GCHP Medi-Cal Clinical Guidelines
Certolizumab Pegol (Cimzia™)

PA Criteria	Criteria Details
Covered Uses (FDA Approved Indication)	• Ankylosing spondylitis (AS) • Non-radiographic axial spondyloarthritis (nr-AxSpA) • Moderate to severely active Crohn's disease (CD) • Active plaque psoriasis (PSO) • Active psoriatic arthritis (PsA) • Moderate to severely active rheumatoid Arthritis (RA)
Exclusion Criteria	• Demyelinating disease (e.g., MS, optic neuritis) • Moderate to severe heart failure (NYHA Class III/IV) • Malignancy • Active, serious infection, or latent (untreated) tuberculosis • Combination with another monoclonal antibody/biologic therapy
Required Medical Information	Dosage form that is being requested for administration during the medical visit (Syringes vs. Vials) ▪ Cimzia™ Prefilled Syringes: FDA approved for self or caregiver administration with proper training. ▪ Cimzia™ Vials: FDA approved for administration by health care provider. **AS** – Inadequate response, intolerance or contraindication to at least two NSAIDs over total period of at least four or more weeks of therapy **Nr-AxSpA** – Inadequate response, intolerance or contraindication to at least 2 NSAIDs over total period of at least four or more weeks of therapy **CD** – Inadequate response, intolerance or contraindication to at least one of the following: i. Oral corticosteroids (e.g., prednisone, methylprednisolone, budesonide) ii. Mercaptopurine iii. Azathioprine iv. Methotrexate **PSO** – Inadequate response, intolerance or contraindication to at least one of the following: i. Topical corticosteroids ii. Topical vitamin D analogs (e.g. calcitriol, calcipotriene) iii. Topical tazarotene iv. Topical calcineurin inhibitors (e.g. tacrolimus, pimecrolimus) v. Topical Anthralin vi. Coal Tar vii. Phototherapy

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<tr><td></td><td>PsA – Inadequate response, intolerance or contraindication to at least one conventional DMARD (e.g., methotrexate) for period of at least three months or more of therapy.

RA – History of failure to a three-month trial of one non-biologic disease modifying anti-rheumatic drug (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine).</td></tr>
<tr><td>Age Restriction</td><td>18 years of age and older.</td></tr>
<tr><td>Prescriber Restrictions</td><td>AS & nr- AxSpA: Rheumatologist
PSO: Dermatologist
PsA: Rheumatologist (prescribed or recommend by); a dermatologist may continue treatment that was initiated based on a rheumatologist recommendation
RA: Rheumatologist</td></tr>
<tr><td>Coverage Duration</td><td>Vials: 1 dose to allow administration of starting dose with the goal of transitioning to the prefilled syringe for maintenance treatment at home (provided by the pharmacy).</td></tr>
<tr><td>Other Criteria / Information</td><td>Criteria adapted from DHCS March 2024

Cimzia™ Prefilled Syringe is FDA approved as a self-administered injection and should be provided to the member by a pharmacy through pharmacy benefit.

Vials: Requests will be approved up to one month, if the health care provider prefers to administer the first dose for new start requests, by obtaining it though the practice until safety is determined.

If administration by the provider is requested beyond the time frames shown above, the provider must include reason(s) on the renewal referral stating why the member or caregiver cannot obtain the drug through the pharmacy benefit for self- or caregiver administration.

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<tr><th>HCPCS</th><th>Description</th><th>Dosing, Units</th></tr>
<tr><td>J0717</td><td>Injection, certolizumab pegol, 1mg (Cimzia™ Prefilled syringes, Vials)</td><td>AS, nr- AxSpA, PsA, & RA: 400 mg at week zero, two, & four then 200 mg every two weeks or 400 mg monthly.
CD: 400 mg at week zero, two & four then every four weeks.
Ps: 400 mg at week zero, two & four then every four weeks or for wt ≤ 90 kg, 200 mg every two weeks may be considered.</td></tr>
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STATUS	DATE REVISED	REVIEW DATE	APPROVED / REVIEWED BY	EFFECTIVE DATE
Created	5/1/2024	5/1/2024	Yoonhee Kim, Clinical Programs Pharmacist Lily Yip, Director of Pharmacy Services	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