Kineret® (anakinra)
Effective 08/01/2022

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:

- 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)
- Treatment of hidradenitis suppurativa (HS) – off label indication
- Treatment of acute gout – off label indication
- Treatment of Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells syndrome (MWS) – off label indication
- Recurrent Pericarditis – off label indication

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to AllWays Health Partners 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:

<u>Moderate to Severe Rheumatoid Arthritis (RA)</u>

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

1. Appropriate diagnosis
2. Paid claims or physician documented inadequate response, adverse reaction, or contraindication to at least **ONE** traditional DMARD that is FDA-approved for the rheumatoid arthritis (See Appendix B)

3. **ONE** of the following:
    a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for the rheumatoid arthritis
    b. Contraindication to **ALL** biologic DMARDs that are FDA-approved for 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. Appropriate diagnosis*
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. Appropriate diagnosis
2. Confirmation of diagnosis through genetic testing
3. Appropriate dosing (weight required)

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. Acute Gout, Familial Cold Autoinflammatory Syndrome (FCAS), and Muckle-Wells syndrome: 3 months
    b. Rheumatoid Arthritis, NOMID/CINCA, DIRA, HS, recurrent pericarditis: 6 months
2. Reauthorizations will be for 12 months
3. The following quantity limits apply:

Kineret Inj	28 injections per 28 days

Appendices
Appendix A: Dosing

	Pediatric Dosing	Other Dosing
Kineret® (anakinra)	**Neonatal-onset multisystem inflammatory disease (NOMID)** Initial:1 to 2 mg/kg; maximum 8 mg/kg daily; may be given once or twice daily **Muckle-Wells syndrome (MWS) amd Familial Cold Autoinflammatory Syndrome (FCAS)** Initial: 1mg/kg per day	**Rheumatoid Arthritis (mod-severe):** 100 mg subcutaneously daily **Acute Gout:** 100 mg was subcutaneously daily until symptoms of acute gouty arthritis improved **Hidradenitis Suppurative (HS)** 100 mg subcutaneously daily **Deficiency of Interleukin-1 Receptor Antagonist (DIRA)**

		1-2 mg/kg daily (maximum 8 mg/kg daily) **Recurrent Pericarditis** 100 mg SC once daily

Appendix B. 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 C: 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

Appendix D: Off-Label Indications

Hidradenitis Suppurativa (HS)
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)
4. Dosing of Kineret (anakinra): 100 mg daily

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

1. Appropriate diagnosis
2. Paid claims or physician documented inadequate response, adverse reaction or contraindication to **ALL** the following:
    a. NSAIDs
    b. Colchicine
    c. Oral or intraarticular glucocorticoids

Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells syndrome (MWS)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Appropriate dosing: Kineret (anakinra) 1 mg/kg/day (maximum: 100 mg)

NOTE: Cryopyrin-Associated Periodic Syndrome (CAPS) includes familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS)

Recurrent Pericarditis
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
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 SC once daily

References

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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.

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