

**Clinical Policy: Ledipasvir/Sofosbuvir (Harvoni)**

Reference Number: OH.PHAR.PPA.10

Effective Date: 07/17

Last Review Date: 09/17

Line of Business: Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**Description**

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

**FDA-Approved Indication**

Harvoni is indicated for the treatment of chronic hepatitis C virus (HCV) in:

- Adults with genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis;
- Adults with genotype 1 infection with decompensated cirrhosis, in combination with ribavirin;
- Adults with genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin;
- Pediatric patients 12 years of age and older or weighing at least 35 kg with genotype 1, 4, 5, or 6 without cirrhosis or with compensated cirrhosis.

**Policy/Criteria**

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

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Harvoni 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 multiple detectable HCV RNA levels in the last 6 months;
2. Confirmed HCV genotype is 1, 4, 5, or 6;
3. Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist;
4. Age  $\geq$  12 years or weight  $\geq$  35 kg;
5. Life expectancy  $\geq$  12 months with HCV treatment;
6. Documented sobriety from alcohol and illicit IV drugs for  $\geq$  6 months prior to starting therapy, if applicable;
7. Moderate to Advanced liver disease defined as a or b:
  - a. Moderate to Advanced fibrosis indicated by i or ii:
    - i. Liver biopsy showing a METAVIR score of F2 or equivalent (Knodell, Scheuer, Batts-Ludwig – F2; Ishak – F3);
    - ii. One serologic test and one radiologic test showing an equivalent score to METAVIR F2 per Appendix C;

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- b. Cirrhosis indicated by i, ii, or iii:
  - i. Hepatocellular carcinoma (HCC) - and the HCC is amenable to resection, ablation, or transplant;
  - ii. Liver biopsy showing a METAVIR score of F4 or equivalent (Knodell, Scheuer, Batts-Ludwig – F4; Ishak - F5/6);
  - iii. Both of the following:
    - a) One serologic test showing an equivalent score to METAVIR F4 per Appendix C;
    - b) One radiologic test showing an equivalent score to METAVIR F4 per Appendix C or other radiologic test showing evidence of cirrhosis (e.g., portal hypertension);
8. Prescribed regimen is consistent with an FDA or AASLD-IDSAs recommended regimen (*see Section V Dosage and Administration for reference*);
9. If member is without cirrhosis or with compensated cirrhosis (Child-Pugh A):  
Contraindication or intolerance to Mavyret;
10. Member agrees to participate in a medication adherence program meeting both of the following components:
  - 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;
11. Member is hepatitis B virus (HBV) negative, or if positive, documentation that concurrent HBV infection is being treated (e.g., tenofovir alafenamide, adefovir, entecavir), unless contraindicated or clinically significant adverse effects are experienced (*see Appendix B*);
12. If prescribed with ribavirin, at the time of request, member has none of the following contraindications:
  - a. Pregnancy;
  - b. For Rebetol: creatinine clearance < 50 mL/min;
13. Dose does not exceed ledipasvir/sofosbuvir 90 mg/400 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)

**B. Other diagnoses/indications**

1. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Harvoni for chronic hepatitis C virus infection and has received this medication for at least 30 days;
2. Member is responding positively to therapy (e.g. decreased HCV RNA level, no unacceptable toxicity);
3. Dose does not exceed ledipasvir/sofosbuvir 90 mg/400 mg per day (1 tablet/day).

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**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 CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**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 – CP.PHAR.57 or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

ALT: alanine aminotransferase	IDSAs: Infectious Diseases Society of America
APRI: AST to platelet ratio	MRE: magnetic resonance elastography
AASLD: American Association for the Study of Liver Diseases	NS3/4A, NS5A/B: nonstructural protein
CHC: chronic hepatitis C	Peg-IFN: pegylated interferon
FDA: Food and Drug Administration	PI: protease inhibitor
FIB-4: Fibrosis-4 index	PO: by mouth
HBeAg: hepatitis B virus envelope antigen	QD: once per day
HBV: hepatitis B virus	RBV: ribavirin
HCC: hepatocellular carcinoma	RNA: ribonucleic acid
HCV: hepatitis C virus	

*Appendix B: General Information*

- Hepatitis B Reactivation is a Black Box Warning for all direct-acting antiviral drugs for the treatment of HCV. The provider must provide either:
  - Documentation of absence of concurrent HBV infection as evidenced by laboratory values showing absence of hepatitis B virus envelope antigen (HBeAg) and HBV DNA;
  - Documentation that HBV co-infected patient may not be candidates for therapy as evidenced by one of the following:
    - Absence of HBeAg, HBV DNA less than 2,000 international units/mL, and alanine aminotransferase (ALT) level within 1 to 2 times the upper limit of normal;
    - HBeAg-positive and HBV DNA greater than 1,000,000 international units/mL and ALT level within 1 to 2 times the upper limit of normal;
  - Documentation that concurrent HBV infection is being treated (e.g., tenofovir alafenamide, adefovir, entecavir), unless contraindicated or clinically significant adverse effects are experienced.
- The 2016 AASLD/IDSA treatment guideline for HBV consider ALT levels <30 U/L for men and <19 U/L for women as upper limits of normal.

