AETNA BETTER HEALTH® Coverage Policy/Guideline					
Name:	Duvyzat (givinostat)			Page:	1 of 2
Effective Date:	7/1/2024			Last Review Date:	5/15/2024
Applies to:	☐Illinois ☒Maryland	☐New Jersey ☒Florida Kids		☒Virginia ☒Pennsylvania Kids	

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Duvyzat under the patient's prescription drug benefit.

Description:

Duvyzat is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older.

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Duvyzat

Policy/Guideline:

Documentation
Submission of the following information is necessary to initiate the prior authorization review:

A. Initial requests:
   1. Laboratory confirmation of the DMD diagnosis by genetic testing or muscle biopsy.
B. Continuation requests:
   1. Chart notes and/or medical records documenting a response to therapy.

Prescriber Specialties
This medication must be prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy (DMD).

Criteria for Initial Approval:

Duchenne Muscular Dystrophy (DMD)
Authorization of 6 months may be granted for treatment of DMD when ALL the following criteria are met:

A. Member is 6 years of age or older.
B. The diagnosis of DMD was confirmed by EITHER of the following:
   1. Genetic testing documenting a mutation in the DMD gene.
   2. Muscle biopsy documenting absent dystrophin.
C. Member has clinical signs and symptoms of DMD (e.g., proximal muscle weakness, Gower's maneuver, elevated serum creatine kinase level).
D. Member is ambulant.
E. The requested medication will be used in combination with a corticosteroid (e.g., prednisone) unless contraindicated or not tolerated.

Criteria for Continuation of Therapy

Authorization of 12 months may be granted for members requesting continuation of therapy when the member has demonstrated a response to therapy as evidenced by remaining ambulatory (e.g., able to walk with or without assistance, not wheelchair dependent).

Approval Duration and Quantity Restrictions:

Initial Approval: 6 months

Renewal Approval: 12 months

Quantity Level Limit: Duvyzat (givinostat) 8.86 mg/mL oral suspension (140 mL per bottle): 3 bottles (420 mL) per 30 days

References:

1. Duvyzat [package insert]. Concord, MA: ITF Therapeutics LLC; March 2024.