Medical Policy:

Columvi (glofitamab-gxbm) intravenous solution

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.388	March 13, 2025	July 28, 2023

Definitions

COLUMVI is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy.

Length of Authorization

Coverage will be provided for 12 months

Dosing Limits [Medical Benefit]

2.5mg-30mg/cycle for a maximum of 12 cycles

Max Units (per dose and over time) [HCPCS Unit]:

Diffuse Large B-Cell Lymphoma (21-day cycles)

- Cycle 1: 2.5 mg on day 8 and 10 mg on day 15
- Cycles 2 to 12: 30 mg on day 1

Guideline

I. INITIAL CRITERIA

1. **Diffuse Large B-Cell Lymphoma.** Approve if the patient meets the following criteria (A, B, C, D, and E):
   Note: Diffuse large B-cell lymphoma (DLBCL) includes DLBCL not otherwise specified and large B-cell lymphoma arising from indolent lymphoma
   A. Patient is ≥ 18 years of age; **AND**
   B. Patient has received two or more lines of systemic therapy; **AND**
      Note: Examples of systemic therapy include RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) and DHA (dexamethasone, cytarabine) + platinum (carboplatin, cisplatin, or oxaliplatin) ± rituximab.
   C. Medication is given as a single agent; **AND**
   D. Patient has or will receive pretreatment with Gazyva (obinutuzumab intravenous infusion) before the first dose of Columvi; **AND**
   E. Medication is prescribed by or in consultation with an oncologist

II. RENEWAL CRITERIA

Coverage may be renewed based upon the following criteria:

1. Patient continues to meet Initial Criteria; **AND**
2. Absence of unacceptable toxicity from the drug. *Examples of unacceptable toxicity include: serious infections, serious or life-threatening cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS), serious tumor flare, etc.*; **AND**
3. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

Applicable Procedure Codes

Code	Description
J9286	Injection, glofitamab-gxbm, 2.5 mg

Applicable NDCs

Code	Description
50242-0125-01	Columvi 1mg/mL 2.5mL
50242-0127-01	Columvi 1mg/mL 10mL

ICD-10 Diagnoses

Code	Description
C83.30	Relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32	Diffuse large B-cell lymphoma, intrathoracic lymph nodes
C83.33	Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
C83.34	Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.36	Diffuse large B-cell lymphoma, intrapelvic lymph nodes
C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma, lymph nodes of multiple sites
C83.39	Diffuse large B-cell lymphoma, extranodal and solid organ sites

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/13/2025	Removed ICD- 10 Code C83.39. Diffuse Large B-Cell Lymphoma: Note revised from diffuse large B-cell lymphoma (DLBCL) arising from follicular lymphoma or nodal marginal zone lymphoma to DLBCL arising from indolent lymphoma.
EmblemHealth & ConnectiCare	3/20/2024	Annual Review: Updated dosing limits, removed J9999, added J9286, Added C83.31-C83.39, added renewal criteria
EmblemHealth & ConnectiCare	07/28/2023	New Policy

References

1. Product Information: COLUMVI**.** intravenous solution, glofitamab-gxbm intravenous solution. Genentech, Inc. (per FDA), South San Francisco, CA, 2023.