

SPECIALTY GUIDELINE MANAGEMENT

DUVYZAT (givinostat)

POLICY

I. 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 Indication

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.

II. 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.

III. PRESCRIBER SPECIALTIES

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

IV. CRITERIA FOR INITIAL APPROVAL

Duchenne Muscular Dystrophy (DMD)

Authorization of 6 months may be granted for treatment of DMD when all of 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.

V. CONTINUATION OF THERAPY

Reference number(s)
6437-A

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).

VI. REFERENCES

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