

Clinical Policy: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors

Reference Number: DE.PMN.14

Effective Date: 01.23 Last Review Date: 01.23 Line of Business: Medicaid

Revision Log

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

Description

The following agents contain a sodium-glucose co-transporter 2 (SGLT2) inhibitor and require prior authorization: canagliflozin (Invokana®), canagliflozin/metformin (Invokamet®, Invokamet® XR), dapagliflozin (Farxiga®), dapagliflozin/metformin (Xigduo® XR), dapagliflozin/saxagliptin (Qtern®), empagliflozin (Jardiance®), empagliflozin/linagliptin (Glyxambi®), empagliflozin/linagliptin/metformin (Trijardy™ XR), empagliflozin/metformin (Synjardy®, Synjardy® XR), and ertugliflozin/sitagliptin (Steglujan™).

FDA Approved Indication(s)

SGLT2 inhibitors are indicated as adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Dapagliflozin-, canagliflozin-, and empagliflozin-containing products are also indicated in adult patients with type 2 diabetes mellitus and established cardiovascular (CV) disease (or multiple CV risk factors [dapagliflozin only]) to:

- Reduce the risk of hospitalization for heart failure (HF) (dapagliflozin)
- Reduce the risk of major adverse CV events: CV death, nonfatal myocardial infarction, and nonfatal stroke (*canagliflozin*)
- Reduce the risk of CV death (*empagliflozin*)

Canagliflozin-containing products are additionally indicated to reduce the risk of end-stage kidney disease, doubling of serum creatinine, CV death, and hospitalization for HF in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria > 300 mg/day.

Farxiga is additionally indicated to:

- Reduce the risk of CV death and hospitalization for HF in adults with heart failure with reduced ejection fraction (HFrEF) (New York Heart Association [NYHA] class II-IV)
- Reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease (CKD) at risk of progression

Jardiance is additionally indicated to reduce the risk of CV death and hospitalization for HF in adults with HF.

Limitation(s) of use:

• SGLT2 inhibitors should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. SGLT2 inhibitors may increase the risk of diabetic ketoacidosis.

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- Farxiga is not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR less than 45 mL/min/1.73 m². Farxiga is likely to be ineffective in this setting based upon its mechanism of action.
- Farxiga and Xigduo XR are not recommended for the treatment of CKD in patients with polycystic kidney disease or patients requiring or with a recent history of immunosuppressive therapy for the treatment of kidney disease. Farxiga and Xigduo XR are not expected to be effective in these populations.
- Jardiance and Glyxambi are not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR less than 30 mL/min/1.73 m². They are likely to be ineffective in this setting based upon their mechanism of action.
- Steglujan has not been studied in patients with a history of pancreatitis.
- Because of the metformin component, the use of Xigduo XR is limited to adults with type 2 diabetes mellitus for all indications.

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 SGLT2 inhibitors are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

- A. Type 2 Diabetes Mellitus (must meet all):
 - 1. Diagnosis of type 2 diabetes mellitus;
 - 2. Age \geq 18 years;
 - 3. Member meets one of the following (a or b):
 - a. Failure of ≥ 3 consecutive months of metformin, unless contraindicated or clinically significant adverse effects are experienced;
 - b. For antidiabetic medication-naïve members, requested agent is approvable if intended for concurrent use with metformin due to HbA1c \geq 8.5% (drawn within the past 3 months);
 - 4. Request meets one of the following (a, b, or c):
 - a. Request is for a preferred agent (i.e. Farxiga, Jardiance, Invokana, Invokamet, Synjardy, Xigduo XR) unless clinically significant adverse effects are experienced or both are contraindicated;
 - b. Member has established CV disease (e.g., ASCVD or HF) or diabetic nephropathy/CKD, and request is for a formulary dapagliflozin- or empagliflozin-containing product, unless clinically significant adverse effects are experienced or all are contraindicated:
 - c. Member has multiple risk factors for CV disease (*see Appendix D*), and request is for a formulary dapaglifozin-containing product, unless contraindicated or clinically significant adverse effects are experienced;
 - 5. Requests for Glyxambi, Steglatro, Qtern, Synjardy XR, Segluromet, Trijardy XR, Steglujan: failure of an adequate trial of at least two preferred* FDA-approved drugs for the indication and/or drugs that are considered the standard of care within the same drug class on the PDL, when such agents exist, at maximum indicated doses,

