

Kineret (anakinra)
Effective 01/01/2025

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

Overview

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Moderately to severely active rheumatoid arthritis (RA)
2. Cryopyrin-Associated Periodic Syndromes (CAPS)
3. Neonatal-Onset Multisystem Inflammatory Disease (NOMID)
4. Deficiency of interleukin one receptor antagonist (DIRA)

Compendial Uses

1. Systemic juvenile idiopathic arthritis (sJIA)
2. Adult-onset Still's disease
3. Non-Hodgkin's lymphoma – Castleman's disease
4. Recurrent pericarditis
5. Hyperimmunoglobulin D syndrome [Mevalonate Kinase Deficiency (MKD)]

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted for members who meet all of the diagnosis-specific criteria:

Moderately to Severely Active Rheumatoid Arthritis (RA)

1. Diagnosis of moderately to severely active rheumatoid arthritis

2. Member has minimum duration of a 3-month trial and failure, intolerance, or contraindication to ONE of the following conventional therapies at maximally tolerated doses:
 - a. Methotrexate
 - b. Leflunomide
 - c. Sulfasalazine
3. Member has trial and failure, contraindication or intolerance to TWO of the following:
 - a. Cimzia
 - b. Enbrel
 - c. Humira (Abbvie), Adalimumab-adaz, Adalimumab-fkjp, Hadlima, or Amjevita (Nuvaila)
 - d. Rinvoq
 - e. Simponi
 - f. Xeljanz or Xeljanz XR
4. Member has trial and failure, contraindication or intolerance to BOTH of the following:
 - a. Actemra
 - b. Orencia

Adult-Onset Still's Disease

1. Diagnosis of Adult-Onset Still's Disease
2. Member meets ONE of the following:
 - a. Member has experienced an inadequate response to at least a 3-month trial of methotrexate
 - b. Member has intolerance or contraindication to methotrexate
 - c. Member has a febrile disease

Active Systemic Juvenile Idiopathic Arthritis (sJIA)

1. Diagnosis of active systemic juvenile idiopathic arthritis (sJIA)
2. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies at maximally tolerated doses:
 - a. Minimum duration of 3-month trial and failure of methotrexate
 - b. Minimum duration of 1-month trial of nonsteroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, naproxen)
 - c. Minimum duration of 2-week trial of a systemic glucocorticoid (e.g., prednisone)

Neonatal-Onset Multisystem Inflammatory Disease (NOMID)

1. Member has one of the following diagnoses:
 - a. Cryopyrin-associated periodic syndromes (CAPS)
 - b. NOMID (also known as Chronic Infantile Neurological Cutaneous and Articular syndrome [CINCA])

Recurrent Pericarditis

1. Diagnosis of recurrent pericarditis
2. Trial and failure with a first-line therapy agent (e.g., colchicine)

Non-Hodgkin's Lymphoma – Multicentric Castleman's Disease

1. Diagnosis of multicentric Castleman's disease.

Hyperimmunoglobulin D Syndrome [Mevalonate Kinase Deficiency (MKD)]

1. Diagnosis of hyperimmunoglobulin D syndrome



Deficiency of Interleukin One Receptor Antagonist (DIRA)

1. Diagnosis of Deficiency of Interleukin One Receptor Antagonist (DIRA) that has been confirmed by genetic testing documenting mutations involving the IL1RN
2. The diagnosis of primary immunodeficiency has been ruled out
3. The member has experienced at least one of the following conditions:
 - Infantile pustulosis (neonatal onset pustulosis)
 - Infantile pustular psoriasis
 - SAPHO syndrome (synovitis, acne, pustulosis, hyperostosis and osteitis)
4. The member has failed high-dose corticosteroids

Continuation of Therapy

Requests for reauthorizations for all diagnoses will be approved when the following criteria are met:

1. Documentation is submitted supporting improvement in member's condition as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

