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 |

Appendices
Appendix A: Dosing

<table>
<thead>
<tr>
<th>Pediatric Dosing</th>
<th>Other Dosing</th>
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<tbody>
<tr>
<td><strong>Pediatric</strong></td>
<td><strong>Neonatal-onset multisystem inflammatory disease (NOMID)</strong></td>
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<tr>
<td>Kineret® (anakinra)</td>
<td>Initial: 1 to 2 mg/kg; maximum 8 mg/kg daily; may be given once or twice daily</td>
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<tr>
<td><em>Muckle-Wells syndrome (MWS) and Familial Cold Autoinflammatory Syndrome (FCAS)</em></td>
<td>Initial: 1mg/kg per day</td>
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<tr>
<td><strong>Rheumatoid Arthritis (mod-severe):</strong></td>
<td>100 mg subcutaneously daily</td>
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<tr>
<td><strong>Acute Gout:</strong></td>
<td>100 mg was subcutaneously daily until symptoms of acute gouty arthritis improved</td>
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<tr>
<td><strong>Hidradenitis Suppurative (HS)</strong></td>
<td>100 mg subcutaneously daily</td>
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Appendix B. Conventional Therapies for Plaque Psoriasis

<table>
<thead>
<tr>
<th>Conventional Treatment Lines</th>
<th>Agents Used</th>
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<tbody>
<tr>
<td><strong>Topical Agents</strong></td>
<td>emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene, calcitriol, calcineurin inhibitors</td>
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<tr>
<td><strong>Systemic Agents</strong></td>
<td>Traditional DMARDS: methotrexate, apremilast, acitretin,</td>
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<tr>
<td><strong>Phototherapy</strong></td>
<td>ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB)</td>
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</table>

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**


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

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