STATE OF WEST VIRGINIA
DEPARTMENT OF HUMAN SERVICES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Services
Prior Authorization Criteria

ELEVIDYS® (delandistrogene moxeparvovec-rokl)
Billed under: J1413

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. Elevidys is for single-dose intravenous infusion only. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Initial authorization requires review by the Medical Director and may be approved when all of the following criteria is met:

1. Must be prescribed by, or in consultation with, a Neuromuscular Specialist; **AND**
2. Patient must be aged 4 through 5 years and currently ambulatory; **AND**
3. Patient must be diagnosed with DMD who has a confirmed mutation in the dystrophin gene; **AND**
4. Patients with deletions in the DMD gene in exons 1 to 17 and /or exons 59 to 71 may be at risk for severe immune-mediated myositis reaction and must be monitored; **AND**
5. Elevidys is contraindicated in patients having a deletion in exon 8 and/or exon 9 of the DMD gene; **AND**
6. Anti-AAVrh74 total binding antibody titers must be < 1:400; **AND**
7. 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**

8. Patient must be started on a corticosteroid regimen one day prior to the infusion of Elevidys and continued on this regimen for at least 60 days post infusion

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.

References:

Government Agency, Medical Society, and Other Authoritative Publications:

1. https://investorrelations.sarepta.com/news-releases/news-release-details/sarepta-therapeutics-announces-fda-approval-elevidys-first-gene/ (Accessed 11/28/2023)
2. Elevidys [package insert]. Cambridge, MA: Sarepta Therapeutics, Inc.; 2023. https://www.fda.gov/media/169679/download (Accessed 4/16/2024)

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member according to BMS coverage and policy guidelines.