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| <b>Clinical Policy Title:</b>              | deflazacort                             |
| <b>Policy Number:</b>                      | RxA.364                                 |
| <b>Drug(s) Applied:</b>                    | Deflazacort, Agamree, Jaythari, Pyquvi  |
| <b>Original Policy Date:</b>               | 03/06/2020                              |
| <b>Last Review Date:</b>                   | 12/11/2025                              |
| <b>Line of Business Policy Applies to:</b> | All lines of business (except Medicare) |

## Criteria

### I. Initial Approval Criteria

#### A. Duchenne Muscular Dystrophy (must meet all):

1. Diagnosis of DMD confirmed by one of the following (a or b):
  - a. Genetic testing confirming dystrophin deletion or duplication mutation;
  - b. Muscle biopsy confirming absence of dystrophin protein
2. Trial and failure of a  $\geq$  6-month trial of prednisone or prednisolone, unless contraindicated or clinically significant adverse effects are experienced.

#### Initial Approval duration

**All Lines of Business (except Medicare):** 12 months

### II. Continued Therapy Approval

#### A. Duchenne Muscular Dystrophy (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

#### Approval duration

**All Lines of Business (except Medicare):** 12 months

## References

1. Gloss D, Moxley RT, 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. doi:10.1212/WNL.0000000000002337. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4773944/>. Accessed August 26<sup>th</sup>, 2024.
2. 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: 251-267. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5869704/>. Accessed August 26<sup>th</sup>, 2024.

| Review/Revision History  | Review/Revision Date | P&T Approval Date |
|--|----------------------|-------------------|
| Policy established.  | 01/2020              | 03/06/2020        |
| Policy updated. <ol style="list-style-type: none"> <li>1. Formatting updated.</li> <li>2. Continued therapy criteria updated.</li> </ol> | 07/01/2020           | 09/14/2020        |

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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| 3. References updated.   |            |            |
| <p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>Continued Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...".</li> <li>References were reviewed and updated.</li> </ol> | 05/29/2021 | 09/14/2021 |
| <p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>References were reviewed and updated.</li> </ol>  | 3/23/2022  | 07/18/2022 |
| <p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>References were reviewed and updated.</li> </ol>  | 04/18/2023 | 07/13/2023 |
| Policy was reviewed.   | 10/19/2023 | 10/19/2023 |
| <p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>Removed age and dosing.</li> <li>Added prednisolone as another drug option. Updated continued therapy criteria.</li> </ol>  | 04/1/2024  | 04/01/2024 |
| <p>Policy was reviewed.</p> <ol style="list-style-type: none"> <li>Removed Emflaza from Drug(s) Applied.</li> <li>Added generic to Drug(s) Applied for clarification.</li> <li>Updated lookback period to 120 days for continued therapy approval.</li> </ol>        | 8/26/2024  | 09/12/2024 |
| <p>Policy was reviewed.</p> <ol style="list-style-type: none"> <li>Added Agamree to policy.</li> </ol>   | 8/25/2025  | N/A        |
| <p>Policy was reviewed.</p> <ol style="list-style-type: none"> <li>Added Jaythari and Pyquvi to policy.</li> </ol>   | 9/23/25    | N/A        |
| Policy was reviewed.   | 12/11/2025 | 12/11/2025 |