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PHARMACY POLICY STATEMENT
Kentucky 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, for **reauthorization** or for **retreatment**:

1. Member must be treatment-experienced, without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh Class A); AND
2. Member must be 18 years of age or older; AND
3. Member has genotype 1, 2, 3, 4, 5, or 6 (laboratory documentation required) and have previously been treated with an HCV regimen containing an NS5A inhibitor[1]; OR
4. Member has genotype 1a or 3 (laboratory documentation required) and have previously been treated[2] with an HCV regimen containing sofosbuvir without an NS5A inhibitor; AND
5. Medication must be prescribed by a board certified hepatologist, gastroenterologist, infectious disease specialist or a nurse practitioner working with the above specialists;
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).
7. **Dosage allowed:** One tablet once daily for 12 weeks.

Note: Member's life expectancy must be no less than one year due to non-liver related comorbidities. Please submit fibrosis score and drug screening with prior authorization.

[1]NS5A inhibitor experience included daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir.
[2]Prior treatment experience included sofosbuvir with or without any of the following: peginterferon alfa/ribavirin, ribavirin, HCV NS3/4A protease inhibitor (boceprevir, simeprevir, or telaprevir).

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

For **reauthorization** or for **retreatment**:

1. Member must be in compliance with ALL other initial criteria; AND
2. Prescriber must submit completed "Supplemental Form Hepatitis C for KY Medicaid" with reauthorization request (see Appendix A below); AND
3. Member is compliant with drug therapy regimen by paid pharmacy claims; AND
4. Member has documented current monthly negative urine drug and alcohol screens for 3 consecutive months (laboratory documentation required); AND
5. If the member has a recent history (within the past 6 months) of alcohol or substance abuse, the following is required:
   a) Documentation that the member has completed or is participating in a recovery program, receiving alcohol or substance abuse counseling services, or seeing an addiction specialist as part of HCV treatment; AND
   b) Documentation that the member is not actively participating in illicit substance use or alcohol abuse with confirmatory laboratory testing (e.g., urine drug screen); AND
6. Member has evidence of liver fibrosis stage 3 or 4 confirmed by liver biopsy, or elastography only (lab chart notes required) unless one of the following (fibrosis stage F0-4 covered):
   a) Hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation);
   b) Post liver transplantation;
   c) Extrahepatic disease (i.e., kidney disease: proteinuria, nephrotic syndrome or membranoproliferative glomerulonephritis; cryoglobulinemia with end- organ manifestations (e.g., vasculitis));
   d) HIV or HBV coinfection.
7. **Dosage allowed:** One tablet once daily for 12 weeks.

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

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
05/01/2019	New policy for Vosevi created.

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

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Appendix A. Supplemental Form Hepatitis C for KY Medicaid

1. Prescriber **must answer ALL** of the following questions with prior authorization submission:
   a) Is retreatment necessary due to treatment failure or reinfection?

   b) Was the member compliant (e.g., few to no missed doses) with previous Direct-Acting Antiviral (DAA) therapy? If not, why?

   c) Were there any additional factors that led to DAA treatment failure? If so, describe these factors and how they have been addressed or are no longer relevant.

2. Member **has been evaluated** for potential clinically significant drug interactions. Please see package insert for details: https://www.rxabbvie.com/pdf/mavyret_pi.pdf.

3. Provider **attests** that:
   a) Member is willing and able to comply with the requirements of the proposed retreatment plan; AND
   b) Any factors that may have led to noncompliance with previous treatment(s) have been addressed; AND
   c) Member has received education regarding risk behaviors (e.g., IV drug use) associated with HCV infection.

Prescriber's name:

Signature: Date: