Clinical Policy: Ledipasvir/Sofosbuvir (Harvoni)

Reference Number: GA.PMN.13
Effective Date: 12/16
Last Review Date: 4/2020
Line of Business: Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Sofosbuvir/Ledipasvir (Harvoni®/™) is a fixed-dose combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor, and ledipasvir, an HCV NS5A inhibitor.

FDA Approved Indication(s)
Harvoni is indicated for the treatment of adult and pediatric patients 3 years of age and older with chronic HCV in:
- Genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis
- Genotype 1 infection with decompensated cirrhosis, in combination with ribavirin
- Genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® that Harvoni is medically necessary when the following criteria are met:

I. Approval Criteria
** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria **

A. Chronic Hepatitis C Infection (must meet all):
1. Diagnosis of chronic hepatitis C virus (HCV) infection as evidenced by detectable HCV ribonucleic acid (RNA) levels in the last 6 months;
   *For treatment-naïve adult members without cirrhosis with genotype 1 and baseline viral load <6 million IU/mL will be approved for a maximum duration of 8 weeks (see Section V)*
2. Confirmed HCV genotype is 1, 4, 5 or 6;
   *Chart note documentation and copies of labs results are required
3. Authorized generic version of Harvoni is prescribed, unless medical justification supports inability to use the authorized generic (e.g., contraindications to excipients in the authorized generic);
4. Documentation of the treatment status of the patient (treatment-naïve or treatment-experienced);
5. Documentation of cirrhosis status of the patient (no cirrhosis, compensated cirrhosis, or decompensated cirrhosis);
6. Age ≥ 3 years;
7. Member meets one of the following (a or b):
   a. If age between 6 and 11 years, or weight 17 kg to 44 kg, member must use sofosbuvir/velpatasvir (Epclusa®) (authorized generic preferred), unless are contraindicated or clinically significant adverse effects are experienced
   b. If age ≥ 12 years or weight ≥ 45 kg: member must use Mavyret™ or sofosbuvir/velpatasvir (Epclusa®) (authorized generic preferred), unless both are contraindicated or clinically significant adverse effects are experienced;
8. Life expectancy ≥ 12 months with HCV treatment;
9. Prescribed regimen is consistent with an FDA or AASLD-IDSA recommended regimen (in Section III Dosage and Administration);
10. Member is hepatitis B virus (HBV) negative, or if positive, documentation that concurrent HBV infection is being treated (e.g., tenofovir alafenamide, adefovir, entecavir), unless contraindicated or clinically significant adverse effects are experienced (see Appendix E);
11. If prescribed with ribavirin, member has none of the following contraindications:
   a. Pregnancy or possibility of pregnancy - member or partner;
   b. For Rebetol: creatinine clearance < 50 mL/min;
   c. Hypersensitivity to ribavirin;
   d. Coadministration with didanosine;
   e. Significant/unstable cardiac disease;
   f. Hemoglobinopathy (e.g., thalassemia major, sickle cell anemia);
   g. Hemoglobin < 8.5 g/dL.

**Approval duration: up to a total of 24 weeks*** *(Approved duration should be consistent with a regimen in in Section III Dosage and Administration)*

B. Other diagnoses/indications: Refer to CP.PHAR.53 – No Coverage Criteria/Off-Label Use Policy if diagnosis is NOT specifically listed under section I.

II. Appendices/General Information
   *Appendix A: Abbreviation/Acronym Key*
   AASLD: American Association for the Study of Liver Diseases
   APRI: AST to platelet ratio
   CTP: Child Turcotte Pugh
   CrCl: creatinine clearance
   FDA: Food and Drug Administration
   FIB-4: Fibrosis-4 index
   HCC: hepatocellular carcinoma
   HCV: hepatitis C virus
   IDSA: Infectious Diseases Society of America

