Medical Policy:

Kebilidi™ (eladocagene exuparvovec-tneq) Intraputaminal

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.432	March 24, 2025	March 24, 2025

Definitions

Kebilidi (eladocagene exuparvovec-tneq) is an adeno-associated virus (AAV) vector-based gene therapy indicated for the treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency.

Length of Authorization

Coverage will be provided for one dose and may not be renewed.

Dosing Limits [Medical Benefit]

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

- $1.8x10^{11}$ vg (0.32 mL) one time only

Guideline

1. Aromatic L-amino acid decarboxylase (AADC) deficiency

A. Patient is at least 16 months of age through 10 years of age; **AND**

B. Patient has a diagnosis of severe Aromatic L-amino acid decarboxylase (AADC) deficiency as established by the following:

i. Patient has a biallelic pathogenic variants in DDC gene identified by molecular genetic testing; **OR**
ii. Patient cerebrospinal fluid (CSF) or plasma neurotransmitter profile is consistent with AADC deficiency; **AND**

C. Patient has significantly reduced AADC enzyme activity in plasma.; **AND**
D. Patient 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*; **AND**
E. Patient is unable to ambulate independently; **AND**
F. Patient has achieved skull maturity as assessed by neuroimaging; **AND**
G. Patient does not have pyridoxine 5'-phosphate oxidase or tetrahydrobiopterin (BH4) deficiency; **AND**
H. Patient has not received prior gene therapy; **AND**
I. Patient must not have a baseline anti-AAV2 antibody titer above the established threshold for a positive result; **AND**
J. Patient does not have any contraindications that would preclude the surgical intra-putaminal administration

Applicable Procedure Codes

Code	Description
J3590	Unclassified Biologics
C9399	Unclassified drugs or biologicals

Applicable NDCs

Code	Description
52856-0601-xx	Kebilidi 5.6 × 10^{11} vector genomes (vg) per mL – 2 mL single dose vial

ICD-10 Diagnoses

Code	Description
E70.81	Aromatic L-amino acid decarboxylase deficiency

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	03/24/2025	New Policy

References

1. Kebilidi™ suspension for intraputaminal infusion [prescribing information]. Warren, NJ: PTC Therapeutics; November 2024.