

POLICY NAME	Emflaza (deflazacort)	POLICY #	2607P
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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 2 years of age 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** Documented trial of prednisone for 6 months and documentation that the member 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 adverse effects 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
- ☐ **1.5** Documentation of a baseline motor milestone score from one of the following assessments:
 - 6-Minute Walk Test (6MWT)
 - North Star Ambulatory Assessment (NSAA)
 - Motor Function Measure (MFM)
 - Hammersmith Functional Motor Scale (HFMS)
- ☐ **1.6** Coverage of brand Emflaza requires a documented allergic reaction to generic deflazacort