PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	**Emflaza (deflazacort)**
BILLING CODE	**Must use valid NDC code**
BENEFIT TYPE	**Pharmacy**
SITE OF SERVICE ALLOWED	**Home**
COVERAGE REQUIREMENTS	**Prior Authorization Required (Non-Preferred Product)** **Alternative preferred product includes Prednisone** **QUANTITY LIMIT— 6 mg tablets - 60 per 30 days** **18 mg tablets - 30 per 30 days** **30 mg tablets - 90 per 30 days** **36 mg tablets - 90 per 30 days** **22.75 mg/mL suspension – 9 bottles (117 mL) per 30 days**
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	**Click Here**

Emflaza (deflazacort) is a non-preferred product and will only be considered for coverage under the pharmacy benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

DUCHENNE MUSCULAR DYSTROPHY (DMD)

For initial authorization:

1. **Member must be 2 years of age or older; AND**
2. **Medication is being prescribed by or in consultation with a DMD specialist (i.e., neurologist); AND**
3. **Member has a confirmed diagnosis of Duchenne Muscular Dystrophy (DMD) with evidence of dystrophin gene mutation (genetic testing result required); AND**
4. **Member has documented trial and failure of prednisone for at least 6 months.**
5. **Dosage allowed: 0.9 mg/kg/day once daily.**

If member meets all the requirements listed above, the medication will be approved for 3 months.

For reauthorization:

1. **Member must be in compliance with all other initial criteria; AND**
2. Chart notes must show stability or slowed rate of decline of the member's **motor function and muscle strength.**

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Emflaza (deflazacort) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
05/15/2017	New policy for Emflaza created.
07/25/2019	Age coverage expanded from 5 years of age and older to 2 years of age and older.

01/15/2021	Added quantity limit for oral suspension. Removed serum CK requirement. Removed onset of weakness before 5 years of age, added must have genetic testing to confirm dystrophin gene mutation. Removed MRC score requirement in initial and reauth. Added that member must show stability or slowed rate of decline of motor function/muscle strength for reauth.

References:

1. Emflaza [package insert]. Northbrook, IL; Marathon Pharmaceuticals, LLC: June, 2019.
2. Griggs RC, Miller JP, Greenberg CR, et al. Efficacy and safety of deflazacort vs prednisone and placebo for Duchenne muscular dystrophy. Neurology. 2016;87(20):2123-2131.
3. McDonald CM, Henricson EK, Abresch RT, et al. Long-term effects of glucocorticoids on function, quality of life, and survival in patients with Duchenne muscular dystrophy: a prospective cohort study. Lancet. 2018;391(10119):451-461.
4. Bello L, Gordish-Dressman H, Morgenroth LP, et al. Prednisone/prednisolone and deflazacort regimens in the CINRG Duchenne Natural History Study. Neurology. 2015;85(12):1048-1055.
5. Gloss D, Moxley RT 3rd, Ashwal S, Oskoui M. Practice guideline update summary: Corticosteroid treatment of Duchenne muscular dystrophy: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016;86(5):465-472.
6. Birnkrant DJ, Bushby K, Bann CM, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management [published correction appears in Lancet Neurol. 2018 Apr 4;:]. Lancet Neurol. 2018;17(3):251-267.
7. Ciafaloni E, Kumar A, Liu K, et al. Age at onset of first signs or symptoms predicts age at loss of ambulation in Duchenne and Becker Muscular Dystrophy: Data from the MD STARnet. J Pediatr Rehabil Med. 2016;9(1):5-11.

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