Clinical Policy Title:	Ledipasvir/sofosbuvir, sofosbuvir/velpatasvir, Mavyret®
Policy Number:	RxA.214
Drug(s) Applied:	Ledipasvir/sofosbuvir, sofosbuvir/velpatasvir, Mavyret®
Original Policy Date:	02/07/2020
Last Review Date:	7/10/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Chronic Hepatitis C (CHC) Infection (must meet all)**:**

1. Member has a diagnosis of chronic hepatitis C (CHC);
2. Ledipasvir/Sofosbuvir: member must have a diagnosis for CHC genotypes 1, 4, 5, 6;
3. Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist;
4. Prescribed regimen is consistent with an FDA or AASLD-IDSA recommended regimen;
5.
6.

5. If the member has liver cirrhosis, the request must meet one of the following (a or b):
    a. Compensated cirrhosis (Child-Pugh Class A): The request is for ledipasvir/sofosbuvir, Mavyret®, or sofosbuvir/velpatasvir.
    b. Decompensated cirrhosis (Child-Pugh Class B or C): The request is for sofobuvir/velpatasvir in combination with ribavirin OR ledipasvir/sofosbuvir.

6. Medication is not used in combination with another direct acting antiviral agent for hepatitis C virus (HCV) (e.g. Zepatier, Vosevi, Viekira, Epclusa, Harvoni, Sovaldi)Approval Duration
All lines of business (except Medicare): 4 months

II. Continued Therapy Approval

A. Chronic Hepatitis C Infection

1. Member is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples.
2. Member requires an additional course of therapy per FDA or AASLD IDSA guidelines.

Approval Duration
All lines of business (except Medicare):4 months

References

1. American Association for the Study of Liver Diseases/ Infectious Disease Society of America (AASLD-IDSA). HCV guidance: recommendations for testing, managing, and treating hepatitis C. Last updated October 24, 2022. Available: https://www.hcvguidelines.org/. Accessed February 10, 2023.

Review/Revision History	Review/Revised Date	P&T Approval Date

Policy established.	01/2020	02/07/2020
Policy was reviewed: 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: 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: 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: 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 1. Consolidated hepatitis C drugs to one policy: ledipasvir/sofobuvir, 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.	7/15/2024	

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 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.		