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

Effective: January 1, 2026

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: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617-673-0939	

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

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Hepatitis C has been identified as a significant etiology of chronic liver disease, associated comorbidities, liver cancer, need for transplantation and death.

Mavyret (glecaprevir/pibrentasvir) is the preferred Medication for the Treatment of Hepatitis C. The following medications are non-preferred and require prior authorization: **Epclusa**, **Harvoni**, **ledipasvir/sofosbuvir**, **sofosbuvir/velpatasvir**, **Sovaldi**, **Vosevi** and **Zepatier.**

COVERAGE GUIDELINES

Note: Prescribers must be enrolled as a billing provider or an ordering, prescribing or referring (OPR) provider with Rhode Island Medicaid.

The Plan may authorize coverage of a non-preferred Medication for the Treatment of Hepatitis C for Members when all the following criteria are met:

1. Documented diagnosis of hepatitis C virus

AND

2. Documentation of hepatitis C genotyping that is supported by FDA-approved labeling of the requested agent

AND

3. Documentation of prior chronic hepatitis C virus therapy if relevant based on FDA-approved labeling of requested agent

AND

4. Documentation of treatment plan, including all of the following:
    a. Medication name, dose, and duration
    b. Agreement to submit post treatment viral load data

AND

5. Documentation of clinical need for an alternative, non-preferred agent

LIMITATIONS

- Medication approval will be for a full course of treatment.
- Treatment recommendations:
    - Preferred agents: Mavyret
    - Non-preferred agents: All other agents with the exception of ribavirin
- 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. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. October 2024.
2. Mavyret (glecaprevir/pibrentasvir) [prescribing information]. North Chicago, IL; AbbVie Inc.; October 2023.

APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- December 12, 2023: Moved Vosevi to non-preferred status (eff 3/1/24).
- November 12, 2024: No changes (eff 11/12/24)

- December 9, 2025: removed Viekira Pak from MNG due to product discontinuation (eff 1/1/26).

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.