

STATE OF WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES

BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Service

Prior Authorization Criteria

Elevidys

Effective 1/1/2024

Billed under J1413 (effective 1/1/24)

Elevidys is an adeno-associated virus vector-based gene therapy indicated for the treatment of ambulatory pediatric patients aged 4 through 5 years with Duchenne Muscular Dystrophy (DMD) with a confirmed mutation in the DMD gene. This indication is approved under accelerated approval based on expression of Elevidys microdystrophin in skeletal muscle observed in patients treated with Elevidys.

All requests require review by the Medical Director and may be approvable once the following criteria are met:

1. Must be prescribed by, or in consultation with, a neuromuscular specialist; AND
2. Patient must be age 4 years to <6 years and currently ambulatory; AND
3. Patient must have a confirmed diagnosis of DMD which has been genetically characterized:
 - a. Patients with deletions in the DMD gene occurring in exons 1 to 17 and/exons 59 to 71 must be monitored for immune-mediated myositis.
 - b. Elevidys is contraindicated in patients having a deletion in exon 8 and/or 9 of the DMD gene.
4. Anit-AAVrh74 total binding antibody titers must be <1:400; AND
5. Patient's current weight, liver function (ALT, AST, GGT, ALP, total bilirubin, and INR), platelet counts, and troponin-1 levels must be assessed, and results submitted along with the request for prior authorization; AND
6. Patient must be started on a corticosteroid regimen one day prior to the infusion of Elevidys and continue this regimen for at least 60 days post infusion; AND
7. All criteria requirements must be acknowledged and documented prior to approval of Elevidys.

If any of the above criteria are not met or not documented in the prior authorization request, coverage will be denied.

<https://investorrelations.sarepta.com/news-releases/news-release-details/sarepta-therapeutics-announces-fda-approval-elivevidys-first-gene/>

