Columvi™ (glofitamab-gxbm)
(Intravenous)

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I. Length of Authorization [1]

Coverage will be provided for 6 months *(after the initial first step-up dose)* and may be renewed once for a total of 12 treatment cycles.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Columvi 2.5 mg/2.5 mL single-dose vial: 1 vial on day 8 of cycle 1
- Columvi 10 mg/10 mL single-dose vial: 1 vial on day 15 of cycle 1; and 3 vials on day 1 of cycles 2 to 12

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

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

- Cycle 1: 1 billable unit (2.5 mg) on day 8 and 4 billable units (10 mg) on day 15
- Cycles 2 to 12: 12 billable units (30 mg) on day 1

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria [1]

- Prophylaxis for infection will be followed according to local guidelines (e.g., *Pneumocystis jirovecii pneumonia (PJP), Herpes virus, cytomegalovirus, etc.)*; **AND**
- Patient does not have a clinically significant active systemic infection; **AND**
- Patient does not have primary central nervous system (CNS) lymphoma or CNS involvement of disease; **AND**
- Patient has not received prior allogeneic hematopoietic stem cell transplantation (HSCT); **AND**
- Patient will receive tumor lysis syndrome prophylaxis during therapy (e.g., anti-hyperuricemics and adequate hydration); **AND**

Diffuse Large B-cell lymphoma (DLBCL) † [1,2]

- Patient has a diagnosis of DLBCL *(Note: includes LBCL arising from follicular lymphoma and DLBCL, not otherwise specified);* **AND**
- Patient has relapsed or refractory disease; **AND**
- Patient does not have a history of refractoriness to obinutuzumab and will be pretreated with obinutuzumab prior to treatment with glofitamab; **AND**
- Used after at least two prior lines of systemic therapy

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **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

V. Dosage/Administration [1]

Indication	Dose
Diffuse Large B-Cell Lymphoma (DLBCL)	**Pretreatment with Obinutuzumab** Pretreat all patients with a single 1,000 mg dose of obinutuzumab administered as an intravenous infusion on Cycle 1 Day 1 to deplete the circulating and lymphoid tissue B cells. Refer to the obinutuzumab prescribing information for complete dosing information. **Columvi Step-up Dose Schedule *(21-day treatment cycles)*** Columvi dosing begins with a step-up dose schedule. Following completion of pretreatment with obinutuzumab on Cycle 1 Day 1, administer Columvi as an intravenous infusion according to the step-up dose schedule below. • **Cycle 1**: – Obinutuzumab 1,000 mg day 1 – Step-up dose 1: 2.5 mg day 8 (should be hospitalized during and for 24 hours after) – Step-up dose 2: 10 mg day 15 • **Cycles 2 to 12**: – 30 mg day 1 ***Continue Columvi for a maximum of 12 cycles (inclusive of Cycle 1 step-up dosing) or until disease progression or unacceptable toxicity, whichever occurs first.***
Note: – *Administer only as an intravenous infusion through a dedicated infusion line that includes a sterile 0.2-micron in-line filter.*	

– *Should only be administered by a healthcare professional with immediate access to appropriate medical support, including supportive medications to manage severe CRS.*
– *Ensure adequate hydration before administering therapy. Premedicate before each dose.*
– *Due to the risk of CRS, patients should be hospitalized during and for 24 hours after completion of infusion of step-up dose 1 (2.5 mg on Cycle 1 Day 8).*

VI. Billing Code/Availability Information

HCPCS Code:

- J9999 – Not otherwise classified, antineoplastic drug *(Discontinue use on 01/01/2024)*
- J9286 – Injection, glofitamab-gxbm, 2.5 mg; 1 billable unit = 2.5 mg *(Effective 01/01/2024)*

NDC(s):

- Columvi 2.5 mg/2.5 mL single-dose vial: 50242-0125-xx
- Columvi 10 mg/10 mL single-dose vial: 50242-0127-xx

VII. References

1. Columvi [package insert]. South San Francisco, CA; Genentech, Inc.; June 2023. Accessed June 2023.
2. Hutchings M, Morschhauser F, Iacoboni G, et al. Glofitamab, a Novel, Bivalent CD20-Targeting T-Cell-Engaging Bispecific Antibody, Induces Durable Complete Remissions in Relapsed or Refractory B-Cell Lymphoma: A Phase I Trial. J Clin Oncol. 2021 Jun 20;39(18):1959-1970. doi: 10.1200/JCO.20.03175. Epub 2021 Mar 19.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) glofitamab. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed May 2023.
4. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas, Version 3.2023. National Comprehensive Cancer Network, 2023. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed May 2023.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C83.30	Diffuse large B-cell lymphoma unspecified site
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
C83.90	Non-follicular (diffuse) lymphoma, unspecified site
C83.91	Non-follicular (diffuse) lymphoma, unspecified lymph nodes of head, face, and neck
C83.92	Non-follicular (diffuse) lymphoma, unspecified intrathoracic lymph nodes
C83.93	Non-follicular (diffuse) lymphoma, unspecified intra-abdominal lymph nodes
C83.94	Non-follicular (diffuse) lymphoma, unspecified lymph nodes of axilla and upper limb
C83.95	Non-follicular (diffuse) lymphoma, unspecified lymph nodes of inguinal region and lower limb
C83.96	Non-follicular (diffuse) lymphoma, unspecified intrapelvic lymph nodes
C83.97	Non-follicular (diffuse) lymphoma, unspecified spleen
C83.98	Non-follicular (diffuse) lymphoma, unspecified lymph nodes of multiple sites
C83.99	Non-follicular (diffuse) lymphoma, unspecified extranodal and solid organ sites
C85.20	Mediastinal (thymic) large B-cell lymphoma, unspecified site
C85.21	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of head, face and neck
C85.22	Mediastinal (thymic) large B-cell lymphoma, intrathoracic lymph nodes
C85.23	Mediastinal (thymic) large B-cell lymphoma, intra-abdominal lymph nodes
C85.24	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of axilla and upper limb
C85.25	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.26	Mediastinal (thymic) large B-cell lymphoma, intrapelvic lymph nodes
C85.27	Mediastinal (thymic) large B-cell lymphoma, spleen
C85.28	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of multiple sites
C85.29	Mediastinal (thymic) large B-cell lymphoma, extranodal and solid organ sites

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC