Pharmacy Drug Policy & Procedure

Policy Name:	Kineret (anakinra)	Policy#:	1844P

Purpose of the Policy

The purpose of this policy is to define coverage criteria for Kineret (anakinra).

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Kineret (anakinra) under the specialty pharmacy benefit if the following criteria are met.

Criteria

1. Coverage Criteria for Rheumatoid Arthritis

1.1 See Rheumatoid Arthritis Immunomodulator Therapies policy

2. Coverage Criteria for Juvenile Idiopathic Arthritis

2.1 See Polyarticular Juvenile Idiopathic Arthritis Immunomodulator Therapies policy

3. Coverage Criteria for Cryopyrin-Associated Periodic Syndromes (CAPS)

3.1 Diagnosis of CAPS, including Familial Cold Auto-inflammatory Syndrome, Muckle-Wells Syndrome, or Neonatal-Onset Multisystem Inflammatory Disease/Chronic Infantile Neurologic Cutaneous or Articular Syndrome

3.2 Ordered by a specialist

4. Coverage Criteria for Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

4.1 Diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

4.2 Ordered by a Specialist

5. Coverage Criteria for Adult-Onset Still's Disease (AOSD)

5.1 Diagnosis of Adult-Onset Still's Disease (AOSD) that is considered to be moderate to severe in nature

5.2 Documentation the patient has moderate-to-severe disease including any one of the following systemic manifestations:

- Fever
- Rash
- Arthritis or arthralgia (joint aches or inflammation)

5.3 Ordered by a Rheumatologist (musculoskeletal doctor)

5.4 For patients with moderate disease that has primarily systemic symptoms with no joint erosions:

- Documented failure to respond, intolerance, or contraindication to non-steroidal anti-inflammatory drugs (NSAIDs, such as ibuprofen or naproxen)
- Documented failure to respond, intolerance, or contraindication to glucocorticoids

5.5 For patients with severe disease such as life-threatening organ involvement and/or conditions such as severe hepatic (liver) involvement, cardiac tamponade (serious medical condition in which blood or fluids fill the space between the sac that encases the heart and the heart muscle), and/or disseminated intravascular coagulation (condition in which blood clots form throughout the body, blocking small blood vessels:

- Documented failure to respond, intolerance, or contraindication to glucocorticoids

6. Exclusion Criteria

6.1 Hypersensitivity to E. coli-derived proteins, anakinra, or any component in Kineret
6.2 Inadequate response to initial or previous anakinra therapy
6.3 Health Alliance does not cover concurrent therapy with other immunomodulators based upon the possible increased risk for infections and other potential pharmacological interactions

7. Approval Period

7.1 Initial Authorization will be placed for 12 months
7.2 All subsequent authorizations will be placed for 12 months, based upon clinical response to therapy

CPT Codes	
HCPCS Codes	

References

1. Kineret (anakinra) [prescribing information]. Stockholm, Sweden: Swedish Orphan Biovitrum AB; December 2020.
2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res (Hoboken). 2021 Jul;73(7):924-939.
3. Onel KB, Horton DB, Lovell DJ, 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 Rheumatol. 2022 Apr;74(4):553-569.
4. Goldbach-Mansky R, Dailey NJ, Canna SW, et al. Neonatal-onset multisystem inflammatory disease responsive to interleukin-1beta inhibition. N Engl J Med 2006; 355:581.
5. Maksimovic L, Stirnemann J, Caux F, et al. New CIAS1 mutation and anakinra efficacy in overlapping of Muckle-Wells and familial cold autoinflammatory syndromes. Rheumatology (Oxford) 2008; 47:309.
6. Miyamae T. Cryopyrin-Associated Periodic Syndromes: Diagnosis and Management. Pediatr Drugs. 2012;14(2):109-117.
7. Yu JR, Leslie KS. Cryopyrin-associated periodic syndrome: an update on diagnosis and treatment response. Curr Allergy Asthma Rep. 2011;11:12-20.
8. Aksentijevich I, Masters SL, Ferguson PJ, et al. An autoinflammatory disease with deficiency of the interleukin-1-receptor antagonist. N Engl J Med 2009; 360:2426.
9. Jamilloux Y, Gerfaud-Valentin M, Henry T, Sève P. Treatment of adult-onset Still's disease: a review. Ther Clin Risk Manag. 2014;11:33-43.
10. Vastert SJ, Jamilloux Y, Quartier P, et al. Anakinra in children and adults with Still's disease. Rheumatology (Oxford) 2019; 58:vi9.

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review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.