Clinical Policy: Sofosbuvir/Velpatasvir/Voxilaprevir (Vosevi)

Reference Number: IL.PHAR.347
Effective Date: 09.17
Last Review: 9.22.22
Line of Business: Medicaid

Revision Log

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

Description

Sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) is a fixed-dose combination oral tablet. Sofosbuvir is a nucleotide analog hepatitis C virus (HCV) NS5B polymerase inhibitor, velpatasvir is an NS5A inhibitor, and voxilaprevir is an NS3/4A protease inhibitor.

FDA Approved Indication(s)

Vosevi is indicated for the treatment of adult patients with chronic HCV infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have:

- Genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor*;
- Genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor**.
    - Additional benefit of Vosevi over sofosbuvir/velpatasvir was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with sofosbuvir without an NS5A inhibitor.

* In clinical trials, prior NS5A inhibitor experience included daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir.
** In clinical trials, prior treatment experience included sofosbuvir with or without any of the following: peginterferon alfa/ribavirin, ribavirin, HCV NS3/4A protease inhibitor (boceprevir, simeprevir or telaprevir).

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 Vosevi is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. The patient is 3 years of age or over, and has a diagnosis of Chronic Hepatitis C infection genotype 1, 2, 3, 4, 5 or 6 confirmed by lab documentation and quantitative baseline HCV-RNA
2. 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™.

3. 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.pdfAge ≥ 3 years;, or telaprevir);

   **Chart note documentation and copies of lab results are required*
4. Member must use Mavyret or **sofosbuvir/velpatasvir (Epclusa®) (*authorized generic preferred*)** if member meets one of the following (a, b, c or d, unless contraindicated or clinically significant adverse effects are experienced (*see Appendix F)*:
   a. HCV genotype 1 and member has previously been treated with an HCV regimen containing an NS5A inhibitor without an NS3/4A protease inhibitor (i.e., Daklinza, Epclusa, Harvoni);
   b. HCV genotype is 1a or 3 and member has previously been treated with an HCV regimen containing sofosbuvir with or without any of the following: peginterferon alfa/ribavirin, ribavirin, HCV NS3/4A protease inhibitor (boceprevir, simeprevir or telaprevir);
   c. For HCV genotype 1 through 6 and previous treatment with Vosevi: Mavyret must be used in combination with Sovaldi® and RBV;
   d. For HCV genotype 3, treatment-naive, compensated cirrhosis with documentation of the presence of baseline NS5A RAS Y93H for velpatasvir: Member must use Epclusa (*authorized generic preferred*) in combination with RBV or Mavyret;

5. 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.
6. 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.
7. 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.

8. 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 G*);
9. 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.
10. 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.
11. Requests for exceptions to these criteria can be made when the services are medically necessary to meet the medical needs of the patient. Requests for exceptions to these criteria can be made on the prior approval form itself and will be reviewed on a case-by-case basis.For HCV treatment-experienced member:
12. Dose does not exceed one of the following (a, b, or c):
    a. Adult and pediatric members with body weight ≥ 30 kg: sofosbuvir/velpatasvir 400 mg/100 mg (1 tablet) per day;
    b. Pediatric members 3 years of age and older with body weight < 17 kg: sofosbuvir/velpatasvir 150 mg/37.5 mg per day;
    c. Pediatric members 3 years of age and older with body weight 17 kg to < 30 kg: sofosbuvir/velpatasvir 200 mg/50 mg per day.
13. Dose does not exceed sofosbuvir 400 mg/velpatasvir 100 mg/voxilaprevir 100 mg (1 tablet) per day.

Approval duration: up to 24 weeks*

*(*Approved duration should be consistent with a regimen in Section V Dosage and Administration)*

a. **Other diagnoses/indications** (must meet all)
    1. Member must use **Mavyret®** or **sofosbuvir/velpatasvir (Epclusa®) (*authorized generic preferred*),** if applicable for the requested indication, unless clinically significant adverse effects are experienced or both are contraindicated;
    2. Must meet one of the following (a or b):
        a. 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 (i or ii):
            i. For drugs on the PDL, refer to the no coverage criteria policy: CP.PMN.255; or

ii. 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

b. 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: CP.PMN.53.

14. Continued Therapy

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

1. Member meets one of the following (a, b, or c):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
   c. Must meet both of the following (i and ii):
      i. Documentation supports that member is currently receiving Vosevi for chronic HCV infection and has recently completed at least 60 days of treatment with Vosevi;
      ii. Member meets one of the following (1, 2, or 3):
         1) HCV genotype is 1, 2, 3, 4, 5 or 6, and member has previously been treated with an HCV regimen containing one of the following NS5A inhibitors: daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir;
         2) HCV genotype is 1a or 3 and member has previously been treated with an HCV regimen containing sofosbuvir with or without any of the following: peginterferon alfa/ribavirin, ribavirin, HCV NS3/4A protease inhibitor (boceprevir, simeprevir or telaprevir);
         3) HCV genotype is 3, member is treatment-naïve with compensated cirrhosis, and documentation for the presence of baseline NS5A RAS Y93H for velpatasvir;

2. Member is responding positively to therapy;
3. Dose does not exceed sofosbuvir 400 mg/velpatasvir 100 mg/voxilaprevir 100 mg (1 tablet) per day.

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

B. Other diagnoses/indications (must meet all)**:**

i. Member must use **Mavyret®** or **sofosbuvir/velpatasvir (Epclusa®) (*authorized generic preferred*),** if applicable for the requested indication, unless clinically significant adverse effects are experienced or both are contraindicated;

ii. Must meet one of the following (a or b):

a. 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 (i or ii):
   i. For drugs on the PDL refer to the no coverage criteria policy: CP.PMN.255; or
   ii. For drugs NOT on the PDL, refer to the non-formulary policy: CP.PMN.16; or

b. 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 CP.PMN.53.

