AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Duvyzat™ (givinostat)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

Recommended Dosing:

Weight	Dosage	Oral Suspension Volume
10 kg to < 20 kg	22.2 mg twice daily	2.5 mL twice daily
20 kg to < 40 kg	31 mg twice daily	3.5 mL twice daily
40 kg to < 60 kg	44.3 mg twice daily	5 mL twice daily
≥ 60 kg	53.2 mg twice daily	6 mL twice daily

Quantity Limit: 12 mL per day

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 12 months

(Continued on next page)

- ❑ Member is 6 years of age or older
- ❑ Medication is prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy and/or neuromuscular disorders
- ❑ Member has a diagnosis of Duchenne Muscular Dystrophy confirmed by genetic testing with a confirmed pathogenic variant in the dystrophin gene **(must submit documentation)**
- ❑ Member is ambulatory
- ❑ Member has been on a stable systemic corticosteroid therapy regimen for at least 6 months **(verified by chart notes and/or pharmacy paid claims)**
- ❑ Member has documentation of a baseline evaluation, including a standardized assessment of motor function such as **ONE** of the following **(must submit documentation, check all that apply)**:
  - ❑ 4 Standard Stairs (4SC) Climb
  - ❑ Rise From Floor
  - ❑ Total North Star Ambulatory Assessment (NSAA)
  - ❑ Six-Minute Walk Test (6MWT)
- ❑ Member does **NOT** have any of the following clinically significant abnormal lab values:
  - 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

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet **ALL** initial authorization criteria
- ❑ Member is continuing to receive stable systemic corticosteroid therapy **(verified by chart notes and/or pharmacy paid claims)**
- ❑ Provider must submit documentation to confirm the member continues to benefit from therapy, as demonstrated by a stabilization or slowed decline on timed function tests (e.g., 4-stair climb, 6-minute walk test, time-to-rise) or in the North Star Ambulatory Assessment (NSAA) score

Medication being provided by Specialty Pharmacy – Proprium Rx

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****