UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 3161-1
Program	Step Therapy
Medications	Kineret® (anakinra)
P&T Approval Date	1/2022
Effective Date	4/1/2022; Oxford only: N/A

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).

Humira® (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) and Simponi® (golimumab), both TNF blockers, are indicated for the treatment of adults with moderately to severely active 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). Olumiant® (baricitinib) is a JAK inhibitor indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies. 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.

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2. Coverage Criteria[a]:

A. Rheumatoid Arthritis (RA)

1. **Kineret** will be approved based on **one** of the following criteria:

   a. **Both** of the following:

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

         (a) Cimzia (certolizumab)
         (b) Humira (adalimumab)
         (c) Simponi (golimumab)
         (d) Olumiant (baricitinib)
         (e) Rinvoq (upadacitinib)
         (f) Xeljanz/Xeljanz XR (tofacitinib)

      -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.

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.; March 2021.
6. Xeljanz/Xeljanz XR/Xeljanz Oral Solution [package insert]. New York, NY: Pfizer Labs; December 2021.
7. Olumiant [package insert]. Indianapolis, IN: Lilly USA, LLC; July 2020.
8. Rinvoq [package insert]. North Chicago, IL: AbbVie Inc.; December 2021.
9. Orenica [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; June 2020.

Program	Step Therapy - Kineret (anakinra)
Change Control	
1/2022	New program.