   MRE: magnetic resonance elastography
   NS3/4A, NS5A/B: nonstructural protein
   Peg-IFN: pegylated interferon
   PI: protease inhibitor
   RBV: ribavirin
   RNA: ribonucleic acid
Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
</table>
| Epclusa® (sofosbuvir/velpatasvir)  | **Genotype 1, 4, 5, or 6:** Without cirrhosis or with compensated cirrhosis, treatment-naïve or pegIFN/RBV-experienced patient  
One tablet PO QD for 12 weeks | One tablet (Adult/Peds ≥ 30 kg: sofosbuvir 400 mg /velpatasvir 100 mg; Peds 17 to 29 kg: sofosbuvir 200 mg /velpatasvir 50 mg) per day |
| Epclusa® (sofosbuvir/velpatasvir)  | **Genotype 1, 4, 5, or 6:** With decompensated cirrhosis treatment-naïve or treatment-experienced* patient  
One tablet PO QD with weight-based RBV for 12 weeks  
(GT 1, 4, 5, or 6 with decompensated cirrhosis and RBV-ineligible may use: one tablet PO QD for 24 weeks) ‡ | One tablet (Adult/Peds ≥ 30 kg: sofosbuvir 400 mg /velpatasvir 100 mg; Peds 17 to 29 kg: sofosbuvir 200 mg /velpatasvir 50 mg) per day |
| Epclusa® (sofosbuvir/velpatasvir)  | **Genotype 1, 4, 5, or 6:** With decompensated cirrhosis in whom prior sofosbuvir- or NS5A-based treatment experienced failed  
One tablet PO QD with weight-based RBV for 24 weeks | One tablet (sofosbuvir 400 mg /velpatasvir 100 mg) per day |
| Epclusa® (sofosbuvir/velpatasvir)  | **Genotype 1b:** With compensated cirrhosis or without cirrhosis and non-NS5A inhibitor, sofosbuvir-containing regimen-experienced  
One tablet PO QD for 12 weeks | One tablet (sofosbuvir 400 mg /velpatasvir 100 mg) per day |
| Mavyret™ (glecaprevir/pibrentasvir) | **Treatment-naïve chronic HCV infection:**  
**Genotypes 1, 4, 5, or 6**  
Without cirrhosis or with compensated cirrhosis:  
Three tablets PO QD for 8 weeks | Mavyret: glecaprevir 300 mg/pibrentasvir 120 mg (3 tablets) per day |
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
</table>
| Mavyret™ (glecaprevir/pibrentasvir) | Treatment-experienced with IFN/pegIFN + RBV +/- sofosbuvir chronic HCV infection:  
  **Genotypes 1, 4, 5, or 6**  
  Without cirrhosis: Three tablets PO QD for 8 weeks  
  With compensated cirrhosis: Three tablets PO QD for 12 weeks | Mavyret: glecaprevir 300 mg/pibrentasvir 120 mg (3 tablets) per day |
| Mavyret™ (glecaprevir/pibrentasvir) | Treatment-experienced with NS5A inhibitor without prior NS3/4A protease inhibitor chronic HCV infection:  
  **Genotype 1**  
  Without cirrhosis or with compensated cirrhosis: Three tablets PO QD for 16 weeks | Mavyret: glecaprevir 300 mg/pibrentasvir 120 mg (3 tablets) per day |
| Mavyret™ (glecaprevir/pibrentasvir) | Treatment-experienced with NS3/4A protease inhibitor without prior NS5A inhibitor chronic HCV infection:  
  **Genotype 1**  
  Without cirrhosis or with compensated cirrhosis: Three tablets PO QD for 12 weeks | Mavyret: glecaprevir 300 mg/pibrentasvir 120 mg (3 tablets) per day |

*Therapeutic alternatives are listed as Brand Name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

**Appendix C: Contraindications/Boxed Warnings**
- **Contraindication(s):** if used in combination with RBV, all contraindications to RBV also apply to Harvoni combination therapy.
- **Boxed warning(s):** risk of hepatitis B virus reactivation in patients coinfected with HCV and HBV.
Appendix D: Direct-Acting Antivirals for Treatment of HCV Infection

