CareSource

PHARMACY POLICY STATEMENT **Ohio Medicaid**	
DRUG NAME	Vosevi (sofosbuvir/velpatasvir/voxilaprevir)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Mavyret and Sofosbuvir/velpatasvir (generic for Epclusa) QUANTITY LIMIT— 28 for a 28 day supply
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Vosevi (sofosbuvir/velpatasvir/voxilaprevir) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

HEPATITIS C (without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh Class A)

For **initial** authorization:
Member must meet all criteria below Step 1 and Step 2 and Step 3.

Step 1 (evaluation of member's readiness):

1. Member must be 18 years of age or older; AND
2. Member must be free for 6 months from alcohol use, controlled drug abuse, and illicit drug use before consideration of therapy (laboratory documentation required for month 1 and for month 6 and for one additional month between month 2-5); AND
3. Member must meet kidney function as indicated in package labeling for product (No dosage adjustment of Vosevi is required for members with mild or moderate renal impairment. The safety and efficacy of Vosevi have not been established in members with severe renal impairment (eGFR less than 30 mL/min/1.73 m^2) or ESRD requiring hemodialysis); AND
4. Member must not be concomitantly taking drugs that have significant clinical interaction as described in the prescribing information (Coadministration with rifampin is contraindicated); AND
5. Member must agree to be adherent with office visits, lab testing, imaging, procedures and, if deemed a candidate, the HCV medication regimen. Prescribers must submit documentation demonstrating the member attests to meet these requirements (Office notes documenting this are sufficient to meet this criteria); AND

Step 2 (clinical assessment of disease):

6. Member has tried and failed courses of treatment with Sofosbuvir/velpatasvir (generic for Epclusa) and Mavyret (Dates and HCV RNA values must be documented in chart notes). *Note: See policies for Sofosbuvir/velpatasvir (generic for Epclusa) and for Mavyret for details on treatment-experienced members*; AND
7. Member has confirmation of chronic hepatitis C (CHC):
   a) Hepatitis C Virus (HCV) antibody test reactive; AND
   b) Provide HCV RNA load measured within 90 days prior to starting DAA therapy; AND

c) Specify the Genotype (choose one of the following statuses):
   i) Treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh Class A) with Genotype 1, 2, 3, 4, 5 or 6 (laboratory documentation required); OR
   ii) Treatment-experienced genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor (laboratory documentation required). *Note: Additional benefit of Vosevi over Epclusa (sofosbuvir/velpatasvir) was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with sofosbuvir without an NS5A inhibitor*; AND

8. Member has documented progression of disease:
   a) Document the degree of liver fibrosis:
      i) Liver biopsy; OR
      ii) One radiological and one serological test; AND
   b) If cirrhosis is present, indicate whether cirrhosis is compensated or decompensated and provide the Child-Turcotte-Pugh (CTP) score; AND
9. Document that member does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions; AND
10. Document any previously tried Hepatitis C treatments, dates treated, and response/outcome (member will not be approved if any other HCV treatments have been used in the last 6 months); AND

Step 3 (Direct Acting Antivirals (DAA) conditions for coverage):

11. Medication must be prescribed by, or in consultation with, a hepatologist, gastroenterologist, or infectious disease specialist; AND
12. Member's documented HCV RNA testing is required every 4 weeks and submitted with chart notes; AND
13. Providers of HIV/HCV-coinfected persons should recognize and manage interactions with other antiretroviral medications (e.g. DAAs); AND
14. Only regimens listed as recommended or alternative in the current AASLD guidance (http://hcvguidelines.org) will be approved with duration of approval based upon guidelines. Regimens listed as not recommended will not be approved.
15. **Dosage allowed:** One tablet once daily for 12 weeks.

If member meets all the requirements listed above, the medication will be approved for 12 weeks.

For **reauthorization**:

1. Vosevi will not be reauthorized.

CareSource considers Vosevi (sofosbuvir/velpatasvir/voxilaprevir) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
12/17/2018	New policy for Vosevi created. Criteria written based Ohio Department of Medicaid requirements.
05/01/2019	Sofosbuvir/velpatasvir (generic for Epclusa) trial added.

References:

1. Vosevi [package Insert]. Foster City, CA: Gilead Sciences, Inc.; November, 2017.
2. Hepatitis C Information | Division of Viral Hepatitis | CDC. (2015, May 31). Retrieved from https://www.cdc.gov/hepatitis/hcv/index.htm.
3. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America (AASLD) and Infectious Diseases Society of America (IDSA). HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C; 2017. Available at: https://www.hcvguidelines.org/.

4. Afdhal, N. (2012). Fibroscan (Transient Elastography) for the Measurement of Liver Fibrosis. Gastroenterology & Hepatology, 8(9), 605-607.

Effective date: 07/01/2019
Revised date: 05/01/2019