Kaiser Permanente Health Plan of Mid-Atlantic States, Inc.
Duvyzat (givinostat) Prior Authorization (PA)
Pharmacy Benefits Prior Authorization Help Desk
Length of Authorizations: Initial- 6 months; Continuation- 12 months

Instructions:

This form is used by Kaiser Permanente and/or participating providers for coverage of **Duvyzat (givinostat)** for **Commercial, Exchange, FEHB (Federal),** and **MD Medicaid** plans. Please complete all sections, incomplete forms will delay processing. Fax this form back to Kaiser Permanente within 24 hours fax: 1-866-331-2104. If you have any questions or concerns, please call 1-866-331-2103. **Requests will not be considered unless this form is complete. The KP-MAS Formulary can be found at:** Pharmacy | Community Provider Portal | Kaiser Permanente

1 – Patient Information

Patient Name: _____ Kaiser Medical ID#: _____ Date of Birth: _____

2 – Provider Information

Provider Name: _____ Specialty: _____ NPI: _____

Provider Address: _____

Provider Phone #: _____Provider Fax #: _____

Do you have an approved provider referral number from Kaiser Permanente?
□ Yes – please provide your provider referral number here: _____

3 – Pharmacy Information

Pharmacy Name: _____ Pharmacy NPI: _____

Pharmacy Phone #_____ Pharmacy Fax #: _____

4 – Drug Therapy Requested

Drug 1: Name/Strength/Formulation: _____
Sig: _____
Drug 2: Name/Strength/Formulation: _____
Sig: _____

5– Diagnosis/Clinical Criteria

1. Is this request for initial or continuing therapy?
   □ Initial therapy □ Continuing therapy, start date: _____

2. Indicate the patient's diagnosis for the requested medication: _____

Clinical Criteria:

1. Is the prescriber a Neurologist, Pediatric Neurologist, Neuromuscular Specialist, or Medical Geneticist?
   □ No □ Yes

2. Is the patient male and ≥6 years of age?
   □ No □ Yes

3. Is the patient ambulatory?
   □ No □ Yes

4. Does the patient have a diagnosis of Duchenne Muscular Dystrophy (DMD) confirmed by genetic testing?
   □ No □ Yes

5. Is there documentation of DMD-characteristic clinical signs or symptoms present (e.g., proximal muscle weakness, Gowers' maneuver, elevated serum creatinine kinase level)?
   □ No □ Yes

6. Is the patient stable on a systemic steroid regimen (e.g., glucocorticoid, deflazacort, or vamorolone) before treatment initiation with Duvyzat (givinostat)?
   □ No □ Yes

7. Does the patient have ANY of the following reasons for NOT initiating therapy?
   - Current use of any DMD therapies (exon-skipping therapies) excluding systemic steroid regimen (e.g., glucocorticoid, deflazacort, or vamorolone). *Discontinue other therapies (excluding steroid regimen) prior to initiating givinostat*; or
   - Prior receipt of gene therapy for DMD as there is no evidence to support treatment using givinostat after receiving gene therapy; or
   - Platelet count $<150 \times 10^9$/L; or
   - Platelet or white blood cell count, or hemoglobin level below the lower limit of normal as givinostat can cause thrombocytopenia, hemoglobin, and neutropenia; or
   - Current or history of liver disease or impairment, including but not limited to a total bilirubin >1.5 x ULN, unless secondary to Gilbert disease or pattern consistent with Gilbert's; or
   - Inadequate renal function; or
   - Triglycerides >300 mg/dL in fasting condition; or
   - Positive test for hepatitis B surface antigen, hepatitis C antibody, or HIV; or
   - Baseline corrected QT interval, Friderica's correction >450 msec (as the mean of 3 consecutive readings 5 mins apart) or history of additional risk factors for torsardes de pointes (e.g., heart failure, hypokalemia, or family history of long QT syndrome); or
   - Sorbitol intolerance or sorbitol malabsorption, or have the hereditary form of fructose intolerance; or
   - Exposure to another investigational drug within the past three months

   □ No □ Yes

For continuation of therapy, please respond to <u>additional questions</u> below. New members who were initiated on therapy outside of Kaiser, who have not been reviewed previously, must meet all above Clinical Criteria.

1. Is there documented clinically significant benefit from the medication?
   □ No □ Yes

2. Has there been specialist follow-up since the last review?
   □ No □ Yes

3. Does the patient have any of the following criteria for discontinuation of therapy?

- Loss of ambulation
- Intolerance to medication, including significant GI adverse events despite dosage modification
- QTc interval is >500 ms or the change from baseline is >60 ms
- Hematologic abnormalities that worsen despite dose modification
- Elevated triglycerides despite adequate dietary intervention and dosage adjustment (i.e., fasting blood triglycerides >300 mg/dL)
- Non-adherence to medication or follow-up labs and assessments
- Other treatment for DMD therapy is initiated (excluding systemic steroid regimen)

□ No □ Yes

6 – Provider Sign-Off

Additional Information –

1. **Please submit chart notes/medical records for the patient that are applicable to this request.**
2. **If member has not tried preferred agent(s) please provide rationale/explanation and any additional supporting information that should be taken into consideration for the requested medication:**

_____

_____

_____

I certify that the information provided is accurate. Supporting documentation is available for State audits.

Provider Signature:	**Date:**