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Drug Class</th>
<th>NS5A Inhibitor</th>
<th>Nucleotide Analog NS5B Polymerase Inhibitor</th>
<th>Non-Nucleoside NS5B Palm Polymerase Inhibitor</th>
<th>NS3/4A Protease Inhibitor (PI)**</th>
<th>CYP3A Inhibitor</th>
</tr>
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<tbody>
<tr>
<td>Daklinza</td>
<td>Daclatasvir</td>
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<tr>
<td>Epclusa*</td>
<td>Velpatasvir</td>
<td>Sofosbuvir</td>
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<tr>
<td>Harvoni*</td>
<td>Ledipasvir</td>
<td>Sofosbuvir</td>
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<tr>
<td>Olysio</td>
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<tr>
<td>Sovaldi</td>
<td>Sofosbuvir</td>
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<tr>
<td>Technivie*</td>
<td>Ombitasvir</td>
<td></td>
<td></td>
<td>Paritaprevir</td>
<td>Ritonavir</td>
<td></td>
</tr>
<tr>
<td>Viekira XR/PAK*</td>
<td>Ombitasvir</td>
<td>Dasabuvir</td>
<td></td>
<td>Paritaprevir</td>
<td>Ritonavir</td>
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<tr>
<td>Zepatier*</td>
<td>Elbasvir</td>
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*Combination drugs

Appendix E: General Information

- Hepatitis B Virus (HBV) Reactivation is a black box warning for all direct-acting antiviral drugs for the treatment of HCV. HBV reactivation has been reported when treating HCV for patients co-infected with HBV, leading to fulminant hepatitis, hepatic failure, and death, in some cases. Patients should be monitored for HBV reactivation and hepatitis flare during HCV treatment and post-treatment follow-up, with treatment of HBV infection as clinically indicated.

- Treatment with Harvoni for 8 weeks can be considered in treatment-naïve patients without cirrhosis who have pre-treatment HCV RNA less than 6 million IU/mL. In the ION-3 trial, patients with a baseline HCV viral load of < 6 million IU/mL and were treated with Harvoni for 8 weeks achieved SVR-12 at a rate of 97% versus 96% of those treated with Harvoni for 12 weeks.

- Child Pugh Score

<table>
<thead>
<tr>
<th></th>
<th>1 Point</th>
<th>2 Points</th>
<th>3 Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin</td>
<td>Less than 2</td>
<td>2-3 mg/dL</td>
<td>Over 3 mg/dL</td>
</tr>
<tr>
<td></td>
<td>mg/dL</td>
<td>34-50 umol/L</td>
<td>Over 50 umol/L</td>
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<tr>
<td></td>
<td>Less than 34</td>
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<tr>
<td></td>
<td>umol/L</td>
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<td></td>
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<tr>
<td>Albumin</td>
<td>Over 3.5 g/dL</td>
<td>2.8-3.5 g/dL</td>
<td>Less than 2.8 g/dL</td>
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<tr>
<td></td>
<td>g/L</td>
<td>28-35 g/L</td>
<td>Less than 28 g/L</td>
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<td></td>
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<td></td>
<td>Less than 2.2</td>
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<tr>
<td>INR</td>
<td>Less than 1.7</td>
<td>1.7 - 2.2</td>
<td>Over 2.2</td>
</tr>
<tr>
<td>Ascites</td>
<td>None</td>
<td>Mild / medically controlled</td>
<td>Moderate-severe / poorly controlled</td>
</tr>
<tr>
<td>Encephalopathy</td>
<td>None</td>
<td>Mild / medically controlled</td>
<td>Moderate-severe / poorly controlled.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Grade I-II</td>
<td>Grade III-IV</td>
</tr>
</tbody>
</table>

Child-Pugh class is determined by the total number of points: A = 5-6 points; B = 7-9 points; C = 10-15 points
## III. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 1 chronic HCV infection:</td>
<td>One tablet PO QD for:</td>
<td></td>
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<tr>
<td>Treatment-naïve without cirrhosis AND whose HCV viral load is less than 6 million IU/mL: for 8 weeks †</td>
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</tr>
<tr>
<td>Treatment-naïve non-black, HIV-uninfected adult patients without cirrhosis AND whose HCV viral load is greater than or equal to 6 million IU/mL: for 12 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment-naïve with compensated cirrhosis: for 12 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment-experienced with pegIFN/ RBV without cirrhosis: for 12 weeks</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Treatment-experienced with compensated cirrhosis: for 24 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment-experienced with pegIFN/ RBV with compensated cirrhosis: Harvoni plus weight-based RBV† for 12 weeks</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Notes:

