Pharmacy Drug Policy Checklist

POLICY NAME	Duvyzat (givinostat)	POLICY #	3257P

Criteria

Coverage Criteria

- ☐ **1.1** Diagnosis of Duchenne Muscular Dystrophy confirmed by one of the following:
  - Genetic testing documenting a mutation in the dystrophin (DMD) gene
  - Muscle biopsy documenting lack of muscle dystrophin
- ☐ **1.2** Age 6 years or older
- ☐ **1.3** Prescribed by or in consultation with a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders
- ☐ **1.4** Patient is currently ambulatory (able to walk independently)
- ☐ **1.5** Documented concurrent use (for at least the last 6 months) of prednisone unless member has experienced at least one of the following significant intolerable adverse effects (AE)
  - Cushingoid appearance
  - Central (truncal) obesity
  - Undesirable weight gain defined as a 10% of body weight gain increase over a 6-month period
  - Diabetes and/or hypertension that is difficult to manage
  - Severe behavioral AE that would require a prednisone dose reduction
  - Clinically significant growth stunting as evidenced by decline in mean height percentile from baseline, decrease in growth velocity or decrease in serum bone formation biomarkers
- ☐ **1.6** If member is unable to tolerate prednisone, concurrent use of generic deflazacort is required
- ☐ **1.7** Documentation of a baseline motor milestone score from one of the following assessments:
  - 4-stair climb (4SC)
  - North Star Ambulatory Assessment (NSAA)
  - 6-minute walk test (6MWT)
  - Time to stand test (TTSTAND)
- ☐ **1.8** Review of clinical documentation and confirming that patient has met all of the above requirements for treatment completed by both a pharmacist and medical director

Exclusion Criteria – Any of the following prevents coverage

- ☐ **2.1** Duvyzat will not be covered in combination with or in patients who have previously received any

☐ **2.2** dystrophin restoration product (such as Elevidys)