CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Tocilizumab (Actemra, Tyenne, Tofidence)
BENEFIT TYPE	Medical or Pharmacy
STATUS	Prior Authorization Required

Actemra, approved by the FDA in 2010, is an interleukin-6 (IL-6) receptor antagonist. It is supplied as IV and subQ formulations. IL-6 is a pro-inflammatory cytokine produced by a variety of cell types.
Actemra is indicated to treat rheumatoid arthritis, giant cell arteritis (GCA), systemic sclerosis-associated interstitial lung disease (SSc-ILD), polyarticular juvenile idiopathic arthritis (PJIA), systemic juvenile idiopathic arthritis (SJIA), cytokine release syndrome (CRS), and coronavirus disease 2019 (COVID-19). In 2024, Tyenne and Tofidence were approved as biosimilars for some, but not all, of the indications of Actemra.
GCA is a form of systemic vasculitis defined by granulomatous arteritis that affects large-sized and medium-sized blood vessels with a predisposition to affect the cranial arteries.

Tocilizumab (Actemra, Tyenne, Tofidence) will be considered for coverage when the following criteria are met:

Giant Cell Arteritis (GCA)

For **initial** authorization:

1. Member must be 50 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Member has a diagnosis of GCA based on at least one of the following:
   a) Temporal artery biopsy (TAB) revealing features of GCA
   b) Evidence of large-vessel vasculitis by imaging (i.e., ultrasound, MRI, CT angiography, or PET-CT); AND
4. Member demonstrates typical signs and symptoms of active GCA such as elevated erythrocyte sedimentation rate (ESR) or C - reactive protein (CRP), new-onset persistent localized headache, visual symptoms, polymyalgia rheumatica, claudication, weight loss or fever; AND
5. Member has developed or has an increased risk of glucocorticoid side effects OR member has relapsed on or is refractory to glucocorticoids; AND
6. Actemra will be used in adjunct with a tapering course of glucocorticoids; AND
7. Member has tested negative for tuberculosis (TB) within the past 12 months.
8. **Dosage allowed/Quantity limit:**
   a) Intravenous
      i) Actemra/Tyenne/Tofidence: 6 mg per kg every 4 weeks in combination with a tapering course of glucocorticoids. Max dose of 600 mg per infusion.
   b) Subcutaneous
      Actemra/Tyenne: 162 mg subQ once weekly in combination with a tapering course of glucocorticoids. A dose of 162 mg subQ every other week in combination with a tapering course of glucocorticoids may also be considered. Quantity Limit: 4 syringes/autoinjectors per 28 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must demonstrate improvement such as absence of relapse or reduced glucocorticoid dose.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Juvenile Idiopathic Arthritis (JIA) – systemic (sJIA) and polyarticular (pJIA)

For **initial** authorization:
1. Member must be 2 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Member has a diagnosis of active PJIA or active SJIA; AND
4. For PJIA, member has had an 8-week trial and failure of a conventional DMARD (e.g., methotrexate, leflunomide, etc.); OR
5. For SJIA, member has had an inadequate response to **ONE** of the following:
   a) NSAID;
   b) Glucocorticoid; AND
6. Member has tested negative for tuberculosis (TB) within the past 12 months.
7. **Dosage allowed/Quantity limit:**
   a) PJIA intravenously: Actemra/Tyenne
      i) Body weight < 30 kg: 10 mg per kg every 4 weeks
      ii) Body weight ≥ 30 kg: 8 mg per kg every 4 weeks
   b) SJIA intravenously: Actemra/Tyenne
      i) Body weight < 30 kg: 12 mg per kg every 2 weeks
      ii) Body weight ≥ 30 kg: 8 mg per kg every 2 weeks
   c) PJIA subcutaneously: Actemra, Tyenne and Tofidence
      i) Body weight < 30 kg: 162 mg once every three weeks
      ii) Body weight ≥ 30 kg: 162 mg once every two weeks
   d) SJIA subcutaneously: Actemra, Tyenne and Tofidence
      i) Body weight < 30 kg: 162 mg every two weeks
      ii) Body weight ≥ 30 kg: 162 mg every week

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided showing improvement of signs and symptoms of disease such as decreased joint swelling and pain and improved quality of life.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Rheumatoid Arthritis (RA)

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Medication is prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of moderately to severely active RA; AND
4. Member must have a trial and failure of, or intolerance to methotrexate for 3 months; AND
   Note: If methotrexate is contraindicated, one of the following conventional DMARDs must be trialed instead: leflunomide, sulfasalazine, or hydroxychloroquine
5. Member has had a negative tuberculosis test within the past 12 months.
6. **Dosage allowed/Quantity limit:**
   a) Intravenous

i) Actemra/Tyenne/Tofidence: When used in combination with DMARDs or as monotherapy the recommended starting dose is 4 mg per kg every 4 weeks followed by an increase to 8 mg per kg every 4 weeks based on clinical response. Max dose of 800 mg per infusion.

