

#### 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	□Illinois	□New Jersey	⊠Virginia	
to:	⊠Maryland	🛛 Florida Kids	🛛 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. <u>Continuation requests</u>:
  - 1. Chart notes and/or medical records documenting a response to therapy.

# **Prescriber Specialties**

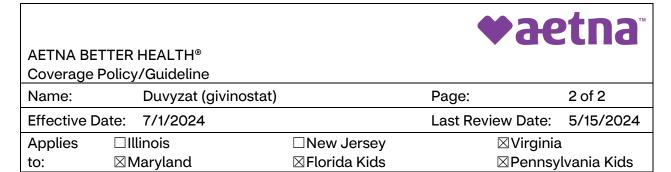
This medication must be prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy (DMD).

# 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.