Evolent Clinical Guideline 3008 for Datroway™ (datopotamab deruxtecan-dlnk)

Guideline Number:	Applicable Codes	
Evolent_CG_3008		
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Original Date:	**Last Revised Date:**	**Implementation Date:**
February 2025	February 2025	February 2025

TABLE OF CONTENTS

STATEMENT

Purpose

To define and describe the accepted indications for Datroway (datopotamab deruxtecan-dlnk) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

INDICATIONS

Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

Breast Cancer

- Datroway (datopotamab deruxtecan-dlnk) may be used in adult members with unresectable or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (HR+/HER2−) (immunohistochemistry [IHC] 0, IHC 1+, or IHC 2+/in situ hybridization [ISH]−) breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease.

CONTRAINDICATIONS/WARNINGS

- Warnings
  - Interstitial Lung Disease (ILD) and Pneumonitis: Datroway (datopotamab deruxtecan-dlnk) can cause severe and fatal cases of ILD/pneumonitis. Monitor for new or worsening signs and symptoms of ILD/pneumonitis. If ILD/pneumonitis is suspected, withhold Datroway (datopotamab deruxtecan-dlnk) and initiate corticosteroids. Permanently discontinue Datroway (datopotamab deruxtecan-dlnk) in patients with confirmed Grade 2 or higher ILD/pneumonitis.
  - Ocular Adverse Reactions: Datroway (datopotamab deruxtecan-dlnk) can cause ocular adverse reactions including dry eye, keratitis, blepharitis and meibomian

gland dysfunction, increased lacrimation, conjunctivitis, and blurred vision. Monitor patients for ocular adverse reactions during treatment with Datroway (datopotamab deruxtecan-dlnk). Advise patients to use preservative-free lubricating eye drops and to avoid using contact lenses during treatment with Datroway (datopotamab deruxtecan-dlnk). Dose delay, dose reduce, or permanently discontinue Datroway (datopotamab deruxtecan-dlnk) based on the severity of ocular adverse reactions. Refer patients to an eye care professional for any new or worsening ocular signs and symptoms.

EXCLUSION CRITERIA

- Disease progression while taking Datroway (datopotamab deruxtecan-dlnk).
- Concurrent use with other anticancer therapies.
- Members with a history of interstitial lung disease/pneumonitis requiring treatment with steroids, ongoing interstitial lung disease /pneumonitis, clinically active brain metastases, or clinically significant corneal disease.
- Dosing exceeds single dose limit of 6 mg/kg (up to a maximum of 540 mg for patients ≥90 kg).
- Investigational use of Datroway (datopotamab deruxtecan-dlnk) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
    - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
    - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
    - Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of < 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
    - Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
    - That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
    - That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
    - That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

CODING AND STANDARDS

Codes

- J9999 - datopotamab deruxtecan-dlnk injection

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
February 2025	• New drug policy

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

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5. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2025.
6. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2025.
7. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. *J Clin Oncol*. 2014 Apr 20;32(12):1277-80.
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9. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.