

Clinical Policy Title:	Hepatitis C Medications
Policy Number:	RxA.214
Drug(s) Applied:	Ledipasvir/sofosbuvir, sofosbuvir/velpatasvir, Mavyret®
Original Policy Date:	02/07/2020
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Hepatitis C Infection (must meet all):

1. Diagnosis of hepatitis C;
2. Prescribed regimen and diagnosis are supported by one of the following (a or b):
 - a. FDA-approved indications as outlined in Appendix A;
 - b. AASLD-IDSA recommended regimen.

Approval Duration

All lines of business (except Medicare): Length of course of therapy

II. Continued Therapy Approval

A. Hepatitis C Infection

1. Reauthorization not permitted. Member must meet initial criteria.

Appendix A

Medication	FDA-Approved Indications
Ledipasvir/sofosbuvir	<ol style="list-style-type: none"> 1. Genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis 2. Genotype 1 infection with decompensated cirrhosis, in combination with ribavirin 3. Genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin
Mavyret	<ol style="list-style-type: none"> 1. Genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) 2. Genotype 1 infection in patients previously treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor
Sofosbuvir/velpatasvir	<ol style="list-style-type: none"> 1. Genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) 2. Genotype 1, 2, 3, 4, 5 or 6 infection with decompensated cirrhosis for use in combination with ribavirin

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

References

1. Debika Bhattacharya, Andrew Aronsohn, Jennifer Price, Vincent Lo Re, the American Association for the Study of Liver Diseases–Infectious Diseases Society of America HCV Guidance Panel , Hepatitis C Guidance 2023 Update: American Association for the Study of Liver Diseases– Infectious Diseases Society of America Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection, Clinical Infectious Diseases, 2023 Available at: <https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciad319/7179952?login=false> Accessed March 28, 2025.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Clinical Policy title was updated 2. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 3. Lines of business 'Policy Applies to' was updated to 'All lines of business'. 4. Approval Duration changed from 16 weeks to 4 months (consistency). 5. References reviewed and updated. 	06/18/2020	09/14/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Clinical Policy title was updated. 2. Continued Therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance..." 3. References were reviewed and updated. 	03/08/2021	06/10/2021
Policy was reviewed: <ol style="list-style-type: none"> 1. Initial Approval Criteria I.A.2.d: Updated to include genotype criteria for Hepatitis C in its entirety. 2. Initial Approval Criteria, 1.A.10: Updated dose limit from standard dose of glecaprevir 300 mg/pibrentasvir 120 mg per day to age/weight-based criteria listed in a and b. 3. Continued Therapy Approval Criteria, II.A.3: Updated dose limit from standard dose of glecaprevir 300 mg/pibrentasvir 120 mg per day to age/weight-based criteria listed in a and b. 4. References were reviewed and updated. 	01/19/2022	04/18/2022
Policy was reviewed: <ol style="list-style-type: none"> 1. Continued Therapy Approval, II.A.3: Updated to include new prior treatment criteria Member is not treatment-experienced with both NS3/4A protease inhibitor AND NS5A inhibitors, such as combination therapies including Technivie™, Viekira, and Zepatier®; 2. References were reviewed and updated. 	02/10/2023	04/13/2023

Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: Initial Approval	7/15/2024	7/15/2024
<ol style="list-style-type: none"> 1. Consolidated hepatitis C drugs to one policy: ledipasvir/sofosbuvir, Mavyret, and sofosbuvir/velpatasvir. 2. Removed diagnosis confirmation by assay. 3. Added specific genotype for ledipasvir/sofosbuvir. Removed genotype for other medications since all genotypes apply. 4. Differentiated compensated and decompensated cirrhosis and applicable drugs. 5. Revised combination therapy language and treatment experience. 6. Removed life expectancy criteria. 7. Removed participation in a medication adherence program. 		
Continued Approval		
<ol style="list-style-type: none"> 1. Removed authorization by RxAdvance. 2. Removed confirmation of continuation of therapy and genotype criteria. 3. Removed combination therapy language and treatment experience. 4. Removed responding positively to therapy. 5. Removed dosing. 		
Policy was reviewed:	3/28/2025	4/10/2025
<ol style="list-style-type: none"> 1. Reformatted policy to include all FDA approved indications. 		
Policy was reviewed:	6/26/2025	6/26/2025
<ol style="list-style-type: none"> 1. Reformatted policy to include all FDA approved indications; 2. Removed prescriber restrictions. 		
Policy reviewed.	12/11/2025	12/11/2025