Tocilizumab *(Actemra)* Biosimilars, injection for IV use

PA Criteria	Criteria Details
Description	Tocilizumab and its biosimilars are interleukin-6 (IL-6) receptor antagonists. Brand Name: **Actemra®** Biosimilars: • **Avtozma®** (tocilizumab-anoh) • **Tofidence™** (tocilizumab-bavi) • **Tyenne®** (tocilizumab-aazg)
Covered Uses (FDA approved indication)	Tocilizumab and its biosimilars are indicated for the treatment of: • Adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs) • Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis (PJIA) • Patients 2 years of age and older with active systemic juvenile idiopathic arthritis (SJIA) • Adult patients with giant cell arteritis (GCA) • **Actemra ONLY:** slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD) • **Actemra, Avtozma and Tyenne ONLY:** chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS) in adults and pediatric patients 2 years of age and older
Dosing and Administration	See table below

Indication	Dosing Regimen	Maximum Dosage
PJIA	**Actemra, Avtozma, Tofidence, Tyenne:** • Weight < 30 kg: 10 mg/kg IV every four weeks • Weight ≥ 30 kg: 8 mg/kg IV every four weeks	IV: 10 mg/kg every four weeks
RA	**Actemra, Avtozma, Tofidence, Tyenne:** IV: 4 mg/kg every four weeks followed by an increase to 8 mg/kg every four weeks based on clinical response	IV: 800 mg every four weeks
SJIA	**Actemra, Avtozma, Tofidence, Tyenne:** • Weight < 30 kg: 12 mg/kg IV every two weeks • Weight ≥ 30 kg: 12 mg/kg IV every two weeks	IV: 12 mg/kg every two weeks
GCA	**Actemra, Avtozma, Tofidence, Tyenne:** IV: 6 mg/kg every four weeks in combination with a tapering course of glucocorticoids	IV: 6 mg/kg every four weeks
CRS	**Actemra, Avtozma, and Tyenne:** • Weight < 30 kg: 12 mg/kg IV per infusion • Weight ≥ 30 kg: 8 mg/kg IV per infusion If no clinical improvement in the signs and symptoms of CRS occurs after the first dose, up to three additional doses of tocilizumab may be administered. The interval between consecutive doses should be at least eight hours.	IV: 800 mg/infusion, up to four doses

GOLD COAST HEALTH PLAN
TOTAL Care ADVANTAGE℠

Billing and Coding Information

	10-digit NDC	11-digit NDC
Actemra	80 mg: 50242-135-01 200 mg: 50242-136-01 400 mg: 50242-137-01	80 mg: 50242-0135-01 200 mg: 50242-0136-01 400 mg: 50242-0137-01
Avtozma	80 mg: 72606-042-01 200 mg: 72606-043-01 400 mg: 72606-044-01	80 mg: 72606-0042-01 200 mg: 72606-0043-01 400 mg: 72606-0044-01
Tofidence	80 mg: 64406-024-01 200 mg: 64406-022-01 400 mg: 64406-023-01	80 mg: 64406-0024-01 200 mg: 64406-0022-01 400 mg: 64406-0023-01
Tyenne	80 mg: 65219-590-04 200 mg: 65219-592-10 400 mg: 65219-594-20	80 mg: 65219-0590-04 200 mg: 65219-0592-10 400 mg: 65219-0594-20

	HCPCS Code	Description
Actemra	J3262	Injection, tocilizumab, 1 mg
Avtozma	Q5156	Injection, tocilizumab-anoh, biosimilar, 1 mg
Tofidence	Q5133	Injection, tocilizumab-bavi, biosimilar, 1 mg
Tyenne	Q5135	Injection, tocilizumab-aazg, biosimilar, 1 mg

CPT Procedural Codes	Description
96365	IV infusion for therapy, prophylaxis or diagnosis; initial; up to one hour
96413	Chemotherapy IV infusion, up to one hour

Product Availability

IV solution:
- Avtozma: 80 mg/4 mL (4 mL); 200 mg/10 mL (10 mL); 400 mg/20 mL (20 mL)
- Tyenne: 200 mg/10 mL (10 mL); 400 mg/20 mL (20 mL)

IV solution – **preservative free**:
- Actemra: 80 mg/4 mL (4 mL); 200 mg/10 mL (10 mL); 400 mg/20 mL (20 mL)
- Tofidence: 80 mg/4 mL (4 mL); 200 mg/10 mL (10 mL); 400 mg/20 mL (20 mL)
- Tyenne: 80 mg/4 mL (4 mL)

Contraindications

Known hypersensitivity to tocilizumab products.

Recommended Medical Monitoring

Tocilizumab has been associated with:
- Serious infections.
- Gastrointestinal (GI) perforation.
- Hepatotoxicity.
- Lab abnormalities, including neutrophils, platelets, lipids, and liver function tests.
- Hypersensitivity reactions, including anaphylaxis, death, and serious cutaneous reactions, including Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

Patients should be monitored for any of these reactions. Tocilizumab dose may be delayed, reduced or permanently discontinued based on the severity of adverse reactions.

Tocilizumab should NOT be used in patients with:
- Active infection, including localized infections
- Live-vaccines

Approval Criteria	A. Physician administered IV infusion; in-office or HOPD 1. Cannot be self-administered B. **Coronavirus-19 Infection:** 1. Initiation of outpatient treatment will NOT be authorized as Actemra, Avtozma, Tofidence, and Tyenne are FDA-approved for use in COVID19 infection only in the hospitalized (inpatient) setting. C. **Cytokine Release Syndrome (must meet all):** 1. Request is for Actemra, Avtozma, or Tyenne; 2. Request is for IV formulation; 3. Age ≥ 2 years; 4. Member meets **one** of the following (a, b, or c): a. Member has a scheduled CAR T cell therapy (e.g., Abecma®, Breyanzi®, Carvykti™, Kymriah™, Tecartus®, Yescarta™); b. Used as supportive care in severe CRS related to blinatumomab therapy; c. Used as prophylaxis to reduce the risk of CRS when administering teclistamab-cqyv; 5. Request meets **one** of the following (a or b): a. Dose does not exceed 800 mg per infusion for up to four total doses; b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence). 6. **Approval duration: up to four doses total** D. **Giant Cell Arteritis (must meet all):** 1. Diagnosis of GCA; 2. Prescribed by or in consultation with a rheumatologist; 3. Age ≥ 18 years; 4. ANC ≥ 2000/mm3 5. Platelets ≥ 100,000/mm^3 6. ALT/AST are ≤ 1.5 times ULN 7. Failure of a systemic corticosteroid at up to maximally tolerated doses, unless contraindicated, clinically significant adverse effects are experienced, unless previously failed a biologic agent for GCA; 8. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors; 9. Dose does not exceed 6 mg/kg IV every four weeks 10. **Approval Duration: up to 12 months** E. **Polyarticular Juvenile Idiopathic Arthritis (must meet all):** 1. Diagnosis of PJIA* as evidenced by ≥ five joints with active arthritis; 2. Prescribed by or in consultation with a rheumatologist; 3. Age ≥ 2 years; 4. ANC ≥ 2000/mm3 5. Platelets ≥ 100,000/mm3 6. ALT/AST are ≤ 1.5 times ULN

	7. Member meets one of the following, unless previously failed a biologic agent for pJIA (a, b, c, or d): a. Failure of a ≥ three consecutive month trial of MTX at up to maximally indicated doses; b. If intolerance or contraindication to MTX (see Appendix D), failure of a ≥ three consecutive month trial of leflunomide or sulfasalazine at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated; c. For sacroiliitis/axial spine involvement (i.e., spine, hip), failure of a ≥ four-week trial of an NSAID at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced; d. Documentation of high disease activity; 8. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors; 9. Dose does not exceed one of the following (a or b): a. Weight < 30 kg: 10 mg/kg IV every four weeks b. Weight ≥ 30 kg: 8 mg/kg IV every four weeks 10. **Approval Duration: up to 12 months** F. **Rheumatoid Arthritis (must meet all):** 1. Diagnosis of RA per American College of Rheumatology (ACR) criteria 2. Prescribed by or in consultation with a rheumatologist; 3. Age ≥ 18 years; 4. Member meets one of the following, unless previously failed a biologic agent for RA (a or b): a. Failure of ≥ three consecutive month trial of methotrexate (MTX) at up to maximally indicated doses; b. Member has intolerance or contraindication to MTX and failure of ≥ three consecutive month trial of at least ONE conventional DMARD (e.g., sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated; 5. If request is for Avtozma, Tofidence, or Tyenne, member meets ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b): a. Failure of one adalimumab product (e.g., Hadlima, Simlandi, Yusimry, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred), unless the member has had a history of failure of two TNF blockers; b. If member has not responded or is intolerant to one or more TNF blockers, failure of Xeljanz/Xeljanz XR®, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment; 6. Documentation of one of the following baseline assessment scores (a or b): a. Clinical disease activity index (CDAI) score; b. Routine assessment of patient index data 3 (RAPID3) score 7. Dose does not exceed 800 mg IV every four weeks; 8. **Approval duration: up to 12 months**

	G. **Systemic Juvenile Idiopathic Arthritis (must meet all):** 1. Diagnosis of SJIA; 2. Prescribed by or in consultation with a dermatologist, rheumatologist, or gastroenterologist; 3. Age ≥ 2 years; 4. Member meets one of the following, unless previously failed a biologic agent for sJIA (a, b, or c): a. Failure of an NSAID at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced; b. Failure of a ≥ three consecutive month trial of methotrexate or leflunomide at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated; c. Failure of a ≥ two-week trial of a systemic corticosteroid at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced; 5. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors; 6. Dose does not exceed one of the following (a or b): a. Weight < 30 kg: 12 mg/kg IV every two weeks b. Weight ≥ 30 kg: 8 mg/kg IV every two weeks 7. **Approval duration: up to 12 months**
Age Restriction	Indication dependent; see Approval Criteria
Coverage Duration	**Initial/Reauthorization:** up to 12 months; except for CRS (up to 4 doses total) Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
Other Criteria (LCD, NCD, etc.)	None.
Misc Info, Appendix Etc.	None.

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	4/10/26	4/10/26	Tamara Chinarian, PharmD, Clinical Pharmacist	N/A
Approved	N/A	5/14/26	Pharmacy & Therapeutics (P&T) Committee	5/14/26