BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Pharmacy Policy

Hepatitis C

Policy Number: 9.404
Version Number: 2.0
Version Effective Date: 6/1/2021

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☐ New Hampshire Medicaid	☐ MassHealth - MCO ☐ MassHealth - ACO ☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Sofosbuvir/velpatasvir
- Sofosbuvir/ledipasvir
- Vosevi
- Mavyret

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	• Member is pregnant • Any regimen combination or monotherapy not addressed with specific approval criteria in the policy. • Newly approved regimens for hepatitis C that do not meet required clinical justification as to why none of the preferred and non-preferred regimens in this policy are appropriate for the member.

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	• Vosevi will not be authorized for any initial requests (treatment naïve).
Required Medical Information	Documentation of all of the following: 1. Diagnosis of Hepatitis C with confirmation of genotype 2. Quantitative HCV RNA (viral load) confirmed by HCV RNA level taken within 6 months prior to initiation of treatment 3. Patient's cirrhosis status 4. Prior treatment history and response to prior treatment (if applicable) 5. Planned duration of therapy with the requested medication 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 7. Documented attestation from the prescriber that the Member has been assessed for potential non-adherence 8. If request is for Ledipasvir/Sofosbuvir (generic Harvoni) for 12 weeks, clinical rationale why member cannot use Mavyret for 8 weeks or Sofosbuvir/Velpatasvir for 12 weeks 9. If request is for VOSEVI, documentation of the following: a. Member is without decompensated cirrhosis b. Clinical rationale why Member cannot use Mavyret, Sofosbuvir/Velpatasvir, or Ledipasvir/Sofosbuvir
Age Restriction	Sofosbuvir/Velpatasvir (Epclusa): 6 years or older Vosevi, Zepatier: Member is at least 18 years of age Ledipasvir/Sofosbuvir (Harvoni): Member is at least 3 years of age Mavyret: Member is at least 12 years of age
Prescriber Restriction	Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist
Coverage Duration	Duration of approval per AASLD Guidelines
Quantity Limit	Appropriate dosing per manufacturer

Clinical Background Information and References

1. HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C. American Association for the Study of liver Disease (AASLD) and Infectious Disease Society of America (IDSA). Available from http://www.hcvguidelines.org
2. Epclusa (sofosbuvic/velpatasvir) [prescribing information]. Foster City (CA): Gilead Science, Inc.; March 2020.
3. Harvoni (ledipasvir/sofosbuvir) [prescribing information]. Foster City (CA): Gilead Science, Inc.; March 2020.
4. Mavyret (glecaprevir/pibrentasvir) [prescribing information]. North Chicago (IL): AbbVie, Inc.; September, 2019.

5. Vosevi (sofosbuvir/velpatasvir/voxilaprevir) [prescribing information]. Foster City (CA): Gilead Science, Inc.; November, 2019.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.123 Hepatitis C Policy for retired, new policy created; updated approval criteria to remove the diagnosis of chronic hepatitis C to hepatitis C only	1/1/2021	P&T Commitee
2/11/2021	P&T annual review: Updated age limit for Epclusa based on recent FDA labeling changes; updated exclusion criteria	6/1/2021	P&T Committee

Next Review Date

2/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the

medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.