Utilization Review Policy 357

POLICY: Oncology (Injectable) – Datroway Utilization Management Medical Policy
- Datroway® (datopotamab deruxtecan-dlnk intravenous infusion – Daiichi Sankyo)

EFFECTIVE DATE: 5/1/2025
LAST REVISION DATE: 01/29/2025

COVERAGE CRITERIA FOR: All UCare Plans

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.

Guidelines

Datroway is not addressed in National Comprehensive Cancer Network (NCCN) Breast Cancer guidelines (version 6.2024 – November 11, 2024).[2] For HR-positive, HER2-negative recurrent unresectable or stage IV disease, systemic chemotherapy (e.g., doxorubicin, Doxil [liposomal doxorubicin intravenous infusion], paclitaxel, capecitabine, gemcitabine, vinorelbine, eribulin) is recommended for no germline Breast Cancer (BRCA) 1/2 mutation, first-line therapy. Enhertu® (fam-trastuzumab deruxtecan-nxki intravenous infusion) is recommended as second line therapy for HER2 IHC 1+ or 2+/ISH negative disease (category 1, "Preferred"). Trodelvy® (sacituzumab govitecan-hziy intravenous infusion) is listed as a "Preferred" therapy (category 1) for patients with HR positive, HER2 negative cancers after prior treatment, including endocrine therapy, a cyclin dependent kinase (CDK) 4/6 inhibitor, and at least two lines of chemotherapy (one of which was a taxane, and at least one of which was in the metastatic setting), and if not a candidate for Enhertu therapy. It may be considered for later line if not used a second-line therapy.

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

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.

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; January 2025.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 6.2024 – November 11, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 24, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	01/29/2025
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	03/10/2025