Clinical Policy: Daclatasvir (Daklinza)
Reference Number: CP. PCH.15
Effective Date: 01.01.20
Last Review Date: 02.20
Line of Business: Commercial, HIM

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

Description
Daclatasvir (Daklinza™) is a hepatitis C virus (HCV) NS5A inhibitor.

FDA Approved Indication(s)
Daklinza is indicated for use with sofosbuvir, with or without ribavirin, for the treatment of chronic HCV genotype 1 or 3 infection.

Limitation(s) of use: Sustained virologic response (SVR12) rates are reduced in genotype 3 patients with cirrhosis receiving Daklinza in combination with sofosbuvir for 12 weeks.

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 Daklinza 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 1, 2, 3, 4, 5, or 6;
         *Chart note documentation and copies of lab results are required
      3. Documentation of the treatment status of the patient (treatment-naive or treatment-experienced);
      4. Documentation of cirrhosis status of the patient (no cirrhosis, compensated cirrhosis, or decompensated cirrhosis);
      5. Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician, or provider who has expertise in treating HCV based on a certified training program (see Appendix F);
      6. Age ≥ 18 years;
      7. Prescribed for use in combination with Sovaldi®;
      8. For genotype 1a with cirrhosis, laboratory testing confirming the absence of NS5A resistance-associated polymorphisms at amino acid positions M28, Q30, L31 and Y93;
      9. Member must meet one of the following (a, b, or c):
         a. For adults with genotype 1: Member must use Harvoni® (authorized generic or brand for 8 weeks only), sofosbuvir/velpatasvir (Epclusa®) (authorized generic...
**CLINICAL POLICY**

**Daclatsvir**

preferred), Mavyret™, or Zepatier® unless all are contraindicated or clinically significant adverse effects are experienced;

b. For adults with genotype 4: Member must use sofosbuvir/velpatasvir (Epclusa) (authorized generic preferred), Mavyret, or Zepatier unless all are contraindicated or clinically significant adverse effects are experienced;

c. For adults with genotype 2, 3, 5, or 6: Member must use sofosbuvir/velpatasvir (Epclusa) (authorized generic preferred) or Mavyret, unless all are contraindicated or clinically significant adverse effects are experienced;

10. Life expectancy ≥ 12 months with HCV treatment;

11. Member agrees to participate in a medication adherence program meeting 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;

12. Prescribed regimen is consistent with an FDA or AASLD-IDSA recommended regimen (see Section V Dosage and Administration for reference);

13. Dose does not exceed 90 mg (1 tablet) per day.

**Approval duration: up to a total of 24 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): CP.CPA.09 for commercial and 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. Documentation supports that member is currently receiving Daklinza for chronic HCV infection and has recently completed at least 60 days of treatment with Daklinza;

2. Member is responding positively to therapy;

3. Dose does not exceed 90 mg (1 tablet) per day.

**Approval duration: up to a total of 24 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): CP.CPA.09 for commercial and 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 policies – CP.CPA.09 for commercial and HIM.PHAR.21 for health insurance marketplace or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AASLD: American Association for the Study of Liver Diseases
FDA: Food and Drug Administration
HBV: hepatitis B virus
HCV: hepatitis C virus
HIV: human immunodeficiency virus
IDSA: Infectious Diseases Society of America
NS3/4A, NS5A/B: nonstructural protein
PegIFN: pegylated interferon
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>
<tbody>
<tr>
<td><strong>Harvoni®</strong> (sofosbuvir/ledipasvir)</td>
<td>Without cirrhosis, treatment-naïve, whose HCV viral load is less than 6 million IU/mL: <strong>Genotypes 1</strong> One tablet PO QD for 8 weeks</td>
<td>Harvoni: sofosbuvir 400 mg/ledipasvir 90 mg (1 tablet) per day</td>
</tr>
<tr>
<td><strong>Epclusa®</strong> (sofosbuvir/velpatasvir)</td>
<td>Without cirrhosis or with compensated cirrhosis, treatment naïve or treatment experienced: <strong>Genotypes 1 through 6</strong> One tablet PO QD for 12 weeks</td>
<td>Epclusa: sofosbuvir 400 mg/velpatasvir 100 mg (1 tablet) per day</td>
</tr>
<tr>
<td><strong>Epclusa®</strong> (sofosbuvir/velpatasvir) plus RBV</td>
<td>With decompensated cirrhosis (Child-Pugh class B or C) treatment-naïve or treatment experienced: <strong>Genotypes 1 through 6</strong> One tablet PO QD plus weight-based RBV for 12 weeks</td>
<td>Epclusa: sofosbuvir 400 mg/velpatasvir 100 mg (1 tablet) per day</td>
</tr>
<tr>
<td><strong>Mavyret™</strong> (glecaprevir/pibrentasvir)</td>
<td>Treatment-naïve: <strong>Genotypes 1, 2, or 3</strong> Without cirrhosis or with compensated cirrhosis: Three tablets PO QD for 8 weeks</td>
<td>Mavyret: glecaprevir 300 mg/pibrentasvir 120 mg (3 tablets) per day</td>
</tr>
<tr>
<td>Drug Name</td>
<td>Dosing Regimen</td>
<td>Dose Limit/Maximum Dose</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>-------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| **Mavyret™ (glecaprevir/pibrentasvir)** | Treatment-experienced with IFN/pegIFN + RBV:  
**Genotypes 1, 2, or 3**  
Without cirrhosis:  
Three tablets PO QD for 8 weeks  

**Genotype 3**  
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-naïve or treatment-experienced, post-liver transplantation in the allograft with or without compensated cirrhosis:  
**Genotypes 1, 4, 5, or 6**  
Three tablets PO QD for 12 weeks | Mavyret: glecaprevir 300 mg/pibrentasvir 120 mg (3 tablets) per day |
| **Zepatier® (grazoprevir/elbasvir)** | **Genotype 1a:**  
Treatment-naïve or pegIFN/RBV-experienced with or without compensated cirrhosis without baseline NS5A polymorphisms at amino acid positions 28, 30, 31, or 93 | One tablet (grazoprevir 100 mg/elbasvir 50 mg) per day |
| **Zepatier® (grazoprevir/elbasvir)** | **Genotype 1a:**  
Treatment-naïve or PegIFN/RBV experienced with or without compensated cirrhosis with baseline NS5A polymorphisms at amino acid positions 28, 30, 31, or 93 | One tablet (grazoprevir 100 mg/elbasvir 50 mg) per day |
| **Zepatier® (grazoprevir/elbasvir)** | **Genotype 1b:**  
Treatment-naïve or PegIFN/RBV experienced with or without compensated cirrhosis  
One tablet PO QD for 12 weeks | One tablet (grazoprevir 100 mg/elbasvir 50 mg) per day |
| **Zepatier® (grazoprevir/elbasvir)** | **Genotype 1a or 1b:**  
pegIFN/RBV/NS3 PI*-experienced with or without compensated cirrhosis without baseline NS5A polymorphisms at amino acid positions 28, 30, 31, or 93 | One tablet (grazoprevir 100 mg/elbasvir 50 mg) per day |
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/ Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Zepatier®</strong> (grazoprevir/elbasvir)</td>
<td><strong>Genotype 1a or 1b:</strong> pegIFN/RBV/NS3 PI*-experienced with or without compensated cirrhosis with baseline NS5A polymorphisms at amino acid positions 28, 30, 31, or 93</td>
<td>One tablet PO QD plus weight-based RBV for 16 weeks</td>
</tr>
<tr>
<td></td>
<td>One tablet PO QD plus weight-based RBV for 16 weeks</td>
<td></td>
</tr>
<tr>
<td><strong>Zepatier®</strong> (grazoprevir/elbasvir)</td>
<td><strong>Genotype 3:</strong> pegIFN/RBV-experienced with compensated cirrhosis</td>
<td>One tablet (grazoprevir 100 mg/ elbasvir 50 mg) per day</td>
</tr>
<tr>
<td></td>
<td>One tablet PO QD plus sofosbuvir 400 mg for 12 weeks</td>
<td></td>
</tr>
<tr>
<td><strong>Zepatier®</strong> (grazoprevir/elbasvir)</td>
<td><strong>Genotype 4:</strong> Treatment-naïve with or without compensated cirrhosis</td>
<td>One tablet (grazoprevir 100 mg/ elbasvir 50 mg) per day</td>
</tr>
<tr>
<td></td>
<td>One tablet PO QD for 12 weeks</td>
<td></td>
</tr>
<tr>
<td><strong>Zepatier®</strong> (grazoprevir/elbasvir)</td>
<td><strong>Genotype 4:</strong> PegIFN/RBV-experienced with or without compensated cirrhosis with virologic relapse/failure</td>
<td>One tablet (grazoprevir 100 mg/ elbasvir 50 mg) per day</td>
</tr>
<tr>
<td></td>
<td>Virologic relapse after prior pegIFN/RBV therapy:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>One tablet PO QD for 12 weeks</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Virologic failure while on pegIFN/RBV therapy:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>One tablet PO QD plus weight-based RBV for 16 weeks</td>
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</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.*

**Appendix C: Contraindications/Boxed Warnings**

- **Contraindication(s):**
  - When Daklinza is used in combination with other agents, the contraindications applicable to those agents are applicable to the combination regimen. Refer to the respective prescribing information for a list of contraindications.
  - Daklinza is contraindicated in combination with drugs that strongly induce CYP3A and, thus, may lead to lower exposure and loss of efficacy of Daklinza. Contraindicated drugs include, but are not limited to: phenytoin, carbamazepine, rifampin, and St. John’s wort.

- **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>
</thead>
<tbody>
<tr>
<td>Daklinza</td>
<td>Daclatasvir</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Epclusa*</td>
<td>Velpatasvir</td>
<td>Sofosbuvir</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harvoni*</td>
<td>Ledipasvir</td>
<td>Sofosbuvir</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mavyret*</td>
<td>Pibrentasvir</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Glecaprevir</td>
</tr>
</tbody>
</table>

*Combination drugs

### 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.

- For patients infected with HCV Genotype 1a with cirrhosis: Testing for the presence of virus with NS5A resistance-associated polymorphisms is recommended.

- According to the September 2017 AASLD/IDSA HCV guidance updates, Daklinza plus Sovaldi is a treatment option for patients with genotypes 1 through 6 in decompensated cirrhosis and post-liver transplantation in the allograft.

- 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</td>
<td>2-3 mg/dL</td>
<td>Over 3 mg/dL</td>
</tr>
<tr>
<td></td>
<td>Less than 34 umol/L</td>
<td>34-50 umol/L</td>
<td>Over 50 umol/L</td>
</tr>
<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>
</tr>
<tr>
<td></td>
<td>Over 35 g/L</td>
<td>28-35 g/L</td>
<td>Less than 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>
</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>Genotype 1: Treatment-naïve or treatment-experienced without cirrhosis</td>
<td>Daklinza 60 mg PO QD plus Sovaldi 400 mg PO QD for 12 weeks</td>
<td>Daklinza: 90 mg per day</td>
<td>1) FDA-approved labeling 2) AASLD-IDSA (updated May 2018)</td>
</tr>
<tr>
<td>Genotype 1, 2†, 3, or 4‡: Decompensated cirrhosis (including those with hepatocellular carcinoma)</td>
<td>Daklinza 60 mg PO QD plus Sovaldi 400 mg PO QD with low initial dose of RBV (600 mg) and increased as tolerated for 12 weeks</td>
<td>Daklinza: 90 mg per day</td>
<td>1) FDA-approved labeling 2) AASLD-IDSA (updated May 2018)</td>
</tr>
<tr>
<td>Genotype 1, 2†, 3, or 4‡: Decompensated cirrhosis (including those with hepatocellular carcinoma) and intolerant to RBV</td>
<td>Daklinza 60 mg PO QD plus Sovaldi 400 mg PO QD for 24 weeks</td>
<td>Daklinza: 90 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‡: Treatment-naïve or</td>
<td>Daklinza 60 mg PO QD plus Sovaldi 400 mg PO</td>
<td>Daklinza: 90 mg per day</td>
<td>1) FDA-approved</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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<td>-----------------------------------------------</td>
</tr>
<tr>
<td>treatment-experienced, post-liver transplantation in the allograft with or without compensated cirrhosis</td>
<td>QD with low initial dose of RBV (600 mg) and increased as tolerated for 12 weeks</td>
<td>Daklinza: 90 mg per day</td>
<td>FDA-approved labeling 2) AASLD-IDSA (updated May 2018)</td>
</tr>
<tr>
<td>Genotype 2⁺: Treatment- naïve or treatment- experienced without cirrhosis</td>
<td>Daklinza 60 mg PO plus Sovaldi 400 mg PO QD for 12 weeks</td>
<td>Daklinza: 90 mg per day</td>
<td>AASLD-IDSA (updated May 2018)</td>
</tr>
<tr>
<td>Genotype 2⁺: Treatment-naïve or treatment-experienced with compensated cirrhosis</td>
<td>Daklinza 60 mg PO plus Sovaldi 400 mg PO QD for 16 to 24 weeks</td>
<td>Daklinza: 90 mg per day</td>
<td>AASLD-IDSA (updated May 2018)</td>
</tr>
<tr>
<td>Genotype 2⁺ or 3: Treatment-naïve or treatment-experienced, post-liver transplantation in the allograft with or without compensated or decompensated cirrhosis</td>
<td>Daklinza 60 mg PO QD plus Sovaldi 400 mg PO QD with low initial dose of RBV (600 mg) and increased as tolerated for 12 weeks</td>
<td>Daklinza: 90 mg per day</td>
<td>1) FDA-approved labeling 2) AASLD-IDSA (updated May 2018)</td>
</tr>
<tr>
<td>Genotype 3: Treatment- naïve or treatment-experienced without cirrhosis</td>
<td>Daklinza 60 mg PO plus Sovaldi 400 mg PO QD for 12 weeks</td>
<td>Daklinza: 90 mg per day</td>
<td>FDA-approved labeling 2) AASLD-IDSA (updated May 2018)</td>
</tr>
<tr>
<td>Genotype 3: Treatment- naïve with compensated cirrhosis</td>
<td>Daklinza 60 mg PO plus Sovaldi 400 mg PO QD with or without weight-based RBV for 24 weeks</td>
<td>Daklinza: 90 mg per day</td>
<td>AASLD-IDSA (updated May 2018)</td>
</tr>
<tr>
<td>Daklinza dose modification</td>
<td>Reduce dosage to 30 mg PO QD with strong CYP3A4 inhibitors and increase to 90 mg PO QD with moderate CYP3A inducers.</td>
<td>Daklinza: 90 mg per day</td>
<td>FDA-approved labeling</td>
</tr>
</tbody>
</table>

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. Treatment-experienced refers to previous treatment with peginterferon/RBV unless otherwise stated. Off-label, AASLD-IDSA guideline-supported dosing regimen.
VI. Product Availability
Tablets: 30 mg, 60 mg, 90 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; per SDC and prior clinical guidance added HIM line of business to the existing Commercial policy (modified policy number to CP.PCH.15, retired HIM.PA.SP27 and CP.CPA.283); added requirement that life expectancy ≥ 12 months with HCV treatment and participation in a medication adherence program.</td>
<td>12.03.19</td>
<td>02.20</td>
</tr>
<tr>
<td>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; updated Mavyret dosing recommendations to 8 weeks total duration of therapy for treatment-naïve HCV with compensated cirrhosis across all genotypes (1-6).</td>
<td>11.07.19</td>
<td>02.20</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
Daclatsvir

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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