Clinical Policy: Glecaprevir/Pibrentasvir (Mavyret)
Reference Number: HIM.PA.SP36
Effective Date: 08.01.17
Last Review Date: 08.20
Line of Business: HIM*

*Revision Log

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

Description
Glecaprevir and pibrentasvir (Mavyret®) are a fixed-dose combination of glecaprevir, a hepatitis C virus (HCV) NS3/4A protease inhibitor, and pibrentasvir, an HCV NS5A inhibitor.

*This criteria does NOT apply to California Commercial Exchange Plans.

FDA Approved Indication(s)
Mavyret is indicated for the treatment of:

- Adult and pediatric patients 12 years and older or weighing at least 45 kg with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis and with compensated cirrhosis (Child-Pugh A)
- Adult and pediatric patients 12 years and older or weighing at least 45 kg with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor* or an NS3/4A protease inhibitor**, but not both

* In clinical trials, prior NS5A inhibitor experience included ledipasvir and sofosbuvir or daclatasvir with pegylated interferon and ribavirin.
** In clinical trials, prior NS3/4A protease inhibitor experience included regimens containing Simeprevir and sofosbuvir, or simeprevir, boceprevir, or telaprevir with pegylated interferon and ribavirin.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

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

I. Initial Approval Criteria
   A. Chronic Hepatitis C Infection (must meet all):
      1. Diagnosis of chronic HCV infection as evidenced by detectable serum HCV RNA levels by quantitative assay in the last 6 months;
      2. Confirmed HCV genotype is one of the following (a, b, c, or d);
         a. For treatment-naïve members: genotypes 1, 2, 3, 4, 5, or 6;
         b. For members treatment-experienced with interferon (IFN)/pegylated-interferon (pegIFN), ribavirin (RBV), and/or sofosbuvir only: genotypes 1, 2, 3, 4, 5, or 6;
         c. For members treatment-experienced with either an NS5A inhibitor or an NS3/4A protease inhibitor: genotype 1 (see Appendix E);
         d. For Vosevi-experienced members: genotype 1, 2, 3, 4, 5, or 6;
*Chart note documentation and copies of lab results are required*

3. Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease specialist, or provider who has expertise in treating HCV based on a certified training program (*see Appendix F*);
4. Age ≥ 12 years or weight ≥ 45 kg;
5. If cirrhosis is present, confirmation of Child-Pugh A status;
6. Member is not treatment-experienced with both NS3/4A protease inhibitor AND NS5A inhibitors, such as combination therapies including Technivie™, Viekira™, and Zepatier®;
7. Member must use Epclusa® or Vosevi®, unless clinically significant adverse effects are experienced or all are contraindicated;
8. Life expectancy ≥ 12 months with HCV treatment;
9. Member agrees to participate in a medication adherence program including both of the following components (a and b):
   a. Medication adherence monitored by pharmacy claims data or member report;
   b. Member’s risk for non-adherence identified by adherence program or member/prescribing physician follow-up at least every 4 weeks;
10. Prescribed regimen is consistent with an FDA or AASLD-IDSA recommended regimen (*see Section V for reference*);
11. Dose does not exceed glecaprevir 300 mg and pibrentasvir 120 mg (3 tablets) per day.
**Approval duration: up to a total of 16 weeks***
(*Approved duration should be consistent with a regimen in Section V Dosage and Administration*)

**B. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

**II. Continued Therapy**

**A. Chronic Hepatitis C Infection** (must meet all):

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Must meet both of the following (i and ii):
      i. Documentation supports that member is currently receiving Mavyret for chronic HCV infection and has recently completed at least 40 days of treatment with Mavyret;
      ii. Confirmed HCV genotype is one of the following (1, 2, 3, or 4);
         1) For treatment-naïve members: genotypes 1, 2, 3, 4, 5, or 6;
         2) For members treatment-experienced with interferon (IFN)/pegylated-interferon (pegIFN), ribavirin (RBV), and/or sofosbuvir only: genotypes 1, 2, 3, 4, 5, or 6;
         3) For members treatment-experienced with either an NS5A inhibitor or an NS3/4A protease inhibitor: genotype 1 (*see Appendix E*);
         4) For Vosevi-experienced members: genotype 1, 2, 3, 4, 5, or 6;
2. Member is not treatment-experienced with both NS3/4A protease inhibitor AND NS5A inhibitors, such as combination therapies including Technivie, Viekira, and Zepatier;
3. Member is responding positively to therapy;
4. Dose does not exceed glecaprevir 300 mg and pibrentasvir 120 mg (3 tablets) per day.

**Approval duration: up to a total of 16 weeks***
(*Approved duration should be consistent with a regimen in Section V Dosage and Administration)

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – HIM.PHAR.21 for health insurance marketplace, or evidence of coverage documents;

B. Treatment-experienced members with both NS3/4A protease inhibitor AND NS5A inhibitors, such as combination therapies including: Technivie, Viekira, and Zepatier.

IV. Appendices/General Information

**Appendix A: Abbreviation/Acronym Key**

AASLD: American Association for the Study of Liver Diseases

IDSA: Infectious Diseases Society of America

FDA: Food and Drug Administration

NS3/4A, NS5A/B: nonstructural protein

HBV: hepatitis B virus

PegIFN: pegylated interferon

HCV: hepatitis C virus

RBV: ribavirin

HIV: human immunodeficiency virus

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</th>
</tr>
</thead>
<tbody>
<tr>
<td>sofosbuvir/velpatasvir (Epclusa®)</td>
<td>Without cirrhosis or with compensated cirrhosis, treatment naïve or pegIFN/ RBV-experienced: <strong>Genotypes 1 through 6</strong></td>
<td>sofosbuvir 400 mg/ velpatasvir 100 mg (1 tablet) per day</td>
</tr>
<tr>
<td>Drug Name</td>
<td>Dosing Regimen</td>
<td>Dose Limit/ Maximum</td>
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</tr>
<tr>
<td>sofosbuvir/velpatasvir (Epclusa®)</td>
<td>With decompensated cirrhosis treatment-naïve or treatment experienced: <strong>Genotypes 1 through 6</strong> One tablet PO QD plus weight-based RBV for 12 weeks</td>
<td>sofosbuvir 400 mg/ velpatasvir 100 mg (1 tablet) per day</td>
</tr>
<tr>
<td>Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)</td>
<td>Genotype 1-6 treatment-experienced with NS5A inhibitor* with or without compensated cirrhosis: One tablet PO QD for 12 weeks</td>
<td>One tablet (sofosbuvir 400 mg/ velpatasvir 100 mg/ voxilaprevir 100 mg) per day</td>
</tr>
<tr>
<td>Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)</td>
<td>Genotype 1a or 3 treatment-experienced with a sofosbuvir-containing regimen without NS5A inhibitor* with or without compensated cirrhosis: One tablet PO QD for 12 weeks</td>
<td>One tablet (sofosbuvir 400 mg/ velpatasvir 100 mg/ voxilaprevir 100 mg) per day</td>
</tr>
<tr>
<td>Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)</td>
<td>Genotype 1-6 treatment-experienced with Vosevi with or without compensated cirrhosis: Vosevi one tablet PO QD with weight-based RBV for 24 weeks</td>
<td>One tablet (sofosbuvir 400 mg/ velpatasvir 100 mg/ voxilaprevir 100 mg) per day</td>
</tr>
</tbody>
</table>

*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. Treatment-experienced refers to previous treatment with NS3 protease inhibitor (telaprevir, boceprevir, or simeprevir) and/or peginterferon/RBV unless otherwise stated.

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

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**Appendix C: Contraindications/Boxed Warnings**

- **Contraindication(s):**
  - Patients with severe hepatic impairment (Child-Pugh C)
  - Co-administration with atazanavir or rifampin
- **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>NS5A Inhibitor</th>
<th>Drug Class</th>
<th>Non-Nucleoside NS5B 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>Eplcura*</td>
<td>Velpatasvir</td>
<td>Sofosbuvir</td>
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<tr>
<td>Harvoni*</td>
<td>Ledipasvir</td>
<td>Sofosbuvir</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mavyret*</td>
<td>Pibrentasvir</td>
<td>Glecaprevir</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Olysio†</td>
<td></td>
<td>Simeprevir</td>
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<td></td>
<td></td>
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<tr>
<td>Sovaldi</td>
<td>Sofosbuvir</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Technivie*</td>
<td>Ombitasvir</td>
<td>Paritaprevir</td>
<td>Ritonavir</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Viekira PAK*</td>
<td>Ombitasvir</td>
<td>Dasabuvir</td>
<td>Paritaprevir</td>
<td>Ritonavir</td>
<td></td>
</tr>
<tr>
<td>Vosevi*</td>
<td>Velpatasvir</td>
<td>Sofosbuvir</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zepatier*</td>
<td>Elbasvir</td>
<td>Grazoprevir</td>
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</tbody>
</table>

*Combination drugs
† Olysio and Technivie are no longer commercially available.

