

Clinical Policy: Lomitapide (Juxtapid)

Reference Number: CP.PHAR.283

Effective Date: 10.01.16

Last Review Date: 02.26

Line of Business: Commercial, Medicaid

[Revision Log](#)

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

Description

Lomitapide (Juxtapid[®]) is a microsomal triglyceride transfer protein inhibitor.

FDA Approved Indication(s)

Juxtapid is indicated as an adjunct to a low-fat diet and exercise and other low-density lipoprotein cholesterol (LDL-C) therapies to reduce LDL-C in adults and pediatric patients aged 2 years and older with homozygous familial hypercholesterolemia (HoFH).

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

I. Initial Approval Criteria**A. Homozygous Familial Hypercholesterolemia (must meet all):**

1. Diagnosis of HoFH defined as one of the following (a, b, or c):
 - a. Genetic mutation indicating HoFH (e.g., mutations in low density lipoprotein receptor [LDLR] gene, proprotein convertase subtilisin kexin 9 [PCSK9] gene, apo B gene, low density lipoprotein receptor adaptor protein 1 [LDLRAP1] gene);
 - b. Treated LDL-C \geq 300 mg/dL or non-HDL-C \geq 330 mg/dL;
 - c. Untreated LDL-C \geq 400 mg/dL, and one of the following (i or ii):
 - i. Tendinous or cutaneous xanthoma prior to age 10 years;
 - ii. Evidence of familial hypercholesterolemia (HeFH or HoFH) in at least one parent (e.g., documented history of elevated LDL-C \geq 190 mg/dL prior to lipid-lowering therapy);
2. Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist;
3. Age \geq 2 years;
4. Member meets one of the following (a, b, c, or d):
 - a. Age \geq 2 years and \leq 6 years;
 - b. If age \geq 7 years and \leq 9 years, LDL-C \geq 130 mg/dL within the last 60 days despite statin therapy, unless member has a contraindication (*see Appendix F*) or history of intolerance to each such therapy;

- c. If age ≥ 10 years and ≤ 17 years, LDL-C ≥ 130 mg/dL within the last 60 days despite statin and ezetimibe therapy, unless member has a contraindication (*see Appendix F*) or history of intolerance to each such therapy;
 - d. If age ≥ 18 years, documentation of recent (within the last 60 days) LDL-C of one of the following (i or ii):
 - i. ≥ 70 mg/dL;
 - ii. ≥ 55 mg/dL if member has ASCVD and is at very high risk (*see Appendix H*);
5. For members ≥ 18 years old and on statin therapy, both of the following (a and b):
- a. Juxtapid is prescribed in conjunction with a statin at the maximally tolerated dose;
 - b. Member has been adherent for at least the last 8 weeks to maximally tolerated doses of one of the following statin regimens (i or ii):
 - i. A high intensity statin (*see Appendix D*);
 - ii. A moderate or low intensity statin (*see Appendix D*), and member has one of the following (1 or 2):
 - 1) Previous use of one high-intensity statin (i.e., atorvastatin ≥ 40 mg daily; rosuvastatin ≥ 20 mg daily [as a single-entity or as a combination product]) for a minimum of 8 weeks continuously and LDL-C remained ≥ 70 mg/dL;
 - 2) Member has tried both rosuvastatin and atorvastatin and has experienced skeletal-muscle related symptoms on both agents which also resolved upon discontinuation;
6. For members ≥ 18 years old and not on statin therapy, member meets one of the following (a or b):
- a. Statin therapy is contraindicated per Appendix E;
 - b. For members who are statin intolerant, both of the following (i and ii):
 - i. Member has tried at least two statins, one of which must be hydrophilic (pravastatin, fluvastatin, or rosuvastatin);
 - ii. Member meets one of the following (1 or 2):
 - 1) Member has documented statin risk factors (*see Appendix F*);
 - 2) Member is statin intolerant due to statin-associated muscle symptoms (SAMS) and meets both of the following (a and b):
 - a) Documentation of intolerable SAMS persisting at least two weeks, which disappeared with discontinuing the statin therapy and recurred with a statin re-challenge;
 - b) Documentation of re-challenge with titration from lowest possible dose and/or intermittent dosing frequency (e.g., 1 to 3 times weekly);
7. If age ≥ 18 years, member has been adherent to ezetimibe therapy used concomitantly with a statin at the maximally tolerated dose for at least the last 4 months, unless contraindicated per *Appendix E* or member has a history of ezetimibe intolerance (e.g., associated diarrhea or upper respiratory tract infection);
8. Failure of an 8 week trial of a preferred PCSK9 inhibitor, if applicable, unless contraindicated or clinically significant adverse effects are experienced;
**Prior authorization may be required for PCSK9 inhibitors*
9. Treatment plan does not include coadministration with Leqvio[®], Repatha[®], or Praluent[®];

