UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2194-12
Program	Prior Authorization/Medical Necessity
Medication	*Actemra® (tocilizumab) and Tyenne® (tocilizumab-aazg) *This program applies to the subcutaneous formulation of tocilizumab.
P&T Approval Date	5/2020, 4/202, 6/2021, 12/2021, 4/2022, 11/2022, 1/2023, 4/2023, 7/2023, 2/2024, 10/2024, 12/2024
Effective Date	4/1/2025

1. Background:

Tocilizumab [Actemra (tocilizumab) and Tyenne (tocilizumab-aazg)] is an interleukin-6 (IL-6) receptor antagonist, available in both an intravenous and a subcutaneous formulation. Subcutaneous formulations of tocilizumab are 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). It is also indicated for giant cell arteritis in adult patients, the treatment of active polyarticular juvenile idiopathic arthritis (PJIA) and active systemic juvenile idiopathic arthritis (SJIA) in patients 2 years of age and older, and for slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).

2. Coverage Criteria[a]:

A. Giant Cell Arteritis (GCA)

1. **Initial Authorization**

   a. **Actemra or Tyenne** will be approved based on **all** of the following criteria:

      (1) Diagnosis of giant cell arteritis

      -AND-

      (2) Patient is not receiving Actemra or Tyenne in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

      -AND-

      (3) Prescribed by or in consultation with a rheumatologist

      Authorization will be issued for 12 months.

2. **Reauthorization**

   a. **Actemra or Tyenne** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Actemra or Tyenne therapy

-AND-

(2) Patient is not receiving Actemra or Tyenne in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

B. Rheumatoid Arthritis (RA)

1. **Initial Authorization**

a. **Actemra or Tyenne** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderately to severely active rheumatoid arthritis

-AND-

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

(a) History of failure to a 3 month trial of **one** non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial).[b^]

-OR-

(b) Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

-AND-

(3) **One** of the following:

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

i. One of the preferred adalimumab products (i.e. Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, Humira)
ii. Cimzia (certolizumab)
iii. Enbrel (etanercept)
iv. Rinvoq (upadacitinib)

v. Simponi (golimumab)
vi. Xeljanz/Xeljanz XR (tofacitinib)

-OR-

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

i. Patient is currently on Actemra or Tyenne therapy as documented by claims history or submission of medical records (Document date and duration of therapy)

-AND-

ii. 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 Actemra or Tyenne*

-AND-

(4) Patient is not receiving Actemra or Tyenne in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

-AND-

(5) Prescribed by or in consultation with a rheumatologist

* 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.

2. **Reauthorization**

a. **Actemra or Tyenne** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Actemra or Tyenne therapy

-AND-

(2) Patient is not receiving Actemra or Tyenne in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

C. Polyarticular Juvenile Idiopathic Arthritis (PJIA)

1. **Initial Authorization**

   a. **Actemra or Tyenne** will be approved based on **all** of the following criteria:

      (1) Diagnosis of active polyarticular juvenile idiopathic arthritis

      -AND-

      (2) Patient is not receiving Actemra or Tyenne in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

      -AND-

      (3) Prescribed by or in consultation with a rheumatologist

      Authorization will be issued for 12 months.

2. **Reauthorization**

   a. **Actemra or Tyenne** will be approved based on **both** of the following criteria:

      (1) Documentation of positive clinical response to Actemra or Tyenne therapy

      -AND-

      (2) Patient is not receiving Actemra or Tyenne in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

      Authorization will be issued for 12 months.

D. Systemic Juvenile Idiopathic Arthritis (SJIA)

1. **Initial Authorization**

   a. **Actemra or Tyenne** will be approved based on **all** of the following criteria:

      (1) Diagnosis of active systemic juvenile idiopathic arthritis

      -AND-

      (2) Patient is not receiving Actemra or Tyenne in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia

(certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

-AND-

(3) Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Actemra or Tyenne** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Actemra or Tyenne therapy

-AND-

(2) Patient is not receiving Actemra or Tyenne in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

E. Systemic sclerosis-associated interstitial lung disease

1. **Initial Authorization**

a. **Actemra or Tyenne** will be approved based on **all** of the following criteria:

(1) Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) as documented by **all** of the following criteria:[4]

(a) **One** of the following:

i. Skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints

-OR-

ii. At least **two** of the following:

- Skin thickening of the fingers (e.g., puffy fingers, sclerodactyly of the fingers)
- Fingertip lesions (e.g., digital tip ulcers, fingertip pitting scars)
- Telangiectasia
- Abnormal nailfold capillaries
- Pulmonary arterial hypertension
- Raynaud's phenomenon
- SSc-related autoantibodies (e.g., anticentromere, anti-topoisomerase

I, anti-RNA polymerase III)

-AND-

(b) Presence of interstitial lung disease as determined by finding evidence of pulmonary fibrosis on HRCT, involving at least 10% of the lungs

-AND-

(2) Patient is not receiving Actemra or Tyenne in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

-AND-

(3) Prescribed by or in consultation with a pulmonologist

Authorization will be issued for 12 months

2. **Reauthorization**

a. **Actemra or Tyenne** will be approved based on **both** of the following criterion:

(1) Documentation of positive clinical response to Actemra or Tyenne therapy.

-AND-

(2) Patient is not receiving Actemra or Tyenne in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

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 Connecticut, Kentucky and Mississippi business only a 30-day trial will be required.
^ Tried/Failed alternative(s) are supported by FDA labeling

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.

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.; June 2022.
2. Tyenne [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; March 2024
3. Pavy S. Constantin A, Pham T, et al. Methotrexate therapy for rheumatoid arthritis: clinical practice guidelines based on published evidence and expert opinions. Joint Bone Spine 2006;73(4):388-95.
4. Singh JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. Arthritis Rheum. 2016;68(1):1-26.
5. van den Hoogen F, Khanna D, Fransen J, et al. 2013 Classification criteria for systemic sclerosis: an American College of Rheumatology/European League against Rheumatism collaborative initiative. Ann Rheum Dis 2013;72:1747-1755.

Program	Prior Authorization/Medical Necessity - Actemra (tocilizumab) and Tyenne (tocilizumab-aazg)
Change Control	
5/2020	New program.
4/2021	Added coverage criteria for systemic sclerosis-associated interstitial lung disease. Updated background and references.
6/2021	Removed prescriber requirement from reauthorization criteria. Added coverage criteria for patients previously treated with a biologic DMARD for rheumatoid arthritis. Added clarification that submission of medical records is required documenting current therapy with Actemra in order to bypass step if claim history not available for rheumatoid arthritis.
12/2021	Updated the following with no change to clinical intent: updated conventional DMARD bypass language for rheumatoid arthritis, removed "biologic" from required preferred product criteria language and updated CT/KY footnote.
4/2022	Updated background to reflect both formulations being approved for GCA. Updated references.
11/2022	Added Enbrel as a preferred product step option for RA. Added Enbrel as an example where appropriate. Added Mississippi to state mandate footnote. Updated reference.
1/2023	Updated step therapy requirements to Humira or Amjevita. Updated listed examples from Humira to adalimumab.
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 examples JAK-I with Rinvoq.
7/2023	Updated not receiving in combination language to targeted immunomodulator and updated examples.
2/2024	Removed Olumiant as a preferred product for RA. Updated state mandate footnote to 30-day trial for Connecticut.
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. Added T/F footnote. Updated background and references.