New Hampshire Medicaid Fee-for-Service Program
Kebilidi™ (eladocagene exuparvovec-tneq) Criteria

Approval Date: June 5, 2025

Medications

Brand Name	Generic Name	Indication
Kebilidi™	eladocagene exuparvovec-tneq	treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency

Criteria for Approval

1. Patient is ≥ 16 months of age through 10 years of age; **AND**
2. Patient has a diagnosis of severe aromatic L-amino acid decarboxylase (AADC) deficiency as established by the following:
   a. Patient has biallelic pathogenic variants in DOPA decarboxylase (DDC) gene identified by molecular genetic testing; **OR**
   b. 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**
3. Patient is experiencing persistent neurological defects (e.g., autonomic dysfunction, hypotonia, dystonia and other movement disorders) secondary to AADC deficiency despite standard medical therapy (e.g., dopamine agonists, monoamine oxidase inhibitor, pyridoxine, other forms of vitamin B6) Note: patients should be on stable dosages for ≥ 3 months prior to treatment with Kebilidi; **AND**
4. Patient is unable to ambulate independently; **AND**
5. Patient has achieved skull maturity as assessed by neuroimaging; **AND**
6. Patient does NOT have pyridoxine 5'-phosphate oxidase or tetrahydrobiopterin (BH4) deficiency; **AND**
7. Patient has NOT received prior gene therapy; **AND**
8. Patient must NOT have a baseline anti-adeno-associated virus, serotype 2 (anti-AAV2) antibody titer above the established threshold for a positive result; **AND**
9. Patient does NOT have any contraindications that would preclude the surgical intra-putaminal administration; **AND**
10. For females of reproductive potential, a negative pregnancy test is required prior to administration.

Limitation

A single dose per lifetime.

Criteria for Denial

Criteria for approval are not met.

Revision History

Reviewed by	Reason for Review	Date Approved
DUR Board	New	04/08/2025
Commissioner Designee	Approval	06/05/2025