Effective Date: 02/01/2021
Reviewed: 11/2020, 5/2021 Scope: Medicaid

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
B. Emflaza is prescribed by or given in consultation with a neurologist
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 based on documentation of 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

- Initial: 6 months
- Renewal: 12 months