Clinical Policy: Glofitamab-gxbm (Columvi)

Reference Number: CP.PHAR.636
Effective Date: 09.01.23
Last Review Date: 08.24
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Glofitamab-gxbm (Columvi™) is a bispecific CD20-directed CD3 T-cell engager.

FDA Approved Indication(s)

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.

This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Columvi is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Diffuse Large B-Cell Lymphoma or Large B-Cell Lymphoma (must meet all)**:**

1. Diagnosis of one of the following (a, b, or c):
   a. DLBCL (*see subtypes in Appendix D)*;
   b. LBCL arising from follicular lymphoma;
   c. Histologic transformation of follicular or marginal zone lymphoma to DLBCL (off-label);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Member has received ≥ 2 line of systemic therapy (*see Appendix B*);
5. Member had partial response, no response, progressive, relapsed, or refractory disease following prior systemic therapy;
6. Member is prescribed obinutuzumab (Gazyva®)* as pretreatment, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for Gazyva*
7. Request meets one of the following (a, b, or c):*
   a. Cycle 1: Dose does not exceed 2.5 mg on Day 8 and 10 mg on Day 15;

b. Cycles 2 to 12: Dose does not exceed 30 mg on Day 1 of a 21-day cycle, for a maximum of 12 cycles;
c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Diffuse Large B-Cell Lymphoma or Large B-Cell Lymphoma (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Columvi for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. Member has received < 12 cycles of Columvi;
4. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 30 mg on Day 1 of a 21-day cycle, for a maximum of 12 cycles;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DLBCL: diffuse large B-cell lymphoma
FDA: Food and Drug Administration
NOS: not otherwise specified
LBCL: large B-cell lymphoma

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
DLBCL Examples of chemotherapy regimens: • RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) • Pola-R-CHP (polatuzumab vedotin-piiq, rituximab, cyclophosphamide, doxorubicin, prednisone) • Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) + rituximab	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): cytokine release syndrome

Appendix D: DLBCL Subtypes per the National Comprehensive Cancer Network (NCCN)

- DLBCL, NOS (FDA-approved use)
- DLBCL coexistent with follicular lymphoma of any grade
- DLBCL coexistent with estranodal marginal zone lymphoma (EMZL) of stomach
- DLBCL coexistent with ENZL of nongastric sites
- Follicular lymphoma grade 3
- Intravascular LBCL
- DLBCL associated with chronic inflammation
- ALK-positive LBCL
- EBV-positive DLBCL, NOS
- T-cell/histiocyte-rich large B-cell lymphoma
- LBCL with *IRF4/MUM1* rearrangement
- Double expressor DLBCL
- Fibrin-associated LBCL
- Primary mediastinal LBCL
- Mediastinal gray zone lymphoma
- High-grade B-cell lymphomas with *MYC and BCL2* rearrangements
- High-grade B-cell lymphomas, NOS
- Primary cutaneous DLBCL

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
DLBCL, NOS or LBCL	Pretreat with a single 1,000 mg dose of obinutuzumab IV 7 days before Columvi (Cycle 1 Day 1) Cycle 1: 2.5 mg IV on Day 8 (step-up dose 1) and 10 mg IV on Day 15 (step-up dose 2) Cycles 2 to 12: 30 mg IV on Day 1 repeated every 21 days. Continue until disease progression, unacceptable toxicity, or a maximum of 12 cycles.	30 mg every 21 days (maximum of 12 cycles)

VI. Product Availability

Single-dose vials: 2.5 mg/2.5 mL, 10 mg/10 mL

VII. References

1. Columvi Prescribing Information. South San Francisco, CA: Genentech, Inc.; June 2023. Available at: https://www.gene.com/download/pdf/columvi_prescribing.pdf. Accessed May 6, 2024.
2. National Comprehensive Cancer Network Guidelines. B-Cell Lymphomas Version 2.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed May 16, 2024.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9286	Injection, glofitamab-gxbm, 2.5 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	07.04.23	08.23
Added HCPCS code [J9286]	10.27.23	
3Q 2024 annual review: added NCCN Compendium supported off-label use in histologic transformation of follicular or marginal zone lymphoma to DLBCL; added allowances for partial response, no response, or progressive disease after prior therapy; references reviewed and updated.	05.06.24	08.24

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy,

contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.