10. Dose does not exceed both of the following (a and b):

- a. One of the following (i, ii, or iii):
 - i. Age \geq 2 years to \leq 10 years: 20 mg per day;
 - ii. Age \geq 11 years to \leq 17 years: 40 mg per day;
 - iii. Age \geq 18 years: 60 mg per day;
- b. 2 capsules per day.

Approval duration: 12 months

B. 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.CPA.190 for commercial and 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.CPA.190 for commercial and 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.CPA.09 for commercial and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Homozygous Familial Hypercholesterolemia (must meet all):

1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. 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*);
2. If statin tolerant, documentation of adherence to a statin at the maximally tolerated dose;
3. Member is responding positively to therapy as evidenced by lab results within the last 3 months showing an LDL-C reduction since initiation of Juxtapid therapy;
4. Treatment plan does not include coadministration with Leqvio, Repatha, or Praluent;
5. If request is for a dose increase, new dose does not exceed (a and b):
 - a. One of the following (i, ii, or iii):
 - i. Age \geq 2 years to \leq 10 years: 20 mg per day;
 - ii. Age \geq 11 years to \leq 17 years: 40 mg per day;
 - iii. Age \geq 18 years: 60 mg per day;
 - b. 2 capsules per day.

Approval duration: 12 months

B. 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.CPA.190 for commercial and 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.CPA.190 for commercial and 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.CPA.09 for commercial and 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.CPA.09 for commercial and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALT: alanine aminotransferase	LDL-C: low density lipoprotein cholesterol
apoB: apolipoprotein B	LDLR: low density lipoprotein receptor
ASCVD: atherosclerotic cardiovascular disease	LDLRAP1: low density lipoprotein receptor adaptor protein 1
FDA: Food and Drug Administration	PCSK9: proprotein convertase subtilisin kexin 9
HDL-C: high-density lipoprotein cholesterol	SAMS: statin-associated muscle symptoms
HeFH: heterozygous familial hypercholesterolemia	TC: total cholesterol
HoFH: homozygous familial hypercholesterolemia	ULN: upper limit of normal

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
ezetimibe/simvastatin (Vytorin [®])	10/40 mg PO QD	10 mg-40 mg/day (use of the 10/80 mg dose is restricted to patients who have been taking simvastatin 80 mg for

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
		12 months or more without evidence of muscle toxicity)
ezetimibe (Zetia [®])	10 mg PO QD	10 mg/day
atorvastatin (Lipitor [®])	40 mg PO QD	80 mg/day
rosuvastatin (Crestor [®])	5 - 40 mg PO QD	Adults: 40 mg/day Pediatrics: 20 mg/day
pravastatin	10 - 80 mg PO QD	80 mg/day
fluvastatin (Lescol [®])	20 - 80 mg PO QD	80 mg/day
PCSK9 Inhibitors		
Repatha [®] (evolocumab)	420 mg SC once monthly	420 mg/month
Praluent [®] (alirocumab)	150 mg SC every 2 weeks	300 mg/month

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):
 - Pregnancy
 - Concomitant use with strong or moderate CYP3A4 inhibitors
 - Moderate or severe hepatic impairment (Child-Pugh B or C) or active liver disease, including unexplained persistent elevations of serum transaminases
- Boxed warning(s): risk of hepatotoxicity

Appendix D: High and Moderate Intensity Daily Statin Therapy for Adults

<p>High Intensity Statin Therapy <i>Daily dose shown to lower LDL-C, on average, by approximately ≥ 50%</i></p> <ul style="list-style-type: none"> • Atorvastatin 40-80 mg • Rosuvastatin 20-40 mg
<p>Moderate Intensity Statin Therapy <i>Daily dose shown to lower LDL-C, on average, by approximately 30% to 50%</i></p> <ul style="list-style-type: none"> • Atorvastatin 10-20 mg • Fluvastatin XL 80 mg • Fluvastatin 40 mg BID • Lovastatin 40 mg • Pitavastatin 1-4 mg • Pravastatin 40-80 mg • Rosuvastatin 5-10 mg • Simvastatin 20-40 mg
<p>Low Intensity Statin Therapy <i>Daily dose shown to lower LDL-C, on average, by < 30%</i></p> <ul style="list-style-type: none"> • Simvastatin 10 mg • Pravastatin 10–20 mg • Lovastatin 20 mg • Fluvastatin 20–40 mg

Appendix E: Statin and Ezetimibe Contraindications

Statin
<ul style="list-style-type: none"> Decompensated liver disease (development of jaundice, ascites, variceal bleeding, encephalopathy) Laboratory-confirmed acute liver injury or rhabdomyolysis resulting from statin treatment Pregnancy*, actively trying to become pregnant, or nursing Immune-mediated hypersensitivity to the HMG-CoA reductase inhibitor drug class (statins) as evidenced by an allergic reaction occurring with at least TWO different statins
Ezetimibe
<ul style="list-style-type: none"> Moderate or severe hepatic impairment [Child-Pugh classes B and C] Hypersensitivity to ezetimibe (e.g., anaphylaxis, angioedema, rash, urticaria)

**In July 2021, the FDA requested removal of the contraindication against use of statins in pregnant women. Because the benefits of statins may include prevention of serious or potentially fatal events in a small group of very high-risk pregnant patients, contraindicating these drugs in all pregnant women is not appropriate. <https://www.fda.gov/safety/medical-product-safety-information/statins-drug-safety-communication-fda-requests-removal-strongest-warning-against-using-cholesterol>*

Appendix F: Statin Risk Factors

Statin Risk Factors
<ul style="list-style-type: none"> Multiple or serious comorbidities, including impaired renal or hepatic function Unexplained alanine transaminase (ALT) elevations > 3 times upper limit of normal, or active liver disease Concomitant use of drugs adversely affecting statin metabolism Age > 75 years, or history of hemorrhagic stroke Asian ancestry

Appendix G: General Information

- Because of the risk of hepatotoxicity, Juxtapid is available only through a Risk Evaluation and Mitigation Strategy (REMS) program called the Juxtapid REMS Program.
- Low density lipoprotein receptor adaptor protein 1 (LDLRAP1) gene is also known as autosomal recessive hypercholesterolemia (ARH) adaptor protein 1 gene.
- The diagnosis of SAMS is often on the basis of clinical criteria. Typical SAMS include muscle pain and aching (myalgia), cramps, and weakness. Symptoms are usually bilateral and involve large muscle groups, including the thigh, buttock, back, and shoulder girdle musculature. In contrast, cramping is usually unilateral and may involve small muscles of the hands and feet. Symptoms may be more frequent in physically active patients. Symptoms often appear early after starting statin therapy or after an increase in dose and usually resolve or start to dissipate within weeks after cessation of therapy, although it may take several months for symptoms to totally resolve. Persistence of symptoms for more than 2 months after drug cessation should prompt a search for other causes or for underlying muscle disease possibly provoked by statin therapy. The reappearance of

symptoms with statin rechallenge and their disappearance with drug cessation offers the best evidence that the symptoms are truly SAMS.

- Pravastatin, fluvastatin, and rosuvastatin are hydrophilic statins which have been reported to confer fewer adverse drug reactions than lipophilic statins.

