Original Effective Date: 04/2014
Current Effective Date: 12/17/2025
Last P&T Approval/Version: 10/29/2025
Next Review Due By: 10/2026
Policy Number: C10265-A

Actemra (tocilizumab) and Biosimilars

PRODUCTS AFFECTED

Actemra (tocilizumab), Avtozma (tocilizumab-anoh), Tofidence (tocilizumab-bavi), Tyenne (tocilizumab-aazg)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Rheumatoid arthritis (RA), Polyarticular juvenile idiopathic arthritis, Systemic juvenile idiopathic arthritis, Giant cell arteritis (GCA), Chimeric antigen receptor (CAR) T-cell- induced severe or life-threatening cytokine release syndrome (CRS), Systemic sclerosis-associated interstitial lung disease (SSc-ILD)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. FOR ALL INDICATIONS (EXCEPT CRS):

1. Prescriber attests member does not have an active or latent untreated infection (e.g., Hepatitis B, tuberculosis, etc.), including clinically important localized infections, according to the FDA label
   AND
2. Member is not on concurrent treatment or will not be used in combination with TNF- inhibitor, biologic response modifier or other biologic DMARDs, Janus kinase Inhibitors, or Phosphodiesterase 4 inhibitor (i.e., apremilast, tofacitinib, baricitinib) as verified by prescriber attestation, member medication fill history, or submitted documentation
   AND
3. Member does NOT have an ANC less than 2000/mm3, platelets less than 100,000/mm3 or liver transaminases above 1.5 times ULN
   AND
4. (a) IF THIS IS A PHARMACY BENEFIT REQUEST FOR A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Documentation of medication(s) tried, dates of trial(s) and reason for treatment failure(s) is required.
   AND
   (b) If request is for reference product with a biosimilar available for initial or continuation of therapy requests: Documentation of a trial and failure, serious side effects or contraindication to a majority (not more than 3) biosimilar product(s) is required (unless otherwise specified per applicable state regulations and/or there is data demonstrating clinical superiority of reference drugs over the FDA approved biosimilar drugs).
   [DOCUMENTATION REQUIRED: Document when the preferred biologic product or biosimilar was tried and the length of the trial period. Provide specific clinical documentation of therapeutic failure on the preferred biologic product or biosimilar whenever possible. Describe the medical problem caused by the preferred referenced biologic. Vague and non-descriptive symptoms are not adequate rationale (e.g., stomachache).]
   MOLINA REVIEWER NOTE: For Illinois Marketplace, please see Appendix.
   OR
5. FOR INITIAL OR CONTINUATION OF THERAPY REQUESTS OF A PHYSICIAN ADMINISTERED MEDICATION: BIOSIMILAR DRUGS are preferred when requested as a physician administered drug per applicable state regulations and/or there is a lack of data demonstrating clinical superiority of reference drugs over the FDA approved biosimilar drugs. A reference medication is approved under the following conditions:
   a. Treatment with at least two associated biosimilar drug(s) has been ineffective, resulted in serious side effects, or is contraindicated (i.e., an allergic reaction to a specific inactive ingredient in the preferred biologic product or biosimilar OR an adverse reaction to a specific inactive ingredient in the preferred biologic product or biosimilar OR therapeutic success while taking a non-preferred biologic product or biosimilar and therapeutic failure while taking the preferred biologic product or biosimilar documented by patient diary or medical charted notes)

   [DOCUMENTATION REQUIRED: Document when the preferred biologic product or biosimilar was tried and the length of the trial period. Provide specific clinical documentation of therapeutic failure on the preferred biologic product or biosimilar whenever possible. Describe the medical problem caused by the preferred referenced biologic. Vague and non-descriptive symptoms are not adequate rationale (e.g., stomachache).]

B. MODERATE TO SEVERE RHEUMATOID ARTHRITIS:
   1. Documentation of moderate to severe rheumatoid arthritis diagnosis
      AND
   2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
      AND
   3. (a) Member is currently receiving maximally tolerated dose of methotrexate and is not at goal disease activity

OR

(b) Member has an FDA labeled contraindication or serious side effects to methotrexate, as determined by the prescribing physician AND member has tried one additional disease-modifying antirheumatic drug (DMARD) (brand or generic; oral or injectable) for at least 3 months
NOTE: An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the Member has already had a 3-month trial of at least one biologic. These patients who have already tried a biologic for RA are not required to "step back" and try a conventional synthetic DMARD.

