Clinical Policy: Datopotamab Deruxtecan-dlnk (Datroway)

Reference Number: CP.PHAR.715
Effective Date: 06.01.25
Last Review Date: 05.26
Line of Business: Commercial, HIM/ICHRA, 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®) is a Trop-2-directed antibody and topoisomerase inhibitor conjugate.

FDA Approved Indication(s)

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*
- 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.

** This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial*

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® 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 one of the following (a or b):
   a. Triple negative (i.e., estrogen receptor-, progesterone receptor-, and HER2-negative) breast cancer (TNBC) and both of the following (i and ii):
      i. Tumor expresses PD-L1 (Combined Positive Score [CPS] < 10);
      ii. Disease is negative for germline *BRCA* 1/2 pathogenic variant;
   b. HR-positive disease and HER2-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) disease and both of the following (i and ii):
      i. Member received prior endocrine based therapy (*see Appendix B);*

ii. Member received prior chemotherapy for unresectable or metastatic disease (*see Appendix B*);

5. Prescribed as a single agent;
6. 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/ICHRA/Medicaid – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Non-Small Cell Lung Cancer (must meet all)**:**

1. Diagnosis of locally advanced, recurrent, or metastatic NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Documentation of EGFR mutation positive disease;
5. Member received prior EGFR-directed therapy and platinum-based chemotherapy (*see Appendix B);*
6. Prescribed as a single agent;
7. 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/ICHRA/Medicaid – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

C. 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/ICHRA) 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/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) 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/ICHRA, 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/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (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/ICHRA/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/ICHRA) 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/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) 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/ICHRA, 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/ICHRA, 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/ICHRA, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

EGFR: epidermal growth factor receptor
FDA: Food and Drug Administration
HER2: human epidermal growth factor receptor 2
HR: hormone receptor
NSCLC: non-small cell lung cancer
TNBC: triple negative breast cancer

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
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
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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
NSCLC		
Examples of targeted EGFR therapies: • EGFR exon 19 deletion or exon 21 L858R: afatinib, erlotinib ± ramucirumab or bevacizumab, dacomitinib, gefitnib, osimertinib, amivantamab-vmjw/lazertinib • EGFR S768I, L861Q, and/or G719X: afatinib, erlotinib, dacomitinib, gefitinib, osimertinib • EGFR exon 20 insertional mutation: amivantamab-vmjw/ carboplatin/premetrexed Examples of platinum-based chemotherapy: • (carboplatin or cisplatin)/ pembrolizumab/premetrexed • (carboplatin or cisplatin)/cemiplimab-rwlc/premetrexed • carboplatin/paclitaxel/bevacizumab/ atezolizumab	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, NSCLC	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.; June 2025. Available at: https://daiichisankyo.us/prescribing-information-portlet/getPIContent?productName=Datroway&inline=true. Accessed January 23, 2026.
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. Datopotamab. In: National Comprehensive Cancer Networks Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed January 30, 2026.
4. National Comprehensive Cancer Network Guidelines. Breast Cancer Version 1.2026. Available at https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed January 30, 2026.
5. National Comprehensive Cancer Network Guidelines. Non-Small Cell Lung Cancer Version 3.2026. Available at https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed January 30, 2026.

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
J9011	Injection, datopotamab deruxtecandlnk, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
RT4: Policy created.	01.23.25	05.25
HCPCS code added [C9174] and removed codes [J3490, J3590, C9399, J9999].	06.03.25	
RT4: added newly approved indication for NSCLC per updated PI.	07.03.25	
HCPCS code added [J9011], HCPCS code removed [C9174].	09.11.25	
2Q 2026 annual review: added criteria for TNBC per NCCN; for all indications for Medicaid and HIM, extended initial approval duration from 6 to 12 months; references reviewed and updated. Added ICHRA line of business.	03.30.26	05.26

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.