weeks
- Member is ≥3 and <18 years: 12 weeks

Note: Baseline viral load required within the last six month from date of coverage request

Treatment-naïve genotype 4-6

1. Documentation of genotype 4, 5, or 6

AND

2. Documentation the Member is treatment-naïve

AND

3. Documentation the Member is without decompensated cirrhosis

AND

4. Documentation of one of the following:
    a. Member is ≥3 and <18 years
    b. Member is ≥18 years AND clinical rationale for use instead of sofosbuvir/velpatasvir

Approval duration:

- 12 weeks

Note: 8 weeks can be approved in Members ≥18 years with genotype 4 (except genotype 4r) who do not have cirrhosis and who have a baseline viral load (within the last 6 months) <6 million IU/mL.

Treatment-experienced (Members who have failed any regimen that does not contain an HCV NS5A inhibitor)

1. Documentation of genotype 1, 4, 5, or 6

AND

2. Documentation the Member has not received previous treatment with an NS5A inhibitor containing regimen

AND

3. Documentation the Member is without decompensated cirrhosis

AND

4. Documentation of one of the following:
    a. Documentation Member is ≥12 and <18 years
    b. Documentation Member is ≥18 years AND clinical rationale for use instead of sofosbuvir/velpatasvir

Approval duration:

- For Members ≥3 to <18 years with genotype 1 and compensated cirrhosis: 24 weeks
- For Members ≥3 to 18 years with genotype 1 without cirrhosis: 12 weeks
- For Members ≥3 to 18 years with genotype 4, 5, or 6: 12 weeks
- For Members ≥18 years: 12 weeks
- Requests for 24 weeks duration in Members >18 years with genotype 1, require documentation of clinical inappropriateness of 12 weeks of Harvoni

2. Mavyret

Treatment-naïve

1. Documentation of genotype 1, 2, 3, 4, 5, or 6

AND

2. Documentation the Member is treatment-naïve

AND

3. Documentation the Member is without decompensated cirrhosis

Approval duration:

- 8 weeks

Previous Treatment with Interferon/Pegylated interferon and Ribavirin, Sovaldi and pegylated interferon and ribavirin, or Sovaldi and Ribavirin

1. Documentation of genotype 1, 2, 3, 4, 5, or 6

AND

2. Documentation the Member has received previous therapy with at least one of the following regimens:
    a. Interferon/pegylated interferon and ribavirin
    b. Sovaldi and pegylated interferon and ribavirin
    c. Sovaldi and ribavirin

AND

3. Documentation the Member is without decompensated cirrhosis

Approval duration:

- Genotypes 1, 2, 4, 5, or 6 without cirrhosis: 8 weeks
- Genotype 1, 2, 4, 5, or 6 with compensated cirrhosis: 12 weeks
- Genotype 3: 16 weeks

Previous Treatment with a Protease Inhibitor and Pegylated Interferon and Ribavirin, or Sovaldi and Olysio

1. Documentation of genotype 1

AND

2. Documentation the Member has received previous therapy with one of the following regimens:
    a. Pegylated interferon and ribavirin with a protease inhibitor
    b. Sovaldi and Olysio

AND

3. Documentation the Member is without decompensated cirrhosis

Approval duration:
- 12 weeks

HCV NS5A Inhibitor Treatment-experienced

1. Documentation of genotype 1

AND

2. Documentation the Member has previously received an NS5A inhibitor containing regimen

AND

3. Documentation the Member is without decompensated cirrhosis

Approval duration
- 16 weeks

3. Sofosbuvir/velpatasvir

Treatment-naïve and treatment-experienced (Members who have failed any regimen that does not contain an HCV NS5A inhibitor)

1. Documentation of genotype 1, 2, 3, 4, 5, or 6

AND

2. Documentation the Member has not received previous treatment with an NS5A inhibitor containing regimen

Approval duration:
- 12 weeks

NON-PREFERRED PRODUCTS

1. Daklinza

1. Documentation of genotype 3

AND

2. Documentation of use in combination with Sovaldi

AND

3. Clinical rationale for use instead of sofosbuvir/velpatasvir and Mavyret

Approval duration
- 12 weeks

2. Sovaldi

1. Documentation of genotype 2 or 3

AND

2. Documentation of one of the following:
    a. Documentation Member is ≥3 and <12 years
    b. Documentation Member is ≥12 and <18 years AND clinical rationale for use instead of Mavyret

