Reference number(s)
6817-A

Standard Medicare Part B Management Datroway

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Datroway	datopotamab deruxtecan-dlnk

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[1]

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[2]

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

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

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Documentation

The following documentation must be available, upon request, where applicable:

Test results confirming status of the following:

- 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[1-3]

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)[1,2]

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

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.

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- The requested medication is being used to treat an indication listed in the Coverage Criteria section.
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen and
    - No evidence of disease progression while on the current regimen

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Datroway
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Breast Cancer
- NCCN Guideline: Non-Small Cell Lung Cancer

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Datroway are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing 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.

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