# Pharmacy Drug Policy & Procedure

| Policy Name: | Duvyzat (givinostat) | Policy#: | 3257P |
|---|---|---|---|

## Purpose of the Policy

The purpose of this policy is to define coverage criteria for Duvyzat (givinostat)

## Statement of the Policy

Health Alliance Medical Plans will approve the use of Duvyzat (givinostat) under the specialty pharmacy benefit if the following criteria are met.

## Criteria

**1. Coverage Criteria**

1.1 Diagnosis of Duchenne Muscular Dystrophy confirmed by one of the following:
- Genetic testing documenting a mutation in the dystrophin (DMD) gene
- Muscle biopsy documenting lack of muscle dystrophin

1.2 Age 6 years or older

1.3 Prescribed by or in consultation with a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders

1.4 Patient is currently ambulatory (able to walk independently)

1.5 Documented concurrent use (for at least the last 6 months) of prednisone unless member has experienced at least one of the following significant intolerable adverse effects (AE)
- Cushingoid appearance
- Central (truncal) obesity
- Undesirable weight gain defined as a 10% of body weight gain increase over a 6-month period
- Diabetes and/or hypertension that is difficult to manage
- Severe behavioral AE that would require a prednisone dose reduction
- Clinically significant growth stunting as evidenced by decline in mean height percentile from baseline, decrease in growth velocity or decrease in serum bone formation biomarkers

1.6 If member is unable to tolerate prednisone, concurrent use of generic deflazacort is required

1.7 Documentation of a baseline motor milestone score from one of the following assessments:
- 4-stair climb (4SC)
- North Star Ambulatory Assessment (NSAA)
- 6-minute walk test (6MWT)
- Time to stand test (TTSTAND)

1.8 Review of clinical documentation and confirming that patient has met all of the above requirements for treatment completed by both a pharmacist and medical director

**2. Exclusion Criteria**

2.1 Duvyzat will not be covered in combination with or in patients who have previously received any

2.2 dystrophin restoration product (such as Elevidys)

**3. Managed Dose Limit**

3.1 2 bottles (280mL) per 30 days

**4. Approval Period**

4.1 Initial: 12 months

4.2 Reauthorization: 12 months with BOTH of the following:

- Clinical documentation to support a slowed decline of motor function
- Patient remains ambulatory

| CPT Codes | |
|---|---|
| | |

| HCPCS Codes | |
|---|---|
| | |

**References**


1. Duvyzat (givinostat) [prescribing information]. Concord, MA: ITF Therapeutics LLC; March 2024.
2. Mercuri E, Vilchez JJ, Boespflug-Tanguy O, et al; EPIDYS Study Group. Safety and efficacy of givinostat in boys with Duchenne muscular dystrophy (EPIDYS): a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial. Lancet Neurol. 2024 Apr;23(4):393-403.
3. Birnkrant DJ, Bushby K, Bann CM, et al; DMD Care Considerations Working Group. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management. Lancet Neurol. 2018 Mar;17(3):251-267.
4. Gloss D, Moxley RT 3rd, Ashwal S, Oskoui M. Practice guideline update summary: Corticosteroid treatment of Duchenne muscular dystrophy: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016 Feb 2;86(5):465-72.



**Created Date:** 08/07/24
**Effective Date:** 08/07/24
**Posted to Website:** 08/07/24
**Revision Date:**