



October 7, 2025

Commissioner James V. McDonald, M.D., M.P.H.

New York State Department of Health

NYS State Capitol Building

Albany, NY 12224

The Honorable Kathy Hochul Governor of New York

NYS State Capitol Building

Albany, NY 12224

Subject: Urging Coverage of Therapies to the FDA-Approved Label

Dear commissioner McDonald and Governor Hochul,

On behalf of the neuromuscular disease community the Muscular Dystrophy Association writes to express our concern over the New York DURB decision to not only decline to cover ELEVDIS to the FDA-approved label, but also to decline to cover a therapy duly approved by the FDA generally.

MDA is the #1 voluntary health organization in the United States for people living with muscular dystrophy, ALS, and related neuromuscular diseases. For 75 years, MDA has led the way in accelerating research, advancing care, and advocating for the support of our community. MDA's mission is to empower the people we serve to live longer, more independent lives. This, crucially, includes unimpeded access to Medicaid benefits.

We are concerned by the DURB's position to rescind coverage of a duly approved therapy by the FDA. Disregarding the rigorous process provided by the FDA in this manner casts harmful doubt toward scientific process and throws yet more uncertainty on healthcare providers, patients, and their families attempting to provide and access the care they need.

Perhaps more concerning than this individual decision by the DURB, is the fact that it flies in the face of the Social Security Act, and the implications therein. Under Section 1927(a)(1) et. seq. as they apply to Sections 505 and 1927(k) of the Federal Food Drug, and Cosmetic Act, to participate in the Medicaid Drug Rebate Program (MDRP) a Medicaid program must cover a duly approved therapy by the FDA.¹ Without question this includes coverage of therapies

¹ 42 U.S.C. 1369r-9 (as later amended Sec 1927 https://www.ssa.gov/OP_Home/ssact/title19/1927.htm). 42 CFR Parts 433, 438, and 447 See also, Centers for Medicare and Medicaid Services, *Medicaid Drug Rebate Program Notice Release No. 185* <https://www.medicare.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-185.pdf>.

approved via accelerated approval processes.² Failure to do so would result in a massive loss in rebates for the program.

Failing to provide coverage and leaving the MDRP would be an extraordinary step for the Department of Health to take and would have catastrophic consequences for patients and their families. In 2023 for outpatient prescription drugs alone, the MDRP received 54 billion dollars in rebates.³ Disqualifying the Department of Health from its share of these rebates would lead to a massive shortfall for the state's Medicaid program which would then result in fewer services such as home and community based services (which are currently only covered by waiver), and further delays in other areas due to a lack of resources.⁴

Finally, the DURB recommends that coverage be offered again only if a further clinical trial on an immunosuppressant regimen is completed. Medicaid programs do not have the authority to subject coverage of a duly approved therapy to further clinical trials.⁵ The actions proposed by the DURB violate multiple statutes and go beyond the pail of even other utilization management tactics employed by other programs.⁶ We urge the Department of Health to Reject these recommendations and continue to comply with the law for the forgoing reasons.

We appreciate this opportunity to provide the Department of Health with the perspectives of the neuromuscular disease community. For questions regarding MDA or the above comments, please contact Joel Cartner, Director of Access Policy at jcartner@mdausa.org.

Sincerely,



Joel Cartner, Esq.
Director Access Policy
Muscular Dystrophy Association

² Centers for Medicare and Medicaid Services, *Medicaid Drug Rebate Program Notice Release No. 185*
<https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-185.pdf>

³ <https://www.kff.org/medicaid/recent-trends-in-medicaid-outpatient-prescription-drugs-and-spending/#:~:text=What%20are%20recent%20trends%20in%20Medicaid%20prescription%20drug%20spending?,of%20inflation%20in%20recent%20years.>

⁴

<https://d3dkdvqff0zqx.cloudfront.net/groups/mda/attachments/6.16.2025%20Neuromuscular%20Advocacy%20Groups%20Oppose%20Reconciliation%20Cuts%20to%20Care%20-%20Final.pdf> Page 3.

⁵ <https://www.macpac.gov/wp-content/uploads/2023/03/Chapter-3-Strengthening-Evidence-under-Medicaid-Drug-Coverage.pdf> page 10.

⁶ We have data on specific coverage of accelerated approval therapies in the neuromuscular space that is currently making its way through the publication process. In the meantime see, <https://pubmed.ncbi.nlm.nih.gov/36852834/>