Clinical Policy: Canakinumab (Ilaris)

Reference Number: CP.PHAR.246
Effective Date: 08.01.16
Last Review Date: 05.25
Line of Business: Commercial, HIM, Medicaid

Revision Log

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

Description

Canakinumab (Ilaris®) is an interleukin-1 blocker.

FDA Approved Indication(s)

Ilaris is indicated for the treatment of:

- Periodic fever syndromes:
  - Cryopyrin-associated periodic syndromes (CAPS) in adults and children 4 years of age and older including:
    - Familial cold autoinflammatory syndrome (FCAS)
    - Muckle-Wells syndrome (MWS)
  - Tumor necrosis factor receptor associated periodic syndrome (TRAPS) in adult and pediatric patients
  - Hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD) in adult and pediatric patients
  - Familial Mediterranean fever (FMF) in adult and pediatric patients
- Active Still's disease, including adult-onset Still's disease (AOSD) and systemic juvenile idiopathic arthritis (SJIA) in patients aged 2 years and older
- Gout flares in adults in whom non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate

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

I. Initial Approval Criteria

A. Periodic Fever Syndromes (must meet all)**:**

1. Diagnosis of FCAS, MWS, TRAPS, HIDS/MKD, or FMF;
2. Prescribed by or in consultation with a rheumatologist;
3. Member meets one of the following (a or b):
   a. FCAS or MWS: Age ≥ 4 years;
   b. TRAPS, HIDS/MKD, or FMF: Age ≥ 2 years;
4. Documentation of one of the following (a – e):

a. For FCAS, classic signs and symptoms (e.g., recurrent, intermittent fever and rash often exacerbated by exposure to generalized cool ambient temperature) AND functional impairment limiting activities of daily living;
b. For MWS, classic signs and symptoms (e.g., chronic fever and rash of waxing and waning intensity, sometimes exacerbated with exposure to generalized cool ambient temperature) AND functional impairment limiting activities of daily living;
c. For TRAPS, chronic or recurrent disease activity with history of ≥ 6 flares within the last 12 months;
d. For HIDS/MKD, ≥ 3 febrile acute flares within the last 6 months;
e. For FMF, active disease with at least one flare per month and one of the following (i or ii):
   i. Age < 4 years;
   ii. Failure of a ≥ 6-month trial of colchicine at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;

5. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
6. Dose does not exceed one of the following (a or b):
   a. FCAS or MWS (i or ii):
      i. Weight 15 to 40 kg: 3 mg/kg/dose every 8 weeks;
      ii. Weight > 40 kg: 150 mg every 8 weeks;
   b. TRAPS, HIDS/MKD, or FMF (i or ii):
      i. Weight ≤ 40 kg: 4 mg/kg/dose every 4 weeks;
      ii. Weight > 40 kg: 300 mg every 4 weeks.

Approval duration:
Medicaid/HIM – 3 months for FCAS or MWS; 6 months for all other indications
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Systemic Juvenile Idiopathic Arthritis (must meet all)**:**
1. Diagnosis of SJIA;
2. Prescribed by or in consultation with a dermatologist, rheumatologist, or gastroenterologist;
3. Age ≥ 2 years;
4. Member meets one of the following (a, b, or c):
   a. Failure of a ≥ 3 consecutive month trial of methotrexate (MTX) or leflunomide at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
   b. Failure of a ≥ 2-week trial of a systemic corticosteroid at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   c. Failure of an NSAID at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);

6. Dose does not exceed both of the following (a and b):
   a. 300 mg every 4 weeks;
   b. 2 vials every 4 weeks.

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

C. Adult-Onset Still's Disease (must meet all)**:**

1. Diagnosis of AOSD;
2. Prescribed by or in consultation with a rheumatologist or hematologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
   a. Failure of a ≥ 2-week trial of a systemic corticosteroid at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   b. Failure of an NSAID at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
6. Dose does not exceed both of the following (a and b):
   a. 300 mg every 4 weeks;
   b. 2 vials every 4 weeks.

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

D. Treatment of Acute Gout Flare

1. Diagnosis of acute gout flare;
2. Age ≥ 18 years;
3. Failure of colchicine, unless contraindicated or clinically significant adverse effects are experienced;
4. Failure of an NSAID used for gout flare (e.g., naproxen, indomethacin, sulindac), unless member has one of the following contraindications (a, b, c, or d):
   a. Heart failure or uncontrolled hypertension;
   b. Current use of an anticoagulant (e.g., aspirin, warfarin, low molecular weight heparin, direct thrombin inhibitors, factor Xa inhibitors, clopidogrel);
   c. Active duodenal or gastric ulcer (not gastroesophageal reflux disease [GERD]);
   d. Chronic kidney disease with CrCl < 60 mL/min per 1.73 m^2;
5. Member meets both of the following (a and b):
   a. Failure of a corticosteroid used for gout flare, unless contraindicated or clinically significant adverse effects are experienced;
   b. Repeated courses of corticosteroids are not appropriate (*see Appendix D*);
6. Member is currently taking or will be initiating a urate-lowering therapy (e.g., allopurinol, Uloric®, or probenecid), unless contraindicated or clinically significant adverse effects are experienced;

7. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
8. Dose does not exceed 150 mg per 12 weeks.

Approval duration: 3 months

E. 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, HIM.PA.33 for health insurance marketplace, 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, HIM.PA.103 for health insurance marketplace, 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, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Treatment of Acute Gout Flare

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. Member is responding positively to therapy;
3. Member is currently prescribed a urate-lowering agent (e.g., allopurinol, Uloric, or probenecid), unless contraindicated or clinically adverse effects are experienced;
4. Previous Ilaris dose was administered ≥ 12 weeks prior;
5. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
6. Dose does not exceed 150 mg per 12 weeks.

Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. All Other Indications in Section I (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. Member is responding positively to therapy;
3. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
4. If request is for a dose increase, new dose does not exceed one of the following (a, b, or c):
   a. FCAS or MWS (i or ii):
      i. Weight 15 to 40 kg: 3 mg/kg/dose every 8 weeks;
      ii. Weight > 40 kg: 150 mg every 8 weeks;
   b. TRAPS, HIDS/MKD, FMF, or SJIA (i or ii):
      i. Weight ≤ 40 kg: 4 mg/kg/dose every 4 weeks;
      ii. Weight > 40 kg: 300 mg every 4 weeks;
   c. SJIA or AOSD: 300 mg every 4 weeks.

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

C. 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, HIM.PA.33 for health insurance marketplace, 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, HIM.PA.103 for health insurance marketplace, 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, HIM.PA.154 for health insurance marketplace, 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, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents;

B. Combination use with biological disease-modifying antirheumatic drugs (bDMARDs) or potent immunosuppressants, including but not limited to any tumor necrosis factor (TNF) antagonists [e.g., Cimzia®, Enbrel®, Humira® and its biosimilars, Remicade® and its biosimilars, Simponi®], interleukin agents [e.g., Actemra® (IL-6RA) and its biosimilars, Arcalyst® (IL-1 blocker), Bimzelx® (IL-17A and F antagonist), Cosentyx® (IL-17A inhibitor), Ilaris® (IL-1 blocker), Ilumya™ (IL-23 inhibitor), Kevzara® (IL-6RA), Kineret® (IL-1RA), Omvoh™ (IL-23 antagonist), Siliq™ (IL-17RA), Skyrizi™ (IL-23 inhibitor), Spevigo® (IL-36 antagonist), Stelara® (IL-12/23 inhibitor) and its biosimilars, Taltz® (IL-17A inhibitor), Tremfya® (IL-23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Cibinqo™, Olumiant™, Rinvoq™, Xeljanz®/Xeljanz® XR,], anti-CD20 monoclonal antibodies [Rituxan® and its biosimilars], selective co-stimulation modulators [Orencia®], integrin receptor antagonists [Entyvio®], tyrosine kinase 2 inhibitors [Sotyktu™], and sphingosine 1-phosphate receptor modulator [Velsipity™] because of the additive immunosuppression, increased risk of neutropenia, as well as increased risk of serious infections.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AOSD: adult-onset Still's disease
CAPS: cryopyrin-associated periodic syndromes
FCAS: familial cold autoinflammatory syndrome
FDA: Food and Drug Administration
FMF: familial Mediterranean fever
GI: gastrointestinal
HIDS: hyperimmunoglobulin D syndrome
JAKi: Janus kinase inhibitors
MKD: mevalonate kinase deficiency
MTX: methotrexate
MWS: Muckle-Wells syndrome
NSAID: non-steroidal anti-inflammatory drugs
SJIA: systemic juvenile idiopathic arthritis
TRAPS: tumor necrosis factor receptor associated periodic syndrome

