



## Commercial PA Criteria

*Effective: July 31, 2024*

**Prior Authorization:** Duvyzat

**Products Affected:** Duvyzat (givinostat oral suspension)

**Medication Description:** Duvyzat, a histone deacetylase inhibitor, is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients  $\geq 6$  years of age.

**Covered Uses:** Treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older.

**Exclusion Criteria:** N/A

**Required Medical Information:**

1. Diagnosis
2. Previous therapies tried and failed

**Prescriber Restriction:** The medication is prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy and/or neuromuscular disorders.

**Age Restriction:** 6 years of age and older

**Coverage Duration:** 12 months

**Other Criteria:**

**Initial Approval Criteria**

1. **Duchenne Muscular Dystrophy.** Approve for 1 year if the patient meets the following Initial Therapy. Approve if the patient meets ALL of the following (A, B, C, D, **AND** E)
  - A. Patient is  $\geq 6$  years of age; **AND**
  - B. Patient's diagnosis of Duchenne Muscular Dystrophy is confirmed by genetic testing with a confirmed pathogenic variant in the dystrophin gene; **AND**
  - C. Patient is ambulatory; **AND**
  - D. Patient is on a stable systemic corticosteroid therapy for at least 6 months; **AND**
  - E. The medication is prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy and/or neuromuscular disorders.

**Renewal Criteria**

1. Patient is Currently Receiving Duvyzat. Approve if the patient meets ALL of the following (A, B, C, D, **AND** E)
  - A. Patient is  $\geq 6$  years of age; **AND**
  - B. Patient is ambulatory; **AND**
  - C. Patient is continuing to receive stable systemic corticosteroid therapy; **AND**

July 2024



Confidential Information

This document is confidential and proprietary to ConnectiCare. Unauthorized use and distribution are prohibited.



- D. According to the prescriber, the patient continues to benefit from therapy, as demonstrated by a stabilization or slowed decline on timed function tests (e.g., 4-stair climb, 6-minute walk test, time-to-rise) or in the North Star Ambulatory Assessment (NSAA) score; **AND**
- E. The medication is prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy and/or neuromuscular disorders.

**References:**

1. Duvyzat® oral suspension [prescribing information]. Concord, MA: ITF Therapeutics, LLC; March 2024.

**Policy Revision history**

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	07/31/2024