CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

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

REVIEW DATE: 05/06/2026

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.

Guidelines

Columvi has been addressed by National Comprehensive Cancer Network (NCCN) guidelines:

- **B-Cell Lymphomas:** NCCN guidelines (version 3.2026 – March 12, 2026) 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 (category 2A/2B).[2,3] Columvi is also recommended for the treatment of mantle cell lymphoma for subsequent therapy as a single agent (category 2A). Columvi is also recommended for the treatment of Burkitt lymphoma for subsequent therapy, in combination with Polivy® (polatuzumab intravenous infusion), as a bridge to transplant for allogeneic hematopoietic cell transplant (category 2A).
- **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma:** NCCN guidelines (version 2.2026 – December 22, 2025) recommend Columvi for the treatment of histologic transformation (Richter) [category 2A].[4]

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 or hematologist.

   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. **Burkitt Lymphoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
   A) Patient is ≥ 18 years of age; AND
   B) The medication is used as subsequent therapy; AND
   C) The medication is used in combination with Polivy (polatuzumab intravenous infusion); AND
   D) The medication is used as a bridge for allogeneic hematopoietic cell transplant; AND
   E) The medication is prescribed by or in consultation with an oncologist or hematologist.

   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.

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3. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. Approve for 1 year if the patient meets ALL of the following (A, B, and C):
A) Patient is ≥ 18 years of age; AND
B) Patient has Richter transformation; AND
C) The medication is prescribed by or in consultation with an oncologist or hematologist.

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

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4. 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 or hematologist.

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.

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5. Mantle Cell Lymphoma. Approve for 1 year if the patient meets ALL of the following (A, B, and C):
A) Patient is ≥ 18 years of age; AND
B) Patient has received at least one covalent Bruton tyrosine kinase inhibitor; AND
Note: Examples of a covalent Bruton tyrosine kinase inhibitors include Brukinsa (zanubrutinib capsules and tablets), Calquence (acalabrutinib tablets), and Imbruvica (ibrutinib capsules, oral suspension, and tablets).
C) The medication is prescribed by or in consultation with an oncologist or hematologist.

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.

6. **Post-Transplant Lymphoproliferative Disorders.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **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 RCEPP (rituximab, cyclophosphamide, etoposide, prednisone, procarbazine).
   - **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 or hematologist.

   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; October 2025.
2. The NCCN Drugs and Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 30, 2026. Search term: glofitamab.
3. The NCCN B-Cell Lymphoma Clinical Practice Guidelines in Oncology (version 3.2026 – March 12, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 30, 2026.
4. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (version 2.2026 – December 22, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 30, 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
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. 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
Selected Revision	**Burkitt Lymphoma**: Burkitt lymphoma was added as a new condition for approval. **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma**: Chronic lymphocytic leukemia/small lymphocytic lymphoma was added as a new condition for approval. **Mantle Cell Lymphoma**: Mantle cell lymphoma was added as a new condition for approval.	01/28/2026
Annual Revision	For all the indications, hematologist was added to the requirement that "the medication is prescribed by or in consultation with an oncologist." **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma:** The wording "histologic" was removed from the requirement that previously stated, "patient has histologic Richter transformation."	05/06/2026