YouthCare
HealthChoice Illinois

Clinical Policy: Anakinra (Kineret)

Reference Number: IL.PHAR.244
Effective Date: 1.14.2020
Last Review Date: 4.15.25
Line of Business: Medicaid

Coding Implications
Revision Log

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

Description

Anakinra (Kineret®) is an interleukin-1 (IL-1) receptor antagonist.

FDA Approved Indication(s)

Kineret is indicated for the treatment of:

- Rheumatoid arthritis (RA): Reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active RA, in patients 18 years of age or older who have failed 1 or more disease modifying antirheumatic drugs (DMARDs). Kineret can be used alone or in combination with DMARDs other than tumor necrosis factor blocking agents.
- Cryopyrin-associated periodic syndromes (CAPS): Treatment of neonatal-onset multisystem inflammatory disease (NOMID)
- Deficiency of interleukin-1 receptor antagonist (DIRA): Treatment of DIRA.

Emergency Use Authorization

- The U.S. Food and Drug Administration (FDA) has issued an emergency use authorization (EUA) for the emergency use of Kineret for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults with positive results of direct SARS-CoV-2 viral testing with pneumonia requiring supplemental oxygen (low- or high-flow oxygen) who are at risk of progressing to severe respiratory failure and likely to have an elevated plasma soluble urokinase plasminogen activator receptor (suPAR).

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 Kineret 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 F);
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, unless contraindicated or clinically significant adverse effects are experienced;
b. If intolerance or contraindication to MTX (*see Appendix D*), 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 contraindicated or clinically significant adverse effects are experienced;

5. Failure of ALL of the following, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced (a and b):
   a. Enbrel®, Adalimumab-adbm, adalimumab-ryvk (Simlandi) , Cimzia®, (unless the member has had a history of failure of two TNF blockers), Xeljanz®
   b. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz®/Xeljanz XR®, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;

   **Prior authorization may be required for Enbrel, Adalimumab-adbm, adalimumab-ryvk (Simlandi) , Cimzia 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 G*);
   b. Routine assessment of patient index data 3 (RAPID3) score (*see Appendix H*);
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 100 mg (1 syringe) per day.

Approval duration: 6 months

B. Cryopyrin-Associated Periodic Syndromes (must meet all)**:**
1. Diagnosis of NOMID;
2. Prescribed by or in consultation with a rheumatologist;
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. Dose does not exceed 8 mg/kg per day.

Approval duration: 6 months

C. Deficiency of Interleukin-1 Receptor Antagonist (must meet all)**:**
1. Diagnosis of DIRA confirmed by presence of loss-of-function *ILRN* mutations;
2. Prescribed by or in consultation with a rheumatologist;
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. Dose does not exceed 8 mg/kg per day (*see Appendix E for dose rounding guidelines*).

Approval duration: 6 months

D. Coronavirus-19 Infection (FDA Emergency Use Authorization):

1. Initiation of outpatient treatment will not be authorized as Kineret is authorized for emergency use only in the hospitalized setting (*see Appendix I*).

Approval duration: Not applicable

E. Other diagnoses/indications

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. All 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 meets one of the following (a or b):
   a. For RA: member is responding positively to therapy as evidenced by one of the following (i or ii):
      i. A decrease in CDAI (see Appendix G) or RAPID3 (see Appendix H) score from baseline;
      ii. 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;
   b. For all other indications: 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 or b):
   a. RA: 100 mg per day;
   b. NOMID: 8mg/kg per day.

Approval duration: 12 months

B. Coronavirus-19 Infection (FDA Emergency Use Authorization):

1. Continuation of therapy in the outpatient setting will not be authorized as Kineret is authorized for emergency use only in the hospitalized setting as a subcutaneous injection administered daily for 10 days (*see Appendix I*).

Approval duration: Not applicable

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.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 policies – 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 (Avsola™, Inflectra™, Renflexis™, Zymfentra®), Simponi®], interleukin agents [e.g., Actemra® (IL-6RA), 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), Stelara® (IL-12/23 inhibitor), Taltz® (IL-17A inhibitor), Tofidence™ (IL-6), Tremfya® (IL-23 inhibitor), Wezlana™ (IL-12/23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Cibinqo™, Olumiant™, Rinvoq™, Xeljanz®/Xeljanz® XR,], anti-CD20 monoclonal antibodies [Rituxan® and its biosimilars (Riabni™, Ruxience™, Truxima®), Rituxan Hycela®], 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

CAPS: cryopyrin-associated periodic syndromes

CDAI: clinical disease activity index

DIRA: deficiency of Interluekin-1 Receptor Antagonist

DMARD: disease-modifying antirheumatic drug
FDA: Food and Drug Administration
IL-1: interleukin-1
MTX: methotrexate
NOMID: neonatal-onset multisystem inflammatory disease
RA: rheumatoid arthritis
RAPID3: routine assessment of patient index data 3
suPAR: soluble urokinase plasminogen activator receptor

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	2.5 mg/kg/day
Cuprimine® (d-penicillamine)	**RA*** Initial dose: 125 or 250 mg PO QD Maintenance dose: 500 – 750 mg/day PO QD	1,500 mg/day
cyclosporine (Sandimmune®, Neoral®)	**RA** 2.5 – 4 mg/kg/day PO divided BID	4 mg/kg/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** Initial dose (for low risk hepatotoxicity or myelosuppression): 100 mg PO QD for 3 days Maintenance dose: 20 mg PO QD	20 mg/day
methotrexate (Trexall®, Otrexup™, Rasuvo®, RediTrex®, Xatmep™, Rheumatrex®)	**RA** 7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week	30 mg/week
Ridaura® (auranofin)	**RA** 6 mg PO QD or 3 mg PO BID	9 mg/day (3 mg TID)

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
sulfasalazine (Azulfidine®)	**RA** Initial dose: 500 mg to 1,000 mg PO QD for the first week. Increase the daily dose by 500 mg each week up to a maintenance dose of 2 g/day. Maintenance dose: 2 g/day PO in divided doses	3 g/day
Actemra® (tocilizumab)	**RA** IV: 4 mg/kg every 4 weeks followed by an increase to 8 mg/kg every 4 weeks based on clinical response SC: Weight < 100 kg: 162 mg SC every other week, followed by an increase to every week based on clinical response Weight ≥ 100 kg: 162 mg SC every week	IV: 800 mg every 4 weeks SC: 162 mg every week
Hadlima (adalimumab-bwwd), Yusimry (adalimumab-aqvh), adalimumab-adaz (Hyrimoz®), adalimumab-fkjp (Hulio®), adalimumab-adbm (Cyltezo®)	**RA** 40 mg SC every other week	40 mg every other week
Xeljanz® (tofacitinib)	**RA** 5 mg PO BID	10 mg/day
Xeljanz XR® (tofacitinib extended-release)	**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 *E. coli*-derived proteins, Kineret, or any components of the product
- Boxed warning(s): none reported

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
- IL-1 associated autoinflammatory disorders are known collectively as cryopyrinopathies or the cryopyrin-associated periodic syndromes (CAPS):
  - Familial cold autoiflammatory syndrome (FCAS)
  - Muckle-Wells syndrome (MWS)
  - Neonatal-onset multisystem inflammatory disorder (NOMID, also known as chronic infantile neurologic cutaneous and articular (CINCA) syndrome
- DIRA patients are homozygous or compound heterozygous for loss-of-function mutations in *IL1RN*, encoding IL-1Ra. Most mutations are nonsense or frameshift mutations that lead to either no expression of protein or expression of nonfunctional protein. Examples of disease-causing mutations in *IL1RN* identified include: 4 nonsense mutations, 1 in-frame deletion, 3 frameshift deletions, and a 22-kb and a genomic 175-kb deletion on chromosome 2.
- TNF blockers:
  - Etanercept (Enbrel®), adalimumab (Humira®), adalimumab-atto (Amjevita™), infliximab (Remicade®) and infliximab biosimilars (Avsola™, Renflexis™, Inflectra®), certolizumab pegol (Cimzia®), and golimumab (Simponi®, Simponi Aria®).

Appendix E: Dose Rounding Guidelines for NOMID

Weight-based Dose Range	Vial Quantity Recommendation
≤ 104.99 mg	1 syringe of 100 mg/0.67 mL
105 to 209.99 mg	2 syringes of 100 mg/0.67 mL
210 to 314.99 mg	3 syringes of 100 mg/0.67 mL
325 to 419.99 mg	4 syringes of 100 mg/0.67 mL
420 to 524.99 mg	5 syringes of 100 mg/0.67 mL
525 to 629.99 mg	6 syringes of 100 mg/0.67 mL
630 to 734.99 mg	7 syringes of 100 mg/0.67 mL
735 to 839.99 mg	8 syringes of 100 mg/0.67 mL

Appendix F: 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
	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 G: 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 H: 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 I: Coronavirus-19 Infection (FDA Emergency Use Authorization):

- An EUA is an FDA authorization for the emergency use of an unapproved product or unapproved use of an approved product (i.e., drug, biological product, or device) in the

United States under certain circumstances including, but not limited to, when the Secretary of HHS declares that there is a public health emergency that affects the national security or the health and security of United States citizens living abroad, and that involves biological agent(s) or a disease or condition that may be attributable to such agent(s).

