Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

Emflaza® (*deflazacort*) PA CRITERIA:

Select the diagnosis:

☐Duchenne muscular dystrophy (DMD)

ICD-10 code(s):_____

EMFLAZA is a corticosteroid indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older.

Prior authorization is required for EMFLAZA (deflazacort). Prior authorization approval will be considered when **ALL** of the following criteria are met:

Initial authorization: 6 months

1. Patient is 2 years of age or older; **AND**

2. Has a diagnosis of Duchenne muscular dystrophy (DMD) confirmed by one of the following (documentation required); **AND**

- Genetic testing (e.g., dystrophin deletion or duplication mutation found);
- If genetic studies are negative (i.e., no mutation identified), positive muscle biopsy (e.g., absence of dystrophin protein)

3. Onset of weakness before age 2 years; **AND**

4. Prednisone trial* of > 6 months, **AND** have one of the following adverse events as a result of prednisone use; **AND**

5. Experienced failure of ≥ 6-month trial* of prednisone within the past 12 months; **AND**

- Failure is defined as a lack of efficacy, allergy, contraindication to, or intolerable adverse effects as defined below
    - Intolerable adverse effects include: (documentation required)
        - Cushingoid appearance; **OR**
        - Central (truncal) obesity; **OR**
        - Undesirable weight gain defined as a ≥ 10% of body weight gain increase over a 6-month period; **OR**
        - Diabetes and/or hypertension that is difficult to manage per the prescribing physician; **OR**
        - Severe behavioral/psychiatric effects that require a dosage reduction

6. Emflaza dose does not exceed 0.9 mg/kg/day.

*The required trials may be overridden when documented evidence that use of these agents would be medically contraindicated.

<u>Reauthorization:</u> 12 months with evidence of appropriate clinical response to therapy

1. Authorization may be granted when all of the following criteria are met:
    - Initial authorization criteria are still being met
    - Documentation must be submitted that shows the beneficiary is receiving clinical benefit from Emflaza™ therapy, such as:
        - Stabilization, maintenance or improvement of muscle strength or pulmonary function,
          OR
        - Improvement in motor milestone assessment scores from baseline testing,
          OR
        - Improvement of motor function must be superior relative to that projected for the natural course of Duchenne Muscular Dystrophy (slowing of decline or slowing of progression).

Emflaza Dosing:

- Ages ≥ 2 years: Oral dose (tablet or suspension) of approximately 0.9 mg/kg/day

Formulations:

- Tablets: 6 mg, 18 mg, 30 mg, and 36 mg
- Oral suspension: 22.75 mg/mL

Monitor:

- for elevated blood pressure and sodium, and for decreased potassium levels
- for decreases in bone mineral density with chronic use
- for increased intraocular pressure if EMFLAZA is continued for more than 6 weeks