C. JUVENILE IDIOPATHIC ARTHRITIS (ACTIVE SYSTEMIC AND POLYARTICULAR):

1. Documented diagnosis of systemic juvenile idiopathic arthritis (SJIA) or polyarticular juvenile idiopathic arthritis (PJIA) in a pediatric member
   AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
   AND
3. (a) FOR ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS: Documentation of treatment failure, serious side effects or clinical contraindication to an adequate trial (12 weeks) of one NSAID or glucocorticoid
   OR
   (b) FOR POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS: Documentation of treatment failure, serious side effects or clinical contraindication to an adequate trial (generally ≥12 weeks) of one or more of the following: Methotrexate, hydroxychloroquine, sulfasalazine, leflunomide

D. GIANT CELL ARTERITIS (GCA):

1. Documented diagnosis of Giant Cell Arteritis (GCA)
   AND
2. Documented disease activity as evidenced by cranial symptoms of giant- cell arteritis or polymyalgia rheumatica and increased concentrations of serum acute-phase reactants (ESR > 30 mm/hour or CRP > 1 mg/dL)
   AND
3. Member must have documented need for a glucocorticoid sparing agent use such as: presence of significant premorbid diseases, emergence of significant glucocorticoid-related side effects during the course of treatment, a relapsing course necessitating protracted glucocorticoid use, preexisting diabetes mellitus on treatment, osteoporosis, or significant obesity
   AND
4. Documentation of treatment failure, serious side effects, or clinical contraindication to a trial (at least 3 months) of ONE non-glucocorticoid immunosuppressive (i.e., methotrexate)
   AND
5. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

E. CYTOKINE RELEASE SYNDROME (CAR-T THERAPY INDUCED):

1. Documented diagnosis of cytokine release syndrome (CAR-T therapy induced)
   NOTE: Approved only if CART-T is approved by transplant team. Verification of CAR-T is required documentation.
   AND
2. Member does NOT have an ANC less than 2000/mm3, platelets less than 100,000/mm3 or liver transaminases above 1.5 times ULN OR Prescriber attests the benefit of treating cytokine release syndrome (CRS) outweighs the risks of short-term treatment with tocilizumab
   NOTE: Patients with severe or life-threatening CRS frequently have cytopenias or elevated ALT or AST due to the lymphodepleting chemotherapy or the CRS. The decision to administer tocilizumab should take into account the potential benefit of treating the CRS versus the risks of short-term treatment with tocilizumab.

F. SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE (SSc-ILD) (Subcutaneous syringes only):

1. Documented diagnosis of systemic sclerosis-associated interstitial lung disease
   AND
2. Documentation of chest high resolution computed tomography (HRCT) scan confirming diagnosis of interstitial lung disease [DOCUMENTATION REQUIRED]
   AND
3. Documentation member has elevated acute-phase reactants as documented by at least one of the following [DOCUMENTATION REQUIRED]: CRP level ≥ 6 mg/L, erythrocyte sedimentation rate ≥ 28 mm/hour, platelet count ≥ 330 x 10^9/L
   AND
4. Documentation of treatment failure, serious side effects or clinical contraindication to mycophenolate mofetil
   AND
5. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal (e.g., respiratory symptoms, subjective exercise tolerance, physical exam, pulmonary function tests [spirometry, diffusing capacity for carbon monoxide (DLCO), six-minute walk test]) [DOCUMENTATION REQUIRED]

CONTINUATION OF THERAPY:

A. ALL INDICATIONS (EXCEPT CRS):

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms [DOCUMENTATION REQUIRED]
   AND
4. Prescriber attests to ongoing monitoring for development of infection (e.g., tuberculosis, Hepatitis B reactivation, etc.) according to the FDA label

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of therapy: 12 months.