- The EUA decision was based on the results of the SAVE-MORE trial, which was a randomized, double-blinded, placebo-controlled study to evaluate the safety and efficacy of Kineret in adult patients with COVID-19 pneumonia who were at risk of developing severe respiratory failure (SRF). The primary endpoint of the study was the 11-point WHO Clinical Progressional ordinal Scale (CPS) which was compared between the two arms of treatment by Day 28. Patients treated with Kineret had lower odds of more severe disease according to the WHO-CPS at Day 28 compared to placebo (odds ratio: 0.37 [95% CI 0.26 to 0.50]).
- Available alternatives for the EUA authorized use:
  - Veklury® (remdesivir), a SARS-CoV-2 nucleotide analog RNA polymerase inhibitor, is an FDA-approved alternative for the treatment of COVID-19 in hosptilized adults with pneumonia requiring supplemental oxygen (low or high-flow oxygen) who are at risk of progressing to severe respiratory failure.
  - Olumiant® (baricitinib), a Janus kinase (JAK) inhibitor and Actemra® (tocilizumab), an interleukin 6 receptor antagonist, are FDA-approved alternatives for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen and non-invasive ventilation.
- Kineret is authorized under an EUA as a 100 mg subcutaneous injection administered daily for 10 days.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
RA	100 mg SC QD	100 mg/day
NOMID	Initial dose: 1 – 2 mg/kg SC QD or divided BID Maintenance dose: Adjust doses in 0.5 to 1 mg/kg increments. Once daily administration is recommended, but the dose may be split into twice daily administration (a new syringe must be used for each dose).	8 mg/kg/day
DIRA	Initial dose: 1 – 2 mg/kg SC QD Maintenance dose: Adjust doses in 0.5 to 1 mg/kg increments.	8 mg/kg/day

VI. Product Availability

Single-use prefilled syringe: 100 mg/0.67 mL

VII. References

1. Kineret Prescribing Information. Stockholm, Sweden: Swedish Orphan Biovitrum AB; December 2020. Available at: https://www.kineretrx.com/. Accessed January 30, 2024.
2. Smolen JS, Landewé R, Breedveld FC, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2013 update. Ann Rheum Dis. 2014; 73: 492-509.
3. Singh JA, Furst DE, Bharat A, et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. Arthritis Care Res. 2012; 64(5): 625-639.
4. England BR, Tiong BK, and Bergman MJ, et al. 2019 Update of the American College of Rheumatology Recommended Rheumatoid Arthritis Disease Activity Measures. Arthritis Care Res (Hoboken). 2019 Dec;71(12):1540-1555. doi: 10.1002/acr.24042.
5. Kuemmerle-Deschner JB, Ozen S, and Tyrrell PN, et al. Diagnostic criteria for cryopyrin-associated periodic syndrome (CAPS). Ann Rheum Dis. 2017 Jun;76(6):942-947. doi: 10.1136/annrheumdis-2016-209686.
6. Aksentijevich I, Nowak M, Mallah M, and Chae JJ, et al. De novo CIAS1 mutations, cytokine activation, and evidence for genetic heterogeneity in patients with neonatal-onset multisystem inflammatory disease (NOMID): a new member of the expanding family of pyrin-associated autoinflammatory diseases. Arthritis Rheum. 2002 Dec;46(12):3340-8. doi: 10.1002/art.10688.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created, adapted CP.PHAR.244 Anakinra (Kineret) for migration to HFS PDL.	1.13.2020	
2Q 2021 Annual Review : Added criteria for RAPID3 assessment for RA given limited in-person visits during COVID-19 pandemic, updated appendices; 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	4.12.2021	
2Q 2022 Annual Review: Updated initial approval criteria for rheumatoid arthritis, added interleukin-1 receptor antagonist deficiency criteria, added specific criteria for diagnoses not covered, updated appendix B therapeutic alternatives not covered, added DIRA information to general information appendix, added DIRA dose and administration information, reviewed and updated references.	4.26.22	
RT4: added information regarding Kineret EUA for COVID-19 hospitalized patients.	1.19.23	
2Q 2023 annual review: for RA, added TNFi criteria to allow bypass if member has had history of failure of two TNF blockers; updated appendix D with general information for CAPS; Template changes	4.18.23	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
applied to other diagnoses/indications and continued therapy section; references reviewed and updated.		
2Q 2024 annual review: for Appendix I, added Actemra information as an FDA-approved alternative for COVID-19; added Bimzelx, Zymfentra, Omvoh, Tofidence, Sotyktu, Wezlana, and Velsipity to section III.B; references reviewed and updated.	5.7.24	
Added preferred adalimumab products; references reviewed.	4.15.25	

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.