BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.21.207

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	July 14, 2023
Subject:	Columvi	**Page:**	1 of 4

Last Review Date: March 7, 2025

Columvi

Description

Columvi (glofitamab-gxbm)

Background
Columvi (glofitamab-gxbm) is a bispecific antibody that binds to CD20 expressed on the surface of B cells, and to CD3 receptor expressed on the surface of T cells. Columvi causes T-cell activation and proliferation, secretion of cytokines, and the lysis of CD20-expressing B cells (1).

Regulatory Status
FDA-approved indications: Columvi is a bispecific CD20-directed CD3 T-cell engager 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 (1).

Columvi carries a boxed warning regarding cytokine release syndrome (CRS). Premedicate before each dose, and initiate treatment with the Columvi step-up dosing schedule to reduce the risk of CRS. Columvi should be withheld until CRS resolves or permanently discontinued based on severity (1).

Columvi also has warnings regarding neurologic toxicity [including Immune Effector Cell-Associated Neurotoxicity (ICANS)], serious infections, and tumor flare (1).

Columvi may cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with Columvi and for 1 month after the last dose (1).

The safety and effectiveness of Columvi in pediatric patients less than 18 years of age have not been established (1).

Related policies
Epkinly

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Columvi may be considered **medically necessary** if the conditions indicated below are met.

Columvi may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS)
2. Large B-cell lymphoma (LBCL) arising from follicular lymphoma

AND ALL of the following:

1. Patient has received two or more lines of systemic therapies
2. Prescriber agrees to monitor for signs and symptoms of cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS)
3. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Columvi and for 1 month after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS)
2. Large B-cell lymphoma (LBCL) arising from follicular lymphoma

AND ALL of the following:

1. **NO** disease progression or unacceptable toxicity
2. Patient has **NOT** received a total of 12 cycles of Columvi treatment
3. Prescriber agrees to monitor for signs and symptoms of cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS)
4. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Columvi and for 1 month after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Columvi is indicated for the treatment of relapsed or refractory DLBCL, NOS, or LBCL arising from follicular lymphoma, after two or more lines of systemic therapy. Columvi carries a boxed warning regarding cytokine release syndrome (CRS). The safety and effectiveness of Columvi in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Columvi while maintaining optimal therapeutic outcomes.

References

1. Columvi [package insert]. South San Francisco, CA: Genentech, Inc.; June 2023.
2. NCCN Drugs & Biologics Compendium® Glofitamab-gxbm 2025. National Comprehensive Cancer Network, Inc. Accessed on January 15, 2025.

Policy History

Date	Action
July 2023	Addition to PA
September 2023	Annual review and reference update
December 2023	Annual review and reference update
March 2024	Annual review and reference update
March 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.