PRESCRIBER REQUIREMENTS:

CYTOKINE RELEASE SYNDROME (CAR-T THERAPY INDUCED): Prescribed by or in consultation with a board-certified oncologist.
SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE (SSc-ILD): Prescribed by or in consultation with a board-certified rheumatologist or pulmonologist.
ALL OTHER INDICATIONS: Prescribed by or in consultation with a board-certified rheumatologist.
[If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

PJIA, SJIA and CAR T-cell-induced cytokine release syndrome: 2 years of age and older
All other indications: 18 years of age and older

QUANTITY:

CYTOKINE RELEASE SYNDROME (CAR-T THERAPY INDUCED): max 8 single dose vials per lifetime, not to exceed 800 mg per dose. NOTE: Please review for authorization concurrently with CAR-T

therapy.

ALL OTHER INDICATIONS:
Subcutaneous:
Rheumatoid arthritis: Up to 162 mg every week
Giant cell arteritis: Up to 162 mg every week
SSc- ILD: 162 mg every week
PJIA: < 30 kg – 162 mg every 3 weeks; 30 kg or greater – 162 mg every 2 weeks
SJIA: <30 kg – 162 mg every 2 weeks; 30 kg or greater – 162 mg every week

Intravenous:
Rheumatoid arthritis: 4 mg/kg every 4 weeks, may increase to 8 mg/kg every 4 weeks, not to exceed 800 mg per infusion
Giant cell arteritis: 6 mg/kg every 4 weeks, not to exceed 600 mg per infusion
PJIA: < 30 kg – 10 mg/kg every 4 weeks; 30 kg or greater – 8 mg/kg every 4 weeks
SJIA: < 30 kg – 12 mg/kg every 2 weeks; 30 kg or greater – 8 mg/kg every 2 weeks
CRS: < 30 kg – 12 mg/kg; 30 kg or greater – 8 mg/kg, not to exceed 800 mg per infusion

Maximum Quantity Limits –
SC: 4 packages (4 syringes) per 28 days
IV: 80 mg/4 mL vial: 1 vial per 14 days, 200 mg/10 mL vial: 1 vial per 14 days, 400 mg/20 mL vial: 2 vials per 14 days

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-hospital facility-based location as per the Molina Health Care Site of Care program.

Note: Site of Care Utilization Management Policy applies for Actemra (tocilizumab) IV. For information on site of care, see Specialty Medication Administration Site of Care Coverage Criteria molinamarketplace.com)

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous, Subcutaneous

DRUG CLASS:
Interleukin-6 Receptor Inhibitors

FDA-APPROVED USES:
Actemra, Tyenne IV and SQ, Avtozma IV and SQ:
- 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).
- Indicated for the treatment of adult patients with giant cell arteritis (GCA).
- Indicated for the treatment of patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis.
- Indicated for the treatment of patients 2 years of age and older with active systemic juvenile idiopathic arthritis.

Actemra SQ (only): Indicated for slowing the rate of decline in pulmonary function in adult patients

with systemic sclerosis- associated interstitial lung disease (SSc-ILD).

Actemra IV (only): Indicated for the treatment of adults and pediatric patients 2 years of age and older with chimeric antigen receptor (CAR) T-cell-induced severe or life-threatening cytokine release syndrome (CRS).

Actemra IV, Avtozma IV:

- Indicated for treatment of hospitalized adult patient with coronavirus disease 2019 (COVID-19) who are receiving systemic corticosteroids and required supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Tofidence IV:

- 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).
- Indicated for the treatment of patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis.
- Indicated for the treatment of patients 2 years of age and older with active systemic juvenile idiopathic arthritis.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information
State Marketplace
Illinois (Source: Illinois General Assembly)
"(215 ILCS 134/45.1) Sec. 45.1. Medical exceptions procedures required. (c) An off-formulary exception request shall not be denied if: (1) the formulary prescription drug is contraindicated; (2) the patient has tried the formulary prescription drug while under the patient's current or previous health insurance or health benefit plan and the prescribing provider submits evidence of failure or intolerance; or (3) the patient is stable on a prescription drug selected by his or her health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan. (d) Upon the granting of an exception request, the insurer, health plan, utilization review organization, or other entity shall authorize the coverage for the drug prescribed by the enrollee's treating health care provider, to the extent the prescribed drug is a covered drug under the policy or contract up to the quantity covered. (e) Any approval of a medical exception request made pursuant to this Section shall be honored for 12 months following the date of the approval or until renewal of the plan."

