Datopotamab Deruxtecan-dlnk (Datroway®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Datroway is indicated for the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor (EGFR)-mutated non-small cell lung cancer (NSCLC) who have received prior EGFR-directed therapy and platinum-based chemotherapy.

Datroway is 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 endocrine based therapy and chemotherapy for unresectable or metastatic disease.

Compendial Uses

- Breast Cancer
- Non-Small Cell Lung Cancer (NSCLC)

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Test results confirming status of the following (where applicable):

- Human epidermal growth factor receptor 2 (HER2)
- Estrogen receptor
- Progesterone receptor
- PD-L1 combined tumor positive score (CPS)
- BRCA 1/2 mutation testing
- EGFR mutation testing

COVERAGE CRITERIA

Breast cancer

Authorization of 12 months may be granted for treatment of breast cancer, as a single agent, when all of the following criteria are met:

- The disease is unresectable or metastatic.
- The cancer cells are hormone receptor positive and HER2-negative.
- The member has received prior treatment including endocrine based therapy and chemotherapy for unresectable or metastatic disease.
- The member is not a candidate for treatment with fam-trastuzumab deruxtecan-nxki (Enhertu).

Authorization of 12 months may be grated for the first-line treatment of triple negative breast cancer (TNBC), as a single agent, when all of the following criteria are met:

- The disease is recurrent unresectable or metastatic.
- The cancer cells are estrogen receptor, progesterone receptor, and HER2 (ERBB2) negative.
- The tumor's PD-L1 CPS is <10 and there are no germline BRCA 1/2 pathogenic variants.

Non-Small Cell Lung Cancer (NSCLC)

Authorization of 12 months may be granted for subsequent treatment of EGFR mutation positive recurrent, advanced, or metastatic non-small cell lung cancer when the requested medication is used as a single agent.

CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Datroway [package insert]. Basking Ridge, NJ: Daiichi Sankyo, Inc; June 2025.
2. The NCCN Drugs & Biologics Compendium® ©2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed March 2, 2026.

3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Version 2.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed March 2, 2026.

EFFECTIVE DATE 9/30/2026

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