Kymriah *(tisagenlecleucel)*

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	Kymriah is a CD19-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of: 1. Patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse. 2. Adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma.
Exclusion Criteria	None.
Required Medical Information	Medical records supporting the request must be provided.
Other Criteria	Must follow NCD 110.24 for Chimeric Antigen Receptor (CAR) T-Cell Therapy. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374
Age Restriction	None.
Prescriber Restrictions	None.
Coverage Duration	In accordance with the FDA approved labeling or 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
Q2042	Kymriah (tisagenlecleucel)	**Billing unit: per dose** SD infusion bag

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