

PA Criteria	Criteria Details						
<b>Covered Uses (FDA approved indication)</b>	<p>Breyanzi is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of:</p> <p>Adult patients with large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B, who have:</p> <p>Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or</p> <p>Refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age; or</p> <p>Relapsed or refractory disease after two or more lines of systemic therapy.</p>						
<b>Exclusion Criteria</b>	None.						
<b>Required Medical Information</b>	Medical records supporting the request must be provided.						
<b>Other Criteria</b>	Must follow NCD 110.24 for Chimeric Antigen Receptor (CAR) T-Cell Therapy. <a href="https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374">https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374</a>						
<b>Age Restriction</b>	None.						
<b>Prescriber Restrictions</b>	None.						
<b>Coverage Duration</b>	In accordance with the FDA-approved labeling or accepted standards of medical practice.						
<b>Other Criteria/Information</b>	<p>Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.</p> <table border="1"> <thead> <tr> <th>HCPCS</th> <th>Description</th> <th>Billing Units/How Supplied</th> </tr> </thead> <tbody> <tr> <td>Q2054</td> <td>Breyanzi (lisocabtagene maraleucel)</td> <td><b>Billing unit: per dose</b>  SD infusion bag</td> </tr> </tbody> </table>	HCPCS	Description	Billing Units/How Supplied	Q2054	Breyanzi (lisocabtagene maraleucel)	<b>Billing unit: per dose</b>  SD infusion bag
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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