UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3161-5
Program	Step Therapy
Medications	Kineret® (anakinra)
P&T Approval Date	1/2022, 11/2022, 1/2023, 4/2023, 2/2024
Effective Date	5/1/2024

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try preferred products before providing coverage for Kineret (anakinra).

Kineret (anakinra) is an interleukin-1 receptor antagonist indicated for reducing the signs and symptoms and slowing progression of structural damage in moderately to severely active rheumatoid arthritis, in patients 18 years of age or older who have failed one or more disease-modifying anti-rheumatic drugs (DMARDs). Kineret is also indicated for the treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID) and the treatment of deficiency of interleukin-1 receptor antagonist (DIRA).

Adalimumab, tumor necrosis factor (TNF) blocker is indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Cimzia® (certolizumab), Enbrel® (etanercept), and Simponi® (golimumab), all TNF blockers, are indicated for the treatment of adults with rheumatoid arthritis. Simponi is FDA approved for use with methotrexate (MTX) in these patients. Actemra® (tocilizumab), an interleukin-6 (IL-6) receptor antagonist is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Rinvoq™ (upadacitinib) and Xeljanz®/Xeljanz® XR (tofacitinib) are JAK inhibitors indicated for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an adequate response or intolerance to one or more TNF antagonist therapies. Orencia® (abatacept) is indicated for moderately to severely active rheumatoid arthritis in adults. Orencia may be used as monotherapy or concomitantly with DMARDs other than JAK inhibitors or biologic DMARDs (e.g., TNF antagonists).

Members currently on Kineret therapy as documented in claims history will be allowed to continue their current therapy. Members new to therapy will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

A. <u>Rheumatoid Arthritis (RA)</u>

1. **Kineret** will be approved based on **<u>one</u>** of the following criteria:

   a. **<u>Both</u>** of the following:

      (1) History of failure, contraindication, or intolerance to **<u>two</u>** of the following preferred products (Document drug, date, and duration of trial):

(a) Cimzia (certolizumab)
(b) One of the preferred adalimumab products[b]
(c) Simponi (golimumab)
(d) Rinvoq (upadacitinib)
(e) Xeljanz/Xeljanz XR (tofacitinib)
(f) Enbrel (etanercept)

-AND-

(2) History of failure, contraindication, or intolerance to **both** of the following preferred products (Document drug, date, and duration of trial):

(a) Actemra (tocilizumab)
(b) Orencia (abatacept)

-OR-

b. **Both** of the following:

(1) Patient is currently on Kineret therapy

-AND-

(2) Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Sobi sponsored Kineret ON TRACK™ (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Kineret*

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Sobi sponsored Kineret ON TRACK™ **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

B. Other Diagnoses

1. **Kineret** will be approved

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
[b] For a list of preferred adalimumab products please reference drug coverage tools.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits may be in place

- Notification may be in place

4. References:

1. Kineret [package insert]. Waltham, MA: Sobi; December 2020.
2. Humira [package insert]. North Chicago, IL: AbbVie Inc.; February 2021.
3. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; September 2019.
4. Simponi [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2019.
5. Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; June 2022.
6. Xeljanz/Xeljanz XR/Xeljanz Oral Solution [package insert]. New York, NY: Pfizer Labs; January 2022.
7. Rinvoq [package insert]. North Chicago, IL: AbbVie Inc.; April 2022.
8. Orenica [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; June 2020.
9. Enbrel [package insert]. Thousand Oaks, CA: Immunex Corp.; June 2022.

Program	Step Therapy - Kineret (anakinra)
Change Control	
1/2022	New program.
11/2022	Added Enbrel as a preferred product step option. Updated background and references.
1/2023	Updated step therapy requirements to Humira or Amjevita. Updated background and references.
4/2023	Updated step therapy requirement from Humira or Amjevita to one of the preferred adalimumab products and added the footnote “For a list of preferred adalimumab products please reference drug coverage tools.” Updated references.
2/2024	Removed Olumiant as a preferred product for RA.