Clinical Policy: Upadacitinib (Rinvoq)

Reference Number: MDN.CP.PHAR.443
Effective Date: 12.01.19
Last Review Date: 11.30.22
Line of Business: Meridian IL Medicaid

Revision Log

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

Description

Upadacitinib (Rinvoq™) is a Janus kinase (JAK) inhibitor.

FDA Approved Indication(s)

Rinvoq is indicated for treatment of:

- Adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers.
- Adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers.
- Adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable.
- Adult patients with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers.
- Adults with active ankylosing spondylitis who have had an inadequate response or intoleranace to one or more TNF blockers.
- Adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy

Limitation(s) of use: Use of Rinvoq in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended.

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

I. Initial Approval Criteria

A. Rheumatoid Arthritis (must meet all)**:**

1. Diagnosis of RA per American College of Rheumatology (ACR) criteria (*see Appendix E*);
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):

   a. Failure of a ≥ 3 consecutive month trial of methotrexate (MTX) at up to maximally indicated doses;
   b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a ≥ 3 consecutive month trial of at least ONE conventional DMARD (e.g., sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless clinically significant adverse effect are experienced or all are contraindicated;
5. Failure of TWO of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, c, and d):
   a. Cimzia®;
   b. Enbrel®;
   c. Humira®;
   d. Xeljanz®/Xeljanz XR®;
   **Prior authorization may be required for Cimzia, Enbrel, Humira, and Xeljanz/Xeljanz XR*
6. Documentation of one of the following baseline assessment scores (a or b):
   a. Clinical disease activity index (CDAI) score (*see Appendix F*);
   b. Routine assessment of patient index data 3 (RAPID3) score (*see Appendix G*);
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 15 mg (one tablet) per day.

Approval duration: 6 months

B. Psoriatic Arthritis (must meet all):
1. Diagnosis of PsA;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 18 years;
4. Failure of TWO of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, and c):
   a. Cimzia®;
   b. Enbrel®;
   c. Xeljanz®/Xeljanz XR®;
   **Prior authorization may be required for Cimzia, Enbrel, and Xeljanz/Xeljanz XR*
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 15 mg (one tablet) per day.

Approval duration: 6 months

C. Atopic Dermatitis (must meet all):
1. Diagnosis of atopic dermatitis affecting one of the following (a or b): a. At least 10% of the member's body surface area (BSA); b. Hands, feet, face, neck, scalp, genitals/groin, and/or intertriginous areas;
2. Prescribed by or in consultation with a dermatologist or allergist;
3. Age ≥ 18 years;

4. Failure of all of the following (a, b, c, and d), unless contraindicated or clinically significant adverse effects are experienced:
    a. Two formulary medium to very high potency topical corticosteroids, each used for ≥ 2 weeks;
    b. One non-steroidal topical therapy* used for ≥ 4 weeks: topical calcineurin inhibitor (e.g., tacrolimus ointment, pimecrolimus cream) or Eucrisa®;
    **These agents may require prior authorization*
    c. One systemic agent used for ≥ 3 months: azathioprine, methotrexate, mycophenolate mofetil, or cyclosporine;
    d. Dupixent* used for ≥ 3 consecutive months
    **Dupixent may require prior authorization*
5. Rinvoq is not prescribed concurrently with another biologic medication (e.g., Adbry®, Dupixent®) or a JAK inhibitor (e.g., Olumiant®, Cibinqo®, Opzelura™);
6. Dose does not exceed one of the following (a or b):
    a. 15 mg (one tablet) per day;
    b. 30 mg (one tablet) per day and medical justification supports inadequate response to 15 mg daily.

Approval duration: 6 months

D. Axial Spondyloarthritis (must meet all):
1. Diagnosis of AS or nr-axSpA;;
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for ≥ 4 weeks unless clinically significant adverse effects are experienced or all are contraindicated;
5. Failure of TWO of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, c, and d):
    a. Cimzia®;
    b. Enbrel®;
    c. Humira®;
    d. Xeljanz®/Xeljanz XR®;

    **Prior authorization may be required for Cimzia, Enbrel, and Xeljanz/Xeljanz XR*
6. For nr-axSpA: Failure of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced for both are contraindicated: Cimzia;
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 15 mg (one tablet) per day.