APPENDIX 1:
A biosimilar is highly similar version of a brand name biological drug that meets strict controls for structural, pharmaceutical, and clinical consistency. A biosimilar manufacturer must demonstrate that there are no meaningful clinical differences (i.e., safety and efficacy) between the biosimilar and the reference product. Clinical performance is demonstrated through human pharmacokinetic (exposure) and pharmacodynamic (response) studies, an assessment of clinical immunogenicity, and, if needed, additional clinical studies.1 As costs for biological specialty drugs continue to rise, the growing biosimilar market will benefit providers and patients by broadening biological treatment options and expanding access to these medications at lower costs. Molina Healthcare, Inc. continues to be committed to continually reevaluating preferred strategies and applying innovative cost-controls to ensure patients receive safe, effective, and quality healthcare. This commitment includes potentially creating a preference for biosimilars when value can be added without compromising patient satisfaction and safety.

1. Food and Drug Administration. Biosimilar and Interchangeable Products. Retrieved from https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products. Accessed October 8, 2019.

APPENDIX 2:

OBJECTIVE MEASURES FOR RA:

[Clinical Disease Activity Index (CDAI), Disease Activity Score with 28-joint counts (erythrocyte sedimentation rate or C-reactive protein), Member Activity Scale (PAS or PAS- II), Routine Assessment of Member Index Data with 3 measures, Simplified Disease Activity Index (SDAI)] OBJECTIVE MEASURES FOR PJIA:

Global Arthritis Score (GAS), Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS), Disease Activity Score based on 28-joint evaluation (DAS28), Simple Disease Activity Index (SDAI), Health Assessment Questionnaire disability index (HAQ-DI), Visual Analogue Scale (VAS), Likert scales of global response or pain by the member or global response by the physician, Joint tenderness and/or swelling counts, Laboratory data

Table 1. The American College of Rheumatology/European League Against Rheumatism criteria for the classification of systemic sclerosis (SSc)*

Item	Sub-item(s)	Weight/score†
Skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints *(sufficient criterion)*	–	9
Skin thickening of the fingers *(only count the higher score)*	Puffy fingers	2
	Sclerodactyly of the fingers (distal to the metacarpophalangeal joints but proximal to the proximal interphalangeal joints)	4
Fingertip lesions *(only count the higher score)*	Digital tip ulcers	2
	Fingertip pitting scars	3
Telangiectasia	–	2
Abnormal nailfold capillaries	–	2
Pulmonary arterial hypertension and/or interstitial lung disease *(maximum score is 2)*	Pulmonary arterial hypertension	2
	Interstitial lung disease	2
Raynaud's phenomenon	–	3
SSc-related autoantibodies (anticentromere, anti–topoisomerase I [anti–Scl-70], anti–RNA polymerase III) *(maximum score is 3)*	Anticentromere Anti–topoisomerase I Anti–RNA polymerase III	3

* These criteria are applicable to any patient considered for inclusion in an SSc study. The criteria are not applicable to patients with skin thickening sparing the fingers or to patients who have a scleroderma-like disorder that better explains their manifestations (e.g., nephrogenic sclerosing fibrosis, generalized morphea, eosinophilic fasciitis, scleredema diabeticorum, scleromyxedema, erythromyalgia, porphyria, lichen sclerosis, graft-versus-host disease, diabetic cheiroarthropathy).

† The total score is determined by adding the maximum weight (score) in each category. Patients with a total score of ≥9 are classified as having definite SSc.

