blue california
Promise Health Plan

# glofitamab-gxbm (Columvi)

## Medical Benefit Drug Policy

Place of Service
Office Administration
Outpatient Facility Administration
Hospital Administration
Infusion Center Administration

## Drug Details

**USP Category:** Antineoplastics: Monoclonal antibodies
**Mechanism of Action:** Bispecific CD20-directed CD3 T-cell engager
HCPCS:

- **Through 12/31/2023**: C9399, J3490, J3590, J9999
- **Effective 1/1/2024 and after**: J9286 per 2.5 mg

How supplied
NDC:

- 50242-125-01: one 2.5 mg/2.5 mL single-dose vial
- 50242-127-01: one 10 mg/10 mL single-dose vial

## Condition(s) listed in policy *(see coverage criteria for details)*

- B-cell lymphomas

## Special Instructions and pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure member has met all medical necessity requirements.

Covered under the Medical Benefit, please submit clinical information for prior authorization review

## Coverage Criteria

**The following condition(s) require Prior Authorization/Preservice:**

### B-cell lymphomas

1. One of the following B-cell lymphomas:
    a. Diffuse large B-cell lymphoma (DLBCL, including histologic transformation of follicular lymphoma or all subtypes of marginal zone lymphoma to DLBCL), or
    b. High-grade B-cell lymphomas (HGBL), or

c. HIV-related B-cell lymphomas: HIV-related DLBCL, primary effusion lymphoma, HHV8-positive DLBCL not otherwise specified, or
d. Monomorphic post-transplant lymphoproliferative disorders (PTLD), or
e. Large B-cell lymphoma (LBCL) arising from follicular lymphoma (FL)

AND

2. Being used as a single agent, AND
3. Being used for third-line and beyond therapy

**Covered Doses**
Pretreat with a single 1,000 mg dose of obinutuzumab by IV infusion 7 days before starting Columvi (Cycle 1 Day 1).

Given as an IV infusion at the following schedule
A cycle consists of 21 days

| Cycle of treatment | Day of treatment | Dose | |
|---|---|---|---|
| Cycle 1 | 1 | Obinutuzumab 1000 mg | |
| | 8 | Step up dose 1 | 2.5 mg |
| | 15 | Step up dose 2 | 10 mg |
| Cycles 2 - 12 | 1 | 30 mg | |

**Coverage Period**
Allow for 12 cycles

**Additional Information:**

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

<u>Dosing management for cytokine release syndrome (CRS):</u>

- Due to the risk of CRS, patients should be hospitalized during and for 24 hours after completion of step-up dose 1 (2.5 mg on Cycle 1 Day 8).
- Patients who experienced any grade CRS during step-up dose 1 should be hospitalized during and for 24 hours after completion of step-up dose 2 (10 mg on Cycle 1 Day 15). CRS with step-up dose 2 can occur in patients who did not experience CRS with step-up dose 1
- For subsequent doses, patients who experienced Grade ≥ 2 CRS with their previous infusion should be hospitalized during and for 24 hours after the completion of the next Columvi infusion.

## References

1. AHFS®. Available by subscription at http://www.lexi.com
2. DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Columvi (glofitamab-gxgm). [Prescribing information]. South San Francisco, CA: Genentech, Inc.; June 2023.

## Policy Update

Date of Last Annual Review: New policy
Date of last revision: 1/3/2024
Changes from previous policy version:

- Added HCPCS J9286 per 2.5 mg, effective 1/1/2024 and after

*Blue Shield of California Medication Policy to Determine Medical Necessity Reviewed by P&T Committee*