Clinical Policy Title:	sofosbuvir-velpatasvir-voxilaprevir
Policy Number:	RxA.558
Drug(s) Applied:	Vosevi®
Original Policy Date:	03/06/2020
Last Review Date:	7/19/2024
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. Diagnosis of chronic hepatitis C (CHC)
2. Member meets one of the following (a or b):
   a. HCV genotype is 1, 2, 3, 4, 5 or 6, and member has previously been treated with at least 8 weeks of a HCV regimen containing one of the following NS5A inhibitors: daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir;
   b. HCV genotype is 1a or 3, and member has previously been treated with at least 8 weeks of a HCV regimen containing sofosbuvir with or without any of the following: peginterferon alfa/ribavirin, ribavirin, HCV NS3/4A protease inhibitor (boceprevir, simeprevir or telaprevir);
3. Member has tried and failed sofosbuvir/velpatasvir, unless contraindicated or clinically significant adverse effects are experienced;
4. Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease specialist, or a liver transplant physician;
5. If the member has liver cirrhosis, cirrhosis is compensated or Child-Pugh A status;
6. Prescribed regimen is consistent with an FDA or AASLD-IDSA recommended regimen;

Approval Duration
All lines of business (except Medicare): 3 months

II. Continued Therapy Approval

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

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): 3 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 August 27, 2020. Available

at: https://www.hcvguidelines.org/. Accessed August 25, 2022.
2. Bourliere M, et al. Sofosbuvir, velpatasvir, and voxilaprevir for previously treated HCV infection. NEJM 2017;376:2134-46. Available at: https://www.nejm.org/doi/full/10.1056/NEJMoa1613512. Accessed August 25, 2022.
3. CDC. Viral hepatitis: Q&As for health professionals. Available at: https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm. Accessed August 25, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical policy title table was updated. 2. Line of business policy applies to was updated to “All lines of business”. 3. Initial approval duration was updated for “12 weeks” to “84 days” for both commercial and Medicaid and Continued approval duration update from “Up to a total treatment duration of 12 weeks” to “84 days” for both commercial and Medicaid. 4. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 5. References were updated.	08/2020	12/07/2020
Policy was reviewed: 1. Policy title table was updated. 2. Initial approval criteria I.A.3 updated to prefer Epclusa® and reflect use of brand over generic due to rebates available. 3. Continued therapy approval criteria II.A.1.b updated to simplify and align with updated initial approval criteria. 4. References updated.	12/2020	12/07/2020
Policy was reviewed: 1. Initial approval criteria 1.A.3 was updated to remove, ”brand over generic”. 2. Continued Therapy Approval II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 3. References were reviewed and updated.	10/04/2021	12/07/2021
Policy was reviewed: 1. References were reviewed and updated	08/25/2022	10/19/2022
Policy was reviewed.	10/19/2023	10/19/2023

Police was reviewed: Initial Approval 1. Removed diagnosis confirmation by assay. 2. Revised language for compensated cirrhosis. 3. Revised criteria for trial and failure of generic Epclusa (sofosbuvir/velpatasvir). 4. Removed life expectancy criteria. 5. Removed age requirement. 6. Removed participation in a medication adherence program. 7. Removed dosing. Continued Approval 1. Removed authorization by RxAdvance. 2. Removed responding positively to therapy. 3. Removed dosing.	7/19/2024	7/19/2024