Clinical Policy: Sofosbuvir (Sovaldi)

Reference Number: IL.PHAR.281
Effective Date: 09.16
Last Review Date: 5.3.23
Line of Business: Medicaid

Revision Log

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

Description

Sofosbuvir (Sovaldi®) is hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor.

FDA Approved Indication(s)

Sovaldi is indicated for the treatment of chronic HCV infection in:

- Adult patients without cirrhosis or with compensated cirrhosis:
  - Genotype 1 or 4 for use in combination with pegylated interferon and ribavirin (RBV)
  - Genotype 2 or 3 for use in combination with RBV
- Pediatric patients 3 years of age and older with genotype 2 or 3 without cirrhosis or with compensated cirrhosis in combination with RBV

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 Sovaldi 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;
2. Confirmed HCV genotype is one of the following (a or b):
   a. For adults (≥ 18 years): Genotypes 1, 2, 3, 4, 5, or 6;
   b. For pediatrics (age ≥ 3 years): Genotypes 2 or 3;
   **Copies of lab results and quantitative baseline HCV-RNA are required*
3. Patient's Metavir/fibrosis score must be documented in the request for prior approval. The patient's Metavir/fibrosis score can be determined based on Liver Biopsy, Transient Elastography (FibroScan ®), FibroTest®/FibroSure®, or FibroMeter™.
4. Prescriber must provide a copy of the following lab test reports, completed within 3 months prior to the request for prior approval, unless otherwise noted:
   a. Baseline quantitative HCV RNA level (within 1 year of request for prior approval)
   b. ALT and AST
   c. CBC
   d. GFR
   e. INR, albumin, and bilirubin, for stage 4 fibrosis only

   f. Negative HBV screen; or evidence of immunity due to vaccination or previous natural infection, and if member is acutely or chronically infected, must provide quantitative HBV DNA and verification of treatment regimen (Interpretation of Hepatitis B Serologic Test Results: https://www.cdc.gov/hepatitis/hbv/pdfs/serologicchartv8.pdf)
5. Prescriber must provide clinic or consultation notes from specialist consultation (see #9).
6. In the opinion of the prescriber, the patient is able to make appropriate decisions about treatment and comply with dosing and other instructions, and is capable of completing therapy as prescribed. The prescriber must provide a copy of a signed patient commitment letter for all hepatitis C treatment regimens.
7. The treatment regimen prescribed is not for an indication outside of the FDA approved labeling, and no contraindications or significant drug interactions to treatment exist as specified in the product labeling.
8. Prescribing provider is responsible for addressing ongoing misuse of alcohol and/or continued use of illicit IV drugs (if appropriate).
9. The patient has no history of an incomplete course of treatment with DAAs. (Prior treatment with telaprevir, boceprevir, and DAA regimens used in combination with interferons is not taken into consideration for purposes of this criterion.) HFS will review requests and pertinent clinical information for an additional course of DAA, after previous such therapy, on a case-by-case basis, considering whether the person has received counseling for or otherwise addressed the cause of non-adherence, where applicable.
10. The prescriber can be any practitioner licensed to prescribe or licensed to prescribe in collaboration with a physician who holds a current unrestricted license to practice medicine. If the prescriber is NOT a gastroenterologist, hepatologist, transplant hepatologist, or infectious disease specialist, the prescriber must engage in a one-time consultation with one of these specialists within the 3 months prior to the request for prior authorization. This one-time consultation may be via telephone, video-conference, or telehealth technology. The records containing a specialist recommendation for treatment with a DAA regimen must be submitted with the request for prior approval.
11. Non-adherence with the regimen (> 7 days) or patient's failure to obtain refills in a timely manner may result in discontinuation of current prior approval. Non-adherence or failure to obtain refills that result from situations that are beyond the patient's control will not result in discontinuation of a prior approval.
12. The prescriber agrees to submit HCV RNA levels to HFS for patients prescribed DAAs within 8 weeks after beginning treatment, 12 weeks post treatment, and 24 weeks post treatment. If at any point the patient's viral load is undetectable, the prescriber is not required to submit any subsequent test. Prescriber's failure to submit a lab report in a timely fashion due to patient's non-cooperation may result in denial of retreatment, should that situation arise. However, situations beyond the control of the prescriber or the patient will not result in a denial of re-treatment under this criteria.
13. For pediatric patients (age ≥ 3 years) with genotype 2 or 3: use is in combination with RBV;

14. Must meet one of the following (a or b) (*see Appendix F*):
    a. If member has not experienced treatment failure with Vosevi®: Member must use sofosbuvir/velpatasvir (Epclusa®) (*generic preferred*) or Mavyret®, unless both are contraindicated or clinically significant adverse effects are experienced;
    b. If treatment-experienced with Vosevi®: Member must use Sovaldi in combination with Mavyret® and RBV, unless any individual agent is contraindicated or clinically significant adverse effects are experienced;
15. Dose does not exceed 400 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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
    a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
    b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
    a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
    b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

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.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AASLD: American Association for the Study of Liver Diseases
APRI: AST to platelet ratio
FDA: Food and Drug Administration
FIB-4: Fibrosis-4 index
HBV: hepatitis B virus
HCC: hepatocellular carcinoma
HCV: hepatitis C virus
HIV: human immunodeficiency virus
IDSA: Infectious Diseases Society of America
IQR: interquartile range
MRE: magnetic resonance elastography
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.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
sofosbuvir/ velpatasvir (Epclusa®)	Without cirrhosis or with compensated cirrhosis, treatment naïve or treatment experienced: **Genotypes 1 through 6** One tablet PO QD for 12 weeks	Adult/Peds ≥ 30 kg: sofosbuvir 400 mg /velpatasvir 100 mg (one tablet) per day; Peds 17 to < 30 kg: sofosbuvir 200 mg /velpatasvir 50 mg per day; Peds < 17 kg: sofosbuvir 150 mg /velpatasvir 37.5 mg per day
Mavyret® (glecaprevir /pibrentasvir)	Treatment-naïve: **Genotypes 1 through 6** Without cirrhosis or with compensated cirrhosis: 3 tablets PO QD for 8 weeks	Adults/Peds age ≥ 12 years or with body weight ≥ 45 kg: glecaprevir 300 mg/pibrentasvir 120 mg (3 tablets) per day; Peds age 3 years to < 12 years of age with body weight < 20 kg: glecaprevir 150
Mavyret® (glecaprevir /pibrentasvir)	Treatment-experienced with IFN/pegIFN + RBV +/- sofosbuvir: **Genotypes 1, 2, 4, 5, or 6** Without cirrhosis:	

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	3 tablets PO QD for 8 weeks With compensated cirrhosis: 3 tablets PO QD for 12 weeks	mg/pibrentasvir 60 mg per day; Peds age 3 years to < 12 years of age with body weight 20 kg to < 30 kg: glecaprevir 200 mg/pibrentasvir 80 mg per day; Peds age 3 years to < 12 years of age with body weight 30 kg to < 45 kg: glecaprevir 250 mg/pibrentasvir 100 mg per day
Mavyret® (glecaprevir /pibrentasvir)	Treatment-experienced with IFN/pegIFN + RBV +/- sofosbuvir: **Genotype 3** Without cirrhosis or with compensated cirrhosis: 3 tablets PO QD for 16 weeks	

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

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): when used in combination with peginterferon alfa/RBV or RBV alone, all contraindications to peginterferon alfa and/or RBV also apply to Sovaldi 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

Brand Name	Drug Class				
	NS5A Inhibitor	Nucleotide Analog NS5B Polymerase Inhibitor	Non-Nucleoside NS5B Palm Polymerase Inhibitor	NS3/4A Protease Inhibitor (PI)	CYP3A Inhibitor
Epclusa*	Velpatasvir	Sofosbuvir			
Harvoni*	Ledipasvir	Sofosbuvir			
Mavyret*	Pibrentasvir			Glecaprevir	
Sovaldi		Sofosbuvir			
Viekira PAK*	Ombitasvir		Dasabuvir	Paritaprevir	Ritonavir
Vosevi*	Velpatasvir	Sofosbuvir		Voxilaprevir	

Brand Name	Drug Class				
	NS5A Inhibitor	Nucleotide Analog NS5B Polymerase Inhibitor	Non-Nucleoside NS5B Palm Polymerase Inhibitor	NS3/4A Protease Inhibitor (PI)	CYP3A Inhibitor
Zepatier*	Elbasvir			Grazoprevir	

*Combination drugs

Appendix E: General Information

- Acceptable medical justification for inability to use Mavyret (preferred product):
  - Moderate or severe hepatic impairment (Child-Pugh B or C) or those with any history of prior hepatic decompensation: use of Mavyret is not recommended as postmarketing cases of hepatic decompensation/failure have been reported in these patients.
  - Drug-drug interactions with the following agents:
    - Atazanavir
    - Efavirenz
- Unacceptable medical justification for inability to use Epclusa (preferred product):
  - Coadministration with omeprazole up to 20 mg is not considered acceptable medical justification for inability to use Epclusa.
    - Per the Epclusa Prescribing Information: "If it is considered medically necessary to coadminister, Epclusa should be administered with food and taken 4 hours before omeprazole 20 mg."
- 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.
- Child-Pugh Score:

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

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

Indication: Adult patients with chronic HCV infection			
Drugs	**Dosing Regimen**	**Maximum Dose**	**Reference**
Sovaldi + pegIFN + RBV	**Genotype 1 or 4** Treatment-naïve without cirrhosis or with compensated cirrhosis: Sovaldi 400 mg + pegIFN + weight-based RBV for 12 weeks	Sovaldi 400 mg/day	FDA-approved labeling
Sovaldi + RBV	**Genotype 2** Treatment-naïve and treatment-experienced, without cirrhosis or with compensated cirrhosis: Sovaldi 400 mg + weight-based RBV for 12 weeks	Sovaldi 400 mg/day	FDA-approved labeling
Sovaldi + RBV	**Genotype 3** Treatment-naïve and treatment-experienced, without cirrhosis or with compensated cirrhosis: Sovaldi 400 mg + weight-based RBV for 24 weeks	Sovaldi 400 mg/day	FDA-approved labeling
Sovaldi + Mavyret + RBV	**Genotypes 1 through 6** Patients with prior sofosbuvir/ velpatasvir/voxilaprevir treatment failure, with or without compensated cirrhosis Sovaldi 400 mg + Mavyret 300	Sovaldi 400 mg/day	AASLD/IDSA (updated March 2021)

Indication: Adult patients with chronic HCV infection			
Drugs	**Dosing Regimen**	**Maximum Dose**	**Reference**
	mg/120 mg + weight-based RBV for 16 weeks		

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 with or without RBV unless otherwise stated.

Indication: Pediatric patients (age ≥ 3 years) with chronic HCV infection			
Drugs	**Dosing Regimen**	**Maximum Dose**	**Reference**
Sovaldi + RBV	**Genotype 2** Treatment-naïve or treatment-experienced, without cirrhosis or with compensated cirrhosis: • ≥ 35 kg: Sovaldi 400 mg + weight-based RBV for 24 weeks • 17 to < 35 kg: Sovaldi 200 mg + weight-based RBV for 24 weeks • < 17 kg: Sovaldi 150 mg + weight-based RBV for 24 weeks	Sovaldi: 400 mg/day	FDA-approved labeling
Sovaldi + RBV	**Genotype 3** Treatment-naïve or treatment-experienced, without cirrhosis or with compensated cirrhosis: • ≥ 35 kg: Sovaldi 400 mg + weight-based RBV for 24 weeks • 17 to < 35 kg: Sovaldi 200 mg + weight-based RBV for 24 weeks • < 17 kg: Sovaldi 150 mg + weight-based RBV for 24 weeks	Sovaldi: 400 mg/day	FDA-approved labeling

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 with or without RBV unless otherwise stated.