1) FDA-approved labeling
2) AASLD-IDSA (updated May 2018)
**Indication:**
Patients age ≥ 3 years with chronic HCV infection

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment-experienced with NS3 PI*+/- pegIFN/RBV adult patient without cirrhosis for 12 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment-experienced with NS3 PI*+/- pegIFN/RBV with compensated cirrhosis: Harvoni plus weight-based RBV for 12 weeks</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Treatment-experienced with Sofosbuvir (but not with simeprevir) without cirrhosis: Harvoni plus weight-based RBV for 12 weeks</td>
<td></td>
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</tr>
<tr>
<td>Genotype 1, 4, 5, or 6 with decompensated cirrhosis: patients who may or may not be candidates for liver transplantation, including those with hepatocellular carcinoma</td>
<td>One tablet PO QD plus low initial dose of RBV (600 mg, increased as tolerated) for 12 weeks Or without RBV for 24 weeks if RBV ineligible</td>
<td>Weight ≥ 35 kg: One tablet (sofosbuvir 400 mg / ledipasvir 90 mg) per day Weight ≥ 17 to &lt; 35 kg: One tablet (sofosbuvir 200 mg / ledipasvir 45 mg) per day</td>
<td>1) FDA-approved labeling 2) AASLD-IDSA (updated May 2018)</td>
</tr>
<tr>
<td>Genotype 1, 4, 5, or 6 with decompensated cirrhosis: Adult patients in whom a previous sofosbuvir-containing regimen has failed</td>
<td>One tablet PO QD with low initial dose of RBV (600 mg, increased as tolerated) for 24 weeks</td>
<td>Weight &lt; 17 kg: One packet of pellets (sofosbuvir 150 mg / ledipasvir 33.75 mg) per day</td>
<td>AASLD-IDSA (updated May 2018)</td>
</tr>
</tbody>
</table>
### Indication:
Patients age ≥ 3 years with chronic HCV infection

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
<th>Reference</th>
</tr>
</thead>
</table>
| Genotype 1 or 4 post-liver transplantation: Treatment-naive and treatment-experienced patients without cirrhosis, with compensated cirrhosis, or with decompensated cirrhosis | One tablet PO QD plus RBV for 12 weeks               |                                                                              | 1) FDA-approved labeling  
2) AASLD-IDSA (updated May 2018)                                         |
| Genotype 4, 5, or 6: Treatment-naive patients with or without compensated cirrhosis | One tablet PO QD for 12 weeks                        |                                                                              | 1) FDA-approved labeling  
2) AASLD-IDSA (updated May 2018)                                         |
| Genotype 4: Treatment-experienced** patients without compensated cirrhosis | One tablet PO QD for 12 weeks                        | Weight ≥ 35 kg: One tablet (sofosbuvir 400 mg / ledipasvir 90 mg) per day    | 1) FDA-approved labeling  
2) AASLD-IDSA (updated May 2018)                                         |
|                                                                             |                                                     | Weight ≥ 17 to < 35 kg: One tablet (sofosbuvir 200 mg / ledipasvir 45 mg) per day |                                                                            |
| Genotype 4: Treatment-experienced** patients with compensated cirrhosis     | One tablet PO QD plus weight-based RBV for 12 weeks  |                                                                              | 1) FDA-approved labeling  
2) AASLD-IDSA (updated May 2018)                                         |
| Genotype 5 or 6: Treatment-experienced** patients with or without compensated cirrhosis | One tablet PO QD for 12 weeks                        | Weight < 17 kg: One packet of pellets (sofosbuvir 150 mg / ledipasvir 33.75 mg) per day | 1) FDA-approved labeling  
2) AASLD-IDSA (updated May 2018)                                         |

*NS3 protease inhibitor = telaprevir, boceprevir, or simeprevir

**Treatment-experienced refers to previous treatment with peginterferon/RBV unless otherwise stated

† Off-label, AASLD-IDSA guideline-supported dosing regimen

**AASLD/IDSA treatment guidelines for chronic hepatitis C infection are updated at irregular intervals; refer to the most updated AASLD/IDSA guideline for most accurate treatment regimen.**
IV. Product Availability

- Tablet: 90 mg of ledipasvir and 400 mg of sofosbuvir; 45 mg of ledipasvir and 200 mg of sofosbuvir
- Oral pellets: 45 mg of ledipasvir and 200 mg of sofosbuvir; 33.75 mg of ledipasvir and 150 mg of sofosbuvir

V. References


<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>New policy created, split from CP.PHAR.17 Hepatitis C Therapies policy. HCV RNA levels over six-month period added to confirm infection is chronic. Life expectancy “≥12 months if HCC and awaiting transplant” is modified to indicate “≥12 months with HCV therapy.” Testing criteria reorganized by “no cirrhosis”/“cirrhosis” consistent with the regimen tables;</td>
<td>08/16</td>
<td>09/16</td>
</tr>
</tbody>
</table>
## Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Description</th>
<th>Date</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCC population is included under “cirrhosis” and broadened to incorporate HCC amenable to curative measures (resection, ablation, transplant). Methods to diagnose fibrosis/cirrhosis are modified to require presence of HCC, liver biopsy or a combination of one serologic and one radiologic test. Serologic and radiologic tests are updated and correlated with METAVIR per Appendix B. Removed creatinine clearance restriction – not a contraindication. Criteria added excluding post-liver transplantation unless regimen specifically designate. Dosing regimens are presented in Appendix D and E per AASLD guidelines and FDA-approved indications. The initial approval period is shortened to 8 weeks.</td>
<td>10/16</td>
<td>10/2016</td>
</tr>
<tr>
<td>Removed criteria regarding medication prescribed by a specialist                                                              Remove criteria regarding having HCC or advanced liver disease Removed criteria regarding medication adherence program Removed criteria regarding sobriety from alcohol/illicit drugs</td>
<td>4/17</td>
<td>4/17</td>
</tr>
<tr>
<td>Added availability of full course of therapy as initial therapy consistent with appendix recommendation for initial criteria Removed continuation criteria</td>
<td>6/17</td>
<td>6/17</td>
</tr>
<tr>
<td>Added pediatric (≥12 years or ≥35 kg) indication expansion for GT 1,4,5,6</td>
<td>9/17</td>
<td>9/17</td>
</tr>
<tr>
<td>Added preferencing information requiring Mavyret for FDA-approved indications. Added preferencing for pediatric member for Harvoni since Mavyret does not have a pediatric indication. Added requirement for Hep B screening for all patients prior to treatment.</td>
<td>3/18</td>
<td>3/18</td>
</tr>
<tr>
<td>Changed current Georgia policy templates to corporate standard templates for drug coverage criteria to meet corporate compliance. Changes/revisions included; new formatting, font size, use of standard policy language for each section of policy, and rearranged order of certain steps in criteria and sections. Added new preferred treatment tables that includes dosage and frequency based on genotype for Mavyret. Removed background sections. Updated general information and contraindication section to be consistent with corporate HCV policies.</td>
<td>2/21/19</td>
<td>2/19</td>
</tr>
<tr>
<td>Annual review. Added pediatric age to FDA Approved Indication Section. Added specification for Mavyret preferencing based on pediatric age or weight. Combined contraindication section to age/weight preferencing of Mavyret. In the initial approval criteria, changed RNA detectable period from “over a 6 month period” to “in the last 6 months” for infection diagnosis.</td>
<td>10/19</td>
<td>10/19</td>
</tr>
<tr>
<td>RT4: updated Harvoni FDA-approved age (3 years), dosage forms, and pediatric dosing information; updated Mavyret dosing recommendations to 8 weeks total duration of therapy for treatment-naïve HCV with compensated cirrhosis across all genotypes (1-6). Added preferencing for AG Epclusa or Mavyret; removed redirection to Mavyret based on</td>
<td>4/2020</td>
<td>4/2020</td>
</tr>
</tbody>
</table>

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Reviews, Revisions, and Approvals

contraindications criteria. Per March SDC and prior clinical guidance preferencing revised to require AG Epclusa for age 6 to 11 years or weight 17 kg to 44 kg; revised to require Mavyret or AG Epclusa for age 12 or older or weight at least 45 kg. Updated general information section.
Updated order of all other Appendices. Updated references.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.
Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note:** For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.