

Datroway® (datopotamab deruxtecan-dlnk) (Intravenous)

Document Number: IC-0785

Last Review Date: 08/05/2025

Date of Origin: 03/04/2025

Dates Reviewed: 03/2025, 08/2025

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months.
- Renewal: Prior authorization validity may be renewed every 6 months thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 600 billable units every 21 days

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria ¹

- Patient does not have a history of interstitial lung disease (ILD)/pneumonitis requiring treatment with steroids or the presence of ongoing symptomatic ILD/pneumonitis; **AND**
- Patient does not have the presence of clinically significant corneal disease; **AND**
- Patient does not have active untreated brain metastases; **AND**
- Patient will have an ophthalmic exam including visual acuity testing, slit lamp examination (with fluorescein staining), intraocular pressure, and funduscopy best corrected visual acuity (BCVA) conducted at baseline and periodically during treatment; **AND**
- Patient has not previously received or will not be used concomitantly with other *TROP2*- (i.e., sacituzumab govitecan, etc.) or *topoisomerase-I*- (i.e., topotecan, irinotecan, etc.) targeted therapies; **AND**
- Used as a single agent; **AND**

Breast Cancer † ¹

- Patient has human epidermal growth factor receptor 2 (HER2)-negative disease*; **AND**
- Patient has hormone receptor (HR)- positive disease; **AND**

- Patient has unresectable or metastatic disease; **AND**
- Patient has progressed on and is not suitable for continued endocrine therapy; **AND**
- Patient has been treated with chemotherapy in the unresectable or metastatic disease setting

Non-Small Cell Lung Cancer (NSCLC) † ‡^{1,8,9}

- Patient has EGFR-mutated disease as detected by an FDA-approved or CLIA compliant test❖; **AND**
- Patient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
- Used as subsequent therapy; **AND**
 - Patient has EGFR exon 19 deletion or L858R and nonsquamous cell histology; **OR**
 - Patient has received prior EGFR-directed therapy and platinum-based chemotherapy

*HER2-negative expression criteria: ^{1,2,4}

- Immunohistochemistry (IHC) assay is 0 or 1+***; **OR**
- Dual probe in situ hybridization (ISH) assay indicating (Group 5) HER2/CEP17 ratio <2.0 AND average HER2 copy number <4.0 signals/cell; **OR**
- Concurrent dual-probe ISH and IHC assay results indicating one of the following:
 - (Group 2) HER2/CEP17 ratio ≥2.0 AND average HER2 copy number <4.0 signals/cell and concurrent IHC 0-1+ or 2+; **OR**
 - (Group 3) HER2/CEP17 ratio <2.0 AND average HER2 copy number ≥6.0 signals/cell and concurrent IHC 0-1+; **OR**
 - (Group 4) HER2/CEP17 ratio <2.0 AND average HER2 copy number ≥4.0 and <6.0 signals/cell and concurrent IHC 0-1+ or 2+

***The distinction between HER2 IHC 0 with no membrane staining from IHC 0+ with faint, partial membrane staining in ≤10%, 1+, or 2+/ISH negative results (on primary or metastatic samples) is currently clinically relevant since patients with metastatic disease may be eligible for treatment targeting non-amplified levels of HER2 expression.

❖ If confirmed using an immunotherapy assay-<http://www.fda.gov/companiondiagnostics>

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ¹

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include interstitial lung disease (ILD) or pneumonitis, severe ocular adverse reactions (including dry eye,

keratitis, blepharitis, meibomian gland dysfunction, increased lacrimation, conjunctivitis, blurred vision), severe stomatitis (including mouth ulcers and oral mucositis), etc.; **AND**

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

V. Dosage/Administration ¹

Indication	Dose
Breast Cancer & NSCLC	Administer 6 mg/kg (up to a maximum of 540 mg for patients ≥90 kg) intravenously once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity.
NOTE: <ul style="list-style-type: none">• Administer Datroway in a setting where cardiopulmonary resuscitation medication and equipment are available.• Monitor patients for infusion-related reactions for at least 1 hour for the first 2 cycles of Datroway infusions. If there are no infusion-related reactions observed, monitor patients for at least 30 minutes for all subsequent cycles of infusions.• Administer Datroway with premedications and concomitant medications as outlined in the prescribing information.	

VI. Billing Code/Availability Information

HCPCS Code:

- C9174 – Injection, datopotamab deruxtecan-dlnk, 1 mg; 1 billable unit = 1 mg (*Discontinue use on 10/01/2025*)
- J9999 – Not otherwise classified, antineoplastic drugs (*Discontinue use on 10/01/2025*)
- J9011 – Injection, datopotamab deruxtecan-dlnk, 1 mg; 1 billable unit = 1 mg (*Effective 10/01/2025*)

NDC:

- Datroway 100 mg lyophilized powder in a single-dose vial: 65597-0801-xx

VII. References

1. Datroway [package insert]. Basking Ridge, NJ; Daiichi Sankyo, Inc.; June 2025. Accessed July 2025.
2. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer 6.2024. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed January 2025.
3. 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. JCO 43, 285-296(2025). DOI:10.1200/JCO.24.00920

4. Wolff AC, Somerfield MR, Dowsett M, et al. Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: ASCO–College of American Pathologists Guideline Update. JCO 41, 3867-3872(2023). DOI:10.1200/JCO.22.02864
5. Fahrenbruch R, Kintzel P, Bott AM, et al. Dose Rounding of Biologic and Cytotoxic Anticancer Agents: A Position Statement of the Hematology/Oncology Pharmacy Association. J Oncol Pract. 2018 Mar;14(3): e130-e136.
6. Hematology/Oncology Pharmacy Association (2019). Intravenous Cancer Drug Waste Issue Brief. Retrieved from http://www.hoparx.org/images/hopa/advocacy/Issue-Briefs/Drug_Waste_2019.pdf
7. Bach PB, Conti RM, Muller RJ, et al. Overspending driven by oversized single dose vials of cancer drugs. BMJ. 2016 Feb 29;352: i788.
8. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for datopotamab deruxtecan-dlnk. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed July 2025.
9. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Non-Small Cell Lung Cancer, Version 7.2025. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed July 2025.
10. Sands J, Ahn MJ, Lisberg A, et al. Datopotamab Deruxtecan in Advanced or Metastatic Non-Small Cell Lung Cancer with Actionable Genomic Alterations: Results from the Phase II TROPION-Lung05 Study. J Clin Oncol. 2025 Apr;43(10):1254-1265. doi: 10.1200/JCO-24-01349. Epub 2025 Jan 6. PMID: 39761483; PMCID: PMC11949215.
11. Ahn MJ, Tanaka K, Paz-Ares L, et al; TROPION-Lung01 Trial Investigators. Datopotamab Deruxtecan Versus Docetaxel for Previously Treated Advanced or Metastatic Non-Small Cell Lung Cancer: The Randomized, Open-Label Phase III TROPION-Lung01 Study. J Clin Oncol. 2025 Jan 20;43(3):260-272. doi: 10.1200/JCO-24-01544. Epub 2024 Sep 9. PMID: 39250535; PMCID: PMC11771353.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus

ICD-10	ICD-10 Description
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus, or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus, or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus, or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus, or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus, or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast

ICD-10	ICD-10 Description
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.3	Personal history of malignant neoplasm of breast

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC