Commercial/Healthcare Exchange PA Criteria

Effective: August 16, 2017

Prior Authorization: Emflaza

Products Affected: Emflaza (deflazacort) oral tablets, Emflaza (deflazacort) oral suspension

Medication Description: Deflazacort is a heterocyclic glucocorticoid prodrug belonging to the class of oxazoline steroids, whose active metabolite, 21-desDFZ, acts through the glucocorticoid receptor to exert anti-inflammatory and immunosuppressive effects. The precise mechanism by which deflazacort exerts its therapeutic effects in patients with Duchenne muscular dystrophy is unknown.[1,2]

Covered Uses: Treatment of Duchenne muscular dystrophy (DMD) in patients 5 years of age and older.

Exclusion Criteria: N/A

Required Medical Information:

1. Diagnosis
2. Previous therapies tried and failed

Age Restrictions: 2 years of age and older.

Prescriber Restrictions: Prescribed by, or in consultation with a neurologist.

Coverage Duration: 6 months

Other Criteria:

For initiation of treatment, the patient must meet the following:

A. Patient has meaningful voluntary motor function (e.g., patient is able to speak, manipulate objects using upper extremities, ambulate); AND
B. Patient is receiving physical therapy; AND
C. Patient has received a trial of prednisone and experienced one of the following unacceptable adverse reactions directly attributable to previous therapy with prednisone:
    a. Patient has manifested significant behavioral changes negatively impacting function at school, home, day care; OR
    b. Patient has experienced significant weight gain (e.g., crossing 2 percentiles and/or reaching 98th percentile for age and sex).

For continuation of treatment, patient needs to meet the following:

A. Patient retains meaningful voluntary motor function (e.g., patient is able to speak, manipulate objects using upper extremities, ambulate); AND
B. Patient continues to receive physical therapy; AND
C. Patient has received benefit from therapy (i.e. stability or slowing of decline in motor function, respiratory function, sequelae related to diminished strength of stabilizing musculature (e.g. scoliosis); AND
D. Patient demonstrates a decrease or reduction in adverse reactions directly attributable to previous therapy with prednisone.

References:

1. Product Information: EMFLAZA(TM) oral tablets, suspension, deflazacort oral tablets, suspension. Marathon Pharmaceuticals LLC (per FDA), Northbrook, IL, 2017.
2. Griggs RC, Miller JP, Greenberg CR, et al. Efficacy and safety of deflazacort vs prednisone and placebo for Duchenne muscular dystrophy. Neurology. 2016 Nov 15;87(20):2123-2131. doi: 10.1212/WNL.0000000000003217. Accessed March 13, 2017.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	4/14/2017
2	Policy Update	Updated Policy to match FDA Label (change from 5 years to 2 years)	Age Restrictions, Covered Uses	6/18/2019
3	Annual Review	N/A	N/A	3/30/2020