Appendix H: Criteria for Defining Patients at Very High Risk of Future ASCVD Events²

Very high risk is defined as having either a history of multiple major ASCVD events **OR** 1 major ASCVD event and multiple high-risk conditions:

- Major ASCVD events:
 - Recent acute coronary syndrome (within the past 12 months)
 - History of myocardial infarction (other than recent acute coronary syndrome event listed above)
 - History of ischemic stroke
 - Symptomatic peripheral artery disease (history of claudication with ankle-brachial index < 0.85 or previous revascularization or amputation)
- High-risk conditions:
 - Age ≥ 65 years
 - FH
 - History of prior coronary artery bypass surgery or percutaneous coronary intervention outside of the major ASCVD event(s)
 - Diabetes
 - Hypertension
 - Chronic kidney disease (estimated glomerular filtration rate [eGFR] 15-59 mL/min/1.73 m²)
 - Current tobacco smoking
 - Persistently elevated LDL-C (LDL-C ≥ 100 mg/dL [≥ 2.6 mmol/L]) despite maximally tolerated statin therapy and ezetimibe
 - History of congestive heart failure

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
HoFH	Age ≥ 2 to ≤ 10 years: 2 mg PO QD – for 8 weeks, then 5 mg, 10 mg PO QD – for 3 weeks for each dose, then 20 mg PO QD thereafter Age ≥ 11 to ≤ 15 years: 2 mg PO QD – for 4 weeks, then 5 mg, 10 mg, 20 mg PO QD – for 3 weeks for each dose, then 40 mg PO QD thereafter Age ≥ 16 to ≤ 17 years: 5 mg PO QD – for 4 weeks, then 10 mg, 20 mg PO QD – for 3 weeks for each dose, then	Age ≥ 2 years to ≤ 10 years: 20 mg/day Age ≥ 11 years to ≤ 17 years: 40 mg/day Adults: 60 mg/day

Indication	Dosing Regimen	Maximum Dose
	<p>40 mg PO QD thereafter</p> <p>Age ≥ 18 years: 5 mg PO QD – for 2 weeks, then 10 mg, 20 mg, 40 mg PO QD – for 3 weeks for each dose, then 60 mg PO QD thereafter</p> <ul style="list-style-type: none"> • The dosage of Juxtapid may be further titrated according to target LDL-C level, safety, and tolerability, not to exceed the maximum recommended dose • Modify dosing for patients taking concomitant cytochrome P450 (CYP) 3A4 inhibitors, renal impairment, or baseline hepatic impairment. • Dose adjustments are also required for patients who develop transaminase values at least 3x ULN during Juxtapid treatment. 	

VI. Product Availability

Capsules: 2 mg, 5 mg, 10 mg, 20 mg, 30 mg

VII. References

1. Juxtapid Prescribing Information. Parma, Italy: Chiesi Farmaceutici; February 2026. Available at: www.juxtapid.com. Accessed March 6, 2026.
Guidelines
2. Grundy SM, Stone NJ, Bailey AL, et al. 2018 ACC/AHA/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol* 2018;Nov 10:[Epub ahead of print].
3. Lloyd-Jones DM, Morris PB, Minissian MB, et al. 2017 Focused update of the 2016 ACC expert consensus decision pathway on the role of non-statin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk. *J Am Coll Cardiol* 2017; 70(14):1785-1822. <http://dx.doi.org/10.1016/j.jacc.2017.07.745>.
4. Lloyd-Jones DM, Morris PB, Ballntyne CM, et al. 2022 ACC expert consensus decision pathway on the role of nonstatin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk: A report of the American College of Cardiology Solution Set Oversight Committee. *J Am Coll Cardiol*. 2022; 80 (14): 1366-1418.
5. Jacobson TA, et al. National Lipid Association recommendations for patient-centered management of dyslipidemia: part 1 – full report. *Journal of Clinical Lipidology*. March-April 2015; 9(2): 129-169. <http://dx.doi.org/10.1016/j.jacl.2015.02.003>.
6. Goldberg AC, Hopkins PN, Toth PP, et al. Familial hypercholesterolemia: screening, diagnosis and management of pediatric and adult patients: clinical guidance from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. *Journal of Clinical Lipidology*. June 2011; 5(3S): 1-15

