Clinical Policy: Glofitamab-gxbm (Columvi)

Reference Number: PA.CP.PHAR.636
Effective Date: 08/2023
Last Review Date: 07/2023

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 PA Health & Wellness® 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 or b):
   a. DLBCL (*see subtypes in Appendix D)*;
   b. LBCL arising from follicular lymphoma;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Disease is refractory to or has relapsed after ≥ 2 lines of systemic therapy (*see Appendix B*);
5. Member is prescribed obinutuzumab (Gazyva®)* as pretreatment, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for Gazyva*
6. 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*).

Approval duration: 6 months

B. Other diagnoses/indications
1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Diagnosis (must meet all)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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*).

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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 – PA.CP.PMN.53

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:	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
• 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		

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
- Histologic Transformation of Indolent Lymphomas to DLBCL
- HIV-Related B-Cell Lymphomas
- Post-Transplant Lymphoproliferative Disorders

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)	30 mg every 21 days (maximum of 12 cycles)

Indication	Dosing Regimen	Maximum Dose
	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.	

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 June 27, 2023.
2. National Comprehensive Cancer Network Guidelines. B-Cell Lymphomas Version 4.2023. Available at https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed June 27, 2023.

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
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	07/2023	