

Specialty Guideline Management

Duvyzat

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Duvyzat	givinostat

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

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.

Documentation

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

- Initial requests: Laboratory confirmation of the DMD diagnosis by genetic testing or muscle biopsy.
- Continuation of therapy requests: 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).

Coverage Criteria

Duchenne Muscular Dystrophy (DMD)¹

Authorization of 6 months may be granted for treatment of DMD when all of the following criteria are met:

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

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).

References

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