Kineret® (anakinra)
Effective 03/01/2023

Plan	☐ MassHealth ☒ MassHealth (PUF) ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview
Kineret® (anakinra) is an interleukin-1 receptor (IL-1) blocker used for the following FDA-approved indications:

- Treatment of moderate to severe Rheumatoid Arthritis (RA)
- Treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID)
- Treatment of deficiency of interleukin-1 receptor antagonist (DIRA)

Coverage Guidelines
Authorization may be reviewed on a case by case basis 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 if the member meets ALL following criteria and documentation has been submitted:

Moderate to severe rheumatoid arthritis

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of moderate to severe rheumatoid arthritis
2. Paid claims or physician documented inadequate response, adverse reaction to **ONE** or contraindication to **ALL** traditional DMARDs (See Appendix A)
3. Paid claims or physician documented inadequate response or adverse reaction to **ONE** or contraindication to ALL biologic DMARDs that is FDA-approved for the rheumatoid arthritis
4. Appropriate dosing *(See Appendix for more frequent or higher doses)*

Neonatal-onset multisystem inflammatory disease (NOMID)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis neonatal-onset multisystem inflammatory disease*
2. Appropriate dosing *(See Appendix for more frequent or higher doses)*

*NOMID is also known as chronic infantile neurological cutaneous and articular (CINCA) syndrome.

Deficiency of interleukin-1 receptor antagonist (DIRA)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of deficiency of interleukin-1 receptor antagonist
2. Confirmation of diagnosis through genetic testing
3. Appropriate dosing (weight required)

Off-Label Indications
Acute gout
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of acute gout
2. Paid claims or physician documentation of inadequate response, adverse reaction, or contraindication to **ALL** of the following:
    a. NSAIDs
    b. Colchicine
    c. Oral or intraarticular glucocorticoids

Adult-Onset Still's disease (AOSD) or **Systemic Juvenile Idiopathic Arthritis (SJIA)**
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of **ONE** of the following:
    a. Adult-Onset Still's Disease
    b. Systemic Juvenile Idiopathic Arthritis
2. Paid claims or physician documentation of inadequate response or adverse reaction to **ONE** or a contraindication to **ALL** corticosteroids
3. Requested dose is 1 to 2 mg/kg once daily (maximum initial dose of 100 mg); if no response, dose may be titrated up to 4 mg/kg once daily (maximum dose of 200 mg)

Moderate to severe hidradenitis suppurativa
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of moderate to severe hidradenitis suppurativa (Hurley Stage II and Hurley Stage III disease)
2. Paid claims or physician documented inadequate response or adverse reaction to **ONE** oral antibiotic or contraindication to **ALL** oral antibiotics (e.g. rifampin, clindamycin, tetracycline, doxycycline, minocycline)
3. Paid claims or physician documented inadequate response, adverse reaction or contraindication to Humira® (adalimumab)

Hyperimmunoglobulin D syndrome (HIDS)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of hyperimmunoglobulin D syndrome
2. Paid claims or physician documentation of inadequate response or adverse reaction to **ONE** NSAID or contraindication to **ALL** NSAIDs

3. Paid claims or physician documentation of inadequate response or adverse reaction to **ONE** systemic corticosteroid or contraindication to **ALL** systemic corticosteroids

Recurrent pericarditis
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of recurrent pericarditis
2. Paid claims or physician documented inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following:
    a. Nonsteroidal anti-inflammatory drugs (NSAID)
    b. Aspirin
3. Paid claims or physician documented inadequate response or adverse reaction to **ONE** corticosteroid, or a contraindication to **ALL** corticosteroids
4. Paid claims or physician documented inadequate response, adverse reaction, or contraindication to colchicine
5. Dose requested is 100 mg SQ once daily

Synovitis-acne-pustulosis-hyperostosis-osteitis syndrome (SAPHO)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of SAPHO
2. Paid claims or physician documentation of inadequate response or adverse reaction to **ONE** NSAID or contraindication to **ALL** NSAIDs
3. Paid claims or physician documentation of inadequate response or adverse reaction to **ONE** systemic corticosteroid or contraindication to **ALL** systemic corticosteroids

New members currently stable on Kineret® can be approved without documentation of failed trials with the conventional therapies.

Continuation of Therapy
Resubmission by prescriber will infer a positive response to therapy and request can be recertified if dosing is appropriate.

Limitations
1. Initial approvals will be granted for:
    a. Off label indications : 3 months
    b. FDA-approved indications: 6 months
2. Reauthorizations will be for 12 months
3. The following quantity limits apply:

Kineret Inj	28 injections per 28 days

Appendix A: Conventional Therapies for Plaque Psoriasis

Conventional Treatment Lines	Agents Used
Topical Agents	emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene, calcitriol, calcineurin inhibitors
Systemic Agents	Traditional DMARDs: methotrexate, apremilast, acitretin,
Phototherapy	ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB)

Appendix B: More Frequent/Higher Doses

Requests more frequent or higher doses of injectable biologics, may be approved if ALL of the following is provided:

1. Documentation of severe disease
2. **ONE** of the following:
    a. Inadequate response or adverse reaction to **ONE** other injectable biologic which is FDA-approved for the requested indication
    b. Contraindication to **ALL** other injectable biologics which are FDA-approved for the requested indication
3. Documented partial response to FDA-approved dosing of current biologic therapy
4. Documentation of specialist consult for the requested indication

References

1. Kineret [package insert]. Stockholm, Sweden: Swedish Orphan Biovitrum AB (publ); December 2020.
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4. The NCCN Drugs & Biologics Compendium™. National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed April 24, 2017.
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6. National Organization for Rare Disorders. URL: https://www.rarediseases.org/rare-disease-information/rare-diseases/byID/1210/viewFullReport. Accessed April 18, 2017.
7. 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.
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9. National Organization for Rare Disorders. Hyperiimunoglobulin D Syndrome. http://rarediseases.org/rare-diseases/hyper-igd-syndrome. Accessed April 18, 2017.
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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. 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.

Review History

03/21/05 – Reviewed
05/15/05 – Effective
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 – Reviewed and revised (adopted SGM &ST)
03/01/18 – Reviewed and revised (adopted MH RS)
02/20/19 – Reviewed in P&T Meeting
10/21/2020 – Reviewed and Updated; separated out Comm/Exch vs. MassHealth. Matched MassHealth Preferred Unified Formulary for implementation 1/1/2021.
06/22/2022 – Reviewed and Updated for June P&T; matched MH UPPL. Added criteria for Deficiency of Interleukin-1 Receptor Antagonist (DIRA). Continuation of therapy language was updated. Added recurrent pericarditis to Appendix: Off Label Indications. Added Appendix: More Frequent/Higher Doses. Effective 08/01/2022.
01/11/2023 – Reviewed and updated for Jan P&T. Matched MH criteria. Appropriate diagnosis was replaced with a specific indication throughout. Added language regarding stability of requested medication for new members. Off-label indications added for: acute gout, AOSD, SJIA, HS, HIDS, recurrent pericarditis, SAPHO. Removed dosing appendix. Removed FCAS/MWS indication from appendix. Effective 3/1/23.

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