VI. Product Availability

Tablets: 400 mg, 200 mg
Oral pellets: 200 mg, 150 mg

VII. References

1. Illinois Department of Healthcare and Family Services: Criteria for Prior Aproval of Direct-Acting Antivirals (DAAs) for Hepatitis C. Available at: https://www2.illinois.gov/hfs/SiteCollectionDocuments/HFSHepCDAACriteriaWordFINAL11012018.pdf. Accessed April 20,2022.
2) Sovaldi Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; March 2020. Available at http://www.sovaldi.com/. Accessed April 15, 2021.
3) American Association for the Study of Liver Diseases/ Infectious Disease Society of America (AASLD-IDSA). HCV guidance: recommendations for testing, managing, and treating hepatitis C. Last updated March 12, 2021. Available at: https://www.hcvguidelines.org/. Accessed April 30, 2020.
4) CDC. Hepatitis C Q&As for health professionals. Last updated August 7, 2020. Available at: https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm. Accessed April 15, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created, split from CP.PHAR.17. 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; 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. Criteria added excluding post-liver transplantation unless regimens specifically designate. Dosing regimens are presented in Appendix D and E. The initial approval is shortened to 8 weeks.	08.16	09.16
Added criteria for Pediatric Chronic Hepatitis C Infection. Updated contraindications, removed hypersensitivity to drug and cardiac disease per PI;	04.17	05.17
Policy converted to new template. Added requirement for prevention of HBV reactivation; expanded genotypes to reflect AASLD/IDSA CHC tx guidelines. Consolidated appendix D and E into dosing and administration in section V, deleted "up to" in initial approval duration; deleted adherence requirement in continued, added documentation of positive response to therapy and continuity of care, and removed CIs in section II, added reference column in section V. Added preferencing information requiring Mavyret for FDA-approved indications.	08.17	09.17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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.		
Removed the following language: "If a lower cost alternative regimen carries an equal or higher AASLD-IDSA rating, a clinical contraindication or intolerance must be present for the alternative regimen prior to approval."	09.17	
3Q 2018 annual review: removed requirement for HBV verification; added requirement for documentation of previous treatment and cirrhosis status; expanded duration of tx required for COC from 30 days to 60 days; required verification of genotype for COC; removed conditional requirement for RBV CI; references reviewed and updated.	05.22.18	08.18
Removed requirement for advanced fibrosis or other candidacy for therapy following approved clinical guidance and removed sobriety requirement.	2.26.19	4.19
2Q2021 Annual Review: **Updated** FDA approve indication **Updated** diagnosis criteria for pediatrics (age ≥ 3 years): Genotypes 2 or 3; **Added** 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 years or older, or weight at least 45 kg ; **Added** new prescriber requirement to include a "provider who has expertise in treating HCV based on a certified training program"; Dosage and Administration tables updated; **removed** medical justification for ability to use Mavyret from Appendix F; **added** Appendix G (Healthcare Provider HCV Training); **Added** Child-Pugh Score in Appendix E **removed** documented sobriety from alcohol and illicit IV drugs for ≥ 6 months prior to starting therapy; **Removed** *Appendix D: Approximate Scoring Equivalencies using METAVIR F3/F4;* ; **Updated** table Dosing and Administration; references reviewed and updated;	6.17.21	
Updated: updated criteria for age requirement of Epclusa & Mavyret use due to their pediatric age expansions; included reference to Appendix F with the addition of un/acceptable rationale for bypassing preferred agents; updated Appendix B therapeutic alternatives and section V dosing tables; references reviewed and updated.	9.14.21	
1Q 2022 Annual review- no significant change.	3.3.22	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2023 Annual review: update to be in line with IL HFS criteria; added omeprazole coadministration as unacceptable rationale for not using preferred Epclusa to criteria and Appendix E; removed redundant rationale from Appendix E; template changes applied; references reviewed and updated	5.4.23	

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.