

Medical Policy:

Kebilidi™ (eladocogene exuparvovec-tneq) Intraputaminal

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Kebilidi (eladocogene 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]:

- 1.8x10¹¹ vg (0.32 mL) one time only

Guideline

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

- Patient is at least 16 months of age through 10 years of age; **AND**
- 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 eladocogene*; **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 intraputamenal infusion [prescribing information]. Warren, NJ: PTC Therapeutics; November 2024.