

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 twelve 21-day treatment cycles (12 total doses).

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 per cycle for cycles 2 to 12

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

- Cycle 1: 1 billable unit on day 8 and 4 billable units on day 15 of 21-day cycle
- Cycles 2 to 12: 12 billable units every 21 days

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

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

Universal Criteria ¹⁻³

- 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**
- Used as a single agent; **AND**

B-Cell Lymphomas † ‡ ¹⁻⁴

- 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; **AND**
 - Patient has diffuse large B-cell Lymphoma (DLBCL) (*including DLBCL, not otherwise specified*), high-grade B-cell lymphoma, HIV-related B-cell lymphoma (i.e., HIV-related DLBCL, primary effusion lymphoma, or HHV8-positive large B-cell lymphoma, not otherwise specified), or monomorphic post-transplant lymphoproliferative disorder (PTLD) (B-cell type); **AND**
 - Used for partial response, progressive, relapsed, or refractory disease; **OR**
 - Patient has histologic transformation of an indolent lymphoma (follicular lymphoma or marginal zone lymphoma) to DLBCL; **AND**
 - Used for partial response, no response, progressive, relapsed, or refractory disease

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

IV. Renewal Criteria ¹

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 cytokine release syndrome (CRS), serious neurologic toxicity (including 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; **AND**
- Patient has not exceeded a total of twelve 21-day treatment cycles (12 total doses)

V. Dosage/Administration ¹

Indication	Dose
B-Cell Lymphomas	<p><u>Pretreatment with Obinutuzumab</u></p> <p>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.</p> <p>Refer to the obinutuzumab prescribing information for complete dosing information.</p>

	<p>Columvi Step-up Dose Schedule (21-day treatment cycles)</p> <p>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.</p> <ul style="list-style-type: none"> • Cycle 1: <ul style="list-style-type: none"> – Obinutuzumab 1,000 mg day 1 – Step-up dose 1: 2.5 mg day 8 – Step-up dose 2: 10 mg day 15 • Cycles 2 to 12: <ul style="list-style-type: none"> – 30 mg day 1 <p>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.</p>
<p><u>Note:</u></p> <ul style="list-style-type: none"> – 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:

- J9286 – Injection, glofitamab-gxbm, 2.5 mg; 1 billable unit = 2.5 mg

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 February 2024.
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, 2024. 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 February 2024.

4. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas, Version 1.2024. National Comprehensive Cancer Network, 2024. 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 February 2024.

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
C83.80	Other non-follicular lymphoma, unspecified site
C83.81	Other non-follicular lymphoma, lymph nodes of head, face, and neck
C83.82	Other non-follicular lymphoma, intrathoracic lymph nodes
C83.83	Other non-follicular lymphoma, intra-abdominal lymph nodes
C83.84	Other non-follicular lymphoma, lymph nodes of axilla and upper limb
C83.85	Other non-follicular lymphoma, lymph nodes of inguinal region and lower limb
C83.86	Other non-follicular lymphoma, intrapelvic lymph nodes
C83.87	Other non-follicular lymphoma, spleen
C83.88	Other non-follicular lymphoma, lymph nodes of multiple sites
C83.89	Other non-follicular 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
C85.10	Unspecified B-cell lymphoma, unspecified site
C85.11	Unspecified B-cell lymphoma, lymph nodes of head, face, and neck
C85.12	Unspecified B-cell lymphoma, intrathoracic lymph nodes
C85.13	Unspecified B-cell lymphoma, intra-abdominal lymph nodes
C85.14	Unspecified B-cell lymphoma, lymph nodes of axilla and upper limb
C85.15	Unspecified B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.16	Unspecified B-cell lymphoma, intrapelvic lymph nodes
C85.17	Unspecified B-cell lymphoma, spleen
C85.18	Unspecified B-cell lymphoma, lymph nodes of multiple sites
C85.19	Unspecified B-cell lymphoma, 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
C85.80	Other specified types of non-Hodgkin lymphoma, unspecified site
C85.81	Other specified types of non-Hodgkin lymphoma, lymph nodes of head, face, and neck
C85.82	Other specified types of non-Hodgkin lymphoma, intrathoracic lymph nodes
C85.83	Other specified types of non-Hodgkin lymphoma, intra-abdominal lymph nodes
C85.84	Other specified types of non-Hodgkin lymphoma, lymph nodes of axilla and upper limb
C85.85	Other specified types of non-Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C85.86	Other specified types of non-Hodgkin lymphoma, intrapelvic lymph nodes
C85.87	Other specified types of non-Hodgkin lymphoma, spleen
C85.88	Other specified types of non-Hodgkin lymphoma, lymph nodes of multiple sites
C85.89	Other specified types of non-Hodgkin lymphoma, extranodal and solid organ sites
D47.Z1	Post-transplant lymphoproliferative disorder (PTLD)
Z85.72	Personal history of non-Hodgkin lymphomas

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

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied 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