UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Emflaza

Program	Prior Authorization/Medical Necessity
Medication	Emflaza™ (deflazacort)
Markets in Scope	California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	5/2017
Pharmacy and Therapeutics Approval Date	10/2020
Effective Date	12/2020

1. Background:

Emflaza (deflazacort) is a corticosteroid indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 2 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. <u>Duchenne Muscular Dystrophy</u>

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

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Emflaza [package insert]. South Plainfield, NJ: PTC Therapeutics Inc.;July 2020.
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.

Program	Prior Authorization/Medical Necessity - Emflaza™ (deflazacort)
Change Control	
5/2017	New Program
10/2018	Annual review. No changes to criteria. Updated references.
10/2019	Annual review. Updated background to reflect expanded age indication. Updated references.
10/2020	Annual review with no changes to clinical coverage criteria. Updated references. Added Additional Clinical Rules Section,