Effective Date: 11/01/2024
Reviewed: 8/2024 Scope: Medicaid

DUVYZAT (givinostat)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Duvyzat is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Duchenne Muscular Dystrophy (DMD)
Authorization of 6 months may be granted for treatment of DMD when all of the following criteria are met:

A. This medication is prescribed by or in consultation with a neurologist who specializes in the treatment of Duchenne muscular dystrophy (DMD).
B. Member is 6 years of age or older.
C. Documentation that the diagnosis of DMD was confirmed by either of the following:
    1. Genetic testing documenting a mutation in the DMD gene.
    2. Muscle biopsy documenting absent dystrophin.
D. Documentation that member has clinical signs and symptoms of DMD (e.g., proximal muscle weakness, Gower's maneuver, elevated serum creatine kinase level).
E. Documentation that member is ambulatory (e.g., 4-stair climb [4SC] ≤ 8 seconds and time to rise from floor between ≥3 and <10 seconds)
F. The requested medication will be used in combination with a systemic corticosteroid (e.g., prednisone, prednisolone) and must be on a stable dose for a minimum of 6 months, unless contraindicated or not tolerated.
G. Baseline documentation of one or more of the following:
    a. Dystrophin level
    b. Timed function tests (e.g., time to stand [TTSTAND], 6-minute walk test [6MWT], time to run/walk 10 meters [TTRW], time to climb 4 stairs [TTCLIMB] or 4-stair climb [4SC], etc.)
    c. Upper limb function (ULM) test
    d. North Star Ambulatory Assessment (NSAA) score
    e. Forced Vital Capacity (FVC) percent predicted

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for members requesting continuation of therapy when all of the following criteria are met:

A. The member meets all initial authorization criteria.
B. Documentation that the member remains ambulatory (e.g., able to walk with or without assistance, not wheelchair dependent).
C. Documentation that the member is receiving a clinical benefit from Duvyzat therapy compared to pretreatment baseline in one or more of the following (not all-inclusive):
    1. Increase in dystrophin level
    2. Stability, improvement, or slowed rate of decline in timed function tests (e.g., time to stand [TTSTAND], 6-minute walk test [6MWT], time to run/walk 10 meters [TTRW], time to climb 4 stairs [TTCLIMB] or 4-stair climb [4SC])
    3. Stability, improvement, or slowed rate of decline in upper limb function (ULM) test
    4. Stability, improvement, or slowed rate of decline in North Star Ambulatory Assessment (NSAA) score
    5. Stability, improvement, or slowed rate of decline in FVC% predicted
    6. Improvement in quality of life

IV. QUANTITY LIMIT

Duvyzat has a quantity limit of 106.4mg/12ml per day.

V. REFERENCES

1. Duvyzat [package insert]. Concord, MA: ITF Therapeutics LLC; March 2024.