

# Clinical Oversight Review Board (CORB) Criteria for Prescribing/ Criteria-Based Consultation (CBC) Criteria for Coverage

## Givinostat (Duvyzat)

### Notes:

- Quantity Limits: Yes
- ^ Clinical signs and symptoms may include: proximal muscle weakness, Gowers' maneuver, elevated serum creatinine kinase level
- \* Exon-skipping therapies include eteplirsen (Exondys 51), golodirsen (Vyondys 53), viltolarsen (Viltepso), and casimersen (Amopndys 45).

Non-Formulary **ginovostat (Duvyzat)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

**Initiation (new start) criteria, and criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously:** Non-Formulary **ginovostat (Duvyzat)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by Neurology or Genetics
- Patient has a diagnosis of Duchenne muscular dystrophy (DMD) confirmed by genetic testing
- Patient has DMD characteristic clinical signs or symptoms present<sup>^</sup>
- Patient is a male **AND** is 6 years old or older
- Patient is ambulatory
- Patient is on a stable systemic steroid regimen before treatment initiation
- Patient is NOT using other DMD exon-skipping therapies\*
- Patient has NOT received delandistrogene moxeparvovec (Elevidys) or other gene therapy for DMD
- Patient has an anti-adenovirus serotype rh74 (AAVrh74) total binding antibody titer of less than 1:400
- Patient has a corrected QT interval of 450 msec or less
- Patient has fasting triglyceride level of 300 mg/dL or less
- Labs are within normal limits for platelet count, white blood cell count, and hemoglobin level
- Patient has been reviewed by the Kaiser Permanente Interregional Consultative Physician Panel, with recommendation to use medication

**Continued use criteria for patients previously approved per the above criteria who are currently stable on the medication, and criteria for new members entering**

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All plans offered and underwritten by  
Kaiser Foundation Health Plan of the Northwest

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## Givinostat (Duvyzat)

**Kaiser Permanente already taking the medication who have not been reviewed previously:** Non-Formulary **ginovostat (Duvyzat)** will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by Neurology or Genetics
- Patient is a male **AND** is 6 years old or older
- Patient is ambulatory
- Patient is NOT using other DMD exon-skipping therapies\*
- Patient has NOT received delandistrogene moxeparvovec (Elevidys) or other gene therapy for DMD
- QTc interval is 500 ms or less, **AND** the change from baseline is less than 60 ms
- For new members only: Patient has been reviewed by the Kaiser Permanente Interregional Consultative Physician Panel, with recommendation to use medication