

**Kineret® (anakinra)
Effective January 1, 2021**

Plan	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> MassHealth (PUF) <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> 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 hidradenitis suppurative (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

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:

Moderate to Severe Rheumatoid Arthritis (RA)

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

1. Appropriate diagnosis
2. **ONE** of the following:
 - a. 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)



- b. Paid claims or physician documented inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for the rheumatoid arthritis
- 3. Dosing is appropriate

Neonatal-onset multisystem inflammatory disease (NOMID)

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

- 1. Appropriate diagnosis*
- 2. Appropriate dosing

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

Continuation of Therapy

Reauthorization requires physician documentation of continuation of therapy, positive response to therapy, approved indication and appropriate dosing.

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: 6 months.
- 2. Reauthorizations will be for 12 months
- 3. The following quantity limits apply:

Kineret Inj	28 injections per 28 days
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Appendices

Appendix A: Dosing

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

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: Off-Label Indications

Hidradenitis Suppurative (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): 100mg 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) 1mg/kg/day (maximum: 100mg)

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

References

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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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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. Lazarus 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

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