



## Prior Authorization Criteria

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### **DUVYZAT™ (*givinostat*) PA CRITERIA:**

DUVYZAT™ (*givinostat*) is a histone deacetylase inhibitor indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older.

Prior authorization is required for DUVYZAT™ (*givinostat*). Prior authorization approval will be considered when the following criteria are met. Along with the Universal PA Form, please submit any supporting clinical documentation.

#### **Initial Authorization: 12 Months**

1. Patient meets the age requirement outlined in the FDA label; **AND**
2. Documented diagnosis of Duchenne muscular dystrophy (DMD); **AND**
3. Patient is ambulatory; **AND**
4. Patient is currently on a stable corticosteroid dose for a minimum of three months and will remain on stable corticosteroid regimen unless documented contraindication or intolerance; **AND**
5. The following baseline evaluations have been completed, with additional monitoring performed as clinically indicated:
  - a. Baseline complete blood count (CBC) and triglycerides; **AND**
  - b. Baseline electrocardiogram (ECG) if there is underlying cardiac disease or if DUVYZAT™ is taken with concomitant medications that can cause QT prolongation; **AND**
  - c. Baseline timed 4-stair climb (4SC) assessment if patient is able; **AND**
6. Patient's baseline platelet count is greater than  $150 \times 10^9/L$ ; **AND**
7. Prescribed by or in consultation with a specialist with experience in treating DMD.

#### **Re-Authorization: 12 Months**

1. Documentation of clinical benefit as supported by medical records; **AND**
2. Provider attests that the member is tolerating the medication; **AND**
3. Patient is on concomitant corticosteroid therapy unless documented contraindication or intolerance.

**DUVYZAT™ (*givinostat*) Dosing:** The recommended dose is based on body weight and taken orally twice daily with food. Please see the package insert for more information.

**Formulation:** DUVYZAT™ is available as an 8.86 mg/mL oral suspension.