WELL SENSE HEALTH PLAN

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Pharmacy Policy

Hepatitis C

Policy Number: 9.404
Revision Number: R0
Version Effective Date: 1/1/2021

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

Preferred:

- Vosevi®
- Mavyret®
- Ledipasvir /Sofosbuvir (generic for Harvoni)
- Sofosbuvir/velpatasvir (generic for Epclusa)

Non-preferred:

- Zepatier™
- Epclusa
- Harvoni
- Sovaldi

- **Please note:** For review of unique and key populations that are not otherwise listed in the criteria below, please refer to AASLD HCV Treatment Guidelines at: https://www.hcvguidelines.org

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

Covered	All FDA approved indications not otherwise excluded

[+] *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.

Use	
Exclusion Criteria	• Member is pregnant; • Any regimen combination or monotherapy not addressed with specific approval criteria in the policy; • Newly approved regimens for chronic 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; • Vosevi will not be authorized for any initial requests (treatment naïve)
Required Medical Information	**ledipasvir/sofosbuvir (Harvoni)– Approval Criteria** Genotype 1, 4, 5, or 6
	1. Diagnosis of chronic HCV infection as evidenced by detectable serum HCV RNA levels in the last 6 months, quantitative assay documentation must be provided; ***AND*** **2.** Confirmed HCV genotype is 1, 4, 5, or 6; chart note documentation and lab results are required; ***AND*** **3.** Documentation of treatment status (e.g., treatment-naïve or treatment-experienced); ***AND*** **4.** Documentation of cirrhosis status of the member (e.g., no cirrhosis, compensated cirrhosis, or decompensated cirrhosis); ***AND*** **5.** **ONE** of the following: a. Member ≥3 and <18 years old and requested duration is 12 weeks* b. Member ≥18 years of age AND ONE of the following: i. Baseline viral load (within the last six months) < 6 million IU/mL, member is treatment-naïve, and requested duration is eight weeks ii. Baseline viral load (within the last six months) ≥ 6 million IU/mL, or member has cirrhosis, or is treatment-experienced, and requested duration is 12 weeks; ***AND*** 6. Prescribed regimen is consisted with AASLD-IDSA guidelines; ***AND*** 7. Dose does not exceed 1 tablet per day; ***AND*** 8. If request if for brand Harvoni, clinical rationale for why generic cannot be used
	Vosevi® (sofosbuvir/velpatasvir/voxilaprevir) – Approval Criteria
	1. Diagnosis of chronic HCV infection as evidenced by detectable serum HCV RNA levels in the last 6 months, quantitative assay documentation must be provided; ***AND*** **2.** Member meets **ONE** of the following supported by included chart note documentation and lab results: **a.** HCV genotype is 1, 2, 3, 4, 5, or 6 and member has previously been treated with an HCV regimen containing one of the following NS5A inhibitors: declatasvir, elbasvir, ledipasvir, ombitasvir, or veltapatasvir;

	b. HCV genotype is 1a or 3, and member has previously been treated with an HCV regimen containing sofosbuvir with or without any of the following: pegintergeron alfa/ribavirin, ribavirin, HCV NS3/4A protease inhibitor (beceprevir, simeprevir, or teleprevir) **3. <u>Treatment-experienced (failed treatment with an HCV NS5A inhibitor) , or (failed treatment with sofosbuvir without an HCV NS5A inhibitor for Genotype 1 a and 3 only) members with or without compensated cirrhosis (Child Turcotte Pugh [CTP] class A)</u>** Documentation of **ALL** of the following: 4. Diagnosis of hepatitis C 5. Genotype 1, 2, 3, 4, 5, or 6 6. Member ≥18 years of age 7. For members with genotype 3 and compensated cirrhosis, requested regimen includes ribavirin 8. Requested duration is 12 weeks
	Mavyret® (glecaprevir/pibrentasvir) – Approval Criteria
	A. <u>Treatment-naïve members with or without compensated cirrhosis (Child Turcotte Pugh [CTP] class A)</u> Documentation of **ALL** of the following: 1. Diagnosis of hepatitis C 2. Genotype 1, 2, 3, 4, 5, or 6 3. Member ≥12 years of age* 4. Requested duration is 8 weeks
	B. <u>Treatment-experienced (failed treatment with interferon, peginterferon, ribavirin only); sofosbuvir plus peginterferon and ribavirin only; or sofosbuvir plus ribavirin only) members with or without compensated cirrhosis (Child Turcotte Pugh [CTP] class</u> Documentation of **ALL** of the following: 1. Diagnosis of chronic hepatitis C 2. Genotype 1, 2, 3, 4, 5, or 6 3. Member ≥12 years of age* 4. For genotype 1, 2, 4, 5, or 6, **ONE** of the following: a. Absence of cirrhosis and requested duration is eight weeks b. Compensated cirrhosis and requested duration is 12 weeks 5. For genotype 3, requested duration is 16 weeks

