GCHP Medi-Cal Clinical Guidelines
Tocilizumab (Actemra™)

PA Criteria	Criteria Details
Covered Uses (FDA Approved Indication)	• Cytokine release syndrome (CRS), chimeric antigen receptor T-cell-induced severe or life-threatening. • Polyarticular juvenile idiopathic arthritis (PJIA). • Systemic juvenile idiopathic arthritis (SJIA). • Moderate to severely active rheumatoid arthritis (RA). • Giant cell arteritis (GCA). *Non-FDA approved indication or off-label use will be reviewed if there is sufficient documentation of efficacy and safety in published literature.*
Exclusion Criteria	• Active, serious infection, latent (untreated) tuberculosis. • Combination with another monoclonal antibody / biologic therapy.
Required Medical Information	**For ALL indications:** • Specialist's clinic notes confirming the diagnosis and treatment plan. • ANC ≥ 2,000/mm^3 ($2x10^9$/L) • Platelet count > 100,000/mm^3 ($100x10^9$/L) • ALT & AST < 1.5 times upper limit normal (ULN) **PJIA -** Intolerance or inadequate response to traditional DMARD (e.g., methotrexate) **SJIA -** Documentation showing active arthritis **RA** • Intolerance or inadequate response to traditional DMARD AND • Documentation of moderate to severe active rheumatoid arthritis **Renewal** for all indications require documentation of favorable response to tocilizumab. **Off-label indications:** 1) The requested unlabeled use must represent reasonable and current prescribing practices based on current medical literature, provider organizations, or academic & professional specialists. 2) In addition, one of the following is required: a. Documentation of trial & failure (or contraindication) to on-label treatments, or b. There are no FDA-approved drug treatments for the diagnosis.
Age Restriction	CRS, PJIA, SJIA: 2 years of age and older GCA, RA: 18 years of age and older
Prescriber Restrictions	GCA, PJIA, SJIA, RA: Rheumatologist CRS: Oncologist

<table>
<tr><td>Coverage Duration</td><td>Initial: Six months
Renewal: 12 months</td></tr>
<tr><td>Other Criteria / Information</td><td>Criteria adapted from DHCS March 2024 & MCG

<table>
<tr><th>HCPCS</th><th>Description</th><th>Dosing, Units</th></tr>
<tr><td>J3262</td><td>Injection, tocilizumab, 1mg, for intravenous use (Actemra™)</td><td>CRS: ≥30 kg - 8 mg/kg, <30kg - 12mg/kg for up to four doses total at least eight hours apart.
GCA: 6mg/kg every four weeks
PJIA: ≥30 kg -8 mg/kg every four weeks, <30kg - 10mg/kg every four weeks
RA: 4 - 8mg/kg every four weeks
SJIA: ≥30 kg -8 mg/kg every two weeks, <30kg - 12mg/kg every two weeks

Max dose: GCA – 600mg per infusion; CRS & RA – 800mg per infusion</td></tr>
</table></td></tr>
</table>

STATUS	DATE REVISED	REVIEW DATE	APPROVED / REVIEWED BY	EFFECTIVE DATE
Created	5/1/2024	5/1/2024	Lily Yip, Director of Pharmacy Services; Yoonhee Kim, Clinical Programs Pharmacist	N/A
Approved	N/A	5/15/2024	Pharmacy & Therapeutics (P&T) Committee	3/1/2025
Approved	N/A	7/18/2024	Medical Advisory Committee (MAC)	3/1/2025