

Medical Policy:

Columvi (glofitamab-gxbm) intravenous solution

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.388	March 20, 2024	July 28, 2023

Medical Guideline Disclaimer Property of EmblemHealth. All rights reserved.

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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

- 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 follicular lymphoma.
 - Patient is ≥ 18 years of age; **AND**
 - 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) \pm rituximab.
 - Medication is given as a single agent; **AND**
 - Patient has or will receive pretreatment with Gazyva (obinutuzumab intravenous infusion) before the first dose of Columvi; **AND**
 - Medication is prescribed by or in consultation with an oncologist

II. RENEWAL CRITERIA

Coverage may be renewed based upon the following criteria:

- Patient continues to meet Initial Criteria; **AND**
- 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**
- 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	3/20/2024	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.