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Tocilizumab (Actemra) is a recombinant humanized anti-human interleukin-6 (IL-6) receptor monoclonal antibody (IgG1κ). The drug binds to membrane-bound (mIL-6R) and soluble (sIL- 6R) forms of the interleukin-6 receptor, thereby reducing the inflammatory process by inhibiting signaling through these receptors. Interleukin-6 is a pleiotropic pro-inflammatory cytokine involved in multiple phases of the inflammatory response, including T-cell activation and induction of immunoglobulin secretion. Actemra SC has demonstrated efficacy and is indicated for the treatment of rheumatoid arthritis (RA) in adults with moderate to severe active RA who have had an inadequate response to one or more disease modifying anti-rheumatic drugs (DMARDs). Actemra SC has been shown to inhibit and slow structural joint damage, improve physical function, and achieve a major clinical response in patients taking methotrexate (MTX). In addition to RA, Actemra SC is also indicated in adults with giant cell arteritis (GCA). It is recommended to be given once weekly and may be given in combination with a tapering course of glucocorticoids. Actemra SC can be used alone following the discontinuation of glucocorticoids. The subcutaneous formulation is

also indicated for SSc-ILD and has been shown slow the rate of decline in pulmonary function in adult patients. Actemra is also available as an intravenous (IV) formulation which, in addition to RA, is indicated in patients 2 years of age and older for the treatment of active systemic juvenile idiopathic arthritis (SJIA) or polyarticular juvenile idiopathic arthritis (PJIA). The IV formulation is not indicated in GCA or SSc-ILD.

The 2023 American Thoracic Society guidelines on the treatment of Systemic Sclerosis–associated Interstitial Lung Disease (SSc-ILD) strongly recommends mycophenolate mofetil as first-line treatment for SSc-ILD due to its effectiveness in stabilizing or improving lung function. Cyclophosphamide is an alternative for patients unable to tolerate MMF, though its use is limited by side effects. The guidelines also suggest considering nintedanib, an antifibrotic agent, to slow lung function decline in progressive disease. The guidelines conditionally recommend tocilizumab. Tocilizumab may be considered in patients with early SSc-ILD who exhibit progressive disease despite immunosuppressive treatment or for those unable to tolerate standard therapies like MMF or cyclophosphamide. The recommendation is based on its ability to stabilize lung function and potential to reduce skin fibrosis, but long-term efficacy and safety in SSc-ILD remain areas for further research. The recommendations emphasize tailoring therapy to individual patient characteristics and closely monitoring for adverse effects. Supportive care, including pulmonary rehabilitation and managing other systemic manifestations, remains crucial.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of tocilizumab are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to tocilizumab include: patients with known hypersensitivity to tocilizumab, do not administer during an active infection including localized infections, avoid use with live vaccines.

Exclusions/Discontinuation:

Do not use concurrently with Ofev (nintedanib).

Monitor patients for signs and symptoms of hepatic injury. Modify or discontinue tocilizumab if abnormal liver tests persist or worsen or if clinical signs and symptoms of liver disease develop.

Hypersensitivity reactions, including anaphylaxis, have been reported in association with tocilizumab and anaphylactic events with a fatal outcome have been reported with intravenous infusion of tocilizumab. Reactions that required treatment discontinuation included generalized erythema, rash, and urticaria.

OTHER SPECIAL CONSIDERATIONS:

Tocilizumab has a Black Box Warning for risk of serious infections. Serious infections leading to hospitalization or death including tuberculosis (TB), bacterial, invasive fungal, viral, and other opportunistic infections have occurred in patients receiving tocilizumab.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION

J3262	Injection, tocilizumab, 1 mg
Q5133	Injection, tocilizumab-bavi (tofidence), biosimilar, 1 mg
Q5135	Injection, tocilizumab-aazg (tyenne), biosimilar, 1 mg
Q5156	Injection, tocilizumab-anoh (avtozma), biosimilar, 1 mg

AVAILABLE DOSAGE FORMS:
Actemra ACT Pen SOAJ 162MG/0.9ML autoinjector
Actemra SOLN 80MG/4ML, 200MG/10ML, 400MG/20ML single-dose vial
Actemra SOSY 162MG/0.9ML prefilled syringe
Avtozma SOLN 80MG/4ML, 200MG/10ML, 400MG/20ML single-dose vial
Tofidence SOLN 80MG/4ML, 200MG/10ML, 400MG/20ML single-dose vial
Tyenne SOAJ 162MG/0.9ML autoinjector
Tyenne SOLN 80MG/4ML, 200MG/10ML, 400MG/20ML single-dose vial
Tyenne SOSY 162MG/0.9ML prefilled syringe

