Alyglo *(immune globulin intravenous, human-stwk)*

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	Alyglo is approved for the treatment of primary humoral immunodeficiency (PI) in adults. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency (CVID), Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.
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 for Immune Globulins. 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
J1552	Alyglo (immune globulin intravenous, human-stwk)	**Billing unit: 500 mg** 5 g/50 mL, 10g/ 100 mL, 20 g/200 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