

Emflaza (deflazacort)

POLICY

I. CRITERIA FOR APPROVAL

An authorization of 6 months may be granted for the treatment of Duchenne Muscular Dystrophy if:

- A. Member is at least 2 years of age **AND**
- B. Therapy is prescribed by or given in consultation with a neurologist **AND**
- C. Member has had intolerable side effects to at least a three month trial of maximal Prednisone dosing
- D. Baseline Documentation of One or More of the following
 - a. Dystrophin level
 - b. 6-minute walk test (6MWT) or other timed function tests (e.g., time to stand [TTSTAND], time to run/walk 10 meters [TTRW], time to climb 4 stairs [TTCLIMB])
 - c. Upper limb function (ULM) test
 - d. North Star Ambulatory Assessment (NSAA)
 - e. Forced Vital Capacity (FVC) percent predicted

II. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for all members (including new members) who meet both of the following:

Patient has responded to therapy compared to pretreatment baseline in one or more of the following (not all-inclusive):

- a. Increase in dystrophin level
- b. Stability, improvement, or slowed rate of decline in 6MWT or other timed function tests (e.g., time to stand [TTSTAND], time to run/walk 10 meters [TTRW], time to climb 4 stairs [TTCLIMB])
- c. Stability, improvement, or slowed rate of decline in ULM test
- d. Stability, improvement, or slowed rate of decline in NSAA
- e. Stability, improvement, or slowed rate of decline in FVC% predicted
- f. Improvement in quality of life

III. QUANTITY LIMIT

- Emflaza Suspension: 1.8mL per 30 days
- Emflaza 18mg, 30mg, and 36mg Tablet: 1 Tablet per day
- Emflaza 6mg Tablet: 2 Tablets per day

IV. COVERAGE DURATION

- 6 months- initial
- 12 months- continuation