UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – Bispecific – CD20-Directed) – Columvi Utilization Management Medical Policy
- Columvi™ (glofitamab-gxbm intravenous infusion – Genentech)

REVIEW DATE: 06/04/2025

OVERVIEW

Columvi, a bispecific anti-CD20-directed CD3 T-cell engager, is indicated for the treatment of **relapsed or refractory diffuse large B-cell lymphoma** (DLBCL) not otherwise specified or **large B-cell lymphoma** (LBCL) arising from follicular lymphoma, in adults after two or more lines of systemic therapy.[1] 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).

Dosing Information

Columvi is administered by intravenous (IV) infusion and is given in 21-day cycles.[1] On Day 1 of Cycle 1, Gazyva® (obinutuzunab intravenous infusion) 1,000 mg IV is administered to deplete circulating and lymphoid tissue B-cells. Then Columvi 2.5 mg is administered on Day 8 and 10 mg is administered on Day 15 of Cycle 1, followed by Columvi 30 mg administered on Day 1 of Cycles 2 through 12. Treatment may continue until disease progression, unacceptable adverse events, or for a total of 12 cycles. Patients should be premedicated with acetaminophen and an antihistamine before each dose of Columvi and with a corticosteroid before all doses of Columvi in Cycles 1 through 3. For subsequent cycles, premedicate with a corticosteroid if the patient had any grade cytokine release syndrome with the previous dose.

Guidelines

The National Comprehensive Cancer Network **B-cell lymphoma** clinical practice guidelines (version 2.2025 – February 10, 2025) recommend Columvi for the second-line and subsequent treatment of DLBCL, high-grade B-cell lymphoma, histologic transformation of indolent lymphoma to DLBCL, human immunodeficiency virus (HIV)-related B-cell lymphoma, and post-transplant lymphoproliferative disorders.[2,3]

Safety

Columvi has a Boxed Warning for cytokine release syndrome.[1]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Columvi. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Columvi as well as the monitoring required for adverse events and long-term efficacy, approval requires Columvi to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Columvi is recommended in those who meet the following criteria:

FDA-Approved Indication

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1. **Diffuse Large B-Cell Lymphoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D,):
   Note: Examples of diffuse large B-cell lymphoma (DLBCL) include DLBCL not otherwise specified, high-grade B-cell lymphoma, and DLBCL arising from indolent lymphoma.
   A) Patient is ≥ 18 years of age; AND
   B) Patient has received one 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) ± rituximab.
   C) Patient has or will receive pretreatment with Gazyva (obinutuzumab intravenous infusion) before the first dose of Columvi; AND
   D) The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve the following dosing regimen (A and B):
   A) The dose of Columvi is up to 30 mg administered as an intravenous infusion; AND
   B) Columvi is given no more frequently than twice in Cycle 1, and no more frequently than once in Cycles 2 to 12.

Other Uses with Supportive Evidence

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2. **Human Immunodeficiency Virus (HIV)-Related B-Cell Lymphoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   Note: HIV-related B-cell lymphomas includes HIV-related diffuse large B-cell lymphoma (DLBCL), primary effusion lymphoma, and human herpes virus-8 (HHV8) positive DLBCL or for HIV-related plasmablastic lymphoma.
   A) Patient is ≥ 18 years of age; AND
   B) Patient has received one or more lines of systemic therapy; AND
   Note: Examples of systemic therapy include RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) and R-EPOCH (rituximab, etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin).
   C) Patient has or will receive pretreatment with Gazyva (obinutuzumab intravenous infusion) before the first dose of Columvi; AND
   D) The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve the following dosing regimen (A and B):
   A) The dose of Columvi is up to 30 mg administered as an intravenous infusion; AND
   B) Columvi is given no more frequently than twice in Cycle 1, and no more frequently than once in Cycles 2 to 12.

Post-Transplant Lymphoproliferative Disorders. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

E) Patient is ≥ 18 years of age; AND

F) Patient has received one or more lines of systemic therapy; AND
Note: Examples of systemic therapy include RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) and RCEPP (rituximab, cyclophosphamide, etoposide, prednisone, procarbazine).

G) Patient has or will receive pretreatment with Gazyva (obinutuzumab intravenous infusion) before the first dose of Columvi; AND

H) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve the following dosing regimen (A and B):

A) The dose of Columvi is up to 30 mg administered as an intravenous infusion; AND

B) Columvi is given no more frequently than twice in Cycle 1, and no more frequently than once in Cycles 2 to 12.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Columvi is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Columvi™ intravenous infusion [prescribing information]. South San Francisco, CA: Genentech; June 2023.
2. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 28, 2025. Search term: glofitamab.
3. The NCCN B-Cell Lymphoma Clinical Practice Guidelines in Oncology (version 2.2025 – February 10, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 28, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	06/28/2023
Selected Revision	**Diffuse Large B-Cell Lymphoma:** High-grade B-cell lymphoma and DLBCL arising from nodal marginal zone lymphoma were added to the Note. **Human Immunodeficiency Virus (HIV)-Related B-Cell Lymphoma:** New condition of approval added to the policy. **Post-Transplant Lymphoproliferative Disorders:** New condition of approval added to the policy.	07/12/2023
Annual Revision	**Diffuse Large B-Cell Lymphoma:** Note revised from diffuse large B-cell lymphoma (DLBCL) arising from follicular lymphoma or nodal marginal zone lymphoma to DLBCL arising from indolent lymphoma.	06/26/2024
Update	04/08/2025: The policy name was changed from "Oncology (Injectable) – Columvi UM Medical Policy" to "Oncology (Injectable – Bispecific – CD20-Directed) – Columvi UM Medical Policy".	N/A
Annual Revision	**Diffuse Large B-Cell Lymphoma, Human Immunodeficiency Virus (HIV)-Related B-Cell Lymphoma, and Post-Transplant Lymphoproliferative Disorders :** Removed the requirement that the medication is used as a single agent. For the requirement that the patient has received two or more lines of systemic therapy was changed to one or more lines of systemic therapy.	06/04/2025