GCHP Medi-Cal Clinical Guidelines

Infliximab (Remicade™), Infliximab-axxq (Avsola™), Infliximab-dyyb (Inflelctra™), Infliximab-qbtx (Ixifi™) & Infliximab-abda (Renflexis™)

PA Criteria	Criteria Details
Covered Uses (FDA Approved Indication)	• Ankylosing spondylitis (AS) • Crohn's disease (CD) • Plaque psoriasis (PP) • Psoriatic arthritis (PsA) • Rheumatoid arthritis (RA) • Ulcerative colitis (UC) *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	• Doses greater than 5 mg/kg in patients with moderate or severe heart failure (NYHA Class III/IV). • Active infection. • Positive for HBsAg or anti-HBc, without concurrent HBV therapy. • Untreated or active tuberculosis. • Concurrent treatment with other biological drugs (e.g., anakinra, abatacept, or another tumor necrosis factor (TNF) inhibitor).

Required Medical Information	**ALL** the following:
	• Specialist's clinical notes documenting disease course and treatment plan.
	• Previous trial and failure or contraindication on conventional therapy:
	  ○ **AS** – Two more different NSAIDs at maximum recommended doses over at least four or more weeks of therapy
	  ○ **CD** – At least one of the following: 6-mercaptopurine, azathioprine, methotrexate, or oral corticosteroids
	  ○ **PP** – At least one of the following
	  ▪ Immunosuppressive treatments (e.g., Cyclosporine, methotrexate)
	  ▪ Photochemotherapy (e.g., Psoralen plus ultraviolet A therapy)
	  ▪ Topical agents (e.g., anthralin, calcipotriene, coal tars, corticosteroids, tazarotene)
	  ▪ TNF inhibitor
	  ○ **PsA** – Three or more months of treatment with NSAIDs
	  ○ **RA** – Inadequate response to three or more months of treatment with at least one disease-modifying antirheumatic drug (e.g., hydroxychloroquine, leflunomide, methotrexate, sulfasalazine, TNF inhibitor)

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UC – At least one of the following: 6-mercaptopurine, azathioprine, oral corticosteroids, or salicylates.
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.
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<tr><td>Age Restriction</td><td>For UC/CD: 6 years of age and older.
For all other indications: 18 years of age or older</td></tr>
<tr><td>Prescriber Restrictions</td><td>

AS, RA: Rheumatologist
PsA: Dermatologist or Rheumatologist
PP: Dermatologist
CD, UC: Gastroenterologist

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<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
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<tr><th>HCPCS</th><th>Description</th><th>Dosing, Units</th></tr>
<tr><td>J1745</td><td>Infliximab Injection, excludes biosimilar, 10mg (Remicade™)</td><td rowspan="5">AS – 5mg/kg IV at week zero, two and six then every six weeks.

CD & UC – 5mg/kg IV at week zero, two and six then every eight weeks. May increase dose up to 10mg/kg every eight weeks.

PP – 5mg/kg IV at week zero, two, and six then every eight weeks. May increase dose up to 10mg/kg every eight weeks or every four weeks.

PsA – 5mg/kg IV at week zero, two, and six then every eight weeks.

RA – 3mg/kg IV at week zero, two, and six then every eight weeks. May increase dose up to 10mg/kg every eight weeks or every four weeks.</td></tr>
<tr><td>Q5103</td><td>Infliximab-dyyb Injection, biosimilar, 10mg (Inflectra™)</td></tr>
<tr><td>Q5104</td><td>Infliximab-abda Injection, biosimilar, 10mg (Reflexis™)</td></tr>
<tr><td>Q5109</td><td>Infliximab-qbtx Injection, biosimilar, 10mg (Ixifi™)</td></tr>
<tr><td>Q5121</td><td>Infliximab-axxq Injection, biosimilar, 10mg (Avsola™)</td></tr>
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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	8/15/2024	Pharmacy & Therapeutics (P&T) Committee	3/1/2025
Approved	N/A	7/18/2024	Medical Advisory Committee (MAC)	3/1/2025