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: Kebilidi (eladocagene exuparvovec-tneq) **(J3590) (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.

Dosing Limits

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

- Kebilidi is supplied in a single-dose vial that contains 2.8 x 10^{11} vg of eladocagene exuparvovec-tneq in an extractable volume of 0.5 mL of suspension. Each mL of suspension contains 5.6 x 10^{11} vg of eladocagene exuparvovec-tneq **[NDC 52856-0601-XX]**

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

- One treatment (dose) per lifetime.
- Administer a total dose of 1.8×10^{11} vg (0.32 mL total volume) delivered as four 0.08 mL (0.45×10^{11} vg) infusions (two sites per putamen-anterior and posterior) at a rate of 0.003 mL/minute (0.18 mL/hour) for a total of 27 minutes per site, administered in a single stereotactic surgery using a cannula that is FDA-authorized for intraparenchymal infusion.

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.

Length of Authorization: 3 months with an allowance of only 1 dose per lifetime

Coverage will be provided for one treatment course and may NOT be renewed.

- ❑ Member is at least 16 months of age through 10 years of age
- ❑ Prescribed by or in consultation with a pediatric neurologist, neurologist or neurosurgeon
- ❑ Member has biallelic pathogenic variants in the dopa decarboxylase (DDC) gene **(submit documentation)**
- ❑ Member has decreased aromatic L-amino acid decarboxylase (AADC) enzyme activity in plasma per current laboratory standards **(submit documentation)**
- ❑ According to the prescribing physician, the patient has continued symptoms of AADC deficiency despite use of at least one standard medication therapy **[Note: Examples of medications used for AADC deficiency include dopamine agonists (e.g., pramipexole, ropinirole, rotigotine), monoamine oxidase inhibitors (e.g., tranylcypromine, selegiline), pyridoxine, and other forms of vitamin B6]**
- ❑ Member is unable to ambulate independently
- ❑ Member has achieved skull maturity as assessed by neuroimaging
- ❑ Member does **NOT** have pyridoxine 5'-phosphate oxidase or tetrahydrobiopterin (BH4) deficiency
- ❑ Member has **NOT** received prior gene therapy or Kebilidi in the past **(verified by medical paid claims)** [**NOTE:** Verify through claims history that the member has not previously received any other gene therapy or Kebilidi. If no claim for Kebilidi is present (or if claims history is not available), the prescribing physician confirms that the member has not previously received any other gene therapy or Kebilidi.]
- ❑ Member must **NOT** have a baseline anti-AAV2 antibody titer above 1:1200 or >1 optical density value by enzyme-linked immunosorbent assay
- ❑ Member does **NOT** have any contraindications that would preclude surgical intra putaminal administration
- ❑ Member has tested negative for coronavirus disease of 2019 (COVID-19) a maximum of 72 hours prior to receiving gene therapy

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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 Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed Health Plan'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.

***Approved by Pharmacy and Therapeutics Committee**: ~~1/23/2025;~~ **3/26/2026**
REVISED/UPDATED/REFORMATTED: ~~2/19/2025;~~ **4/16/2026**