Datopotamab deruxtecan-dlnk (DATROWAY)
Criteria for Use
May 2026

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National Formulary Committee Monograph on this drug at the *PBM INTRAnet* site for further information.

Exclusion Criteria

If any of the following are selected, the patient will NOT meet criteria for datopotamab deruxtecan.

- ☐ Absolute neutrophil count (ANC) <1,500/mm^3 (unless Duffy null phenotype) or platelets <100,000/mm^3
- ☐ Severe renal impairment: CrCl <30 mL/minute
- ☐ Severe hepatic impairment: total bilirubin >1.5 times ULN and any AST/ALT; or total bilirubin >3 times ULN and any AST/ALT if liver metastases
- ☐ Symptomatic or unstable brain metastases
- ☐ History of interstitial lung disease (ILD)/pneumonitis requiring steroids, or active ILD/pneumonitis
- ☐ Uncontrolled or significant cardiac disease*
- ☐ Clinically significant corneal disease
- ☐ Prior treatment with topoisomerase I inhibitor (e.g. fam-trastuzumab deruxtecan or irinotecan) or Trop-2-directed therapy (e.g. sacituzumab govitecan)
- ☐ Known pregnancy
- ☐ Lactating

CrCl=creatinine clearance; ULN=Upper Limit of Normal

*Baseline Left Ventricular Ejection Fraction (LVEF) < 50% via MUGA or echocardiography; uncontrolled hypertension or arrhythmia; myocardial infarction or unstable angina within prior 6 months; symptomatic Congestive Heart Failure (New York Heart Assoc. Class 2 - 4); mean corrected QT interval > 470 msec

Inclusion Criteria

One of the following criteria must be selected to meet criteria.

- ☐ Unresectable or metastatic, hormone receptor (HR)-positive, human epidermal growth factor 2 (HER2)-negative (IHC 0, IHC 1+, or IHC 2+/ISH-) breast cancer after prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease
- ☐ Locally advanced or metastatic epidermal growth factor receptor (EGFR)-mutated non-small cell lung cancer (NSCLC) after prior EGFR-directed therapy and platinum-based chemotherapy

Additional Inclusion Criteria

All of the following criteria must be met:

- ☐ In-person baseline ophthalmic exam (visual acuity testing, slit lamp examination, intraocular pressure, and fundoscopy) prior to treatment initiation
- ☐ Able to administer preservative-free lubricant eye drops at least four times daily and as needed throughout the duration of treatment with datopotamab deruxtecan
- ☐ Able to avoid wearing contact lenses, unless otherwise directed by ophthalmologist
- ☐ Able to administer steroid-containing mouthwash (dexamethasone oral solution 0.1 mg/mL) four times daily and as needed throughout the duration of treatment with datopotamab deruxtecan
- ☐ Care is provided by a VA/VA Community Care oncology provider
- ☐ Eastern Cooperative Oncology Group (ECOG) performance status 0-1
- ☐ Goals of care and role of Palliative Care consult have been discussed and documented

Additional Inclusion Criteria

Select if applicable.

- ☐ Females who can become pregnant and males with partners who can become pregnant: Counseling provided on risks vs benefits and use of effective contraception during therapy and for 7 months after stopping treatment for women and 4 months after for men.

Other Justification

- ☐ _____

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