IOWA Health and Human Services

Request for Prior Authorization
Givinostat (Duvyzat)

FAX Completed Form To
1 (800) 574-2515
Provider Help Desk
1 (877) 776-1567

(PLEASE PRINT – ACCURACY IS IMPORTANT)

IA Medicaid Member ID #	Patient name	DOB
Patient address		
Provider NPI	Prescriber name	Phone
Prescriber address		Fax
Pharmacy name	Address	Phone

Prescriber must complete all information above. It must be legible, correct, and complete or form will be returned.

Pharmacy NPI	Pharmacy fax	NDC

Prior authorization (PA) is required for givinostat (Duvyzat). Payment for non-preferred agents will be considered when there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered for patients when the following criteria are met:

1. Patient has a diagnosis of Duchenne muscular dystrophy (DMD) with documented mutation of the dystrophin gene; and

2. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and

3. Is prescribed by or in consultation with a physician who specializes in treatment of DMD; and

4. Patient has documentation of a trial and inadequate response to an oral glucocorticoid for at least 6 months; and

5. Givinostat will be prescribed concurrently with an oral glucocorticoid; and

6. Patient's current body weight in kilograms (kg) is provided.

If criteria for coverage are met, initial requests will be given for 6 months. Additional authorization will be considered at 12-month intervals when the following criteria are met:

1. **Documentation of a positive response to therapy (e.g. improved strength, pulmonary function test, or functional assessments); and**
2. **Patient continues to receive concomitant glucocorticoid therapy; and**
3. **Patient's current body weight is kg is provided.**

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Non-Preferred

☐ Duvyzat

Strength	Usage Instructions	Quantity	Day's Supply
_____	_____	_____	_____

Diagnosis: _____

Documented mutation of the dystrophin gene? ☐ Yes (attach documentation) ☐ No

Patient's current weight in kg: _____ Date Obtained: _____

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Does prescriber specialize in treatment of DMD?

☐ Yes ☐ No If no, note consultation with physician who specializes in treatment of DMD:

Consultation date:_____ Physician name & phone:_____

Oral Glucocorticoid Trial: Drug name/dose:_____

Trial start date:_____ Trial end date:_____

Will givinostat be prescribed concurrently with an oral glucocorticoid?

☐ Yes Drug Name & Dose: _____

☐ No

Renewal Requests

Document positive response to therapy: _____

_____

_____

Is patient currently receiving concurrent glucocorticoid therapy:

☐ Yes Drug Name & Dose: _____

☐ No

Patient's current weight in kg: _____ Date Obtained: _____

Medical or contraindication reason to override trial requirements:_____

_____

Attach lab results and other documentation as necessary.

Prescriber signature (Must match prescriber listed above.)	Date of submission

IMPORTANT NOTE: *In evaluating requests for prior authorization, the consultant will consider the treatment from the standpoint of medical necessity only. If approval of this request is granted, this does not indicate that the member continues to be eligible for Medicaid. It is the responsibility of the provider who initiates the request for prior authorization to establish by inspection of the member's Medicaid eligibility card and, if necessary, by contact with the county Department of Health and Human Services, that the member continues to be eligible for Medicaid.*