HIGHMARK WHOLECARE

Updated: 05/2024
PARP Approved: 05/2024

Prior Authorization Criteria

Duvyzat (givinostat)

All requests for Duvyzat (givinostat) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Coverage may be provided with a diagnosis of Duchenne muscular dystrophy (DMD) and all of the following criteria is met:

- A confirmed diagnosis of DMD by submission of lab testing demonstrating mutation of the dystrophin gene
- Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature
- The member must have had baseline platelet counts and triglyceride lab work completed
- Member does not have any of the following clinically significant abnormal lab values:
    - QT c interval is > 500 ms or the change from baseline is > 60 ms
    - platelets count ≤ 150 x 10^9/L.
    - white blood cells ≤2.0 x 10^9/L
    - hemoglobin ≤8.0 g/dL
    - Fasting triglycerides >300 mg/dL
- The member will receive concurrent corticosteroids unless contraindicated or intolerant
- Must be prescribed by or in consultation with a neurologist who has experience in the treatment and ongoing management of DMD
- Member has documentation of a baseline evaluation, including a standardized assessment of motor function such as one of the following:
    - 4 Standard Stairs (4SC) Climb
    - Rise From Floor
    - Total North Star Ambulatory Assessment (NSAA)
    - Six-minute walk test (6MWT)
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
    - The member has documentation of an annual evaluation, including laboratory values since starting treatment, by a neurologist who has experience in the treatment and management of DMD
    - The member is receiving concurrent corticosteroids unless contraindicated or intolerant
    - Documentation that the member continues to benefit based on the prescriber's assessment.
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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DUVYZAT (GIVINOSTAT)
PRIOR AUTHORIZATION FORM- PAGE 1 of 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Wholecare Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Mon – Fri 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis: ☐ Duchenne muscular dystrophy (DMD) ☐ Other: _____
Was the diagnosis confirmed with lab testing demonstrating mutation of the dystrophin gene? ☐ Yes ☐ No
Is the member ambulatory? ☐ Yes ☐ No
Has the member had baseline platelet counts and triglyceride lab work completed? ☐ Yes ☐ No
Does the member have any of the following clinically significant abnormal lab values? (check all that apply)

- ☐ QTc interval is > 500 ms or the change from baseline is > 60 ms
- ☐ Platelets count ≤ 150 x 10^9/L.
- ☐ White blood cells ≤2.0 x 10^9/L
- ☐ Hemoglobin ≤8.0 g/dL
- ☐ Fasting triglycerides >300 mg/dL

Is the member taking concurrent corticosteroids unless contraindicated or intolerant? ☐ Yes ☐ No
Is there documentation the member has had a baseline evaluation including a standardized assessment of motor function such as one of the following (select those that apply):

- 4 Standard Stairs (4SC) Climb
- Rise From Floor
- Total North Star Ambulatory Assessment (NSAA)
- Six-minute walk test (6MWT)

REAUTHORIZATION

Does the member have documentation of an annual evaluation, including laboratory values since starting treatment, by a neurologist who has experience in the treatment and management of DMD? ☐ Yes ☐ No
Is the member receiving concurrent corticosteroids unless contraindicated or intolerant? ☐ Yes ☐ No
Is there documentation demonstrating the member is stable or shows clinically significant improvement in DMD symptoms, as demonstrated by stable or improved functional abilities test results compared to baseline or previous functional abilities test whichever is most recent (4SC, Rise from Floor, NSAA, 6MWT.)? Please submit documentation. ☐ Yes ☐ No

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DUVYZAT (GIVINOSTAT)
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2

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If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Mon – Fri 8:30am to 5:00pm

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date