b) Subcutaneous
   i) Actemra/Tyenne: Quantity Limit: 4 syringes/autoinjectors per 28 days

Patients less than 100 kg weight	162 mg administered subcutaneously every other week, followed by an increase to every week based on clinical response
Patients at or above 100 kg weight	162 mg administered subcutaneously every week

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes demonstrate improvement of RA signs and symptoms such as fewer number of painful and swollen joints, achievement of remission, slowed progression of joint damage, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) – Actemra Only

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a pulmonologist or rheumatologist; AND
3. Member has a diagnosis of active systemic sclerosis (SSc); AND
4. Presence of interstitial lung disease (ILD) has been confirmed by high-resolution computed tomography (HRCT); AND
5. Documentation of baseline forced vital capacity (FVC); AND
6. Member's lung disease has progressed despite a trial of cyclophosphamide or mycophenolate mofetil; AND
7. Member is a non-smoker or has been educated regarding smoking cessation; AND
8. Member has tested negative for tuberculosis (TB) within the past 12 months.
9. **Dosage allowed/Quantity limit:** 162mg subQ once weekly. (4 syringes per 28 days)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must demonstrate a slowed rate of pulmonary function decline, as evidenced by stabilized FVC or repeat HRCT.

If all the above requirements are met, the medication will be approved for an additional 12 months.

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Cytokine Release Syndrome (CRS) treatment for CAR-T therapy patients – Actemra Only

Any cancer related request must be submitted through NantHealth/Eviti portal.

CareSource considers Tocilizumab (Actemra, Tyenne, Tofidence) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/08/2017	New policy for Actemra created. Policy SRx-0042 archived. For diagnosis of JIA: length of active disease added. For diagnosis of RA: list of non-biologic DMARDS added. List of diagnoses considered not medically necessary added.
08/30/2017	New diagnosis of GCA was added. For diagnosis of JIA (PJIA and SJIA) leflunomide was added as a treatment option.
10/13/2017	Option to approve under the pharmacy benefit was added.
02/26/2019	Dosing changed for GCA, PJIA and SJIA. ESR and CRP rates expanded for members on glucocorticoid (prednisone) therapy. Actual or recent myocardial infarction (within the last 3 months) criterion removed from GCA. Exception of temporal artery biopsy or other biopsy related to diagnosing GCA was added in criterion on surgical procedures within 8 weeks. References updated. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed.
11/23/2020	Updates for RA section: Removed repeat TB test. Updated references. Changed the trials to require methotrexate as one of the non-biologic DMARD trials; only one trial is needed if member has poor prognostic factors.
03/17/2021	Added criteria for new indication of SSc-ILD. GCA: Updated references. Re-ordered criteria. Removed list of restrictions. Added ultrasound as an option. Combined signs and symptoms into one general criterion addressing key features. Added glucocorticoid rule (per EULAR). Re-wrote renewal criteria and removed repeat TB test. Reduced initial approval to 6 months.
02/17/2022	Transferred to new template. Added section for CRS. RA: Added new reference. Edited the terminology “non-biologic” DMARD to “conventional” DMARD. Changed from requiring 2 csDMARD to just 1.
05/17/2022	Added IV dosing for GCA indication.
07/31/2024	GCA: Added new references. Removed CRP as reauth criteria example and removed the term “flare” (Hellmich 2018). Condensed list of confirmatory diagnostics. Added “refractory” as an option with relapse. SSc-ILD: Added new references. Removed autoinjector from QL (not studied, per label). Removed FVC >55 (keep baseline). Removed specific length from CYC/MMF trial.
08/05/2024	Added/removed references. JIA: added in consultation with for prescriber specialty; removed compliance with initial criteria and tb test requirement from reauthorization; added examples of improvement to reauthorization; removed inadequate response/inability tolerate methotrexate; replaced number of joints involved with diagnoses names; for PJIA, replaced 12-week trial of methotrexate or leflunomide with an 8-week trial of a conventional DMARD; For sJIA, removed NSAID trial length of 12 weeks and removed trial of methotrexate or leflunomide per 2021 ACR guideline; removed list of signs and symptoms for confirmation of diagnosis; removed 6 months disease history requirement.
09/30/2024	Renamed policy to include biosimilars from Actemra to Tocilizumab (Actemra, Tyenne, Tofidence). Added dosing and quantity limits for Tyenne and Tofidence where appropriate.

References:

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