UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1128-15
Program	Prior Authorization/Notification
Medication	*Actemra® (tocilizumab) and Tyenne® (tocilizumab-aazg) *This program applies to the subcutaneous formulation of tocilizumab.
P&T Approval Date	2/2014, 2/2015, 3/2016, 3/2017, 7/2017, 7/2018, 7/2019, 7/2020, 4/2021, 4/2022, 4/2023, 7/2023, 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 **both** 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)]

      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-

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(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) Patient has had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide, sulfasalazine)^

-AND-

(3) 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.

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 **both** of the following criteria:

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(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)]

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 **both** 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)]

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-

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(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 (SSc-ILD)

1. **Initial Authorization**

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

(1) Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD)

-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.

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.

[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.

^ 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)

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and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits and/or Step Therapy 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. Tyenne [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; March 2024

Program	Prior Authorization/Notification - Actemra (tocilizumab) and Tyenne (tocilizumab-aazg)
Change Control	
2/2014	New program.
9/2014	Administrative change - Tried/Failed exemption for State of New Jersey removed.
2/2015	Annual review with no change to coverage criteria. Minor reformatting. Updated references.
3/2016	Annual review with no change to the coverage criteria. Updated background. Updated statement regarding scope of the program. Added reference to UHC drug policy for intravenous infusions. Updated references.
3/2017	Annual review with no change to the coverage criteria. Updated background and references.
7/2017	Added coverage criteria for giant cell arteritis. Updated background and references.
7/2018	Annual review. Added coverage for PJIA. Updated references.
7/2019	Annual review. Added coverage criteria for SJIA. Updated background and references.
7/2020	Annual review. Updated authorization issue to 12 months for renewal. Updated reference.
4/2021	Added coverage criteria for systemic sclerosis-associated interstitial lung disease. Updated background and references.
4/2022	Annual review. Updated background to reflect both formulations being approved for GCA. Updated references.
4/2023	Annual review with no change to coverage criteria. Updated listed examples from Humira to adalimumab and added Rinvoq as JAK-I example. Updated reference. Added state mandate footnote.
7/2023	Updated not receiving in combination language to targeted immunomodulator and updated examples.
10/2024	Annual review with no change to coverage criteria. Updated reference.
12/2024	Added Tyenne to coverage criteria with Actemra. Added T/F footnote. Updated background and references.

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