GCHP Medi-Cal Clinical Guidelines
Risankizumab (Skyrizi™)

PA Criteria	Criteria Details
Covered Uses (FDA Approved Indication)	Moderately to severely active Crohn's disease.
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.

Required Medical Information	• Laboratory test results for baseline liver enzymes and bilirubin levels prior to treatment initiation showing within normal range.
	• 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

Age Restriction	18 years of age and older
Prescriber Restrictions	Gastroenterologist
Coverage Duration	Three months (or three doses) for induction dose only.
Other Criteria / Information	Criteria adapted from DHCS March 2024 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 for induction doses at weeks zero, four and eight.

HCPCS	Description	Dosing, Units
J2327	Injection, Risankizumab-rzaa, intravenous, 1mg (Skyrizi™)	600mg IV at weeks zero, four and eight for induction.

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