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unless clinically significant adverse effect are experienced, or all are contraindicated; *Generic is preferred, if available, and brand is not the preferred agent

6. Dose does not exceed the FDA-approved maximum recommended dose (*see Section V*).

Approval duration: 12 months

B. Heart Failure (must meet all):

- 1. Diagnosis of HF of NYHA Class II, III, or IV;
- 2. Request is for Farxiga or Jardiance;
- 3. Prescribed by or in consultation with a cardiologist;
- 4. Age \geq 18 years;
- 5. If request is for Farxiga, member has HFrEF as evidenced by left ventricular ejection fraction (LVEF) \le 40\%;
- 6. Member does not have a diagnosis of type 1 diabetes mellitus;
- 7. Dose does not exceed 10 mg (1 tablet) per day.

Approval duration: 12 months

C. Chronic Kidney Disease (must meet all):

- 1. Diagnosis of CKD;
- 2. Request is for Farxiga;
- 3. Age \geq 18 years;
- 4. Both of the following (a and b):
 - a. eGFR between 25 and 75 mL/min/1.73 m²;
 - b. Urine albumin creatinine ratio (UACR) \geq 200 mg/g;
- 5. Member does not have a diagnosis of type 1 diabetes mellitus or polycystic kidney disease;
- 6. Member has not received immunosuppressive therapy for the treatment of kidney disease in the past 6 months;
- 7. Member is currently receiving an angiotensin converting enzyme inhibitor or angiotensin receptor blocker at maximally tolerated doses for ≥ 4 weeks, unless clinically significant adverse effects are experienced or all are contraindicated;
- 8. Dose does not exceed 10 mg (1 tablet) per day.

Approval duration: 12 months

D. 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.PMN.53 for Medicaid.

II. Continued Therapy

A. Type 2 Diabetes Mellitus (must meet all):

- 1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
- 2. Member is responding positively to therapy;
- 3. If request is for a dose increase, new dose does not exceed the FDA-approved maximum recommended dose (*see Section V*).

Approval duration: 12 months

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B. Heart Failure (must meet all):

- 1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Farxiga or Jardiance for HFrEF and has received this medication for at least 30 days;
- 2. Request is for Farxiga or Jardiance;
- 3. Member is responding positively to therapy;
- 4. If request is for a dose increase, new dose does not exceed 10 mg (1 tablet) per day.

Approval duration: 12 months

C. Chronic Kidney Disease (must meet all):

- 1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
- 2. Request is for Farxiga;
- 3. Member is responding positively to therapy;
- 4. If request is for a dose increase, new dose does not exceed 10 mg (1 tablet) per day.

Approval duration: 12 months

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or

2. 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.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

AACE: American Association of Clinical Endocrinologists

ACE: American College of Endocrinology

ADA: American Diabetes Association

ASCVD: atherosclerotic cardiovascular

disease

CKD: chronic kidney disease

CV: cardiovascular

DPP-4: dipeptidyl peptidase-4

eGFR: estimated glomerular filtration rate

ER: extended-release

FDA: Food and Drug Administration

GLP-1: glucagon-like peptide-1 HbA1c: glycated hemoglobin

HF: heart failure

HFrEF: heart failure with reduced ejection

fraction

IR: immediate-release

LVEF: left ventricular ejection fraction SGLT2: sodium-glucose co-transporter 2 UACR: urine albumin creatinine ratio