1. Initial approvals will be based on diagnosis:
 - a. Moderately to Severely Active Rheumatoid Arthritis (RA) – 24 months
 - b. Adult-Onset Still's Disease – 24 months
 - c. Active Systemic Juvenile Idiopathic Arthritis (sJIA) – 24 months
 - d. Neonatal-Onset Multisystem Inflammatory Disease (NOMID) – 24 months
 - e. Recurrent Pericarditis – 12 months
 - f. Non-Hodgkin's Lymphoma – Multicentric Castleman's Disease – 12 months
 - g. Hyperimmunoglobulin D Syndrome [Mevalonate Kinase Deficiency (MKD)] – 24 months
 - h. Deficiency of Interleukin One Receptor Antagonist (DIRA) – 12 months
2. Reauthorizations will be based on diagnosis:
 - a. Adult-Onset Still's Disease, Rheumatoid Arthritis and Juvenile Idiopathic Arthritis – 24 months
 - b. Neonatal-Onset Multisystem Inflammatory Disease (NOMID), Multicentric Castleman's disease, Hyperimmunoglobulin D Syndrome and DIRA- 12 months
 - c. Recurrent Pericarditis – 6 months

References

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2. American College of Rheumatology. Hyperimmunoglobulin D Syndrome. <http://www.rheumatology.org/AM-A/Patient-Caregiver/Diseases-Conditions/Hyperimmunoglobulin-D-Syndrome-Juvenile>. Accessed April 18, 2017.
3. Brucato A, Imazio M, Gattorno M, et al. Effect of anakinra on recurrent pericarditis among patients with colchicine resistance and corticosteroid dependence: the AIRTRIP randomized clinical trial. *JAMA*. 2016;316(18):1906-1912. [[PubMed 27825009](#)]
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5. Kineret [package insert]. Stockholm, Sweden: Swedish Orphan Biovitrum AB (publ); December 2020.
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9. National Organization for Rare Disorders. Hyperimmunoglobulin D Syndrome. <http://rarediseases.org/rare-diseases/hyper-igd-syndrome>. Accessed April 18, 2017.
10. Nakagawa K, Gonzalez-Roca E, Souto A, et al. Somatic NLRP3 mosaicism in Muckle-Wells syndrome. A genetic mechanism shared by different phenotypes of cryopyrin-associated periodic syndromes. *Ann Rheum Dis* 2015; 74:603
11. Ortiz-Sanjuán F, Blanco R, Riancho-Zarrabeitia L, et al. Efficacy of Anakinra in Refractory Adult-Onset Still's Disease: Multicenter Study of 41 Patients and Literature Review. *Medicine (Baltimore)* 2015; 94: e1554.
12. Ringold S, Weiss PF, Beukelman T, et al. 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis: Recommendations for the Medical Therapy of Children With Systemic Juvenile Idiopathic Arthritis and Tuberculosis Screening Among Children Receiving Biologic Medications. *Arthritis & Rheumatism*. 2013; 65:2499-2512.

Review History

03/21/05 – Reviewed

05/15/05 – Implemented

02/27/06 – Reviewed

02/25/08 – Reviewed

02/23/09 – Reviewed

02/22/10 – Reviewed

02/28/11 – Reviewed

02/27/12 – Reviewed

02/25/13 – Reviewed

02/24/14 – Reviewed

02/23/15 – Reviewed

02/22/16 – Reviewed

02/27/17 – Adopted SGM & PDS

02/26/18 – Updated

02/20/19 – Updated

11/20/19 - Added Rinvoq as required preferred trial for RA

09/22/2021 – Reviewed and Updated Sept P&T; Added new indication of DIRA with criteria and limitations; References updated. Effective 02/01/2022.

09/21/2022 - Reviewed at Sept P&T; no clinical changes.

11/15/2023 – Reviewed and Updated for Nov P&T; Removed appendix. Consolidated reauthorization criteria. RA - Updated preferred agents and requirement try TWO of the following: Cimzia, Enbrel, Humira or biosimilars, Rinvoq, Simponi, Xeljanz or Xeljanz XR AND Actemra AND Orencia. Updated conventional therapies to include methotrexate, leflunamide, and sulfasalazine. Effective: 1/1/2024

10/09/2024 – Reviewed and updated for October P&T. Updated RA criteria to include Amjevita (Nuvaila) as a preferred adalimumab product. Clarified that all RA criteria must be met. Administrative update to include each diagnosis in the criteria. Effective 1/1/2025.