### Appendix E: General Information

- Hepatitis B Virus Reactivation (HBV) 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.

- Due to higher rates of virologic failure and treatment-emergent drug resistance, the data do not support labeling for treatment of HCV genotype 1 infected patients who are both NS3/4A PI and NS5A inhibitor-experienced.

- 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 mg/dL or 34 umol/L</td>
<td>2-3 mg/dL or 34-50 umol/L</td>
<td>Over 3 mg/dL or 50 umol/L</td>
</tr>
<tr>
<td>Albumin</td>
<td>Over 3.5 g/dL or 35 g/L</td>
<td>2.8-3.5 g/dL or 28-35 g/L</td>
<td>Less than 2.8 g/dL or 28 g/L</td>
</tr>
<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 Grade I-II</td>
<td>Moderate-severe / poorly controlled. 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
Appendix F: Healthcare Provider HCV Training
Acceptable HCV training programs and/or online courses include, but are not limited to the following:
- Hepatitis C online course (https://www.hepatitisc.uw.edu/): University of Washington is funded by the Division of Viral Hepatitis to develop a comprehensive, online self-study course for medical providers on diagnosis, monitoring, and management of hepatitis C virus infection. Free CME and CNE credit available.
- Fundamentals of Liver Disease (https://liverlearning.aasld.org/fundamentals-of-liver-disease): The AASLD, in collaboration with ECHO, the American College of Physicians (ACP), CDC, and the Department of Veterans Affairs, has developed Fundamentals of Liver Disease, a free, online CME course to improve providers’ knowledge and clinical skills in hepatology.
- Clinical Care Options: http://www.clinicaloptions.com/hepatitis.aspx
- CDC training resources: https://www.cdc.gov/hepatitis/resources/professionals/trainingresources.htm

V. 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>Genotypes 1-6: Treatment-naive</td>
<td>Without cirrhosis or with compensated cirrhosis: Three tablets PO QD for 8 weeks</td>
<td>Three tablets (glecaprevir 300 mg/ pibrentasvir 120 mg) per day</td>
<td>1) FDA-approved labeling 2) AASLD-IDSA (updated November 2019)</td>
</tr>
<tr>
<td>Genotypes 1, 2, 4, 5, or 6: Treatment-experienced with IFN/pegIFN + RBV</td>
<td>Without cirrhosis: Three tablets PO QD for 8 weeks</td>
<td>Three tablets (glecaprevir 300 mg/ pibrentasvir 120 mg) per day</td>
<td>1) FDA-approved labeling 2) AASLD-IDSA (updated November 2019)</td>
</tr>
<tr>
<td></td>
<td>With compensated cirrhosis: Three tablets PO QD for 12 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genotypes 1, 2, 4, 5, or 6: Treatment-experienced with IFN/pegIFN, RBV and/or sofosbuvir</td>
<td>Without cirrhosis: Three tablets PO QD for 8 weeks</td>
<td>Three tablets (glecaprevir 300 mg/ pibrentasvir 120 mg) per day</td>
<td>1) FDA-approved labeling 2) AASLD-IDSA (updated November 2019)</td>
</tr>
<tr>
<td></td>
<td>With compensated cirrhosis: Three tablets PO QD for 12 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genotype 3: Treatment-experienced with IFN/pegIFN, RBV and/or sofosbuvir</td>
<td>Without cirrhosis or with compensated cirrhosis: Three tablets PO QD for 16 weeks</td>
<td>Three tablets (glecaprevir 300 mg/ pibrentasvir 120 mg) per day</td>
<td>1) FDA-approved labeling 2) AASLD-IDSA (updated</td>
</tr>
<tr>
<td>Indication</td>
<td>Dosing Regimen</td>
<td>Maximum Dose</td>
<td>Reference</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------</td>
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</tr>
</tbody>
</table>
| **Genotype 1:** Treatment-experienced with NS5A inhibitor* without prior NS3/4A protease inhibitor* | Without cirrhosis or with compensated cirrhosis: Three tablets PO QD for 16 weeks                                                             | Three tablets (glecaprevir 300 mg/ pibrentasvir 120 mg) per day              | 1) FDA-approved labeling  
2) AASLD-IDSA (updated November 2019) |
| **Genotype 1:** Treatment-experienced with NS3/4A protease inhibitor* without prior NS5A inhibitor* | Without cirrhosis or with compensated cirrhosis: Three tablets PO QD for 12 weeks                                                              | Three tablets (glecaprevir 300 mg/ pibrentasvir 120 mg) per day              | 1) FDA-approved labeling  
2) AASLD-IDSA (updated November 2019) |
| **Genotype 1-6:** Treatment-naïve or treatment-experienced, post-liver or kidney transplantation without cirrhosis or with compensated cirrhosis | Three tablets PO QD for 12 weeks  
(A 16-week treatment duration is recommended in genotype 1-infected patients who are NS5A inhibitor experienced without prior treatment with an NS3/4A protease inhibitor or in genotype 3-infected patients who are PRS treatment-experienced)* | Three tablets (glecaprevir 300 mg/ pibrentasvir 120 mg) per day              | 1) FDA-approved labeling  
2) AASLD-IDSA (updated November 2019) |
| **Genotypes 1-6:** Patients with prior sofosbuvir/velpatasvir/voxilaprevir treatment failure | With or without compensated cirrhosis: Mavyret 3 tablets PO QD + Sovaldi 400 mg + weight-based RBV for 16 weeks | Three tablets (glecaprevir 300 mg/pibrentasvir 120 mg) per day              | AASLD-IDSA (updated November 2019) |