REFERENCES

1. Actemra (tocilizumab) injection, for intravenous or subcutaneous use [prescribing information]. South San Francisco, CA: Genentech, Inc.; August 2025.
2. Avtozma (tocilizumab-anoh) injection, for intravenous or subcutaneous use [prescribing information]. Jersey City, NJ: Celltrion USA, Inc.; January 2025.
3. Tofidence (tocilizumab-bavi) injection, for intravenous use [prescribing information]. Cambridge, MA: Biogen MA Inc.; July 2025.
4. Tyenne (tocilizumab-aazg) injection, for intravenous or subcutaneous use [prescribing information]. Lake Zurich, IL: Fresenius Kabi USA, LLC; February 2025.
5. American College of Rheumatology 2008 Recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. Arthritis Rheum.2008;59(6):762-784.
6. Jones G, Sebba A, Gu J, et al. Comparison of tocilizumab monotherapy versus methotrexate monotherapy in patients with moderate to severe rheumatoid arthritis: the AMBITION study. AnnRheum Dis. 2010;69(1):88-96.
7. Smolen JS, Beaulieu A, Rubbert-Roth A, et al. for the OPTION Investigators. Effect of interleukin-6 receptor inhibition with tocilizumab in patients with rheumatoid arthritis (OPTION study): a double- blind, placebo-controlled, randomized trial. Lancet. 2008;371:987-97.
8. Genovese MC, McKay JD, Nasonov EL, et al. Interleukin-6 receptor inhibition with tocilizumab reduces disease activity in rheumatoid arthritis with inadequate response to disease- modifying antirheumatic drugs: The tocilizumab in combination with traditional disease- modifying antirheumatic drug therapy study. Arthritis Rheum. 2008;58(10):2968-80.
9. Emery P, Keystone E, Tony HP, et al. IL-6 receptor inhibition with tocilizumab improves treatment outcomes in patients with rheumatoid arthritis refractory to anti-tumor necrosis factor biologicals: results from a 24-hour week multicenter randomized placebo-controlled trial. Ann Rheum Dis. 2008;67:1516-1523.
10. Ringold S, Weiss PF, Beukelman T, et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. Arthritis Rheum. 2013;65(10):2499-512.
11. De Benedetti F, Brunner H, Ruperto N, et al. Tocilizumab in patients with systemic juvenile idiopathic arthritis: efficacy data from the placebo-controlled 12-week part of the phase 3 TENDER trial. Arthritis Rheum. 2010; 62. Presented at the ACR Annual Meeting; November 6- 7, 2010; Atlanta, GA. Abstract #1434.
12. Gabay C, Emery P, van Vollenhoven R, et al. Tocilizumab monotherapy versus adalimumab monotherapy for treatment of rheumatoid arthritis (ADACTA): a randomized, double-blind, controlled

