



ND

Medical Policies



Print

Policy Number: ME-I-298

Policy Name: Datopotamab deruxtecan-dlnk (Datroway)

Policy Type: Medical

Policy Subtype: Injections

Effective Date: 10-01-2025

Description

Datopotamab deruxtecan-dlnk (Datroway®) is a humanized anti-Top2 antibody and topoisomerase inhibitor conjugate. Following binding to Trop2 on cells, datopotamab deruxtecan-dlnk (Datroway) undergoes internalization and intracellular linker cleavage ultimately causing DNA damage and apoptotic cell death.

Policy Application

All claims submitted for this policy will be processed according to the policy effective date and associated revision effective dates in effect on the date of processing, regardless of service date.

Criteria

Coverage is subject to the specific terms of the member's benefit plan.

Datopotamab deruxtecan-dlnk (Datroway) may be considered medically necessary for **ANY** of the following conditions:

Breast Cancer

- Treatment of individuals 18 years of age or older with unresectable or metastatic, hormone receptor positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer (IHC 0, IHC 1+ or IHC 2+/*ISH*-) who have received prior endocrine-based therapy and chemotherapy; **or**

Non-Small Cell Lung Cancer, NSCLC

- Treatment of individuals 18 years of age or older with locally advanced or metastatic epidermal growth factor receptor (EGFR)-mutated NSCLC who have received prior EGFR-directed therapy and platinum-based chemotherapy; **or**

Compendia Sources

Datopotamab deruxtecan-dlnk (Datroway) may be considered medically necessary for treatment of any of the current category 1, 2A, or 2B NCCN recommendations.

The use of datopotamab deruxtecan-dlnk (Datroway) for all other indications not listed in this policy is considered experimental/investigational and therefore non-covered because the safety and/or effectiveness cannot be established by the available published peer-reviewed literature.

Procedure Code

J9011

NOTE: In addition to the above criteria, product specific dosage and/or frequency limits may apply in accordance with the United States Food and Drug Administration (U.S. FDA)-approved product prescribing information, national compendia, Centers for Medicare and Medicaid Services (CMS) and other peer reviewed resources or evidence-based guidelines.

Diagnosis Codes

C33	C34.00	C34.01	C34.02	C34.10	C34.11	C34.12
C34.2	C34.30	C34.31	C34.32	C34.80	C34.81	C34.82
C34.90	C34.91	C34.92	C50.011	C50.012	C50.019	C50.021
C50.022	C50.029	C50.111	C50.112	C50.119	C50.121	C50.122
C50.129	C50.211	C50.212	C50.219	C50.221	C50.222	C50.229
C50.311	C50.312	C50.319	C50.321	C50.322	C50.329	C50.411
C50.412	C50.419	C50.421	C50.422	C50.429	C50.511	C50.512
C50.519	C50.521	C50.522	C50.529	C50.611	C50.612	C50.619
C50.621	C50.622	C50.629	C50.811	C50.812	C50.819	C50.821
C50.822	C50.829	C50.911	C50.912	C50.919	C50.921	C50.922
C50.929						

References

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1. Bardia A, Jhaveri K, Kalinsky K et al. TROPION-breast01: datopotamab deruxtecan vs chemotherapy in pre-treated inoperable or metastatic HR+/HER2 – breast cancer. *Future Oncol.* 2023;20(8):423-436.
2. 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;19(35):2349-2359.
3. Clinical Pharmacology™ Compendium. 2025. Tampa FL: Gold Standard, Inc. Datopotamab deruxtecan-dlnk.
4. Micromedex DrugDex Compendium. 2025. Datopotamab deruxtecan-dlnk.
5. Datoway (datopotamab deruxtecan-dlnk), for injection, for intravenous use [package insert]. Daiichi Sankyo, Inc. Basking Ridge, NJ. Revised 06/2025

ND Committee Review

Internal Medical Policy Committee 09-04-2025 *Effective October 01, 2025*

- *Adopted* Medicaid Expansion specific policy

Disclaimer

Current medical policy is to be used in determining a Member's contract benefits on the date that services are rendered. Contract language, including definitions and specific inclusions/exclusions, as well as state and federal law, must be considered in determining eligibility for coverage. Members must consult their applicable benefit plans or contact a Member Services representative for specific coverage information. Likewise, medical policy, which addresses the issue(s) in any specific case, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and the Company reserves the right to review and update medical policy periodically.