

Gold Coast Health Plan (GCHP) Medi-Cal Clinical Guidelines Mirikizumab (OmvoTM)

PA Criteria	Criteria Details						
Covered Uses (FDA approved indication)	- Moderately to severely active Crohn disease (CD) in adults - Moderately to severely active ulcerative colitis (UC) in adults						
Exclusion Criteria	Active infection						
Required Medical Information	Initial: Must meet ALL of the following - Evaluated and, if applicable, treated for active or latent Tuberculosis infection prior to initiating treatment - Baseline liver enzymes and bilirubin levels prior to treatment - Current and up to date on age-appropriate immunizations - Inadequate response, intolerance, or contraindication to at least one of the following: ✓ Infliximab ✓ Adalimumab ✓ Golimumab ✓ Vedolizumab ✓ Tofacitinib ✓ Ustekinumab						
Age Restriction	18 years and older 18 to 21 years of age – check for CCS						
Prescriber Restrictions	Gastroenterologist						
Coverage Duration	Initial: 3 months						
Other Criteria/Information	Adapted from DHCS July 2025 Omvo TM Prefilled Syringe and Auto-Injector are FDA approved as a self-administered injection and should be provided to the member by a pharmacy through pharmacy benefit. Maintenance doses are FDA approved for subcutaneous self-administration via Prefilled Syringe or Auto-Injector. Omvo TM Vial is FDA approved for administration by health care provider for Crohn's Disease and for Ulcerative Colitis for induction doses at weeks 0, 4, and 8. Maintenance doses are not FDA-approved for IV administration. <table><tr><th>HCP/CS</th><th>Description</th><th>Dosing, Units</th></tr><tr><td>J2267</td><td>Injection, mirikizumab-mrkz, 1mg (OmvoTM)</td><td>CD: 900mg IV at weeks 0, 4, 8 for induction UC: 300mg IV at weeks 0, 4, 8 for induction</td></tr></table>	HCP/CS	Description	Dosing, Units	J2267	Injection, mirikizumab-mrkz, 1mg (Omvo TM)	CD: 900mg IV at weeks 0, 4, 8 for induction UC: 300mg IV at weeks 0, 4, 8 for induction
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STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	Oct. 14, 2025		Yoonhee Kim, Clinical Pharmacist	