

Program Number	2025 P 2127-10
Program	Prior Authorization/Medical Necessity
Medication	Emflaza® (deflazacort)*, Jaythari (deflazacort)*, Kymbee (deflazacort)*, and Pyquvi (deflazacort)*
P&T Approval Date	5/2017, 10/2018, 10/2019, 10/2020, 10/2021, 10/2022, 10/2023, 10/2024, 10/2025, 12/2025
Effective Date	3/1/2026

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

Jaythari (deflazacort)*, Kymbee (deflazacort)*, and Pyquvi (deflazacort)* are corticosteroids indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 5 years of age and older.²⁻³

The UnitedHealthcare Pharmacy and Therapeutics Committee has determined that Emflaza is Therapeutically Equivalent to prednisone in the treatment of DMD. While adverse effect profiles may differ among glucocorticoids, deflazacort does not offer a clear advantage over other glucocorticoids for DMD with respect to efficacy and overall safety.⁴⁻⁷

2. Coverage Criteria^a:

A. Duchenne Muscular Dystrophy

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

^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, Jaythari, Kymbee, and Pyquvi are 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.

4. References:

1. Emflaza [package insert]. Warren, NJ: PTC Therapeutics Inc.; May 2024.

2. Jaythari [package insert]. Pennington, NJ: Zydu Pharmaceuticals, Inc.; October 2024.
3. Kymbee [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, LLC.; July 2025.
4. Pyquvi [package insert]. Piscataway, NJ: Aucta Pharmaceuticals, Inc.; February 2025.
5. 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.
6. Guglieri M, Bushby K, McDermott MP, et al. Effect of Different Corticosteroid Dosing Regimens on Clinical Outcomes in Boys With Duchenne Muscular Dystrophy: A Randomized Clinical Trial. *JAMA*. 2022;327(15):1456-1468.
7. Biggar WD, Skalsky A, McDonald CM. Comparing Deflazacort and Prednisone in Duchenne Muscular Dystrophy. *J Neuromuscul Dis*. 2022;9(4):463-476.
8. 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. *Lancet Neurol*. 2018;17(3):251-267.

Program	Prior Authorization/Medical Necessity - Deflazacort
Change Control	
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 with no changes to clinical coverage criteria.
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.
10/2025	Annual review with no changes to criteria. Updated background and references.
12/2025	Added Jaythari, Kymbee, and Pyquvi to program.