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.

Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AASLD: American Association for the Study of Liver Diseases
DAA: direct-acting antiviral agent
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
RAS: resistance-associated substitution
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
Mavyret® (glecaprevir/ pibrentasvir)	Treatment-experienced with IFN/pegIFN, RBV and/or sofosbuvir: **Genotypes 1, 2, 4, 5, or 6** Without cirrhosis: Three tablets PO QD for 8 weeks With compensated cirrhosis:	Mavyret: glecaprevir 300 mg/ pibrentasvir 120 mg (3 tablets) per day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Three tablets PO QD for 12 weeks	
Mavyret® (glecaprevir /pibrentasvir)	Treatment-experienced with IFN/pegIFN, RBV and/or sofosbuvir: **Genotype 3** 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 NS5A inhibitor without prior NS3/4A protease inhibitor: **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: **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
Mavyret®(glecaprevir /pibrentasvir) + Sovaldi® (sofosbuvir) + RBV	With prior sofosbuvir/velpatasvir/voxilaprevir treatment failure, with compensated cirrhosis or without cirrhosis" **Genotypes 1-6**ǂ: Sovaldi 400 mg + Mavyret 300 mg/120 mg + weight-based RBV for 16 weeks	Varies

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

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): coadministration with rifampin
- Boxed warning(s): risk of hepatitis B virus reactivation in patients coinfected with HCV and HBV

Appendix E: Direct-Acting Antivirals for Initial 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	
Zepatier*	Elbasvir			Grazoprevir	

*Combination drugs

Appendix F: 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.
- Unacceptable medical justification for inability to use Mavyret (preferred product):
  - Black Box Warning (BBW): currently or previously infected with hepatitis B virus. This BBW is not unique to Mavyret, and it applies across the entire therapeutic class of direct-acting antivirals for treatment of HCV infection. Therefore it is not a valid clinical reason not to use Mavyret.
  - Concurrent anticoagulant therapy: Fluctuations in International Normalized Ratio (INR) have been observed in warfarin recipients who were also receiving treatment for HCV infections. This BBW is not unique to Mavyret, and it applies across the entire therapeutic class of direct-acting antivirals for treatment of HCV infection. Although caution is advised when using Mavyret while receiving concurrent anticoagulant therapy, specifically warfarin, this is not an absolute contraindication as long as patient is adequately monitored and educated during therapy.
  - Drug-drug interactions with one or more of the following agents:
    - Rifampin, carbamazepine, or St. John's wort:
    - These drug-drug interactions are not unique to Mavyret, and they apply across the entire therapeutic class of direct-acting antivirals for treatment of HCV infection.

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	2.8-3.5 g/dL	Less than 2.8 g/dL

	1 Point	2 Points	3 Points
	Over 35 g/L	28-35 g/L	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 G: 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

C. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose	Reference
Genotype 1-6: Treatment-experienced with NS5A inhibitor* with or without compensated cirrhosis	One tablet PO QD for 12 weeks	One tablet (sofosbuvir 400 mg/ velpatasvir 100 mg/ voxilaprevir 100 mg) per day	FDA-approved labeling
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		FDA-approved labeling
Genotype 1-6: Treatment-experienced with Vosevi® with or without compensated cirrhosis	Vosevi one tablet PO QD with weight-based RBV for 24 weeks		AASLD-IDSA (updated March 2021)
Genotype 3: Treatment-naïve with compensated cirrhosis and	One tablet PO QD for 12 weeks		AASLD-IDSA (updated

Indication	Dosing Regimen	Maximum Dose	Reference
baseline NS5A RAS Y93H for velpatasvir			September 2021)

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.
** In clinical trials, prior NS5A inhibitor experience included daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir*
† In clinical trials, prior treatment experience included sofosbuvir with or without any of the following: peginterferon alfa/ribavirin, ribavirin, HCV NS3/4A protease inhibitor (boceprevir, simeprevir, or telaprevir)

D. Product Availability

Tablet: sofosbuvir 400 mg/velpatasvir 100 mg/voxilaprevir 100 mg

E. References

1. Vosevi Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; November 2019. Available at: www.vosevi.com. Accessed May 5, 2022.
2. 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 August 23, 2022.
3. Bourliere M, et al. Sofosbuvir, velpatasvir, and voxilaprevir for previously treated HCV infection. NEJM 2017;376:2134-46.
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 May 5, 2022.

i. 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
Policy created	08.17	09.17
3Q 2018 annual review: removed requirement for HBV verification; expanded duration of tx required for COC from 30 days to 60 days; required verification of genotype for COC; 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
2Q 2021 Annual review: **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; **Added** Appendix F		

Reviews, Revisions, and Approvals	Date	P&T Approval Date
(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; **added** pibrentasvir to criteria HCV genotype is 1, 2, 3, 4, 5 or 6, and member has previously been treated with an HCV regimen containing one of the following NS5A inhibitors; **updated** approval duration up to 24 weeks; Updated *Appendix B: Therapeutic Alternatives*		
Update: updated Appendix B therapeutic alternatives; removed the appendix E acceptable medical justification section for inability to use Mavyret as it overlaps with Vosevi clinical parameters for not using; references reviewed and updated.	9.15.21	
3Q 2022 Annual review: Initial criteria updated according to HFS criteria Added pathway to Vosevi approval for a specific treatment-naïve genotype 3 scenario per AASLD guideline with redirection to preferred Mavyret or Epclusa; clarified prior DAA regimen is a criterion for an HCV treatment-experienced member. Template changes applied to other diagnoses/indications and continued therapy section. References reviewed and updated.	9.22.22	

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.