UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2346-2
Program	Prior Authorization/Medical Necessity
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 **all** of the following criteria:

   a. Diagnosis of Duchenne muscular dystrophy (DMD)

   -AND-

   b. Diagnosis confirmed by the presence of a mutation in the *DMD* gene

   -AND-

   c. Patient is 6 years of age or older

   -AND-

   d. Submission of medical records (e.g., chart notes) confirming that the patient is ambulatory without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)

   -AND-

   e. Patient has been or will be established on a stable corticosteroid regimen

   -AND-

   f. Prescribed by, or in consultation with, a pediatric neuromuscular specialist with expertise in the treatment of DMD

   -AND-

   g. Patient has not received gene therapy for DMD [e.g., Elevidys (delandistrogene moxparvovec-rokl)]

   -AND-

h. Patient will not receive Duvyzat in combination with exon-skipping therapies for DMD [e.g., Amondys (casimersen), Exondys 51 (eteplirsen), Viltepso (viltolarsen), Vyondys 53 (golodirsen)]

Authorization will be issued for 12 months.

B. <u>Reauthorization</u>

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

a. Physician attestation that patient would benefit from continued administration.

-AND-

b. Submission of medical records (e.g., chart notes) confirming that the patient is ambulatory **without** needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)

-AND-

c. Patient continues to receive concomitant corticosteroid regimen

-AND-

d. Prescribed by, or in consultation with, a pediatric neuromuscular specialist with expertise in the treatment of DMD

-AND-

e. Patient has not received gene therapy for DMD [e.g., Elevidys (delandistrogene moxparvovec-rokl)]

-AND-

f. Patient will not receive Duvyzat in combination with exon-skipping therapies for DMD [e.g., Amondys (casimersen), Exondys 51 (eteplirsen), Viltepso (viltolarsen), Vyondys 53 (golodirsen)]

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.
2. Mercuri E, Vilchez JJ, Boespflug-Tanguy O, et al. Safety and efficacy of givinostat in boys with Duchenne muscular dystrophy (EPIDYS): a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial [published correction appears in Lancet Neurol. 2024 Jun;23(6):e10]. *Lancet Neurol*. 2024;23(4):393-403.
3. Gloss D, Moxley III R, Ashwal S, et. al. Practice guideline update summary: Corticosteroid treatment of Duchenne muscular dystrophy: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology 2016; 86;465-472.

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