CVS Caremark®

| Reference number(s) |
| --- |
| 6437-A |

# Specialty Guideline Management Duvyzat

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Duvyzat | givinostat |

## 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 Indications1

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.

## Documentation

Submission of the following information is necessary to initiate the prior authorization review:

### Initial Requests

* Laboratory confirmation of the DMD diagnosis by genetic testing or muscle biopsy.

### Continuation Requests

* Chart notes and/or medical records documenting a response to therapy.

## Prescriber Specialties

This medication must be prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy (DMD).

## Coverage Criteria

### Duchenne Muscular Dystrophy (DMD)1

Authorization of 6 months may be granted for treatment of DMD when all of the following criteria are met:

* Member is 6 years of age or older.
* The diagnosis of DMD was confirmed by either of the following:
  + Genetic testing documenting a mutation in the DMD gene.
  + Muscle biopsy documenting absent dystrophin.
* Member has clinical signs and symptoms of DMD (e.g., proximal muscle weakness, Gower’s maneuver, elevated serum creatine kinase level).
* Member is ambulant.
* The requested medication will be used in combination with a corticosteroid (e.g., prednisone) unless contraindicated or not tolerated.

## Continuation of Therapy

Authorization of 12 months may be granted for members requesting continuation of therapy when the member has demonstrated a response to therapy as evidenced by remaining ambulatory (e.g., able to walk with or without assistance, not wheelchair dependent).

## References

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