AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: 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 Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Datroway® (datopotamab deruxtecan-dlnk) **(J9011) MEDICAL**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

(Continued on next page)

A. Quantity Limit (max daily dose) [NDC Unit]:

- 6 mg/kg once every 3 weeks; maximum dose: 540 mg in patients weighing ≥ 90 kg

B. Max Units (per dose and over time):

- 1 mg = 1 billable unit; maximum 540 billable units per dose

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- ❑ Member is 18 years of age or older
- ❑ Provider is a specialist in oncology
- ❑ Member must have **ONE** of the following diagnoses:
  - ❑ Member has a diagnosis of breast cancer meeting **ALL** the following:
    - ❑ Human epidermal growth factor receptor 2 (HER2)-negative disease (IHC 0, IHC 1+ or IHC 2+/ISH-)
    - ❑ Hormone receptor (HR)-positive disease
    - ❑ Datopotamab will be used as a single agent for unresectable or metastatic disease
    - ❑ Disease progression recorded with, and is not suitable for continued, endocrine therapy
    - ❑ Datopotamab will be used as subsequent therapy to systemic Chemotherapy (e.g., doxorubicin, paclitaxel)
    - ❑ Member must meet **ONE** of the following:
      - ❑ Datopotamab will be used as subsequent therapy to fam-trastuzumab deruxtecan-nxki (i.e., Enhertu®)
      - ❑ If member was not a candidate for fam-trastuzumab deruxtecan-nxki, trial of sacituzumab govitecan (i.e., Trodevly®) has resulted in disease progression
  - ❑ Member has a diagnosis of Non-Small Cell Lung Cancer meeting **ALL** the following:
    - ❑ Epidermal growth factor receptor (EGFR)-mutated [EGFR Exon 19 Deletion or Exon 21 L858R] disease
    - ❑ Disease progression recorded with platinum-based chemotherapy (e.g., cisplatin or carboplatin)
    - ❑ Datopotamab used as subsequent therapy to EGFR-directed therapy (e.g., afatinib, erlotinib, osimertinib)

Reauthorization: 6 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied. **Applicable to ALL continuation of therapy requests.**

- ❑ Member is currently receiving the requested medication and all initial authorization criteria continues to be met

(Continued on next page)

- ❑ Member requires continuation of therapy and is **NOT** experiencing disease progression
- ❑ Ongoing treatment is consistent with FDA-labeling or compendia support
- ❑ Member is **NOT** experiencing an FDA-labeled limitation of use or toxicity
- ❑ The quantity (dose) requested is in accordance with FDA approved labeling
  - **IF** there is an adjustment in quantity (dose) requested, higher than the maximum dose recommendation in FDA-approved labeling (i.e., the package insert), the prescriber must submit clinical literature and medical documentation in support the safety and efficacy of the higher dose (such as evidence from practice guidelines or clinical trials from peer-reviewed medical literature).

    **** Please note: Chart documentation of the above is required to be submitted along with this request ****

    _____

    _____

    _____

    _____

    _____

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****