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
colchicine (Colcrys®)	**FMF** PO in 1-2 divided doses based on age: Age 4– 6 years: 0.3-1.8 mg/day Age 6 – 12 years: 0.9-1.8 mg/day Age > 12 years: 1.2-2.4 mg/day **Gout flare** 1.2 mg at first sign of flare, followed by 0.6 mg one hour later	**FMF** 2.4 mg/day **Gout flare** 1.8 mg/treatment
corticosteroids (e.g., prednisone, methylprednisolone)	**SJIA*** 0.5 – 2 mg/kg/day PO of prednisone or equivalent	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	AOSD* Varies **Gout flare** Varies	
leflunomide (Arava®)	**SJIA*** 10 – 19.9 kg:10 mg PO QD 20- 40 kg: 15 mg PO QD ≥ 40 kg: 20 mg PO QD	20 mg/day
methotrexate (Trexall®, Otrexup®™, Rasuvo®, RediTrex®, Xatmep®™, Rheumatrex®)	**SJIA*** 0.5 – 1 mg/kg/week PO or SC	30 mg/week
NSAIDs (e.g., naproxen, ibuprofen, indomethacin)	**AOSD*, Gout flare, sJIA*** Varies	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.
**Off-label*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): confirmed hypersensitivity to the active substance or to any of the excipients
- Boxed warning(s): none reported

Appendix D: General Information

- Periodic fever syndromes are a group of rare autoinflammatory diseases that include cryopyrin-associated periodic syndromes (CAPS), tumor necrosis factor receptor associated periodic syndrome (TRAPS), hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD), and familial Mediterranean fever (FMF). Diagnosis of these diseases can be confirmed by genetic testing.
- Three related conditions make up the broader disease known as CAPS: familial cold auto-inflammatory syndrome (FCAS), Muckle-Wells syndrome (MWS), and neonatal-onset multisystem inflammatory disease (NOMID), also known as chronic infantile neurologic cutaneous articular syndrome (CINCA). While Ilaris is FDA-approved for FCAS and MWS, it is not FDA-approved for use in patients with NOMID/CINCA.
- Ilaris is the first therapeutic option for TRAPS and HIDS/MKD and the first biologic option for FMF. In FMF, the current standard of care is colchicine, a relatively safe oral therapy indicated in patients ages 4 and up. Colchicine has well-established benefit in FMF and has been used for decades. Although no United States clinical practice guidelines exist for TRAPS, HIDS/MKD, and FMF, the European League Against Rheumatism (EULAR) guidelines for the management of FMF recommend colchicine be initiated at diagnosis for all patients and response to therapy be assessed every 6 months.

- Examples of positive response to therapy:
  - Periodic fever syndromes (FCAS, MWS, TRAPS, HIDS/MKD, and FMF) include reduction/normalization of: C-reactive protein (CRP) levels, serum amyloid A (SAA) levels, flare frequency, or severity and duration of symptoms (e.g., joint pain, rash, fever/chills, eye pain, fatigue).
  - SJIA include improvement in: quantitative measures such as physician global assessment of disease activity, parent or patient global assessment of well-being, number of joints with active arthritis, number of joints with limited range of motion, CRP, and functional ability (CHAQ).
  - AOSD include normalization or improvement in laboratory test results for serum markers of inflammation (e.g., ESR or CRP), sustained improvement in member's symptoms and disease stability. Chart notes indicating improvement in rash, joint pain and/or swelling and fevers.
- Failure of a trial of conventional DMARDs:
  - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.
  - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.
- For acute gout flares: Examples where repeated corticosteroids are not appropriate may include, but are not limited to the following: osteoporosis, osteonecrosis, Cushing syndrome, diabetes mellitus, myopathy, glaucoma, congestive heart failure, or peptic ulcer disease.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CAPS (FCAS and MWS)	Weight > 40 kg: 150 mg SC every 8 weeks Weight ≥ 15 kg to ≤ 40 kg: 2 mg/kg SC every 8 weeks (if inadequate response, may increase to 3 mg/kg)	150 mg/8 weeks
CAPS (TRAPS, HIDS/MKD, FMF)	Weight > 40 kg: 150 mg SC every 4 weeks (if inadequate response, may increase to 300 mg every 4 weeks) Weight ≤ 40 kg: 2 mg/kg SC every 4 weeks (if inadequate response, may increase to 4 mg/kg)	300 mg/4 weeks
SJIA, AOSD	Weight ≥ 7.5 kg: 4 mg/kg SC (up to a maximum of 300 mg) every 4 weeks	300 mg/4 weeks
Treatment of gout flares	150 mg SC (interval of at least 12 weeks before a new dose)	150 mg/ 12 weeks