Approval duration: 6 months

E. Ulcerative Colitis (must meet all):
1. Diagnosis of UC;
2. Prescribed by or in consultation with a gastroenterologist;
3. Age ≥ 18 years;

4. Documentation of a Mayo Score ≥ 6 (see Appendix H);
5. Failure of an 8-week trial of systemic corticosteroids, unless contraindicated or clinically significant adverse effects are experienced;
6. Failure of Humira®, used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or contraindicated
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. Request meets one of the following (a or b): a. For induction: 45 mg (one tablet) once daily for 8 weeks; b. For maintenance: 15 mg (one tablet) once daily.

Approval duration: 6 months

F. 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.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.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.PMN.53 for Medicaid.

II. Continued Therapy

A. Rheumatoid Arthritis (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 as evidenced by one of the following (a or b):
   a. A decrease in CDAI (*see Appendix F*) or RAPID3 (*see Appendix G*) score from baseline;
   b. Medical justification stating inability to conduct CDAI re-assessment, and submission of RAPID3 score associated with disease severity that is similar to initial CDAI assessment or improved;
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 15 mg (one tablet) per day.

Approval duration: 12 months

B. Atopic Dermatitis (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 as evidenced by, including but not limited to, reduction in itching and scratching;
3. Rinvoq is not prescribed concurrently with another biologic medication (e.g., Adbry®, Dupixent®) or a JAK inhibitor (e.g., Olumiant®, Cibinqo®, Opzelura™);
4. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. 15 mg (one tablet) per day;
   b. 30 mg (one tablet) per day and medical justification supports inadequate response to 15 mg daily.

Approval duration: 12 months

C. All Other Indications (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);*

1. Member is responding positively to therapy;
2. 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);
3. 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 (a or b):
   a. For PsA, UC, AS, nr-axSpA: 15 mg (one tablet) per day;
   b. For UC, : 30 mg (one tablet) per day and member has refractory, severe, or extensive disease.

Approval duration: 12 months

D. 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.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.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.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 policy – 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®, Simponi®, Avsola™, Inflectra™, Remicade®, Renflexis™], interleukin agents [e.g., Arcalyst® (IL-1 blocker), Ilaris® (IL-1 blocker), Kineret® (IL-1RA), Actemra® (IL-6RA), Kevzara® (IL-6RA), Stelara® (IL12/23 inhibitor), Cosentyx® (IL-17A inhibitor), Taltz® (IL-17A inhibitor), Siliq™ (IL17RA), Ilumya™ (IL-23 inhibitor), Skyrizi™ (IL-23 inhibitor), Tremfya® (IL-23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Xeljanz®/Xeljanz® XR, Cibinqo™, Olumiant™, Rinvoq™], anti-CD20 monoclonal antibodies [Rituxan®, Riabni™, Ruxience™, Truxima®, Rituxan Hycela®], selective co-stimulation modulators [Orencia®], and integrin receptor antagonists [Entyvio®] 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

CDAI: clinical disease activity index
DMARD: disease-modifying antirheumatic drug
FDA: Food and Drug Administration
JAKi: Janus kinase inhibitors
MTX: methotrexate
nr-axSpA: non-radiographic axial spondyloarthritis
PsA: psoriatic arthritis
RA: rheumatoid arthritis
RAPID3: routine assessment of patient index data 3

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
azathioprine (Azasan®, Imuran®)	**RA** 1 mg/kg/day PO QD or divided BID AD 1-3 mg/kg/day PO QD	3 mg/kg/day
Cuprimine®	**RA***	1,500 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
(d-penicillamine)	Initial dose: 125 or 250 mg PO QD Maintenance dose: 500 – 750 mg/day PO QD	
cyclosporine (Sandimmune®, Neoral®)	**RA** 2.5 – 4 mg/kg/day PO divided BID AD 3-6 mg/kg/day PO BID	RA: 4 mg/kg/day AD: 300 mg/day
hydroxychloroquine (Plaquenil®)	**RA*** Initial dose: 400 – 600 mg/day PO QD Maintenance dose: 200 – 400 mg/day PO QD	600 mg/day
leflunomide (Arava®)	**RA** 100 mg PO QD for 3 days, then 20 mg PO QD	20 mg/day
methotrexate (Rheumatrex®)	**RA** 7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week AD 7.5-25 mg/wk PO once weekly	RA: 30 mg/week AD: 25 mg/week
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	AS Varies	Varies
sulfasalazine (Azulfidine®)	**RA** 2 g/day PO in divided doses	3 g/day
mycophenolate mofetil	AD 1-1.5 g PO BID	3 g/day
Enbrel® (etanercept)	AS 50 mg SC once weekly **RA, PsA** 25 mg SC twice weekly or 50 mg SC once weekly	50 mg/week
Cimzia® (certolizumab)	AS Initial dose: 400 mg SC at 0, 2, and 4 weeks Maintenance dose: 200 mg SC every other week (or 400 mg SC every 4 weeks)	400 mg every 4 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Xeljanz® (tofacitinib)	**AS, PsA, RA** 5 mg PO BID	10 mg/day
Xeljanz XR® (tofacitinib extended-release)	**AS, PsA, RA** 11 mg PO QD	11 mg/day

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): known hypersensitivity to upadacitinib or any of the excipients in Rinvoq
- Boxed warning(s): serious infections, mortality, malignancy, major adverse cardiovascular events, and thrombosis

Appendix D: General Information

- Definition of MTX or DMARD Failure
  - 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.
- Examples of positive response to therapy may include, but are not limited to:
  - Reduction in joint pain/swelling/tenderness
  - Improvement in ESR/CRP levels
  - Improvements in activities of daily living

Appendix E: The 2010 ACR Classification Criteria for RA
Add score of categories A through D; a score of ≥ 6 out of 10 is needed for classification of a patient as having definite RA.

A	**Joint involvement**	Score
	1 large joint	0
	2-10 large joints	1
	1-3 small joints (with or without involvement of large joints)	2
	4-10 small joints (with or without involvement of large joints)	3
	> 10 joints (at least one small joint)	5
B	**Serology (at least one test result is needed for classification)**	
	Negative rheumatoid factor (RF) *and* negative anti-citrullinated protein antibody (ACPA)	0
	Low positive RF *or* low positive ACPA * *Low: < 3 x upper limit of normal*	2

A	**Joint involvement**	Score
	1 large joint	0
	2-10 large joints	1
	1-3 small joints (with or without involvement of large joints)	2
	4-10 small joints (with or without involvement of large joints)	3
	> 10 joints (at least one small joint)	5
	High positive RF *or* high positive ACPA * *High: ≥ 3 x upper limit of normal*	3
C	**Acute phase reactants (at least one test result is needed for classification)**	
	Normal C-reactive protein (CRP) and normal erythrocyte sedimentation rate (ESR)	0
	Abnormal CRP or abnormal ESR	1
D	**Duration of symptoms**	
	< 6 weeks	0
	≥ 6 weeks	1

Appendix F: Clinical Disease Activity Index (CDAI) Score
The Clinical Disease Activity Index (CDAI) is a composite index for assessing disease activity in RA. CDAI is based on the simple summation of the count of swollen/tender joint count of 28 joints along with patient and physician global assessment on VAS (0–10 cm) Scale for estimating disease activity. The CDAI score ranges from 0 to 76.

CDAI Score	Disease state interpretation
≤ 2.8	Remission
> 2.8 to ≤ 10	Low disease activity
> 10 to ≤ 22	Moderate disease activity
> 22	High disease activity

Appendix G: Routine Assessment of Patient Index Data 3 (RAPID3) Score
The Routine Assessment of Patient Index Data 3 (RAPID3) is a pooled index of the three patient-reported ACR core data set measures: function, pain, and patient global estimate of status. Each of the individual measures is scored 0 – 10, and the maximum achievable score is 30.

