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

Alex J. Mayer
Cabinet Secretary

Cynthia Beane, MSW, LCSW
Commissioner

Office of Pharmacy Services
Prior Authorization Criteria
Updated: 4/17/25
ELEVIDYS® (delandistrogene moxeparvovec-rokl)
Billed under: J1413

ELEVIDYS is an adeno-associated virus vector-based gene therapy indicated for the treatment of Duchenne Muscular Dystrophy (DMD) in patients at least 4 years of age. Elevidys is indicated for the treatment of DMD in both ambulatory and non-ambulatory patients with a confirmed mutation in the DMD gene. The DMD indication in non-ambulatory patients is approved under accelerated approval based on expression of Elevidys micro-dystrophin in skeletal muscle. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). Elevidys is for single-dose intravenous infusion only.

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

1. Must be prescribed by, or in consultation with, a Neuromuscular Specialist; **AND**
2. Patient must be at least 4 years of age; **AND**
3. Patient must be diagnosed with DMD who has a mutation in the dystrophin gene confirmed via genetic testing; **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 less than (<) 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.; 2024. https://www.fda.gov/media/169679/download (Accessed 10/30/2024)

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.