BlueCross BlueShield
Federal Employee Program

DATROWAY
(datopotamab deruxtecan-dlnk)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Datroway (datopotamab deruxtecan-dlnk) is a Trop-2-directed antibody-drug conjugate that consists of a humanized anti-Trop2 IgG1. The small molecule, DXd, is a topoisomerase I inhibitor attached to the antibody by a cleavable linker. Following binding to Trop2 on cells, including tumor cells, Datroway undergoes internalization and intracellular linker cleavage by lysosomal enzymes. Upon release, the membrane-permeable DXd causes DNA damage and apoptotic cell death (1).

Regulatory Status

FDA-approved indications: Datroway is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with unresectable or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease (1).

Datroway has been associated with interstitial lung disease (ILD) and pneumonitis, ocular adverse reactions, and stomatitis/oral mucositis. Patients should be monitored for any of these reactions. Dose delay, dose reduce, or permanently discontinue Datroway based on severity of adverse reactions (1).

Datroway can cause fetal harm when administered to a pregnant woman. Female patients of reproductive potential should be advised to use effective contraception during treatment with Datroway and for 7 months after the last dose. Male patients with female partners of reproductive potential should be advised to use effective contraception during treatment with Datroway and for 4 months after the last dose (1).

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

Summary

Datroway (datopotamab deruxtecan-dlnk) is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with unresectable or metastatic breast cancer.

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

References

1. Datroway [package insert]. Baskin Ridge, NJ: Daiichi Sankyo, Inc.; January 2025.
2. NCCN Drugs & Biologics Compendium® Datopotamab deruxtecan-dlnk 2025. National Comprehensive Cancer Network, Inc. Accessed on January 22, 2025.