UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1453-2
Program	Prior Authorization/Notification
Medication	Duvyzat™ (givinostat) oral suspension
P&T Approval Date	7/2024, 7/2025
Effective Date	10/1/2025

1. Background:

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

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Duvyzat** will be approved based upon **both** of the following criteria:

   a. Diagnosis of Duchenne muscular dystrophy (DMD)

   -AND-

   b. Patient is 6 years of age or older

   Authorization will be issued for 12 months.

B. Reauthorization

1. **Duvyzat** will be approved based on the following criterion:

   a. Documentation of positive clinical response to Duvyzat therapy

   Authorization will be issued for 12 months.

[a]State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. Reference:

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

Program	Prior Authorization/Notification - Duvyzat (givinostat)
Change Control	
7/2024	New program
7/2025	Annual review with no changes to criteria. Updated reference.