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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/	
0		Maximum Dose	
metformin	Regular-release (Glucophage): 500 mg PO	Regular-release:	
(Fortamet [®] ,	BID or 850 mg PO QD; increase as needed in	2,550 mg/day	
Glucophage®,	increments of 500 mg/week or 850 mg every 2		
Glucophage® XR,	weeks		
Glumetza®)			
	Extended-release:	Extended-release:	
	• Fortamet, Glumetza: 1,000 mg PO QD;	2,000 mg/day	
	increase as needed in increments of 500		
	mg/week		
	• Glucophage XR: 500 mg PO QD; increase		
	as needed in increments of 500 mg/week		
Segluromet	Individualized dose PO BID	15/2,000 mg/day	
(ertugliflozin/			
metformin)			
Steglatro	5 mg PO QD	15 mg/day	
(ertugliflozin)			
Angiotensin Convert	ing Enzyme Inhibitors	,	
captopril	Initially, 6.25 mg PO 3 times daily, then	450 mg/day	
(Capoten®)	increase to 50 mg PO 3 times daily if tolerated.		
enalapril (Vasotec®,	Initially, 2.5 mg PO twice daily, then increase	40 mg/day	
Epaned®)	to 10 to 20 mg PO twice daily if tolerated.		
fosinopril	Initially, 5 to 10 mg PO once daily, then	80 mg/day	
(Monopril®)	increase to 40 mg/day if tolerated.		
lisinopril (Prinivil®,	Initially, 2.5 to 5 mg PO once daily, then	80 mg/day	
Zestril [®] , Qbrelis [®])	increase to 20 to 40 mg/day if tolerated.	1.6 /1	
perindopril	Initially, 4 mg PO once daily for 2 weeks, then	16 mg/day	
(Aceon®)	increase to 8 mg PO once daily if tolerated.	00 /1	
quinapril	Initially, 5 mg PO twice daily, then increase to	80 mg/day	
(Accupril®)	20 mg PO twice daily of tolerated.	20 /1	
ramipril (Altace®)	Initially, 2.5 mg PO once daily. Gradually	20 mg/day	
	titrate to 5 mg/day PO, then increase if		
	tolerated to the target dosage of 10 mg/day PO,		
trandalanril	given in 1 to 2 divided doses.	Q ma/day	
trandolapril (Mavik [®])	Initially, 1 mg PO once daily, then increase to 4 mg/day if tolerated.	8 mg/day	
Angiotensin Receptor			
candesartan	Initially, 4 to 8 mg PO once daily, then	32 mg/day	
(Atacand®)	increase to 32 mg/day if tolerated.	32 mg/day	
losartan (Cozaar®)	Initially, 25 to 50 mg PO once daily, then	100 mg/day	
iosarian (Cozaar)	increase to 50 to 150 mg/day if tolerated.	100 mg/uay	
	mercase to 50 to 150 mg/day if tolerated.	1	

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Dosing Regimen	Dose Limit/			
00 PO 1 1	Maximum Dose			
80 mg PO once daily	80 mg/day			
Initially, 20 to 40 mg PO twice daily, then	320 mg/day			
increase dose to 160 mg PO twice daily if				
	T			
The recommended starting dose is 49/51 mg	194/206 mg/day			
(sacubitril/valsartan) PO BID. Double the dose				
after 2 to 4 weeks to the target maintenance				
dose of 97/103 mg (sacubitril/valsartan) BID,				
as tolerated by the patient.				
Beta Blockers Recommended for HF				
Initially, 1.25 mg PO QD for 48 hours, then	10 mg/day			
	Immediate-			
for 2 weeks. Dosage may be subsequently	release: 100			
increased to 6.25, 12.5, and then 25 mg PO	mg/day			
BID over successive intervals of at least 2				
weeks.				
Extended-release: Initially, 10 mg PO QD for	Extended-release:			
2 weeks. Dosage may be subsequently	80 mg/day			
25 mg PO QD for 2 weeks in patients with	200 mg/day			
NYHA class II HF, or 12.5 mg PO QD in				
patients with more severe HF. Double the dose				
every 2 weeks as tolerated, up to the target				
	Initially, 20 to 40 mg PO twice daily, then increase dose to 160 mg PO twice daily if tolerated. **Neprilysin Inhibitor/Angiotensin Receptor Blog (sacubitril/valsartan) PO BID. Double the dose after 2 to 4 weeks to the target maintenance dose of 97/103 mg (sacubitril/valsartan) BID, as tolerated by the patient. **Memended for HF** Initially, 1.25 mg PO QD for 48 hours, then 2.5 mg QD for the first month, then 5 mg QD. Immediate-release: Initially, 3.125 mg PO BID for 2 weeks. Dosage may be subsequently increased to 6.25, 12.5, and then 25 mg PO BID over successive intervals of at least 2 weeks. Extended-release: Initially, 10 mg PO QD for 2 weeks. Dosage may be subsequently increased to 20, 40, and then 80 mg PO QD over successive intervals of at least 2 weeks. 25 mg PO QD for 2 weeks in patients with NYHA class II HF, or 12.5 mg PO QD in patients with more severe HF. Double the dose			

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):
 - o History of serious hypersensitivity reaction to the requested drug product;
 - Moderate to severe renal impairment*, end-stage renal disease, or dialysis;
 *Minimum degree of renal impairment varies per agent; refer to individual prescribing information
 - Acute or chronic metabolic acidosis, including diabetic ketoacidosis (*metformin-containing products only*);
- Boxed warning(s): lactic acidosis (*metformin-containing products only*).

Appendix D: General Information

• Per the American Diabetes Association (ADA) and American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) guidelines:

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- o Metformin is recommended for all patients with type 2 diabetes. Monotherapy is recommended for most patients; however:
 - Starting with dual therapy (i.e., metformin plus another agent, such as a sulfonylurea, thiazolidinedione, dipeptidyl peptidase-4 [DPP-4] inhibitor, SGLT2 inhibitor, glucagon-like peptide 1 [GLP-1] receptor agonist, or basal insulin) may be considered for patients with baseline HbA1c ≥ 1.5% above their target per the ADA (≥ 7.5% per the AACE/ACE). According to the ADA, a reasonable HbA1c target for many non-pregnant adults is < 7% (≤ 6.5% per the AACE/ACE).</p>
 - Starting with combination therapy with insulin may be considered for patients with baseline HbA1c > 10% per the ADA (> 9% if symptoms are present per the AACE/ACE).
- o If the target HbA1c is not achieved after approximately 3 months of monotherapy, dual therapy should be initiated. If dual therapy is inadequate after 3 months, triple therapy should be initiated. Finally, if triple therapy fails to bring a patient to goal, combination therapy with insulin should be initiated. Each non-insulin agent added to initial therapy can lower HbA1c by 0.7-1%.
- Although Invokana is currently the only SGLT2 inhibitor with a labeled indication for diabetic nephropathy, Farxiga and Jardiance have also demonstrated renal protective effects. The ADA guidelines recommend SGLT2 inhibitors be considered when treating type 2 diabetic patients with renal concerns, noting that Farxiga, Jardiance, and Invokana all confer renal benefit, with no preference for one over the other;
 - o Farxiga DECLARE-TIMI 58: The cardiorenal secondary composite outcome (sustained decline of at least 40% in eGFR to less than 60 mL/min/1.73 m2, end stage renal disease (ESRD), or death from renal or CV causes) was significantly reduced with Farxiga compared to placebo (HR 0.76, 95% CI 0.67-0.87; p < 0.0001); excluding death from CV causes, the HR for the renal-specific outcome was 0.53 (95% CI 0.43-0.66; p < 0.0001). There was a 46% reduction in sustained decline in eGFR by at least 40% to less than 60 mL/min/1.73 m2 (120 [1.4% vs 221 [2.6%]; HR 0.54 [95% CI 0.43-0.67]; p < 0.0001). The risk of ESRD or renal death was also lower in the Farxiga group than in the placebo group (11 [0.1%] vs 27 [0.3%]; HR 0.41 [95% CI 0.20-0.82]; p = 0.012).
 - O Jardiance EMPA-REG Outcome: Analysis of secondary outcomes yielded a reduction of risk for incident of or worsening nephropathy (HR 0.61 [95% CI 0.53-0.70]), progression to urine albumin to creatinine ratio (UACR) > 300 mg/g (HR 0.62 [95% CI 0.54-0.72]), composite consisting doubling of serum creatinine, initiation of renal replacement therapy, and death from ESRD (HR 0.54 [95% CI 0.40-0.75]).
- Examples of CV risk factors may include but are not limited to: dyslipidemia, hypertension, obesity, a family history of premature coronary disease, and smoking.
- According to the ADA, ASCVD includes coronary heart disease, cerebrovascular disease, or peripheral arterial disease presumed to be of atherosclerotic origin. Indicators of high ASCVD risk are age ≥ 65 years with coronary, carotid, or lower-extremity artery stenosis > 50% or left ventricular hypertrophy.
- Although Farxiga and Invokana are the only SGLT2 inhibitors with labeled indications
 for reducing the risk of HHF, Jardiance has also been shown to reduce the risk of HHF.
 The ADA guidelines acknowledge Farxiga along with Jardiance and Invokana as agents
 which reduce the risk of HHF, without a preference for one agent over the other. Any of

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the three can be used in T2DM patients with established HF; however, the guidelines recommend only Jardiance or Invokana for patients with established ASCVD.

