Mass General Brigham
Health Plan

Kineret (anakinra)
Effective 01/01/2027

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 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. Adult-onset Still's disease
2. Non-Hodgkin's lymphoma – Castleman's disease
3. Recurrent pericarditis
4. Hyperimmunoglobulin D syndrome [Mevalonate Kinase Deficiency (MKD)]

Coverage Guidelines
If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, 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 following 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. Adalimumab-aaty, adalimumab-adaz, or Hadlima
    d. Rinvoq
    e. Simponi
4. Member has trial and failure, contraindication or intolerance to BOTH of the following:
    a. Tyenne or Avtozma
    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

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

<u>Continuation of Therapy</u>

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

1. Submission of medical records (e.g., chart notes) demonstrating an improvement in the 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. Neonatal-Onset Multisystem Inflammatory Disease (NOMID) – 24 months
    d. Recurrent Pericarditis – 12 months
    e. Non-Hodgkin's Lymphoma – Multicentric Castleman's Disease – 12 months
    f. Hyperimmunoglobulin D Syndrome [Mevalonate Kinase Deficiency (MKD)] – 24 months
    g. Deficiency of Interleukin One Receptor Antagonist (DIRA) – 12 months
2. Reauthorizations will be based on diagnosis:
    a. Adult-Onset Still's Disease, Rheumatoid 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
3. The following quantity limitations apply:

Drug Name and Dosage Form	Quantity Limit
Kineret prefilled syringe	1 syringe per day

References

1. Adler Y, Charron P, Imazio M, et al. 2015 ESC Guidelines for the diagnosis and management of pericardial diseases: The Task Force for the Diagnosis and Management of Pericardial Diseases of the European Society of Cardiology (ESC) Endorsed by: The European Association for Cardio-Thoracic Surgery (EACTS). Eur Heart J. 2015 Nov 7; 36 (42): 2921-64.
2. American College of Rheumatology. Hyperimmunoglobulin D Syndrome. http://www.rheumatology.org/I-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]
4. Cowen EW, Goldbach-Mansky R. DIRA, DITRA, and new insights into pathways of skin inflammation: what's in a name? Arch Dermatol 2012; 148:381
5. Kineret (anakinra) [prescribing information]. Stockholm, Sweden: Swedish Orphan Biovitrum AB (publ); September 2024.
6. Kostjukovits S, Kalliokoski L, Antila K, Korppi M. Treatment of hyperummunoglobulinemia D Syndrome with biologics in children: review of the literature and Finnish experience. Eur J Pediatr. 2015 Jun; 174 (6): 707-14
7. Lazaros G, Imazio M, Brucato A, et al. Anakinra: an emerging option for refractory idiopathic recurrent pericarditis: a systematic review of published evidence. J Cardiovasc Med (Hagerstown) 2016; 17:256.
8. National Organization for Rare Disorders. URL: https://www.rarediseases.org/rare-disease-information/rare-diseases/byID/1210/viewFullReport. Accessed April 18, 2017.
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.

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, leflunomide, 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.
04/09/2025 – Reviewed and Updated for April P&T. Updated criteria for RA to include Tyenne as a preferred tocilizumab product. Effective 6/1/2025.
06/11/2025 – Reviewed and Updated for June P&T. Removed diagnosis of SJIA from the policy. Updated Limitations section to include quantity limits. Effective 09/01/2025.
10/08/2025 – Reviewed and updated for October P&T. Updated policy to remove Actemra as a preferred tocilizumab formulation and updated adalimumab preferred product options to Humira, Hadlima, Simlandi, Yuflyma. Effective 01/01/2026.
03/11/2026 – Reviewed and updated for March P&T. Administrative update - changing verbiage in reauthorization criteria from “documentation is submitted” to “submission of medical records (e.g., chart notes…” and updating language for members who are new to the Plan. Effective 05/01/2026.
09/09/2026 – Reviewed and updated at September P&T. Updating preferred adalimumab and tocilizumab products throughout policy. Effective 01/01/2027.
10/14/2026 – Reviewed and updated at October P&T. Removing Xeljanz/tofacitinib as a previous trial option. Effective 01/01/2027.