

PHARMACY POLICY STATEMENT Indiana 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 <b>NOT</b> MEDICALLY NECESSARY	Click Here

Emflaza (deflazacort) is a **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. Member has diagnosis of Duchene Muscular Dystrophy
- 3. 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.



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	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.	
	11/18/2021	Removed all but diagnosis and age requirement	

## 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.

E01/01/202201/01/2022 Revised date: 11/18/2021