- O Jardiance EMPA-REG Outcome, patients with established ASCVD: The primary outcome (composite of death from CV causes, nonfatal MI, or non-fatal stroke) was reduced with Jardiance compared to placebo (HR 0.86, 95% CI 0.74 0.99; p = 0.04). Analysis of secondary outcomes yielded a reduction in hospitalization for heart failure when treated with Jardiance compared to placebo (HR 0.65, 95% CI 0.50 0.85; p = 0.002).
- o Invokana CANVAS Program, patients with established ASCVD or multiple ASCVD risk factors: The primary outcome (composite of death from CV causes, nonfatal MI or nonfatal stroke) was reduced with Invokana compared to placebo (HR 0.86, 95% CI 0.75-0.97; p = 0.02). Analysis of secondary outcomes yielded a reduction in hospitalization for heart failure when treated with Invokana compared to placebo (HR 0.67, 95% CI 0.52-0.87).
- In August 2020, the FDA removed the boxed warning regarding the risk of leg and foot amputations from the canagliflozin prescribing information. Although the risk is still present (and continues to be described in the Warnings and Precautions section of the prescribing information), the FDA notes the significantly enhanced benefit of canagliflozin (e.g., effects in heart and kidney disease) relative to said risk, which safety information from recent trials suggest is lower than previously described.

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose	
Farxiga (dapagliflozin)	Diabetes: 5 mg PO QD	10 mg/day	
	HFrEF, CKD: 10 mg PO QD		
Glyxambi (empagliflozin/linagliptin)	One 10/5 mg tablet PO QD	25/5 mg/day	
Invokamet (canagliflozin/metformin)	One 50/500 mg tablet PO	300/2,000 mg/day	
	BID		
Invokamet XR	Two 50/500 mg tablets PO	300/2,000 mg/day	
(canagliflozin/metformin)	QD		
Invokana (canagliflozin)	100 mg PO QD	300 mg/day	
Jardiance (empagliflozin)	10 mg PO QD	Diabetes: 25	
		mg/day	
		HF: 10 mg/day	
Qtern (dapagliflozin/saxagliptin)	One 5/5 mg tablet PO QD	10/5 mg/day	
Steglujan (ertugliflozin/sitagliptin)	One 5/100 mg tablet PO QD	15/100 mg/day	
Synjardy (empagliflozin/metformin)	Individualized dose PO BID	25/2,000 mg/day	
Synjardy XR	Individualized dose PO QD	25/2,000 mg/day	
(empagliflozin/metformin)			
Trijardy XR	Individualized dose PO QD	25/5/2,000 mg/day	
(empagliflozin/linagliptin/			
metformin)			
Xigduo XR	Individualized dose PO QD	10/2,000 mg/day	
(dapagliflozin/metformin)			

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VI. Product Availability

Drug Name	Availability		
Farxiga (dapagliflozin)	Tablets: 5 mg, 10 mg		
Glyxambi (empagliflozin/linagliptin)	Tablets: 10/5 mg, 25/5 mg		
Invokamet (canagliflozin/metformin)	Tablets: 50/500 mg, 50/1,000 mg, 150/500 mg,		
	150/1,000 mg		
Invokamet XR	Tablets: 50/500 mg, 50/1,000 mg, 150/500 mg,		
(canagliflozin/metformin)	150/1,000 mg		
Invokana (canagliflozin)	Tablets: 100 mg, 300 mg		
Jardiance (empagliflozin)	Tablets: 10 mg, 25 mg		
Qtern (dapagliflozin/saxagliptin)	Tablet: 5/5 mg, 10/5 mg		
Steglujan (ertugliflozin/sitagliptin)	Tablets: 5/100 mg, 15/100 mg		
Synjardy (empagliflozin/metformin)	Tablets: 5/500 mg, 5/1,000 mg, 12.5/500 mg,		
	12.5/1,000 mg		
Synjardy XR	Tablets: 5/1,000 mg, 10/1,000 mg, 12.5/1,000 mg,		
(empagliflozin/metformin)	25/1,000 mg		
Trijardy XR	Tablets: 5/2.5/1,000 mg, 10/5/1,000 mg,		
(empagliflozin/linagliptin/	12.5/2.5/1,000 mg, 25/5/1,000 mg		
metformin)			
Xigduo XR	Tablets: 2.5/1,000 mg, 5/500 mg, 5/1,000 mg,		
(dapagliflozin/metformin)	10/500 mg, 10/1,000 mg		

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	09.22	11.22

CLINICAL POLICY Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors

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.

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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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