PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Columvi Prior Authorization Policy
- Columvi™ (glofitamab-gxbm intravenous infusion – Genentech)

REVIEW DATE: 06/26/2024

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]

Guidelines
The National Comprehensive Cancer Network **B-cell lymphoma** clinical practice guidelines (version 2.2024 – April 30, 2024) recommend Columvi for the third-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 prescription benefit coverage of Columvi. 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

1. **Diffuse Large B-Cell Lymphoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
   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 two 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) Medication is given as a single agent; AND

D) Patient has or will receive pretreatment with Gazyva (obinutuzumab intravenous infusion) before the first dose of Columvi; AND
E) Medication is prescribed by or in consultation with an oncologist.

Other Uses with Supportive Evidence

2. Human Immunodeficiency Virus (HIV)-Related B-Cell Lymphoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
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
A) Patient is ≥ 18 years of age; AND
B) Patient has received two 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) Medication is given as a single agent; AND
D) Patient has or will receive pretreatment with Gazyva (obinutuzumab intravenous infusion) before the first dose of Columvi; AND
E) Medication is prescribed by or in consultation with an oncologist.

3. Post-Transplant Lymphoproliferative Disorders. 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) Patient has received two 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) Medication is given as a single agent; AND
D) Patient has or will receive pretreatment with Gazyva (obinutuzumab intravenous infusion) before the first dose of Columvi; AND
E) Medication is prescribed by or in consultation with an oncologist.

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. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 17, 2024. Search term: glofitamab.
3. The NCCN B-Cell Lymphoma Clinical Practice Guidelines in Oncology (version 2.2024 – April 30, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 17, 2024.