VI. Product Availability

Single-dose vial for injection, solution: 150 mg/mL

VII. References

1. Ilaris Prescribing Information. East Hanover, NJ; Novartis Pharmaceuticals Corporation; November 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/125319s110lbl.pdf. Accessed February 27, 2025.
2. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Care and Research. 2019:71(6):717-734. DOI 10.1002/acr.23870.
3. Onel KB, Horton DB, Lovell DJ, and Shenoi S, Cuello CA, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis Care Res (Hoboken). 2022 Apr;74(4):521-537. doi: 10.1002/acr.24853.
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5. Jamilloux Y, Gerfaud-Valentin M, Henry T, et al. Treatment of adult-onset Still's disease: a review. *Ther Clin Risk Manag*. 2014;11:33-43.
6. Leavis HL, van Daele PLA, Mulders-Manders C, et al. Management of adult-onset Still's disease: evidence- and consensus-based recommendations by experts. Rheumatology (Oxford). 2023 Sep 5:kead461. doi: 10.1093/rheumatology/kead461.
7. Ozen S, Demirkaya E, Erer B, et al. EULAR recommendations for the management of familial Mediterranean fever. Ann Rheum Dis. 2016; 75(4): 644-651.
8. Sag E, Bilginer Y, Ozen S. Autoinflammatory diseases with periodic fevers. *Curr Rheumatol Rep*. 2017; 19: 41.
9. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout. Arthritis Care & Research. June 2020; 0 (0): 1-17.
10. Fautrel B, Mitrovic S, De Matteis A, et al. EULAR/PReS recommendations for the diagnosis and management of Still's disease, comprising systemic juvenile idiopathic arthritis and adult-onset Still's disease. Ann Rheum Dis. 2024 Nov 14;83(12):1614-1627. doi: 10.1136/ard-2024-225851. PMID: 39317417; PMCID: PMC11672000.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0638	Injection, canakinumab, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2021 annual review: added requirements to confirm diagnosis/severity for periodic fever syndromes; added combination of bDMARDs under Section III; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); references reviewed and updated.	02.23.21	05.21
2Q 2022 annual review: applied legacy Wellcare Medicaid line of business; WCG.CP.PHAR.246 to be retired; reiterated requirement against combination use with a bDMARD or JAKi from Section III to Sections I and II; 150 mg lyophilized powder dose form removed from Section VI; references reviewed and updated.	02.19.22	05.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.10.22	
2Q 2023 annual review: no significant changes; updated off-label dosing for Appendix B; references reviewed and updated.	02.10.23	05.23
RT4: added criteria for newly approved gout flare indication	09.18.23	11.23
2Q 2024 annual review: for AOSD, removed redirection to methotrexate per guideline update and competitor analysis and added redirection to NSAID; added Bimzelx, Zymfentra, Omvoh, Wezlana, Sotyktu, Tofidence, and Velsipity to section III.B; references reviewed and updated.	01.29.24	05.24
2Q 2025 annual review: for sJIA, added redirection to NSAID as an option per clinical practice guidelines and competitor analysis; updated section III.B with Spevigo and biosimilar verbiage; references reviewed and updated.	01.23.25	05.25

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.