



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2018 P 2127-2 |
| Program | Prior Authorization/Medical Necessity |
| Medication | Emflaza™ (deflazacort) |
| P&T Approval Date | 5/2017, 10/2018 |
| Effective Date | 2/1/2019; Oxford only: 2/1/2019 |

1. Background:

Emflaza™ (deflazacort) is a corticosteroid indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 5 years of age and older.¹

In a recent report from Guideline Development Subcommittee of the American Academy of Neurology, in regard to selection of prednisone versus deflazacort in the treatment of DMD, the following statement is made: “prednisone and deflazacort are possibly equally effective for improving motor function in patients with DMD (2 Class III studies). There is insufficient evidence to directly compare the effectiveness of prednisone vs deflazacort in cardiac function in patients with DMD (1 Class III study of a combined cohort).² The UnitedHealthcare Pharmacy and Therapeutics committee has determined that Emflaza is Therapeutically Equivalent to prednisone in the treatment of DMD.

2. Coverage Criteria:

A. Duchenne Muscular Dystrophy

1. Published clinical evidence shows Emflaza is likely to produce equivalent therapeutic results as other available corticosteroids (e.g. prednisone); therefore, Emflaza is **not medically necessary** for treatment of Duchenne muscular dystrophy.

3. Additional Clinical Rules:

N/A

4. References:

1. Emflaza [package insert]. PTC Therapeutics Inc. June 2017.
2. Gloss D, Moxley III R, Ashwal S, et. al. 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;465-472.



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| Program | Prior Authorization/Medical Necessity - Emflaza™ (deflazacort) |
| Change Control | |
| 5/2017 | New program |
| 10/2018 | Annual review. No changes to criteria. Updated references. |