GCHP Medi-Cal Clinical Guidelines
Risankizumab (Skyrizi™)

PA Criteria	Criteria Details
Covered Uses (FDA Approved Indication)	• Moderately to severely active Crohn's disease (CD). • Moderately to severely active ulcerative colitis (UC) in adults.
Exclusion Criteria	• Active or serious infection (including latent (untreated) tuberculosis and hepatitis B virus). • Current diagnosis of ulcerative colitis or indeterminate colitis. • Combinations with other monoclonal antibody/biologic therapy. • No concurrent administration of live vaccine during therapy.

Required Medical Information	• Laboratory test results for baseline liver enzymes and bilirubin levels prior to treatment initiation showing within normal range.
	
	Crohn's Disease (CD) – Must meet ALL of the following:
	• Clinic notes confirmation of diagnosis of CD for at least three months prior.
	• Confirmation of diagnosis of moderate to severe CD as assessed by stool frequency (SF), abdominal pain (AP) score, and simple endoscopic score for Crohn's disease (SES-CD).
	• Crohn's disease activity index (CDAI) score 220 to 450 at baseline.
	• Inadequate response, intolerance or contraindication to at least one conventional therapy:
	  ○ Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
	  ○ Mercaptopurine
	  ○ Azathioprine
	  ○ Methotrexate
	• For females, must meet the contraception recommendation.
	• Has not received Crohn's disease approved biologic agents (Remicade, Humira, Cimzia, Entyvio, Tysabri) within eight weeks prior to Baseline or Stelara within 12 weeks prior to baseline).
	
	Ulcerative Colitis (UC)
	▪ Clinical notes confirmation of diagnosis of moderate to severe UC AND
	▪ Inadequate response, or intolerance to oral aminosalicylates, corticosteroids, immunomodulators, biologics, Janus Kinase inhibitors (JAKi), and/or sphingosine-1-phosphate receptor modulators (S1PRM).

Age Restriction	18 years of age and older. 18-21 year of age – check for CCS.
Prescriber Restrictions	Gastroenterologist.

<table>
<tr><td>Coverage Duration</td><td>Three months (or three doses) for induction dose only.</td></tr>
<tr><td>Other Criteria/Information</td><td>Criteria adapted from DHCS May 2025.

Skyrizi™ Prefilled Pen, Prefilled Syringe, and Prefilled Cartridge are FDA approved as a self-administered injection and should be provided to the member by a pharmacy through pharmacy benefit.

Skyrizi™ Vial: FDA approved for administration by health care provider for Crohn’s Disease and for Ulcerative Colitis for induction doses at weeks zero, four and eight.

<table>
<tr><th>HCPCS</th><th>Description</th><th>Dosing, Units</th></tr>
<tr><td>J2327</td><td>Injection, Risankizumab-rzaa, intravenous, 1mg (Skyrizi™)</td><td>CD: 600mg IV at weeks zero, four and eight for induction.
UC: 1,200mg IV at weeks zero, four and eight for induction.</td></tr>
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STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	5/1/2024	5/01/2024	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
Updated	10/9/2025	N/A	Yoonhee Kim, Clinical Programs Pharmacist	N/A
Approved	N/A	11/13/2025	Pharmacy & Therapeutics Committee	12/1/2025