Clinical Policy: Datopotamab deruxtecan-dlnk (Datroway)

Reference Number: PA.CP.PHAR.715
Effective Date: 05/2025
Last Review Date: 04/2025

Description
Datopotamab deruxtecan-dlnk (Datroway®) is a Trop-2-directed antibody and topoisomerase inhibitor conjugate.

FDA Approved Indication(s)
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 prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Datroway is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Breast Cancer (must meet all)**:**

1. Diagnosis of unresectable or metastatic breast cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Documentation of hormone receptor (HR)-positive disease;
5. Documentation of HER2-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) disease;
6. Member received prior endocrine based therapy (*see Appendix B);*
7. Member received prior chemotherapy for unresectable or metastatic disease (*see Appendix B*);
8. Prescribed as a single agent;
9. Request meets one of the following (a or b):
   a. Dose does not exceed both of the following (i and ii) once every 3 weeks (21-day cycle):
      i. 6 mg/kg;
      ii. 540 mg;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Breast Cancer (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed both of the following (i and ii) once every 3 weeks (21-day cycle):
      i. 6 mg/kg;
      ii. 540 mg;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
HER2: human epidermal growth factor receptor 2
HR: hormone receptor

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Examples of systemic therapies for recurrent unresectable or metastatic breast cancer		
paclitaxel	Varies	Varies
Abraxane® (albumin-bound paclitaxel)	Varies	Varies
docetaxel (Taxotere®)	Varies	Varies
doxorubicin	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
liposomal doxorubicin (Doxil®)	50 mg/m^2 IV day 1, cycled every 28 days	Varies
capecitabine (Xeloda®)	1,000-1,250 mg/m^2 PO BID on days 1-14, cycled every 21 days	Varies
gemcitabine (Gemzar®)	800-1,200 mg/m^2 IV on days 1,8 and 15, cycled every 28 days	Varies
vinorelbine	Varies	Varies
Halaven® (eribulin)	1.4 mg/m^2 IV on days 1 and 8, cycled every 21 days	Varies
carboplatin	AUC 6 IV on day 1, cycled every 21-28 days	Varies
cisplatin	75 mg/m^2 IV on day 1, cycled every 21 days	Varies
cyclophosphamide	50 mg PO QD on days 1-21, cycled every 28 days	Varies
epirubicin (Ellence®)	60-90 mg/m^2 IV on day 1, cycled every 21 days	Varies
Ixempra® (ixabepilone)	40 mg/m^2 IV on day 1, cycled every 21 days	40 mg/m^2
Examples of endocrine based therapy for breast cancer		
tamoxifen; aromatase inhibitors: anastrozole (Arimidex®), letrozole (Femara®), exemestane (Aromasin®)	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Breast cancer	6 mg/kg IV once every 3 weeks (21-day cycle)	540 mg/3 weeks

VI. Product Availability

Single-dose vial: 100 mg lyophilized powder for reconstitution

VII. References

1. Datroway Prescribing Information. Basking Ridge, NJ: Daiichi Sankyo, Inc.; January 2025. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761394s000lbl.pdf. Accessed January 23, 2025.
2. Bardia A, Jhaveri K, Im SA, et al. Datopotamab Deruxtecan Versus Chemotherapy in Previously Treated Inoperable/Metastatic Hormone Receptor-Positive Human Epidermal Growth Factor Receptor 2-Negative Breast Cancer: Primary Results From TROPION-Breast01. J Clin Oncol. 2025 Jan 20;43(3):285-296.

3. National Comprehensive Cancer Network Guidelines. Breast Cancer Version 6.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed January 23, 2025.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3490	Unclassified drugs
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals
J9999	Not otherwise classified, antineoplastic drugs

Reviews, Revisions, and Approvals	Date
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