# UTILIZATION MANAGEMENT MEDICAL POLICY

**POLICY:** Oncology (Injectable – Antibody-Drug Conjugate – Trop-2) – Datroway Utilization Management Medical Policy
- Datroway® (datopotamab deruxtecan-dlnk intravenous infusion – Daiichi Sankyo)

**REVIEW DATE:** 01/29/2025; selected revision 07/02/2025

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## OVERVIEW

Datroway, a Trop-2-directed antibody and topoisomerase inhibitor conjugate, is indicated for the following:[1]

- **Breast cancer**, unresectable or metastatic hormone receptor (HR)-positive, human epidermal growth factor 2 (HER2)-negative (immunohistochemistry [IHC] 0, IHC 1+ or IHC 2+/ISH–) breast cancer in adults who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease.
- **Non-small cell lung cancer**, treatment of locally advanced or metastatic epidermal growth factor receptor (*EGFR*)-mutated disease in adults who have received prior *EGFR*-directed therapy and platinum-based chemotherapy.

## Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines have the following recommendations:

- **Breast Cancer:** Guidelines (version 1.2025 ‑ January 31, 2025) have recommendations for the treatment of HR-positive, HER2-negative recurrent unresectable or Stage IV disease with visceral crisis or endocrine refractory.[2] For first-line therapy, in patients with no germline breast cancer (BRCA) mutation and/or IHC HER2 0+, 1+, or 2+/ISH negative, systemic chemotherapy is the "Preferred" option (category 1). Enhertu® (fam-trastuzumab deruxtecan-nxki IV infusion) is noted as an "Other Recommended Regimen" in the first-line setting (category 2A). For second-line therapy, Enhertu is "Preferred" for HER2 IHC 0+, 1+, or 2+/ISH negative disease (category 1). For patients who are not candidates for Enhertu, Trodelvy® (sacituzumab govitecan-hziy IV infusion) is "Preferred" (category 1); in this second-line setting, Datroway is noted as an "Other Recommended Regimen" (category 2A) for HER2 IHC0, 1+, or 2+/ISH negative disease. In a footnote the guidelines state that Datroway did not meet the overall survival endpoint in the TROPION-Breast01 trial; however, previously approved antibody-drug conjugates (ADCs) such as Enhertu and Trodelvy have shown an overall benefit in randomized Phase III trials. It is also noted that the utility of using Datroway in patients with prior ADC treatment are not known since the pivotal study did not include patients who had previously received treatment with ADCs.
- **Non-Small Cell Lung Cancer (NSCLC):** Guidelines (version 6.2025 – July 2, 2025) recommend Datroway as a "Preferred" subsequent therapy for *EGFR* exon 19 deletion or L858R mutation-positive adenocarcinoma, large cell, or NSCLC not otherwise specified (category 2A).[3] It is also an "Other Recommended" option (category 2A) for subsequent progression in *EGFR* exon 19 deletion or L858R NSCLC.

## POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Datroway. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of specialized skills required for evaluation and diagnosis of patients treated with Datroway as well as the monitoring required for adverse events and long-term efficacy, approval requires Datroway to be prescribed by or in consultation with a physician who specializes in the condition being treated.

**Automation:** None.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Datroway is recommended in those who meet the following criteria:

### FDA-Approved Indication

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**1. Breast Cancer**. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, F, and G):

- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient has unresectable or metastatic disease; AND
- **C)** Patient has hormone receptor (HR)-positive disease; AND
- **D)** Patient has human epidermal growth factor receptor (HER2)-negative (immunohistochemistry [IHC] 0, IHC 1+, or IHC 2+/in situ hybridization [ISH]-negative) disease; AND
- **E)** Patient has received prior endocrine-based therapy; AND
  Note: Examples of endocrine therapy are tamoxifen, anastrozole, letrozole, exemestane.
- **F)** Patient has received prior chemotherapy for unresectable or metastatic disease; AND
  Note: Examples are paclitaxel, doxorubicin, liposomal doxorubicin, gemcitabine, capecitabine, vinorelbine, Halaven (eribulin intravenous infusion), cyclophosphamide, docetaxel.
- **G)** The medication is prescribed by or in consultation with an oncologist.

**Dosing.** Approve if each dose does not exceed 6 mg/kg (up to a maximum of 540 mg for patients ≥ 90 kg), administered as an intravenous infusion not more frequently than once every 3 weeks.

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**2. Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):

- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient has locally advanced or metastatic disease; AND
- **C)** Patient has *EGFR*-mutated disease; AND
  Note: Examples of *EGFR* mutations are exon 19 deletion, exon 21 L858R, S768I, L861Q, G719x, exon 20 insertion mutation.
- **D)** Patient meets BOTH of the following (i and ii):
  - **i.** Patient has tried at least one prior *EGFR*-directed therapy; AND
    Note: Examples include Gilotrif® (afatinib tablets), erlotinib, gefitinib, Tagrisso® (osimertinib tablets), Lazcluze™ (lazertinib tablets), Vizimpro® (dacomitinib tablets), Rybrevant™ (amivantamab-vmjw intravenous infusion).
  - **ii.** Patient has tried platinum-based chemotherapy; AND

Note: Examples include cisplatin, carboplatin.

**E)** The medication is prescribed by or in consultation with an oncologist.

**Dosing.** Approve if each dose does not exceed 6 mg/kg (up to a maximum of 540 mg for patients ≥ 90 kg), administered as an intravenous infusion not more frequently than once every 3 weeks.

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Datroway is not recommended in the following situations:

**1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## REFERENCES

1. Datroway® intravenous infusion [prescribing information]. Basking Ridge, NJ: Daiichi Sankyo; June 2025.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 1.2025 – January 31, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 20, 2025.
3. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 6.2025 – July 2, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 3, 2025.

## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| New Policy | -- | 01/29/2025 |
| Update | 02/20/2025: updated guidelines to include Datroway. | N/A |
| Update | 04/21/2025: The policy name was changed from "Oncology (Injectable) – Datroway UM Medical Policy" to "Oncology (Injectable - Antibody-Drug Conjugate – Trop-2) – Datroway UM Medical Policy | N/A |
| Selected Revision | **Non-Small Cell Lung Cancer:** This condition of approval was added. | 07/02/2025 |

N/A – Not applicable.