	C. <u>Treatment-experienced (failed treatment with sofosbuvir plus simeprevir or an HCV protease inhibitor plus peginterferon alfa and ribavirin only) members with or without compensated cirrhosis (Child Turcotte Pugh [CTP] class A)</u> Documentation of **ALL** of the following: 1. Diagnosis of hepatitis C 2. Genotype 1 3. Member ≥12years of age* 4. Requested duration is 12 weeks
	<u>D. Treatment-experienced (failed treatment with an HCV NS5A inhibitor without an HCV protease inhibitor) members with or without compensated cirrhosis (Child Turcotte Pugh [CTP] class A)</u> Documentation of **ALL** of the following: 1. Diagnosis of hepatitis C 2. Genotype 1 3. Member ≥12 years of age* 4. Requested duration is 16 weeks Requests for members <12 years old who weigh >=45 kg can be reviewed using the same criteriaRequests for 12 weeks for treatment naive cirrhotic with HIV-coinfection should be approved. Requests for 8 weeks for treatment naive cirrhotic with HIV-coinfection should be denied.
	sofosbuvir/velpatasvir– Approval Criteria Genotype 1, 2, 3, 4, 5, or 6
	A. <u>Treatment-naïve members or treatment-experienced* members with or without compensated cirrhosis (Child Turcotte Pugh [CTP] class A)</u> Documentation of **ALL** of the following: 1. Diagnosis of hepatitis C 2. Genotype 1, 2, 3, 4, 5, or 6 3. Member ≥18 years of age 4. Requested dose is 400 mg/100 mg once daily 5. Requested duration is 12 weeks 6. **For genotype 3 only, ONE of the following** a. Member is treatment-naïve without cirrhosis b. Member is treatment-naïve with compensated cirrhosis or treatment-experienced with or without compensated cirrhosis and testing results document <u>absence</u> of NS5A Y93H resistance-associated substitution c. Requested regimen includes ribavirin and **ONE** of the following i. Member is treatment-naïve with compensated cirrhosis or treatment-experienced without cirrhosis and testing results document <u>presence</u> of NS5A Y93H resistance-associated substitution ii. Member is treatment-experienced with compensated cirrhosis * *Treatment-experienced members are those who have failed treatment with peginterferon alfa and ribavirin (with or without protease inhibitor). Requests for members with genotypes 1b or 2 who have failed sofosbuvir-containing regimen(s) without HCV NS5A inhibitor can be evaluated using criteria above.*
	Pegasys® (peginterferon alfa-2a) or PegIntron® (peginterferon alfa-2b
	1. Documentation of a diagnosis of Hepatitis B

	2. For PegIntron®, a trial and failure of Pegasys is required.
Age Restriction	sofosbuvir/velpatasvir, Vosevi: Member is at least 18 years of age ledispasvir/sofosbuvir: Member is at least 3 years of age Mavyret: Member is at least 12 years of age
Prescriber Restriction	None
Coverage Duration	Duration of approval per AASLD Guidelines
Other criteria	None

Applicable Coding:

None

Clinical Background Information and References

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

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.123 Hepatitis C Policy retired, new policy created; updated required diagnosis from chronic hepatitis C to hepatitis C; updated age limit for ledipasvir/sofosbuvir and Mavyret; updated criteria for Mavyret to reflect FDA approval of 8 weeks in treatment naiive cirrhotics; removed appendix table; updated coverage duration language; removed Zepatier and Rebetol to align with NH state PDL requirements	1/1/2021	P&T Committee, NH DHHS

Next Review Date

2021

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.