

Specialty Guideline 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 Indications¹

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.

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
- EGFR mutation testing

Coverage Criteria

Breast cancer¹

Authorization of 12 months may be granted for treatment of breast cancer 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

Non-small cell lung cancer (NSCLC)¹

Authorization of 12 months may be granted for treatment of non-small cell lung cancer when all of the following criteria are met:

- The disease is locally advanced or metastatic
- The tumor is EGFR mutation positive
- The member has received prior treatment with EGFR-directed therapy (e.g., osimertinib) and platinum-based chemotherapy

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.

References

1. Datroway [package insert]. Basking Ridge, NJ: Daiichi Sankyo, Inc; June 2025.