Approval duration
- Genotype 2: 12 weeks
- Genotype 3: 24 weeks

3. Vosevi

HCV NS5A Inhibitor Treatment-experienced

1. Documentation of genotype 1, 2, 3, 4, 5, or 6

AND

2. Documentation the Member has previously received an NS5A inhibitor containing regimen

AND

3. Documentation the Member is without decompensated cirrhosis

Approval duration
- 12 weeks

Previous treatment with a Sovaldi-containing regimen

1. Documentation of genotype 1a or 3

AND

2. Documentation the Member has previously received therapy with a Sovaldi-containing regimen

AND

3. Documentation the Member is without decompensated cirrhosis

AND

4. Clinical rationale for use instead of Mavyret

Approval duration
- 12 weeks

4. Zepatier

1. Documentation of genotype 1a, 1b, or 4

AND

2. Documentation the Member is without decompensated cirrhosis

AND

3. Clinical rationale for use instead of sofosbuvir/velpatasvir, ledipasvir/sofosbuvir and Mavyret

AND

4. If genotype 1a, documentation of results of NS5A polymorphism testing

Approval duration
- Genotype 1a
    - Without baseline NS5A polymorphisms: 12 weeks
    - With baseline NS5A polymorphisms: 16 weeks
- Genotype 1b: 12 weeks
- Genotype 4 treatment-naïve: 12 weeks
- Genotype 4 treatment-experienced: 16 weeks

***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

1. Vosevi will not be authorized for initial treatment.
2. The plan does not cover Epclusa and Harvoni. Refer to the Pharmacy Medical Necessity Guidelines for Non-Covered Pharmacy Products.
3. 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. 2017 September 21. URL: https://www.hcvguidelines.org/sites/default/files/full-guidance-pdf/HCVGuidance_September_21_2017_e.pdf. Available from Internet. Accessed 2018 February 1.

2. Epclusa (sofosbuvir/velpatasvir) [prescribing information]. Foster City, CA: Gilead Sciences, Inc.; November 2017.
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.; November 2017.
5. Mavyret (glecaprevir/pibrentasvir) [prescribing information]. North Chicago, IL; AbbVie Inc.; June 2019.
6. Sovaldi (sofosbuvir) [prescribing information]. Foster City, CA: Gilead Sciences, Inc.; November 2017.
7. Vosevi (sofosbuvir/velpatasvir/voxilaprevir). Foster City, CA: Gilead Sciences, Inc.; November 2017.
8. Zepatier (elbasvir/grazoprevir). Whitehouse Station, NJ: Merck & Co., Inc.; November 2017.

APPROVAL HISTORY

February 13, 2017: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- March 13, 2018: Updated duration of approval for Harvoni in treatment-naïve patients with genotype 1 infection to allow for 12 weeks for special populations (pediatric patients, HIV co-infection, African Americans, and IL28B polymorphism CT or TT). Updated Harvoni treatment-naïve genotype type 1 infection criteria to clarify that Members with cirrhosis must try and fail Epclusa.
- July 9, 2019: Updated indication for Mavyret to include pediatric patients age 12 and older or weighing at least 45 kg.
- August 13, 2019: Clarified approval durations for Harvoni and Mavyret based on pediatric indications which required requesting documentation the Member is without decompensated cirrhosis for Harvoni in certain clinical scenarios (treatment-naïve genotype 4-6 and treatment-experiences genotype 1, 4, 5, or 6).
- October 15, 2019: Updated duration of approval for Mavyret to 8 weeks for all treatment naïve patients based on updated package labeling. Effective January 1, 2020, moved Epclusa and Harvoni to non-preferred status and moved ledipasvir/sofosbuvir and sofosbuvir/velpatasvir to preferred status.
- January 14, 2020: Effective January 1, 2020, Mavyret regimens greater than 8 weeks duration are preferred. Updated Sovaldi coverage to limit use for pediatric members with genotypes 2 or 3, with members ≥12 and <18 years to require clinical rationale for use instead of Mavyret. Simplified the approval durations for Zepatier for genotype 1a infections. Effective April 1, 2020, Vosevi is a non-preferred product and requires clinical rationale for use instead of Mavyret in patients previously treated with Sovaldi. Added the following Note for Ledipasvir/sofosbuvir "8 weeks can be approved in Members ≥18 years with genotype 4 (except genotype 4r) who do not have cirrhosis and who have a baseline viral load (within the last 6 months) <6 million IU/mL." Added the following Limitation: "The plan does not cover Epclusa and Harvoni. Refer to the Pharmacy Medical Necessity Guidelines for Non-Covered Pharmacy Products."

5. February 11, 2020: Effective April 1, 2020, removed the Fibrotest (FibroSURE) score as an option for documentation of stage of hepatic fibrosis.
6. September 15, 2020: No changes
7. November 24, 2020: No changes. Effective January 1, 2021, coverage requirements are to be in line with MassHealth ACPP/MCO Partial Unified Formulary.

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.