

Christina Mullins, MA
Acting Cabinet Secretary

Christy D. Donohue, CMC
Commissioner

**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 Duchenne Muscular Dystrophy (DMD) in patients at least 4 years of age. Elevidys is indicated for the treatment of DMD in ambulatory patients with a confirmed mutation in the DMD gene. 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.

Limitations of Use: Elevidys is not recommended in patients with preexisting liver impairment or active viral infection, recent vaccination (within 4 weeks of treatment) and those with active or recent (within 4 weeks) infections due to safety concerns.

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 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 (AST, ALT, GGT, albumin, aPTT, INR, total bilirubin, and ALP), platelet counts, and troponin-1 levels must be assessed, and results submitted along with the request for prior authorization; **AND**
8. Before administration of Elevidys infusion, a monitoring plan must be established and agreed upon by both the patient and prescribing provider that includes ongoing assessment of liver function on a weekly basis for at least the first 3 months following infusion, and continued monitoring thereafter until liver function results are unremarkable; **AND**



9. 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; **AND**
10. Patient must be instructed to maintain proximity to an appropriate healthcare facility, as determined by the prescriber, for at least 2 months following Elevidys 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.; 2025.
https://www.elevidys.com/pi?_gl=1*10fvsr3*_gcl_au*NTYxMzMzNjA2LjE3NzYyNzk2MjM
(Accessed 04/15/2026)

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.

