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Section:	Prescription Drugs	**Effective Date:**	April 1, 2026
Subsection:	Antineoplastic Agents	**Original Policy Date:**	February 21, 2025
Subject:	Datroway	**Page:**	1 of 5

Last Review Date: March 6, 2026

Datroway

Description

Datroway (datopotamab deruxtecan-dlnk)

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: (1)

- 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.
- 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.

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).

Related policies
Trodelvy

Policy

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

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

Datroway 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. Locally advanced or metastatic non-small cell lung cancer (NSCLC)
    a. EGFR mutations in tumor or plasma specimens
    b. Patient has received prior EGFR-directed therapy and platinum-based chemotherapy
2. Unresectable or metastatic breast cancer

a. HR-positive, HER2-negative (IHC 0, IHC 1+, or IHC 2+/ISH-) breast cancer
b. Patient has received prior endocrine-based therapy and chemotherapy

AND ALL of the following:

a. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Datroway and for 7 months after the last dose
b. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Datroway and for 4 months after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

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

1. Locally advanced or metastatic non-small cell lung cancer (NSCLC)
2. Unresectable or metastatic breast cancer

AND ALL of the following:

a. **NO** disease progression or unacceptable toxicity
b. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Datroway and for 7 months after the last dose
c. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Datroway and for 4 months after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 24 vials per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Datroway (datopotamab deruxtecan-dlnk) is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) and unresectable or metastatic breast cancer. Datroway can cause fetal harm when administered to a pregnant woman. The safety and effectiveness of Datroway 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 Datroway while maintaining optimal therapeutic outcomes.

References

1. Datroway [package insert]. Baskin Ridge, NJ: Daiichi Sankyo, Inc.; June 2025.
2. NCCN Drugs & Biologics Compendium® Datopotamab deruxtecan-dlnk 2026. National Comprehensive Cancer Network, Inc. Accessed on January 12, 2026.

Policy History

Date	Action
February 2025	Addition to PA
June 2025	Annual review and reference update
July 2025	Per PI update, added indication of locally advanced or metastatic EGFR-mutated NSCLC
September 2025	Annual review and reference update
March 2026	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.