RAPID3 Score	Disease state interpretation
≤ 3	Remission
3.1 to 6	Low disease activity
6.1 to 12	Moderate disease activity
> 12	High disease activity

Appendix H: Mayo Score
Mayo Score: evaluates ulcerative colitis stage, based on four parameters: stool frequency, rectal bleeding, endoscopic evaluation and Physician's global assessment. Each parameter of the score ranges from zero (normal or inactive disease) to 3 (severe activity) with an overall score of 12.

Score	Decoding
0 - 2	Remission

Score	Decoding
3 - 5	Mild activity
6 - 10	Moderate activity
>10	Severe activity

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
AS, RA, PsA, nr-axSpA,	15 mg PO QD	15 mg/day
AD	Age ≥ 12 years and ≥ 40 kg but < 65 years: 15 mg PO QD; if an adequate response is not achieved, consider increasing the dosage to 30 mg PO QD Age ≥ 65 years: 15 mg PO QD	Age ≥ 12 years and ≥ 40 kg but < 65 years: 30 mg/day Age ≥ 65 years: 15 mg/day
UC	Induction: 45 mg PO Q for 8 weeks Maintenance: 15 mg PO QD. A dosage of 30 mg PO QD may be considered for patients with refractory, severe, or extensive disease.	30 mg/day

VI. Product Availability

Tablets, extended-release: 15 mg, 30 mg, 45mg

VII. References

1. Rinvoq Prescribing Information. North Chicago, IL: AbbVie Inc.; October 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/211675s003lbl.pdf. Accessed October 31,, 2022.
2. Singh JA., Saag KG, Bridges SL, et al. 2015 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Care & Research*. 68: 1–25. doi:10.1002/acr.22783.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: http://www.clinicalpharmacology-ip.com/. Accessed January 11, 2021.
4. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. Ann Rheum Dis. 2015;0:1-12. Doi:10.1136/annrheumdis-2015-208337.
5. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. American College of Rheumatology. 2019; 71(1):5-32. Doi: 10.1002/art.40726.

6. Wollenberg A, Christen-Zäch S, Taieb A, et al. ETFAD/EADV Eczema task force 2020 position paper on diagnosis and treatment of atopic dermatitis in adults and children. J Eur Acad Dermatol Venereol. 2020 Dec;34(12):2717-2744.
7. Eichenfield F, Tom WL, Chamlin SL, et al. Guidelines of Care for the Management of Atopic Dematitis. J Am Acad Dermatol. 2014 February; 70(2): 338–351.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10.15.19	11.19
Removed HIM-TBD line of business; updated preferred redirections based on SDC recommendation and prior clinical guidance: for RA, removed redirection to adalimumab and added redirection to 2 of 3 agents (Enbrel, Kevzara, Xeljanz/Xeljanz XR).	12.13.19	
2Q 2020 annual review: for RA, added specific diagnostic criteria for definite RA, baseline CDAI score requirement, and decrease in CDAI score as positive response to therapy; references reviewed and updated.	04.29.20	05.20
Revised typo in Appendix E from “normal ESR” to “abnormal ESR” for a point gained for ACR Classification Criteria.	11.22.20	
Added criteria for RAPID3 assessment for RA given limited in-person visits during COVID-19 pandemic, updated appendices.	11.24.20	02.21
2Q 2021 annual review: added combination of bDMARDs under Section III; updated CDAI table with “>” to prevent overlap in classification of severity; references reviewed and updated.	02.23.21	05.21
Per August SDC and prior clinical guidance, for RA added Actemra to redirect options and modified to require a trial of all; for Xeljanz redirection requirements added bypass for members with cardiovascular risk and qualified redirection to apply only for member that has not responded or is intolerant to one or more TNF blockers; added Legacy WellCare line of business to policy (WCG.CP.PHAR.443 to be retired).	08.25.21	11.21
Criteria added for new FDA indications: psoriatric arthritis, atopic dermatitis; added newly FDA approved indications for UC and AS; reiterated requirement against combination use with a bDMARD or JAKi from Section III to Sections I and II; references reviewed and updated.	08.12.22	
RT4: criteria added for new FDA indication: nr-axSpA; Template changes applied to other diagnoses/indications and continued therapy section; references reviewed and updated	11.30.22	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical

policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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.