Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 05/01/2026**
Policy Number: PA.CP.PHAR.715	**Effective Date: 05/2025** **Revision Date: 04/2026**
Policy Name: Datopotamab deruxtecan-dlnk (Datroway)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

2Q 2026 annual review: RT4: added newly approved indication for NSCLC per updated PI; HCPCS code added [J9011], HCPCS code removed [J3490, J3590, C9399, J9999]; added criteria for TNBC per NCCN; for all indication, extended initial approval duration from 6 to 12 months; references reviewed and updated.

Name of Authorized Individual (Please type or print):	**Signature of Authorized Individual:**
Craig A. Butler, MD MBA	

Clinical Policy: Datopotamab deruxtecan-dlnk (Datroway)

Reference Number: PA.CP.PHAR.715
Effective Date: 05/2025
Last Review Date: 04/2026

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:

- ✓ 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*
- ✓ 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 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 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*).

Approval duration: 12 months

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*).

Approval duration: 12 months

C. 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. All Indications in Section I (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

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 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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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
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
Policy created	04/2025
2Q 2026 annual review: RT4: added newly approved indication for NSCLC per updated PI; HCPCS code added [J9011], HCPCS code removed [J3490, J3590, C9399, J9999]; added criteria for TNBC per NCCN; for all indication, extended initial approval duration from 6 to 12 months; references reviewed and updated.	04/2026