Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	January 21, 2025

Duvyzat™ (givinostat)

LENGTH OF AUTHORIZATION: 6 months

REVIEW CRITERIA:

- Patient must be ≥ 6 years of age.
- Patient must have a confirmed diagnosis of Duchenne Muscular Dystrophy (DMD). *(Genetics testing results must be provided)*.
- Patient must have baseline platelet count (≥ 150 x 10^9/L) and triglyceride level drawn prior to therapy initiation. *(Official labs required)*.
- Medication is prescribed by or in consultation with a neurologist or a physician who specializes in treatment of DMD (i.e., pediatric neurologist, cardiologist, or pulmonary specialist).
- Patient has been on stable dose of oral corticosteroids for at least 24 weeks prior to starting therapy unless contraindicated or intolerant.
- The patient must be ambulatory and a baseline assessment of ambulatory function (i.e., six-minute walk test {6MWT}, time to run/walk 10-meter test {TTRW}, time to climb 4-stair test {TTCLIMB}, time to stand {TTSTAND} or North Star Ambulatory Assessment {NSAA}) is required.

CONTINUATION OF THERAPY:

- Patient met initial review criteria.
- Documentation of improvement from baseline, maintenance or slowing of disease progression as demonstrated by any of the following: 6MWT, TTRW, TTCLIMB, TTSTAND or NSAA.
- Patient has not experienced any treatment-restricting adverse effects.
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as an 8.86 mg/mL oral suspension (140 ml bottle, discard contents 60 days after opening).