BlueCross BlueShield Federal Employee Program

COLUMVI
(glofitamab-gxbm)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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).

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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 2023. National Comprehensive Cancer Network, Inc. Accessed on September 29, 2023.