

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

Effective: August 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
These pharmacy medical necessity guidelines apply to the following: Commercial Products <input type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans • CareLink SM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization Tufts Health Public Plans Products <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		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 has been identified as a significant etiology of chronic liver disease, associated comorbidities, liver cancer, need for transplantation and death.

Preferred agents include Mavyret (glecaprevir/pibrentasvir) and Vosevi (sofosbuvir/velpatasvir/voxilaprevir).

COVERAGE GUIDELINES

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

Vosevi (sofosbuvir/velpatasvir/voxilaprevir)

Note: Prescriptions for Vosevi that meet the initial step therapy requirements, will adjudicate at the point of service. If the member does not meet the initial step therapy criteria, then the prescription will deny at the point of service with a message indicating that prior authorization is required. Refer to the Coverage Criteria below and submit prior authorization requests to the plan for members who do not meet the step therapy criteria at the point of service.

Automated Step Therapy Coverage Criteria for Vosevi

The plan may cover Vosevi if the following criteria are met:

1. The Member has had a trial and failure of Epclusa, Harvoni, ledipasvir/sofosbuvir, sofosbuvir/velpatasvir, Sovaldi, Viekira Pak, or Zepatier within the previous 180 days as evidenced by a previous paid claim under the prescription benefit administered by Tufts Health Together.

Coverage Criteria for Vosevi for Members not meeting the Automated Step Therapy Coverage Criteria at the Point of Sale

The plan may cover Vosevi if the following criteria are met:

1. Documentation of chronic hepatitis C genotype 1, 2, 3, 4, 5 or 6 infection with previous treatment with a hepatitis C virus regimen containing an NS5A inhibitor
- OR**
2. Documentation of chronic hepatitis C genotype 1a or 3 infection with previous treatment with a hepatitis C virus regimen containing sofosbuvir without an NS5A inhibitor

Non-preferred Agents

The Plan may authorize coverage of Epclusa, Harvoni, ledipasvir/sofosbuvir, sofosbuvir/velpatasvir, Sovaldi, Viekira Pak, or Zepatier for Members when all the following criteria are met:

1. Documented diagnosis of hepatitis C virus

AND

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

AND

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

AND

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

AND

- 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 or Vosevi
 - 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

- 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.
- Eplclusa (sofosbuvir/velpatasvir) [prescribing information]. Foster City, CA: Gilead Sciences, Inc.; June 2021.
- Harvoni (ledipasvir/sofosbuvir) [prescribing information]. Mississauga, Ontario, Canada: Gilead Sciences Inc.; September 2019.
- Mavyret (glecaprevir/pibrentasvir) [prescribing information]. North Chicago, IL; AbbVie Inc.; June 2019.
- Sovaldi (sofosbuvir) [prescribing information]. Foster City, CA: Gilead Sciences, Inc.; September 2019.
- Viekira Pak (dasabuvir/ombitasvir/paritaprevir/ritonavir). North Chicago, IL: AbbVie Inc.; November 2017.
- Vosevi (sofosbuvir/velpatasvir/voxilaprevir). Foster City, CA: Gilead Sciences, Inc.; November 2017.
- 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:

- 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
- 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 Epclusa based on updated package labeling.
6. February 15, 2021: Effective March 1, 2021, removed "Documentation of pretreatment viral load and date of testing. Viral load assessment must be within 90 days of preauthorization request." Updated hepatitis C genotype requirements to not be required if the request is for Mavyret for initial hepatitis C therapy. Administrative update within the Limitations section regarding requests for non-preferred regimens to change the date of the current policy to March 1, 2021.
6. July 13, 2021: Effective August 1, 2021, PA requirements removed for preferred agent Mavyret and implement an automated step therapy program for preferred Vosevi, and updated coverage for non-preferred agent to no longer require documentation of stage or disease but require "Documentation of clinical need for an alternative, non-preferred agent." No changes to coverage criteria for non-preferred agents. Limitations section updated to remove the following: "...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.", and "Non-preferred Regimens: Will be approved if a Member is completing a regimen which was initiated prior to August 1, 2021 (current policy implementation) and 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." Removed the following discontinued medications from the Medical Necessity Guideline: Daklinza, Olysio, Technivie, and Viekira XR.
7. January 1, 2022 Administrative update: Removed Tufts Health Freedom Plan from the template.

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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