Applicable Drugs: Duvyzat (givinostat)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 11/18/2024

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

I. Diagnosis of Duchenne Muscular Dystrophy and the following criteria A through E are met:
   A. Documentation of genetic testing or muscle biopsy.
   B. Platelets are 150 X 10^9 L or greater.
   C. Patient must be ambulant without any devices.
   D. Documentation of inadequate treatment response, contraindication or intolerance of prednisone AND deflazacort for at least six months.
   E. Must be given in combination with corticosteroid.

II. Minimum age requirement: 6 years of age

III. The medication is prescribed by or in consultation with neurologist or Duchenne Muscular Dystrophy specialist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Prolonged QT interval if > 500 ms at baseline
- Platelets are <150 X 10^9 L at baseline
- Co-administration or prior use of gene therapy or exon skipping therapy

OTHER CRITERIA

- Baseline platelets and triglycerides obtained
- Baseline QT interval obtained
- Dose reduction if following are met while on treatment
  - platelets <150 X 10^9 L or greater verified in two assessments one week apart

- Moderate or severe diarrhea
- Fasting triglycerides >300 mg/dL verified by two assessments one week apart

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 10 to <20 kg: 22.2 mg twice daily: 1 bottle (8.86 mg/mL per 140 mL)/27 days
- 20 to <40 kg: 31 mg twice daily: 2 bottles/40 days
- 40 to <60 kg: 44.3 mg twice daily: 3 bottles/42 days
- >60 kg: 53.2 mg twice daily: 3 bottles/34 days

APPROVAL LENGTH

- **Authorization:** 12 months
- **Re-Authorization:** An updated letter of medical necessity or progress notes confirming the current medical necessity criteria are met and showing the medication is effective. Document tolerating therapy with platelets, fasting triglycerides lab values, benefit of treatment documented or clinical benefit through improved strength, pulmonary function test], or functional assessments [4SC, 6MWT, 10MWT, NSAA])

APPENDIX

REFERENCES

1. Duvyzat. Prescribing Information. ITF Therapeutics, LLC; March 2024. Accessed 10/11/2024. https://www.duvyzat.com/PI
2. Mercuri E, Vilchez JJ, Boespflug-Tanguy O, et al. EPIDYS Study Group. Safety and efficacy of givinostat in boys with Duchenne muscular dystrophy (EPIDYS): a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial. Lancet Neurol. 2024 Apr;23(4):393-403. 10.1016/S1474-4422(24)00036-X
3. Gloss D, Moxley RT III, Ashwal S, Oskoui M. Practice guideline update summary: corticosteroid treatment of Duchenne muscular dystrophy—report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2016;86(5):465-472. doi.org/10.1212/wnl.0000000000002337
4. Lamb YN. Givinostat: First Approval. Drugs. 2024;84:849-856. doi.org/10.1007/s40265-024-02052-1