*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.  
* See appendix D  
* PRS: prior treatment experience with regimens containing IFN/pegIFN, RBV, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor
VI. Product Availability
   Tablets: glecaprevir 100 mg and pibrentasvir 40 mg

VII. References

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy created. Safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs. Exception made to require Hep B screening for all patients prior to treatment to ensure that proper risk reduction measures are taking, though this is not specifically addressed in boxed warning.</td>
<td>08.15.17</td>
<td>08.17</td>
</tr>
<tr>
<td>Requirement for Hep B screening was not yet approved by P &amp; T and it was therefore removed as this is under the purview of the specialist</td>
<td>09.14.17</td>
<td>11.19</td>
</tr>
<tr>
<td>3Q18 annual review: repeated in initial and continued approval criteria the requirement against treatment-experience with both NS3/4A protease inhibitor AND NS5A inhibitors, as previously only listed in section III. diagnoses/ indications NOT allowed; expanded duration of tx required for COC from 30 days to 40 days; required verification of genotype for COC; removed requirement for advanced liver disease; references reviewed and updated.</td>
<td>05.22.18</td>
<td>06.18</td>
</tr>
<tr>
<td>No significant change: added financial redirection to Epclusa if contraindicated to Mavyret.</td>
<td>07.13.18</td>
<td></td>
</tr>
<tr>
<td>No significant changes: deleted an error around redirection to Epclusa.</td>
<td>10.17.18</td>
<td></td>
</tr>
<tr>
<td>2Q 2019 annual review: no significant changes; references reviewed and updated.</td>
<td>02.05.19</td>
<td>05.19</td>
</tr>
<tr>
<td>3Q 2019 annual review: updated age ≥ 12 years or weight ≥ 45 kg to be consistent with updated FDA approved indication; removed documented sobriety from alcohol and illicit IV drugs for ≥ 6 months prior to starting therapy; references reviewed and updated.</td>
<td>07.02.19</td>
<td>08.19</td>
</tr>
</tbody>
</table>
Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Description</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Via CP.PCH.18: HIM.PA.SP36 retired and combined with HIM to CP.PCH.18; added new prescriber requirement to include a “provider who has expertise in treating HCV based on a certified training program”; Appendix F (Healthcare Provider HCV Training) added. RT4: updated dosing recommendations to 8 weeks total duration of therapy for treatment naive HCV with compensated cirrhosis across all genotypes (1-6).</td>
<td>12.03.19</td>
<td>02.20</td>
</tr>
<tr>
<td>3Q 2020 annual review: CP.PCH.18 retired and HIM.PA.SP36 unretired per June SDC and prior clinical guidance; no significant changes; references reviewed and updated.</td>
<td>06.10.20</td>
<td>08.20</td>
</tr>
</tbody>
</table>

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.

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