Bivigam *(immune globulin)*

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	Bivigam, an intravenous immunoglobulin (IVIG) that are human derived antibodies used to treat various autoimmune, infectious, and idiopathic diseases including, but not limited to: Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), Chronic Lymphocytic Leukemia (CLL), multiple myeloma, myasthenia gravis, and Immune Thrombocytopenia (ITP).
Exclusion Criteria	None.
Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
Other Criteria	Must follow LCD L34771 (Immune Globulin). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34771&ver=49&=
Age Restriction	None.
Prescriber Restrictions	None.
Coverage Duration	Two years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
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
J1556	Bivigam (immune globulin) intravenous	**Billing unit: 500 mg** 5 gm/50 ml SDV 10 gm/100 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	8/21/2025	Pharmacy & Therapeutics (P&T) Committee	8/21/2025