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
- ❑ Member has a diagnosis of severe Aromatic L-amino acid decarboxylase (AADC) deficiency as established by **ALL** the following **(submit documentation)**:
  - ❑ Genetic testing showing biallelic mutations in the DOPA decarboxylase (DDC) gene
  - ❑ Reduced levels of 5-hydroxyindoleacetic acid (5-HIAA), homovanilic acid (HVA) and 3-methoxy-4-hydroxyphenylglycol (MHPG) and high concentrations of 3-o-methyldopa (3-OMD), L-Dopa, and 5-OH tryptophan (5-HTP) in the cerebral spinal fluid (CSF)
  - ❑ Reduced aromatic L-amino acid decarboxylase (AADC) activity in the plasma
- ❑ Member is experiencing persistent neurological defects (e.g., autonomic dysfunction, hypotonia, dystonia and other movement disorders, etc.) secondary to AADC deficiency despite standard medical therapy (e.g., dopamine agonists, monoamine oxidase inhibitor, pyridoxine, or other forms of vitamin B6) [**NOTE: patients should be on stable dosages for at least 3 months prior to treatment with eladocagene**]
- ❑ 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
- ❑ 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 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.*

***Approved by Pharmacy and Therapeutics Committee: 1/23/2025**
REVISED/UPDATED/REFORMATTED: 2/19/2025