CareSource

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

Sofosbuvir/velpatasvir (generic for Epclusa) is a **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) or with decompensated cirrhosis (Child-Turcotte-Pugh Class B or C))

For **initial** authorization:
Member must meet all criteria below Step 1 and Step 2 and Step 3. **If request is for brand name Epclusa, please follow policy "Medical Necessity for DAW" on CareSource webpage.**

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 sofosbuvir/velpatasvir is required for members with mild or moderate renal impairment. The safety and efficacy of sofosbuvir/velpatasvir 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 (Sofosbuvir/velpatasvir and ribavirin combination regimen is contraindicated in members for whom ribavirin 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 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-naïve or 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-naïve or treatment-experienced with decompensated cirrhosis (Child-Turcotte-Pugh Class B or C) who may or may not be a candidate for liver transplantation, including those with hepatocellular carcinoma with Genotype 1, 2, 3, 4, or 6 (laboratory documentation required); AND

7. 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
   c) Member with decompensated cirrhosis (CTP score 7 or higher) will be approved for therapy only after consultation with a physician in a liver transplant center, and if member has decompensated cirrhosis sofosbuvir/velpatasvir must be prescribed in combination with ribavirin. If ribavirin ineligible must submit documentation of ONE of the following results obtained within the past month:
      i) History of severe or unstable cardiac disease
      ii) Pregnant women and men with pregnant partners
      iii) Diagnosis of hemoglobinopathy (e.g., thalassemia major, sickle cell anemia)
      iv) Hypersensitivity to ribavirin
      v) Baseline platelet count < 70,000 cells/mm^3
      vi) ANC < 1500 cells/mm^3
      vii) Hb < 12 gm/dL in women or < 13 g/dL in men; AND
8. Document that member does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions; AND
9. Document any previously tried Hepatitis C treatments, dates treated, and response/outcome (<u>member will not be approved if any other HCV treatments have been used in the last 6 months</u>); AND

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

10. Medication must be prescribed by, or in consultation with, a hepatologist, gastroenterologist, or infectious disease specialist; AND
11. Member's documented HCV RNA testing is required every 4 weeks and submitted with chart notes; AND
12. Providers of HIV/HCV-coinfected persons should recognize and manage interactions with other antiretroviral medications (e.g. DAAs); AND
13. 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.
14. **Dosage allowed:** One tablet once daily for 12 weeks. If member has decompensated cirrhosis and is ribavirin ineligible and request is for genotype 1, 3, 4 or 6 sofosbuvir/velpatasvir may be approved for additional 12 weeks, not to exceed the total of 24 weeks treatment duration.

If member meets all the requirements listed above, the medication will be approved for 12-24 weeks.

For **<u>reauthorization</u>**:

1. Sofosbuvir/velpatasvir will not be reauthorized for continued therapy.

CareSource considers Sofosbuvir/velpatasvir (generic for Epclusa) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
05/09/2017	New policy for Epclusa created.
06/08/2017	Fibrosis stage 2 and above covered.
11/22/2017	Medication status changed to non-preferred. Substance abuse program information is no longer required. Trial of preferred agent is required for members without cirrhosis or with compensated cirrhosis only.
12/07/2017	Criterion of "life expectancy not less than one year due to non-liver related comorbidities" removed from criteria and added in a form of the note. Hepatitis B testing is no longer required.
12/17/2018	Criteria changed per Ohio Department of Medicaid requirement. Minimum of 3 months of "drug/alcohol free period" criterion changed to 6 months; no fibrosis score required, but documentation of degree liver fibrosis changed; kidney function and clinical interactions addressed; HCV RNA load measurement prior to starting DAA therapy changed from "within 6 months" to "within 90 days"; cirrhosis score required; prescribers specialty changed; HCV RNA testing is now required every 4 weeks.
05/01/2019	Policy modified to Sofosbuvir/velpatasvir (generic for Epclusa); status changed to preferred product. Trial of Mavyret removed.

References:

1. Epclusa [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