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- The 2016 AASLD/IDSA treatment guideline for HBV recommend adults with compensated cirrhosis, even with low levels of viremia (<2,000 IU/mL) be treated with antiviral therapy to reduce the risk of decompensation, regardless of ALT level. The recommendation extends to adults with decompensated cirrhosis be treated with antiviral therapy indefinitely regardless of HBV DNA level, HBeAg status, or ALT level to decrease the risk of worsening liver-related complications.

#### Appendix C: Approximate Scoring Equivalencies using METAVIR F2/F3/F4 as Reference

Fibrosis/ Cirrhosis	Serologic Tests*				Radiologic Tests†		Liver Biopsy‡	
	Fibro Test	FIBRO Spect II	APRI	FIB-4	FibroScan (kPa)	MRE (kPa)	METAVIR	Ishak
Moderate fibrosis	0.48 - 0.58	≥42	0.7 – 1.4	> 3.25	≥7.0	>3.2	F2	F3
Advanced fibrosis	≥0.59	≥42	>1.5	>3.25	≥9.5	≥4.11	F3	F4-5
Cirrhosis	≥0.75	≥42	>1.5	>3.25	≥12.0	≥4.71	F4	F5-6

#### \*Serologic tests:

FibroTest (available through Quest as FibroTest or LabCorp as FibroSure)

FIBROSpect II (available through Prometheus Laboratory)

APRI (AST to platelet ratio index)

FIB-4 (Fibrosis-4 index: includes age, AST level, platelet count)

#### †Radiologic tests:

FibroScan (transient elastography)

MRE (magnetic resonance elastography)

#### ‡Liver biopsy (histologic scoring systems):

METAVIR F2 is equivalent to Knodell, Scheuer, and Batts-Ludwig F2 and Ishak F3

METAVIR F3/F4 is equivalent to Knodell, Scheuer, and Batts-Ludwig F3/F4 and Ishak F4-5/F5-6

METAVIR fibrosis stages: F0 = no fibrosis; F1 = portal fibrosis without septa; F2 = few septa; F3 = numerous septa without cirrhosis; F4 = cirrhosis

#### 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
Daklinza	Daclatasvir				
Epclusa*	Velpatasvir	Sofosbuvir			
Harvoni*	Ledipasvir	Sofosbuvir			
Olysio				Simeprevir	
Sovaldi		Sofosbuvir			
Technivie*	Ombitasvir			Paritaprevir	Ritonavir

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Brand Name	Drug Class				
	NS5A Inhibitor	Nucleotide Analog NS5B Polymerase Inhibitor	Non-Nucleoside NS5B Palm Polymerase Inhibitor	NS3/4A Protease Inhibitor (PI)	CYP3A Inhibitor
Viekira XR/PAK*	Ombitasvir		Dasabuvir	Paritaprevir	Ritonavir
Zepatier*	Elbasvir			Grazoprevir	

\*Combination drugs

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose	Reference
Genotype 1 CHC:	<p>400 mg/90 mg by PO QD</p> <p>Treatment-naïve adult patients without cirrhosis AND whose HCV viral load is less than 6 million IU/mL for 8 weeks †</p> <p>Treatment-naïve adult patients without cirrhosis AND whose HCV viral load is greater than or equal to 6 million IU/mL for 12 weeks</p> <p>Treatment-experienced with peg-IFN/ RBV adult patients without cirrhosis for 12 weeks</p> <p>Treatment-experienced with NS3 PI*/peg-IFN/RBV adult patient without cirrhosis for 12 weeks</p> <p>Treatment-experienced (with NS3 PI*/peg-IFN/RBV or peg-IFN/RBV ) adult patients with compensated cirrhosis: Harvoni plus weight-based RBV for 12 weeks Or without RBV for 24 weeks † if RBV ineligible</p> <p>Treatment-experienced with sofosbuvir/ RBV with or without peg-IFN without cirrhosis: Harvoni plus weight-based RBV for 12 weeks</p> <p>Treatment-experienced with sofosbuvir/RBV with or without peg-IFN with compensated cirrhosis: Harvoni plus weight-based RBV for 24 weeks †</p>	<p>Harvoni (sofosbuvir 400mg / ledipasvir 90mg): 1 tablet per day</p>	<p>1) FDA-approved labeling</p> <p>2) ‡ AASLD-IDSA (updated 04/17)</p>

