

GCHP Medi-Cal Clinical Guidelines Ustekinumab (Stelara™)

| PA Criteria | Criteria Details | | | | | | |
|---|---|--|-------------|---------------|-------|--|--|
| Covered Uses (FDA Approved Indication) | Crohn’s disease (CD) or ulcerative colitis (UC). <i>Non-FDA approved indication or off-label use will be reviewed if there is sufficient documentation of efficacy and safety in published literature.</i> | | | | | | |
| Exclusion Criteria | <ul style="list-style-type: none">Active, serious infection, latent (untreated) tuberculosis.Combination with another monoclonal antibody / biologic therapy. | | | | | | |
| Required Medical Information | <p>CD – Documented therapeutic failure to induce remission with (or contraindication to) immunomodulator or corticosteroids or TNF inhibitor (e.g., adalimumab, certolizumab, or infliximab).</p> <p>UC – (a) Documentation confirming moderate to severe disease AND (b) intolerance, or inadequate response to 6-mercaptopurine, azathioprine, oral corticosteroids, salicylate, or TNF inhibitor.</p> <p>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.</p> | | | | | | |
| Age Restriction | 18 years of age and older | | | | | | |
| Prescriber Restrictions | Gastroenterologist. | | | | | | |
| Coverage Duration | Single fill/date of service. FDA indicated dosing is for a single IV dose for induction, followed by subcutaneous dosing thereafter. | | | | | | |
| Other Criteria / Information | <p>Criteria adapted from DHCS March 2024 & MCG</p> <table><tr><th>HCPCS</th><th>Description</th><th>Dosing, Units</th></tr><tr><td>J3358</td><td>Ustekinumab, for IV injections, 1 mg (Stelara™) (only indicated for Crohn’s or UC induction)</td><td>≤55 kg - 260mg IV x one dose >55 – 85 kg - 390mg IV x one dose >85kg – 520mg IV x one dose</td></tr></table> | HCPCS | Description | Dosing, Units | J3358 | Ustekinumab, for IV injections, 1 mg (Stelara™) (only indicated for Crohn’s or UC induction) | ≤55 kg - 260mg IV x one dose >55 – 85 kg - 390mg IV x one dose >85kg – 520mg IV x one dose |
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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 | 5/15/2024 | Pharmacy & Therapeutics (P&T) Committee | 3/1/2025 |
| Approved | N/A | 7/18/2024 | Medical Advisory Committee (MAC) | 3/1/2025 |
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