Tremfya *(guselkumab)* IV

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	Tremfya is an interleukin-23 (IL-23) inhibitor and is available in both a subcutaneous (SC) injection and an intravenous (IV) infusion. The IV formulation is currently indicated for the induction phase of ulcerative colitis treatment in adults. The SC formulation is indicated in the maintenance phase of treatment in ulcerative colitis, as well as other inflammatory conditions such as psoriatic arthritis and plaque psoriasis.
Exclusion Criteria	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
Age Restriction	None.
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	Three IV induction doses will be approved in accordance with the FDA-approved labeling. Subsequent maintenance doses must be approved under the pharmacy benefit.
Other Criteria/Information	Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.

HCPCS	Description	Billing Units/How Supplied
J1628	Tremfya (guselkumab) 200mg/20ml vial (IV infusion)	**Billing unit: 1 mg** 200mg20 mL SDV

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	3/26/2025	3/26/2025	Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG)	N/A
Approved	N/A	5/15/2025	Pharmacy & Therapeutics (P&T) Committee	5/15/2025