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Indication	Dosing Regimen	Maximum Dose	Reference
Genotype 1, 4 <sup>‡</sup> , 5 <sup>‡</sup> , or 6 <sup>‡</sup> CHC with decompensated cirrhosis: Adult patients who may or may not be candidates for liver transplantation, including those with hepatocellular carcinoma	400 mg/90 mg PO QD plus low initial dose of RBV (600mg, increased as tolerated) for 12 weeks Or without RBV for 24 weeks if RBV ineligible	Harvoni (sofosbuvir 400mg / ledipasvir 90mg): 1 tablet per day	1) FDA-approved labeling 2) † AASLD-IDSA (updated 04/17)
Genotype 1, 4, 5, or 6 CHC with decompensated cirrhosis: Adult patients in whom a previous sofosbuvir-containing regimen has failed <sup>‡</sup>	400 mg/90 mg PO QD with low initial dose of RBV (600mg, increased as tolerated) for 24 weeks	Harvoni (sofosbuvir 400mg / ledipasvir 90mg): 1 tablet per day	AASLD-IDSA (updated 04/17)
Genotype 1 or 4 CHC and post-liver transplantation: Treatment-naïve and treatment-experienced adult patients with or without compensated cirrhosis	400 mg/90 mg PO QD plus RBV for 12 weeks	Harvoni (sofosbuvir 400mg / ledipasvir 90mg): 1 tablet per day	1) FDA-approved labeling 2) AASLD-IDSA (updated 04/17)
Genotype 1 or 4 CHC and post-liver transplantation, who are intolerant to RBV or RBV ineligible: Treatment-naïve adult patients with HCV in the allograft, including compensated cirrhosis	400 mg/90 mg PO QD for 24 weeks	Harvoni (sofosbuvir 400mg / ledipasvir 90mg): 1 tablet per day	AASLD-IDSA (updated 04/17)
Genotype 1 or 4 CHC and post-liver transplantation: Treatment-naïve and treatment-	400 mg/90 mg PO QD plus low initial dose RBV (600mg, increased as tolerated) for 12 weeks	Harvoni (sofosbuvir 400mg / ledipasvir	AASLD-IDSA (updated 04/17)

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Indication	Dosing Regimen	Maximum Dose	Reference
experienced adult patients with decompensated cirrhosis		90mg): 1 tablet per day	
Genotype 1, 4, 5 or 6 CHC with HIV co-infection: Treatment-naïve adult patients without cirrhosis	400 mg / 90 mg PO QD for 12 weeks	Harvoni (sofosbuvir 400mg / ledipasvir 90mg): 1 tablet per day	1) FDA-approved labeling 2) AASLD- IDSA (updated 04/17)
Genotype 4, 5, or 6 CHC: Treatment-naïve adult patients with or without compensated cirrhosis	400 mg / 90 mg PO QD for 12 weeks	Harvoni (sofosbuvir 400mg / ledipasvir 90mg): 1 tablet per day	1) FDA-approved labeling 2) AASLD- IDSA (updated 04/17)
Genotype 4 CHC: Treatment-experienced adult patients without compensated cirrhosis	400 mg / 90 mg PO QD for 12 weeks	Harvoni (sofosbuvir 400mg / ledipasvir 90mg): 1 tablet per day	1) FDA-approved labeling 2) AASLD- IDSA (updated 04/17)
Genotype 4 CHC: Treatment-experienced adult patients with compensated cirrhosis	400 mg / 90 mg PO QD plus weight-based RBV for 12 weeks  Or without RBV for 24 weeks if RBV ineligible†	Harvoni (sofosbuvir 400mg / ledipasvir 90mg): 1 tablet per day	1) FDA-approved labeling 2) AASLD- IDSA (updated 04/17)
Genotype 5 or 6 CHC: Treatment-experienced adult patients with or without compensated cirrhosis	400 mg / 90 mg PO QD for 12 weeks	Harvoni (sofosbuvir 400mg / ledipasvir 90mg): 1 tablet per day	1) FDA-approved labeling 2) AASLD- IDSA (updated 04/17)

