



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.

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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.