Datroway® (datopotamab deruxtecan-dlnk)
(Intravenous)

-E-

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) thereafter.

II. Dosing Limits

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

- 600 billable units every 21 days

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

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

Universal Criteria [1]

- Member does not have a history of interstitial lung disease (ILD)/pneumonitis requiring treatment with steroids or the presence of ongoing symptomatic ILD/pneumonitis; **AND**
- Member does not have the presence of clinically significant corneal disease; **AND**
- Member does not have active untreated brain metastases; **AND**
- Member will have an ophthalmic exam including visual acuity testing, slit lamp examination (with fluorescein staining), intraocular pressure, and fundoscopy best corrected visual acuity (BCVA) conducted at baseline and as clinically indicated *(Note: visual acuity testing and slit lamp examination must be conducted every 3 cycles*); **AND**
- Member 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 † ‡ [1,3,12,1e]

- Member has unresectable or metastatic disease; **AND**

- Member has hormone receptor (HR)-positive disease, human epidermal growth factor receptor 2 (HER2)-negative disease defined as immunohistochemistry (IHC) 0, 1+, or 2+/in situ hybridization (ISH) negative; **AND**
  - Member has received prior endocrine-based therapy; **AND**
  - Member has been treated with chemotherapy in the unresectable or metastatic disease setting; **AND**

▪ Use of datopotamab deruxtecan-dlnk will be restricted to members with a contraindication or intolerance to fam-trastuzumab deruxtecan-nxki (if not previously used)*; **OR** **Members with IHC 0 (no membrane staining) are not required to meet the product preferencing requirement above.*

- Member has triple-negative breast cancer (TNBC); **AND**
  - Used as first-line therapy; **AND**
  - Member is not a candidate for PD-1/PD-L1 inhibitor therapy; **AND**
  - Member has no germline BRCA 1/2 pathogenic variant

Non-Small Cell Lung Cancer (NSCLC) † ‡ [1,8,9]

- Member has EGFR-mutated disease as detected by an FDA-approved or Clinical Laboratory Improvement Amendments (CLIA) compliant test❖; **AND**
- Member has recurrent, advanced, or metastatic disease; **AND**
- Used as subsequent therapy; **AND**
- Member has EGFR exon 19 deletion/L858R mutation, S768I, L861Q, G719X, or exon 20 insertion, and nonsquamous cell histology; **AND**
- Member 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**
- IHC assay indicating (Group 5) HER2 (ERBB2)/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 (ERBB2)/CEP17 ratio ≥2.0 AND average HER2 (ERBB2) copy number <4.0 signals/cell and concurrent IHC 0-1+ or 2+; OR
  - (Group 3) HER2 (ERBB2)/CEP17 ratio <2.0 AND average HER2 (ERBB2) copy number ≥6.0 signals/cell and concurrent IHC 0-1+; OR
  - (Group 4) HER2 (ERBB2)/CEP17 ratio <2.0 AND average HER2 (ERBB2) copy number ≥4.0 and <6.0 signals/cell and concurrent IHC 0-1+ or 2+

****The distinction between HER2 (ERBB2) IHC 0/absent membrane staining, IHC 0+/ with membrane staining (faint, partial membrane staining, in ≤10%), IHC 1+, or 2+/ISH negative results (on primary or metastatic samples) is currently clinically relevant since members with metastatic disease may be eligible for treatment targeting non-amplified levels of HER2 expression.*

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

❖ *If confirmed using an immunotherapy assay – http://www.fda.gov/companiondiagnostics*

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

IV. Renewal Criteria [1]

Prior authorization validity can be renewed based upon the following criteria:

- Member 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 members ≥90 kg) intravenously once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity.
NOTE: • *Administer Datroway in a setting where cardiopulmonary resuscitation medication and equipment are available.* • *Monitor members 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 members for at least 30 minutes for all subsequent cycles of infusions.* • *Administer Datroway with the premedication and concomitant medications as outlined in the prescribing information.*	

VI. Billing Code/Availability Information

HCPCS Code:

- J9011 – Injection, datopotamab deruxtecan-dlnk, 1 mg; 1 billable unit = 1 mg

NDC:

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

VII. References (STANDARD)

1. Datroway [package insert]. Basking Ridge, NJ; Daiichi Sankyo, Inc.; May 2026. Accessed June 2026.
2. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer 4.2026. National Comprehensive Cancer Network, 2026. 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 June 2026.
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, 2026. 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 June 2026.
9. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Non-Small Cell Lung Cancer, Version 6.2026. National Comprehensive Cancer Network, 2026. 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 June 2026.
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.
12. Dent RA, Cescon DW, Bachelot T, et al. TROPION-Breast02: Datopotamab deruxtecan for locally recurrent inoperable or metastatic triple-negative breast cancer. Future Oncol. 2023 Nov;19(35):2349-2359. doi: 10.2217/fon-2023-0228. Epub 2023 Aug 1. PMID: 37526149.

VIII. References (ENHANCED)

1e. Modi S, Jacot W, Yamashita T, et al; DESTINY-Breast04 Trial Investigators. Trastuzumab Deruxtecan in Previously Treated HER2-Low Advanced Breast Cancer. N Engl J Med. 2022 Jul 7;387(1):9-20. doi: 10.1056/NEJMoa2203690.

2e. Bardia A, Hu X, Dent R, et al; DESTINY-Breast06 Trial Investigators. Trastuzumab Deruxtecan after Endocrine Therapy in Metastatic Breast Cancer. N Engl J Med. 2024 Dec 5;391(22):2110-2122. doi: 10.1056/NEJMoa2407086. Epub 2024 Sep 15. PMID: 39282896.

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4e. Cortés J, Punie K, Barrios C, et al. Sacituzumab Govitecan in Untreated, Advanced Triple-Negative Breast Cancer. *New England Journal of Medicine*. Published online October 18, 2025. doi:https://doi.org/10.1056/nejmoa2511734

5e. Prime Therapeutics Management. Datroway Clinical Literature Review Analysis. Last updated June 2026. Accessed June 2026.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

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
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung

ICD-10	ICD-10 Description
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

ICD-10	ICD-10 Description
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
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

ICD-10	ICD-10 Description
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