UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 3039-20
Program	Step Therapy
Medications	*Tocilizumab: Actemra® (tocilizumab), Actemra (tocilizumab) ACTPen, Avtozma® (tocilizumab-anoh), and **Tyenne® (tocilizumab-aazg) *This step criteria refers to the subcutaneous formulations of tocilizumab. **Tyenne (tocilizumab-aazg) is excluded from coverage for the majority of our benefits.
P&T Approval Date	10/2014, 2/2015, 3/2016, 3/2017, 3/2018, 3/2019, 9/2019, 12/2020, 12/2021, 11/2022, 1/2023, 4/2023, 2/2024, 10/2024, 12/2024, 4/2025, 3/2026
Effective Date	9/1/2026

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 two preferred products before providing coverage for tocilizumab [Actemra (tocilizumab), Avtozma (tocilizumab-anoh), or **Tyenne (tocilizumab-aazg)]. Infused medications approved for the treatment of rheumatoid arthritis are not part of the criteria.

Tocilizumab is an interleukin-6 (IL-6) receptor antagonists 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). Adalimumab is tumor necrosis factor (TNF) blocker 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. 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 methotrexate. Enbrel (etanercept) is a tumor necrosis factor (TNF) blocker indicated for the treatment of rheumatoid arthritis.

Members currently on tocilizumab therapy as documented in claims history will be allowed to continue on 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. **Tocilizumab** will be approved based on **both** of the following criteria:

   a. Diagnosis of moderately to severely active rheumatoid arthritis

   -AND-

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

      -OR-

      (2) **Both** of the following:

         (a) Patient is currently on tocilizumab therapy

         -AND-

         (b) Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored program (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 tocilizumab*

***** 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 a manufacturer sponsored program **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. **Tocilizumab** 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

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management programs may apply.
[b] For a list of preferred products please reference drug coverage tools.

**Tyenne (tocilizumab-aazg) is excluded from coverage for the majority of our benefits.

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 and/or Notification may be in place.
- The intravenous infusion is typically covered under the medical benefit. Please refer to the United Healthcare Drug Policy for Tocilizumab.

4. References:

1. Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; September 2024.
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. Rinvoq [package insert]. North Chicago, IL: AbbVie Inc.; April 2022.
6. Xeljanz/Xeljanz XR/Xeljanz Oral Solution [package insert]. New York, NY: Pfizer Labs; January 2022.
7. Enbrel [package insert]. Thousand Oaks, CA: Immunex Corp.; June 2022.
8. Tyenne [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; March 2024
9. Avtozma [package insert]. Jersey City, NJ: Celltrion USA, Inc.; July 2025.

Program	Step Therapy - Tocilizumab: Actemra (tocilizumab), Actemra (tocilizumab) ACTPen, Avtozma (tocilizumab-anoh), and **Tyenne (tocilizumab-aazg)
Change Control	
10/2014	New step therapy program.
2/2015	Reformatted to clarify intent. Updated sample pack language.
3/2016	Annual review. Updated background. Changed authorization periods from 60 months to 12 months. Added Maryland Continuation of Care. Added reference to UHC drug policy for intravenous infusions. Updated references.
7/2016	Added Indiana and West Virginia coverage information.
11/2016	Administrative change. Added California coverage information.
3/2017	Annual review. Updated coverage criteria to include manufacturer sample language (i.e., Actemra Access Solutions program); added verbiage to simplify initial authorization criteria. Updated coverage criteria to add documentation language of failure of preferred products (i.e., document drug, date and duration of trial). Updated background and references. State mandate reference language updated.
3/2018	Annual review with no updated to coverage criteria. Updated references.
3/2019	Annual review with no updates to coverage criteria. Updated

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	references.
9/2019	Revised step therapy medications. Updated background and references.
12/2020	Annual review. Added ACTPen to medications in-scope for clarity. Specified diagnosis requirements to match other programs but no change to clinical intent. Updated references.
12/2021	Annual review. Removed biologic language with no changes to clinical criteria. Updated background and references.
11/2022	Added Enbrel as a preferred product step option for RA. Updated references.
1/2023	Updated step therapy requirements to Humira or Amjevita. Updated background.
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."
2/2024	Removed Olumiant as a preferred product for RA.
10/2024	Updated RA step requirement noting Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, and Humira as preferred adalimumab products with no change to clinical intent. Removed preferred adalimumab footnote.
12/2024	Added Tyenne to coverage criteria with Actemra. Updated background and references.
4/2025	Removed examples for adalimumab step therapy. Added the footnote "For a list of preferred products please reference drug coverage tools."
3/2026 (5/1/2026 eff)	Renamed program to Tocilizumab. Added Avtozma (tocilizumab-anoh) to the program. Updated Actemra and Tyenne to Tocilizumab throughout the program. Updated background and reference.
03/2026 (9/1/2026 eff)	Tyenne noted as typically excluded from coverage starting 9/1/2026.

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