**Indication: Pediatric patients (≥ 12 years or weighing at least 35 kg) with chronic HCV infection**

Indication	Dosing Regimen	Maximum Dose	Reference
Genotype 1 CHC:	Treatment naïve pediatric patients (≥12 years of >35 kg) without cirrhosis regardless of baseline viral load for 12 weeks	Harvoni (sofosbuvir 400mg / ledipasvir 90mg): 1 tablet per day	FDA-approved labeling

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	<p>Treatment naïve adult or pediatric (<math>\geq 12</math> years of <math>&gt;35</math> kg) patients with compensated cirrhosis for 12 weeks</p> <p>Treatment-experienced with peg-IFN/RBV pediatric (<math>\geq 12</math> years of <math>\geq 35</math> kg) without cirrhosis for 12 weeks</p> <p>Treatment-experienced pediatric patients (<math>\geq 12</math> years of <math>&gt;35</math> kg) with compensated cirrhosis for 24 weeks</p>		
<p>Genotype 4, 5, or 6 CHC: Treatment-naïve or treatment-experienced pediatric (<math>\geq 12</math> years of <math>\geq 35</math> kg) patients with or without compensated cirrhosis</p>	400 mg / 90 mg PO QD for 12 weeks	Harvoni (sofosbuvir 400mg / ledipasvir 90mg): 1 tablet per 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.

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

## VI. Product Availability

Tablet: 400 mg sofosbuvir with 90 mg ledipasvir

## VII. References

1. Harvoni Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; April 2017. Available at [http://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/harvoni/harvoni\\_pi.pdf](http://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/harvoni/harvoni_pi.pdf). Accessed May 2017
2. American Association for the Study of Liver Diseases/ Infectious Disease Society of America (AASLD-IDSA). Recommendations for testing, managing, and treating hepatitis C. <http://www.hcvguidelines.org>. Accessed May, 2017.
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5. Hepatitis C Virus (HCV) FibroSure. Laboratory Corporation of America Holdings and Lexi-Comp, Inc. Available at <https://www.labcorp.com>. 2016. Accessed July 15, 2016.
6. Hepatitis C Virus (HCV) FibroTest-ActiTest Panel. Nichols Institute/Quest Diagnostics. Available at [http://education.questdiagnostics.com/physician\\_landing\\_page](http://education.questdiagnostics.com/physician_landing_page). 2016. Accessed July 15, 2016.
7. Hepatitis C Virus (HCV) FIBROSpect II. Prometheus Therapeutics and Diagnostics. Available



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at [http://www.prometheuslabs.com/Resources/Fibrospect/Fibrospect\\_II\\_Product\\_Detail\\_Sheet\\_FIB16005\\_04-16.pdf](http://www.prometheuslabs.com/Resources/Fibrospect/Fibrospect_II_Product_Detail_Sheet_FIB16005_04-16.pdf). April 2016. Accessed July 15, 2016.

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9. Bruix J and Sherman M. Management of hepatocellular carcinoma: An update. AASLD Practice Guideline. *Hepatology*. 2011; 53(3): 1020-22.
10. Terrault NA, Bzowej NH, Chang KM, et al. AASLD Guidelines for Treatment of Chronic Hepatitis B. *Hepatology* 2016; 62(1): 261-283.

Reviews, Revisions, and Approvals	Date	Approval Date
<p>New policy created, split from CP.PHAR.17 Hepatitis C Therapies policy.</p> <p>HCV RNA levels over six-month period added to confirm infection is chronic. Life expectancy “<math>\geq 12</math> months if HCC and awaiting transplant” is modified to indicate “<math>\geq 12</math> months with HCV therapy.”</p> <p>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).</p> <p>Methods to diagnose fibrosis/cirrhosis are modified to require presence of HCC, liver biopsy or a combination of one serologic and one radiologic test. Serologic and radiologic tests are updated and correlated with METAVIR per Appendix B. Removed creatinine clearance restriction – not a contraindication. Criteria added excluding post-liver transplantation unless regimens specifically designate. Dosing regimens are presented in Appendix D and E per AASLD guidelines and FDA-approved indications. The initial approval period is shortened to 8 weeks.</p>	08/16	09/16
<p>Added pediatric (<math>\geq 12</math> years or <math>\geq 35</math> kg) indication expansion for GT 1,4,5,6. Deleted positive response to therapy requirement per specialist feedback.</p>	04/17	
<p>Policy converted to new template. Added requirement for prevention of HBV reactivation. Consolidated appendix D and E into dosing and administration in section V; extended initial approval duration up to full regimen; deleted adherence requirement in continued therapy; added maximum dose requirement, 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.</p> <p>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.</p>	08/17	09/17

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#### **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

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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.

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