

**Clinical Policy: Datopotamab Deruxtecan-dlnk (Datroway)**

Reference Number: CP.PHAR.715

Effective Date: 06.01.25

Last Review Date: 05.25

Line of Business: Commercial, HIM, Medicaid

[Coding Implications](#)[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**Description**

Datopotamab deruxtecan-dlnk (Datroway<sup>®</sup>) 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 health plans affiliated with Centene Corporation<sup>®</sup> 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  $\geq$  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*).

*\*Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration:**

**HIM/Medicaid** – 6 months

**Commercial** – 6 months or to the member's renewal date, whichever is longer

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**II. Continued Therapy**

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

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Datroway for a covered indication and has received this medication for at least 30 days;
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*).

*\*Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration:**

**HIM/Medicaid** – 12 months

**Commercial** – 6 months or to the member's renewal date, whichever is longer

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business:

- CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
- b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

### 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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

### 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 for all relevant lines of business and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
<b>Examples of systemic therapies for recurrent unresectable or metastatic breast cancer</b>		
paclitaxel	Varies	Varies
Abraxane <sup>®</sup> (albumin-bound paclitaxel)	Varies	Varies
docetaxel (Taxotere <sup>®</sup> )	Varies	Varies
doxorubicin	Varies	Varies
liposomal doxorubicin (Doxil <sup>®</sup> )	50 mg/m <sup>2</sup> IV day 1, cycled every 28 days	Varies
capecitabine (Xeloda <sup>®</sup> )	1,000-1,250 mg/m <sup>2</sup> PO BID on days 1-14, cycled every 21 days	Varies
gemcitabine (Gemzar <sup>®</sup> )	800-1,200 mg/m <sup>2</sup> IV on days 1,8 and 15, cycled every 28 days	Varies
vinorelbine	Varies	Varies
Halaven <sup>®</sup> (eribulin)	1.4 mg/m <sup>2</sup> IV on days 1 and 8, cycled every 21 days	Varies
carboplatin	AUC 6 IV on day 1, cycled every 21-28 days	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
cisplatin	75 mg/m <sup>2</sup> 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 <sup>®</sup> )	60-90 mg/m <sup>2</sup> IV on day 1, cycled every 21 days	Varies
Ixempra <sup>®</sup> (ixabepilone)	40 mg/m <sup>2</sup> IV on day 1, cycled every 21 days	40 mg/m <sup>2</sup>
<b>Examples of endocrine based therapy for breast cancer</b>		
tamoxifen; aromatase inhibitors: anastrozole (Arimidex <sup>®</sup> ), letrozole (Femara <sup>®</sup> ), exemestane (Aromasin <sup>®</sup> )	Varies	Varies

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) 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. Datoway Prescribing Information. Basking Ridge, NJ: Daiichi Sankyo, Inc.; January 2025. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2025/761394s000lbl.pdf](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](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.

<b>HCPCS Codes</b>	<b>Description</b>
C9174	Injection, datopotamab deruxtecan-dlnk, 1 mg

<b>Reviews, Revisions, and Approvals</b>	<b>Date</b>	<b>P&amp;T Approval Date</b>
RT4: Policy created.	01.23.25	05.25
HCPCS code added [C9174] and removed codes [J3490, J3590, C9399, J9999].	06.03.25	

### **Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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