# Elevidys *(delandistrogene moxeparvovec-rokl)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Elevidys is a gene therapy for the treatment of Duchenne muscular dystrophy (DMD). DMD is a rare, progressive X-linked disease resulting from mutation(s) of the DMD gene, also known as the Dystrophin gene. Due to the mutation(s), the dystrophin protein, which is key for maintaining the structural integrity of muscle cells, is not produced or very minimally produced. Elevidys encodes for a micro-dystrophin protein to replace the missing dystrophin protein. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Before the drug is covered, the patient must meet all of the following requirements:<br><br>Documentation of Duchenne muscular dystrophy (DMD) confirmed by genetic mutation in the DMD gene that is not a deletion in exon 8 or exon 9.<br><br>An anti-AAVrh74 titer <1:400. |
| **Age Restriction** | None. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a neurologist or other specialist with experience treating DMD. |
| **Coverage Duration** | Initial and Reauthorization: One year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J1413 | Elevidys (delandistrogene moxeparvovec-rokl) | **Billing unit: per dose**<br><br>1.33 x 1014 vector genomes per kilogram (vg/kg) of body weight as a single dose |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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