

GCHP Medi-Cal Clinical Guidelines Golimumab (Simponi Aria™)

PA Criteria	Criteria Details
Covered Uses (FDA Approved Indication)	<ul style="list-style-type: none"> • Ankylosing spondylitis (AS) • Polyarticular juvenile idiopathic arthritis (PJIA) • Psoriatic arthritis (PsA) • Rheumatoid arthritis (RA)
Exclusion Criteria	<ul style="list-style-type: none"> • Demyelinating disease (e.g., MS, optic neuritis). • Moderate to severe heart failure (NYHA Class III/IV). • Malignancy. • Active, serious infection, or latent (untreated) tuberculosis. • Hepatitis B BsAg positive and not on concurrent treatment with antiviral therapy. • Combination with another monoclonal antibody / biologic therapy.
Required Medical Information	<p>Initial</p> <p>AS – Failure or intolerance of two or more different NSAIDS (at maximum recommended dose or maximum tolerated dose) over total period of at least four or more weeks of therapy.</p> <p>PJIA – Intolerance or inadequate response to traditional DMARD (e.g., methotrexate).</p> <p>PsA – Inadequate response, intolerance, or contraindication to three or more months of treatment with NSAIDs.</p> <p>RA</p> <ul style="list-style-type: none"> • Concurrent treatment with methotrexate • Inadequate response to three or more months of treatment with at least one of the following DMARD <ul style="list-style-type: none"> i. Hydroxychloroquine ii. Leflunomide iii. Methotrexate iv. Sulfasalazine v. Tumor necrosis factor inhibitor <p>Renewal – Favorable response to golimumab.</p>
Age Restriction	<p>PJIA & PsA: 2 years of age and older</p> <p>All other indications: 18 years of age and older</p>
Prescriber Restrictions	<p>AS, PJIA, RA: Rheumatologist.</p> <p>PsA: Rheumatologist (prescribed or recommend by); dermatologist may continue treatment that was initiated based on a rheumatologist's recommendation.</p>
Coverage Duration	<p>Initial: Six months Renewal: 12 months</p>



Other Criteria / Information	Criteria adapted from DHCS March 2024 & MCG		
	HCPCS	Description	Dosing, Units
	J1602	Injection, Golimumab, 1 mg, for intravenous use (Simponi Aria™)	Adults 18 years of age and older: 2mg/kg IV at weeks zero, four and then every eight weeks thereafter. Children ≥ 2 years of age and older: 80mg/m ² /dose IV at week zero, four, then every eight weeks thereafter.

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