UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3095-8
Program	Step Therapy
Medication	Emflaza® (deflazacort)*
P&T Approval Date	5/2017, 10/2018, 10/2019, 10/2020, 10/2021, 10/2022, 10/2023, 10/2024
Effective Date	1/1/2025

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]

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try prednisone or prednisolone prior to receiving coverage for Emflaza.

2. Coverage Criteria[a]:

A. Duchenne Muscular Dystrophy

1. Emflaza* will be approved based on **both** of the following criteria:

   a. Diagnosis of Duchenne muscular dystrophy

   -AND-

   b. Patient has a history of failure, contraindication, or intolerance to prednisone or prednisolone

Authorization will be issued for 12 months.

B. Other Diagnoses

1. Emflaza* will be approved.

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

*Emflaza is typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

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, Medical Necessity and/or Notification may apply

4. References:

1. Emflaza [package insert]. Warren, NJ: PTC Therapeutics, Inc.; May 2024.
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. 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	Step Therapy – Emflaza (deflazacort)
Change Control	
Date	Change
5/2017	New program.
10/2018	Annual review. No changes to criteria. Updated references.
10/2019	Annual review. Updated background updating indication in patients 2 years and older. Updated reference.
10/2020	Annual review with no changes to clinical coverage criteria. Updated references.
10/2021	Annual review with no changes to clinical coverage criteria. Updated references.
10/2022	Annual review. Updated criteria to standard Step Therapy format which includes section for other diagnoses.
10/2023	Annual review with no changes to coverage criteria.
10/2024	Annual review with no changes to coverage criteria. Updated background, added exclusion footnote and updated references.