PHARMACY POLICY STATEMENT
Ohio Medicaid

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>Epclusa (sofosbuvir/velpatasvir)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BILLING CODE</td>
<td>Must use valid NDC code</td>
</tr>
<tr>
<td>BENEFIT TYPE</td>
<td>Pharmacy</td>
</tr>
<tr>
<td>SITE OF SERVICE ALLOWED</td>
<td>Home</td>
</tr>
<tr>
<td>COVERAGE REQUIREMENTS</td>
<td>Prior Authorization Required (Non-Preferred Product)</td>
</tr>
<tr>
<td></td>
<td>Alternative product includes Mavyret</td>
</tr>
<tr>
<td>QUANTITY LIMIT</td>
<td>28 for a 28 day supply</td>
</tr>
<tr>
<td>LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY</td>
<td>Click Here</td>
</tr>
</tbody>
</table>

**Epclusa (sofosbuvir/velpatasvir) 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:
1. Member is treatment-naïve or 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
4. Medication must be prescribed by a board certified hepatologist, gastroenterologist, infectious disease specialist or a nurse practitioner working with the above specialists; AND
5. Member’s documented viral load taken within 6 months of beginning therapy and submitted with chart notes; AND
6. Member has documented current monthly negative urine drug and alcohol screens for 3 consecutive months (laboratory documentation required); AND
7. Member must have evidence of liver fibrosis stage 2, 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; AND
8. Member has tried and failed course of treatment with Mavyret (Dates and HCV RNA values must be documented in chart notes).
9. **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.*

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

For **reauthorization**:
1. Epclusa will not be reauthorized for continued therapy.
HEPATITIS C WITH DECOMPENSATED CIRRHOSIS (Child-Turcotte-Pugh Class B or C)

For initial authorization:
1. Member is 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; AND
2. Member must be 18 years of age or older; AND
3. Member has genotype 1, 2, 3, 4, or 6 (laboratory documentation required); AND
4. Member will be prescribed Epclusa (sofosbuvir/velpatasvir) in combination with ribavirin (if ribavirin ineligible must submit documentation of one of the following results obtained within the past month: neutrophils <750 cells/mm³; hemoglobin <10 g/dL; platelets <50 000 cells/mm³; OR documented hypersensitivity to drugs used to treat HCV); AND
5. Medication must be prescribed by a board certified hepatologist, gastroenterologist, infectious disease specialist or a nurse practitioner working with the above specialists; AND
6. Member’s documented viral load taken within 6 months of beginning therapy and submitted with chart notes; AND
7. Member has documented current monthly negative urine drug and alcohol screens for 3 consecutive months (laboratory documentation required); AND
8. Evidence of stage 4 liver fibrosis confirmed by liver biopsy, or elastography only (lab chart notes required).
9. Dosage allowed: One tablet once daily for 12 weeks. If member is ribavirin ineligible and request is for genotype 1, 3, 4 or 6 Epclusa may be approved for additional 12 weeks, not to exceed the total of 24 weeks treatment duration.

Note: Member’s life expectancy must be no less than one year due to non-liver related comorbidities.

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

For reauthorization:
1. Epclusa will not be reauthorized for continued therapy.

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

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/09/2017</td>
<td>New policy for Epclusa created.</td>
</tr>
<tr>
<td>06/08/2017</td>
<td>Fibrosis stage 2 and above covered.</td>
</tr>
<tr>
<td>11/22/2017</td>
<td>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.</td>
</tr>
<tr>
<td>12/07/2017</td>
<td>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.</td>
</tr>
</tbody>
</table>

References:

Effective date: 12/13/2017
Revised date: 12/07/2017