

Pharmacy Policy

Hepatitis C

Policy Number: 9.404

Revision Number: R3

Version Effective Date: 9/1/2022

Product Applicability ☐ All Plan⁺ Products

Well Sense Health Plan

☒ New Hampshire Medicaid

Boston Medical Center HealthNet Plan

☐ 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®)
- Pegasys (Hepatitis B)

Non-preferred:

- Zepatier®
- Epclusa
- Harvoni®/Harvoni Pellet Pack
- Sovaldi®/Sovaldi Pellet Pack
- **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:

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Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	<ul style="list-style-type: none"> • 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	<p>ledipasvir/sofosbuvir (generic for Harvoni)– Approval Criteria Genotype 1, 4, 5, or 6</p> <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> a. Member ≥3 and <18 years old and requested duration is 12 weeks b. Member ≥18 years of age AND ONE of the following: <ol style="list-style-type: none"> i. For Genotype 1, baseline viral load (within the last six months) < 6 million IU/mL, member is treatment-naïve, and requested duration is eight weeks; OR ii. For Genotype 1, 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; OR iii. For Genotype 4, 5, and 6, member is treatment naïve, or is treatment experienced, with or without cirrhosis 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 is for brand Harvoni, clinical rationale for why generic cannot be used
	Vosevi® (sofosbuvir/velpatasvir/voxilaprevir) – Approval Criteria
	<ol style="list-style-type: none"> 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

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	<ol style="list-style-type: none"> 2. Confirmed HCV genotype is 1, 2,3 4, 5, or 6 (chart note documentation and lab results are required); AND 3. Documentation of cirrhosis status of the member (e.g., no cirrhosis, compensated cirrhosis, or decompensated cirrhosis); AND 4. Member is ≥18 years of age; AND 5. Member is treatment experienced with an HCV regimen containing one of the following NS5A inhibitors: declatasvir, elbasvir, ledipasvir, ombitasvir, or veltapatasvir, with or without compensated cirrhosis (Child Turcotte Pugh [CTP] class A), and ONE of the following: <ol style="list-style-type: none"> a. HCV genotype 1, 2, 4, 5 or 6 and requested duration is 12 weeks; OR b. HCV genotype 3 without compensated cirrhosis, requested duration is 12 weeks; OR c. HCV genotype 3 with compensated cirrhosis, requested duration is 12 weeks and requested regimen also includes ribavirin; OR 6. Member is treatment-experienced with sofosbuvir containing regimens including peginterferon alfa/ribavirin, ribavirin, and HCV protease inhibitor (boceprevir, simeprevir or telaprevir) without an HCV NS5A inhibitor with or without compensated cirrhosis (Child Turcotte Pugh [CTP] class A); AND <ol style="list-style-type: none"> a. HCV genotype 1a or 3 and request is for 12 weeks
	<div style="background-color: #d1c4e9; padding: 5px;">Mavyret® (glecaprevir/pibrentasvir) – Approval Criteria</div> <ol style="list-style-type: none"> 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, 2,3 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. Member is 3 years and older*; AND 6. ONE of the following: <ol style="list-style-type: none"> a. Member is treatment-naïve with or without compensated cirrhosis (Child Turcotte Pugh [CTP] class A); AND <ol style="list-style-type: none"> i. Genotype 1, 2, 3, 4, 5 or 6 and requested duration is 8 weeks; OR b. Member is treatment-experienced (failed treatment with interferon, peginterferon, ribavirin only; sofosbuvir plus peginterferon and ribavirin only; or sofosbuvir plus ribavirin only) with or without compensated cirrhosis Child Turcotte Pugh [CTP] class and ONE of the following:

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	<p>i. For genotype 1, 2, 4, 5, or 6, ONE of the following:</p> <ul style="list-style-type: none"> ○ Absence of cirrhosis and requested duration is eight weeks; OR ○ Compensated cirrhosis and requested duration is 12 weeks; OR <p>ii. For genotype 3, requested duration is 16 weeks; OR</p> <p>c. Member is treatment-experienced (failed treatment with sofosbuvir plus simeprevir or an HCV protease inhibitor plus peginterferon alfa and ribavirin only) with or without compensated cirrhosis (Child Turcotte Pugh [CTP] class; AND</p> <p>i. Genotype 1 and requested duration is 12 weeks; OR</p> <p>d. Member is treatment-experienced (failed treatment with an HCV NS5A inhibitor without an HCV protease inhibitor) with or without compensated cirrhosis (Child Turcotte Pugh [CTP] class A); AND</p> <p>ii. Genotype 1 and requested duration is 16 weeks</p> <p><i>Requests for members <12 years old who weigh ≥45 kg can be reviewed using the same criteria. Requests for 12 weeks for treatment naïve cirrhotic with HIV-coinfection should be approved. Requests for 8 weeks for treatment naïve cirrhotic with HIV-coinfection should be denied</i></p>
	<p>sofosbuvir/velpatasvir (Epclusa)– Approval Criteria Genotype 1, 2, 3, 4, 5, or 6</p> <ol style="list-style-type: none"> 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, 2,3,4, 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. Member is ≥ 3 years of age or older, OR has a weight of at least 17kg ; AND 6. Dose does not exceed 1 tablet per day; AND 7. Requested duration is 12 weeks; AND 8. Member is treatment-naïve or treatment-experienced*with or without compensated cirrhosis (Child Turcotte Pugh [CTP] class A); AND 9. Member has genotype 1, 2, 4, 5, or 6; OR 10. Member has genotype 3, and ONE of the following <ol style="list-style-type: none"> a. Member is treatment-naïve without cirrhosis; OR b. Member is treatment-naïve with compensated cirrhosis or treatment-experienced without compensated cirrhosis and testing results document absence of NS5A Y93H resistance-associated substitution; OR c. Requested regimen includes ribavirin and ONE of the following:

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	<p>i. Member is treatment-naïve with compensated cirrhosis or treatment-experienced without cirrhosis and testing results document presence of NS5A Y93H resistance-associated substitution; OR</p> <p>ii. Member is treatment-experienced with compensated cirrhosis; AND</p> <p>11. If request is for brand Epclusa, clinical rationale for why generic cannot be used</p> <p><i>* 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.</i></p>
	<p>Pegasys® (peginterferon alfa-2a)</p> <p>1. Documentation of a diagnosis of Hepatitis B;</p> <p>2.</p>
Age Restriction	<p>Vosevi: Member is at least 18 years of age</p> <p>Iedipasvir/sofosbuvir(Harvoni) , Sofosbuvir/Velpatasvir (Epclusa), Mavyret:: Member is at least 3 years of age</p>
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	1/1/2021	P&T Committee, NH DHHS

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Policy Revisions History			
	FDA approval of 8 weeks in treatment naive cirrhotics; removed appendix table; updated coverage duration language; removed Zepatier and RebetoI to align with NH state PDL requirements		
2/11/2021	P&T annual review: Updated age limit for Epclusa based on recent FDA labeling changes; updated dosing requirement for Epclusa to 1 tablet per day and added language that if request is for brand, clinical reason why generic cannot be used; updated language for lab requirements consistent across all drugs on the policy; formatting changes for Mavyret and Vosevi	6/1/2021	P&T Committee, NH DHHS
4/15/2021	Updated Non-Preferred agents list to reflect 4/15/21 PDL changes. Harvoni and Sovaldi Pellet Packs added to non-preferred listing	4/15/2021	P&T Committee, NH DHHS
2/10/2022	P&T Review: Update age for Epclusa and Mavyret	6/1/2022	P&T Committee, NH DHHS
8/23/2022	Update to accurately reflect Pegasys in policy and removal of Pegintron since product is discontinued	9/1/2022	P&T Committee, NH DHHS

Next Review Date

2/2023

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.

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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.

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