phase 4 trial. Lancet. 2013;381(9877):1541-1550.
13. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. Arthritis Care Res. 2011;63(4):465-82.
14. Roofeh, D., Lin, C. J., Goldin, J., et al. (2021). Tocilizumab prevents progression of Early systemic Sclerosis–associated Interstitial lung disease. Arthritis & Rheumatology, 73(7), 1301– 1310. https://doi.org/10.1002/art.41668.
15. Roofeh, D., Jaafar, S., Vummidi, D., & Khanna, D. (2019). Management of systemic sclerosis-associated interstitial lung disease. Current opinion in rheumatology, 31(3), 241-249. https://doi.org/10.1097/BOR.0000000000000592
16. van den Hoogen, F., Khanna, D., Fransen, J., Johnson, et al. (2013). 2013 classification criteria for systemic sclerosis: an American College of Rheumatology/European League against Rheumatism collaborative initiative. Arthritis and rheumatism, 65(11), 2737–2747. https://doi.org/10.1002/art.38098
17. Onel, K., Horton, D., Lovell, D., Shenoi, S., Cuello, C., & Angeles-Han, S. et al. (2022). 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis & Rheumatology, 74(4), 553-569. doi: 10.1002/art.42037
18. Ringold, S., Angeles-Han, S., Beukelman, T., Lovell, D., Cuello, C., & Becker, M. et al. (2019). 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Care & Research, 71(6), 717-734. doi: 10.1002/acr.23870
19. Maz, M., Chung, S., Abril, A., Langford, C., Gorelik, M., & Guyatt, G. et al. (2021). 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Giant Cell Arteritis and Takayasu Arteritis. Arthritis & Rheumatology, 73(8), 1349-1365. doi: 10.1002/art.41774
20. Fraenkel, L., Bathon, J., England, B., St. Clair, E., Arayssi, T., & Carandang, K. et al. (2021). 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research, 73(7), 924-939. doi: 10.1002/acr.24596
21. Menter, A., Strober, B., Kaplan, D., Kivelevitch, D., Prater, E., & Stoff, B. et al. (2019). Joint AAD- NPF guidelines of care for the management and treatment of psoriasis with biologics. Journal Of The American Academy Of Dermatology, 80(4), 1029-1072. doi: 10.1016/j.jaad.2018.11.057
22. Menter, A., Gelfand, J., Connor, C., Armstrong, A., Cordoro, K., & Davis, D. et al. (2020). Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. Journal Of The American Academy Of Dermatology, 82(6), 1445-1486. doi: 10.1016/j.jaad.2020.02.044
23. Elmets, C., Lim, H., Stoff, B., Connor, C., Cordoro, K., & Lebwohl, M. et al. (2019). Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy. Journal Of The American Academy Of Dermatology, 81(3), 775-804. doi: 10.1016/j.jaad.2019.04.042
24. Singh, J., Guyatt, G., Ogdie, A., Gladman, D., Deal, C., & Deodhar, A. et al. (2018). 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology, 71(1), 5-32. doi: 10.1002/art.40726
25. National Comprehensive Cancer Network. 2022. Management of Immunotherapy-Related Toxicities (Version 1.2022). [online] Available at: <https://www.nccn.org/professionals/physician_gls/pdf/immunotherapy.pdf> [Accessed 11 August 2022].
26. Katzen, J., Raparia, K., Agrawal, R., Patel, J., Rademaker, A., Varga, J., & Dematte, J. (2015). Early Stage Lung Cancer Detection in Systemic Sclerosis Does Not Portend Survival Benefit: A Cross Sectional Study. PLOS ONE, 10(2), e0117829. doi: 10.1371/journal.pone.0117829
27. Hellmich, B., Agueda, A., Monti, S., Buttgereit, F., de Boysson, H., Brouwer, E., … Tomasson, G. (2019). 2018 Update of the EULAR recommendations for the management of large vessel vasculitis. Annals of the Rheumatic Diseases, 79(1), 19–30. https://doi.org/10.1136/annrheumdis- 2019-215672
28. Raghu, G., et.al.,. (2023). Treatment of Systemic Sclerosis–associated Interstitial Lung Disease: Evidence-based Recommendations. An Official American Thoracic Society Clinical Practice Guideline. American Journal of Respiratory and Critical Care Medicine, 209(2). https://doi.org/10.1164/rccm.202306-1113st

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Products Affected Required Medical Information Continuation of Therapy Place of Administration FDA-Approved Uses Appendix Contraindications/Exclusions/Discontinuation Coding/Billing Information Available Dosage Forms References	Q4 2025
REVISION- Notable revisions: Coding/Billing Information Template Update Required Medical Information Background Coding/Billing Information References	Q4 2024
REVISION- Notable revisions: Products Affected Required Medical Information FDA-Approved Uses Appendix Available Dosage Forms References	Q3 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Quantity FDA-Approved Uses Other Special Considerations References	Q4 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Age Restrictions Quantity FDA-Approved Uses Contraindications/Exclusions/Discontinuation Other Special Considerations Available Dosage Forms References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file