7. Mach F, Baigent C, Catapano AL, et al; ESC Scientific Document Group. 2019 ESC/EAS Guidelines for the management of dyslipidaemias: lipid modification to reduce cardiovascular risk. *Eur Heart J*. 2020 Jan 1;41(1):111-188. doi: 10.1093/eurheartj/ehz455. Erratum in: *Eur Heart J*. 2020 Nov 21;41(44):4255. doi: 10.1093/eurheartj/ehz826.
8. Cuchel M, Raal FJ, Hegele RA, et al. 2023 Update on European Atherosclerosis Society consensus statement on homozygous familial hypercholesterolaemia: new treatments and clinical guidance. *Eur Heart J*. 2023 Jul 1;44(25):2277-2291. doi: 10.1093/eurheartj/ehad197.
9. Virani SS, Newby LK, Arnold SV, et al. 2023 AHA/ACC/ACCP/ASPC/NLA/PCNA Guideline for the Management of Patients With Chronic Coronary Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines [published correction appears in *Circulation*. 2023 Sep 26;148(13):e148]. *Circulation*. 2023;148(9):e9-e119.
Statin Tolerance
10. Fitchett DH, Hegele RA, Verma S. Statin intolerance. *Circulation* 2015;131:e389-391. <https://doi.org/10.1161/CIRCULATIONAHA.114.013189>.
11. Manpuya WM, Cho L, Frid D, et al. Treatment strategies in patients with statin intolerance: the Cleveland Clinic experience. *American Heart Journal* 2013; 166(3):597-603.
12. Zhang H, Plutzky J, Skentzos S, et al. Discontinuation of statins in routine care settings. *Ann of Intern Med* 2013; 158(7):526-534.
13. Backes JM, Ruisinger JF, Gibson CA, et al. Statin-associated muscle symptoms—managing the highly intolerant. *J Clin Lipidol*. 2017 Jan-Feb;11(1):24-33. doi: 10.1016/j.jacl.2017.01.006.
14. Thompson PD, Panza G, Zaleski A, et al. Statin-associated side effects. *J Am Coll Cardiol* 2016 May 24;67(20):2395-2410. doi: 10.1016/j.jacc.2016.02.071.
15. Warden BA, Guyton JR, Kovacs AC, et al. Assessment and management of statin-associated muscle symptoms (SAMS): A clinical perspective from the National Lipid Association. *J Clin Lipidol*. 2023 Jan-Feb;17(1):19-39. doi: 10.1016/j.jacl.2022.09.001.
16. Cheeley MK, Saseen JJ, Agarwala A, et al. NLA scientific statement on statin intolerance: a new definition and key considerations for ASCVD risk reduction in the statin intolerant patient. *J Clin Lipidol*. 2022 Jul-Aug;16(4):361-375. doi: 10.1016/j.jacl.2022.05.068.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2022 annual review: no significant changes; removed references to Kynamro since it has been withdrawn from market; removed 40 mg and 60 mg capsules per updated PI; references reviewed and updated.	10.01.21	02.22
Template changes applied to other diagnoses/indications and continued therapy section.	09.20.22	
1Q 2023 annual review: per 2022 ACC expert consensus decision pathway, lowered minimum LDL requirement to 55 mg/dL for members with ASCVD at very high risk and added corresponding Appendix H; references reviewed and updated.	10.18.22	02.23

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Revised redirection to Repatha to instead state “failure of a preferred PCSK9 inhibitor, if applicable.”	11.16.23	12.23
1Q 2024 annual review: added Leqvio to list of drugs where coadministration is not allowed; added the following requirement from initial approval criteria to also require for continuation of therapy “Treatment plan does not include coadministration with Leqvio, Repatha, or Praluent”; Appendix I clarified that smoking is specific to tobacco and revised HeFH to FH; references reviewed and updated.	11.28.23	02.24
1Q 2025 annual review: per 2022 ACC expert consensus decision pathway, lowered untreated LDL requirement to 400 mg/dL and revised evidence of HeFH in both parents to evidence of familial hypercholesterolemia in at least one parent; references reviewed and updated.	11.05.24	02.25
1Q 2026 annual review: extended initial approval duration from 6 months to 12 months for this maintenance medication for a chronic condition; reduced statin adherence duration from 4 months to 8 weeks; simplified statin trial and failure criteria for moderate- and low-intensity statin regimens to require insufficient therapeutic response to one high intensity statin for 8 weeks or reversible muscle-related symptoms associated with both rosuvastatin and atorvastatin; clarified failure of <i>an 8 week trial of a preferred PCSK9 inhibitor</i> ; references reviewed and updated.	10.22.25	02.26
RT4: revised criteria to allow for age ≥ 2 years per FDA pediatric expansion; added new 2 mg capsule for pediatric population.	03.06.26	

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.

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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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