Clinical Policy: Anakinra (Kineret)

Reference Number: PA.CP.PHAR.244
Effective Date: 01/18
Last Review Date 08/17
Line of Business: Medicaid

Revision Log

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

FDA Approved Indication(s)
Kineret is indicated for the treatment of:

- Rheumatoid arthritis (RA) for the 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)
- Cryopyrin-associated periodic syndromes for neonatal-onset multisystem inflammatory disease (NOMID).

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness® 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 (refer to *Appendix B*);
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 methotrexate (MTX) for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effects are experienced;
   b. If intolerance or contraindication to MTX, failure of sulfasalazine, leflunomide, or hydroxychloroquine for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of etanercept *(Enbrel is preferred)* and adalimumab *(Humira is preferred)*each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization is required for etanercept and adalimumab*
6. Tuberculosis (TB) test within the past 12 months in negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
7. Dose does not exceed 100mg daily.

Approval duration: 6 months

B. Cryopyrin-Associated Periodic Syndromes (must meet all)**:**
1. Diagnosis of neonatal-onset multisystem inflammatory disease (NOMID);
2. Prescribed by or in consultation with a rheumatologist;
3. Tuberculosis (TB) test within the past 12 months in negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
4. Dose does not exceed the following:
   a. Initial dose: 1-2 mg/kg daily;
   b. Maintenance dose: 8mg/kg daily.

Approval duration: 6 months

C. Other diagnoses/indications
1. Refer to PA.CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or Continuity of Care policy applies;
2. Member is responding positively to therapy (examples: sign/symptom reduction, no disease progression, no significant toxicity);
3. If request is for a dose increase, new dose does not exceed:
   a. For RA: 100 mg daily;
   b. For NOMID: 8mg/kg administration.

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to PA.CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – PA.CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ACPA: anti-citrullinated protein antibody
CRP- C-reactive protein
DMARDS: disease-modifying antirheumatic drugs
ESR- erythrocyte sedimentation rate
FDA: Food and Drug Administration
IL-1RI: interleukin-1 type I receptor
MTX: methotrexate
NOMID: neonatal-onset multisystem inflammatory disease
RA: rheumatoid arthritis
RF: rheumatoid factor

Appendix B: 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 normal ESR	1
D	**Duration of symptoms**	
	< 6 weeks	0
	≥ 6 weeks	1

Appendix C: Definition of MTX or DMARD Failure
In RA, failure of MTX or DMARD is defined as ≤ 50% decrease in swollen joint count, ≤ 50% decrease in tender joint count, and ≤ 50% decrease in ESR, or ≤ 50% decrease in CRP.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
RA	100 mg SC daily, at the same time Renal insufficiency (creatinine clearance <30 mL/min): 100 mg every other day	100 mg daily
NOMID	1-2 mg/kg daily Renal insufficiency(creatinine clearance <30 mL/min): 1-2 mg/kg every other day	8 mg/kg daily

VI. Product Availability

Injection: 100 mg/0.67 mL solution in a single-use prefilled syringe for subcutaneous injection. Graduated syringe allows for doses between 20 mg and 100 mg.

VII. References

1. Kineret Prescribing Information. Stockholm, Sweden: Swedish Orphan Biovitrum AB; May 2016. Available at http://www.kineretrx.com/pdf/Full-Prescribing-Information-English.pdf . Accessed August 3, 2017.
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. Aletaha D, Neogi T, Silman AJ, et al. 2010 Rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative, Arthritis Rheum , 2010, vol. 62 (pg. 2569 - 81).
4. 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.

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
N/A	

Reviews, Revisions, and Approvals	Date	Approval Date