Mass General Brigham
Health Plan

Kineret (anakinra)
Effective 01/01/2024

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 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)]

All other indications are considered experimental/investigational and are not a covered benefit.

Coverage Guidelines

Moderately to Severely Active Rheumatoid Arthritis (RA)
Authorization may be granted for members new to the plan who are currently receiving treatment with Kineret, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for treatment of moderately to severely active RA for members who meet one of the following criteria:

1. 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
2. Member has trial and failure, contraindication or intolerance to TWO of the following:
    a. Cimzia
    b. Enbrel
    c. Humira, Adalimumab-adaz, Adalimumab-fkjp, or Hadlima
    d. Rinvoq
    e. Simponi
    f. Xeljanz or Xeljanz XR
3. Member has trial and failure, contraindication or intolerance to BOTH of the following:
    a. Actemra
    b. Orencia

Adult-Onset Still's Disease
Authorization may be granted for members who meet ANY of the following criteria:
1. Member has experienced an inadequate response to at least a 3-month trial of methotrexate
2. Member has intolerance or contraindication to methotrexate
3. Member has a febrile disease

Active Systemic Juvenile Idiopathic Arthritis (sJIA)
Authorization may be granted for members new to the plan who are currently receiving treatment with Kineret, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for the treatment of active sJIA for members who meet the following:
1. 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)
Authorization of 24 months may be granted for the treatment of Cryopyrin-associated periodic syndromes (CAPS), including NOMID (also known as Chronic Infantile Neurological Cutaneous and Articular syndrome (CINCA).

Recurrent Pericarditis
Authorization of 12 months may be granted for the treatment of recurrent pericarditis for members who have failed a first-line therapy agent (i.e., colchicine).

Non-Hodgkin's Lymphoma – Multicentric Castleman's Disease
Authorization of 12 months may be granted for the treatment of multicentric Castleman's disease.

Hyperimmunoglobulin D Syndrome [Mevalonate Kinase Deficiency (MKD)]
Authorization of 24 months may be granted for the treatment of hyperimmunoglobulin D syndrome.

Deficiency of Interleukin One Receptor Antagonist (DIRA)
Authorization may be granted for members who meet all of the following criteria:

1. The diagnosis 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
Reauthorizations for all diagnoses will be granted when documentation is submitted supporting improvement in member's condition 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

1. Kineret [package insert]. Stockholm, Sweden: Swedish Orphan Biovitrum AB (publ); December 2020.
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5. National Organization for Rare Disorders. Hyperimmunoglobulin D Syndrome. http://rarediseases.org/rare-diseases/hyper-igd-syndrome. Accessed April 18, 2017.
6. 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.

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8. 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.
9. 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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11. The NCCN Drugs & Biologics Compendium™. National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed April 24, 2017.
12. 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
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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