



PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Muscular Dystrophy – Deflazacort Preferred Specialty Management Policy

- Emflaza[®] (deflazacort tablets and oral suspension – PTC Therapeutics, generic)
- Jaythari[™] (deflazacort tablets and oral suspension – Zydus)
- Kymbee[™] (deflazacort tablets – Upsher-Smith)
- Pyquvi[™] (deflazacort oral suspension – Aucta)

REVIEW DATE: 01/21/2026

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Deflazacort is a corticosteroid indicated for the treatment of **Duchenne muscular dystrophy (DMD)** in patients ≥ 2 years of age.¹ The efficacy and safety of deflazacort have not been established in patients < 2 years of age. Jaythari, Kymbee, and Pyquvi are indicated for DMD in patients ≥ 5 years of age.²⁻⁵ Due to Emflaza oral suspension marketing exclusivity rights, these agents are not approved in patients < 5 years of age.

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of the Preferred Product. For all medications (Preferred and Non-Preferred), the patient is required to meet the standard *Muscular Dystrophy – Deflazacort Prior Authorization Policy* criteria. The program also directs the patient to try one of the Preferred Products prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). If the patient meets the standard *Muscular Dystrophy – Deflazacort Prior Authorization Policy* criteria but has not tried a Preferred Product, approval for a Preferred Product will be authorized. All approvals are provided for 1 year.

Documentation: Documentation is required for previous use of the preferred products as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information. All documentation must include patient-specific identifying information.

Preferred Products: generic deflazacort tablets, Jaythari tablets, Kymbee

Non-Preferred Products: Emflaza tablets, Emflaza oral suspension, generic deflazacort oral suspension, Jaythari oral suspension, Pyquvi oral suspension

Muscular Dystrophy – Deflazacort Preferred Specialty Management Policy non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.

NON-PREFERRED PRODUCT EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Emflaza tablets	<ol style="list-style-type: none"> 1. Approve for 1 year if the patient meets ALL of the following (A, B, <u>and</u> C): <ol style="list-style-type: none"> A) Patient meets the standard <i>Muscular Dystrophy – Deflazacort Prior Authorization Policy</i> criteria; AND B) Patient has tried one of generic deflazacort tablets, Jaythari tablets, or Kymbee [documentation required]; AND C) Patient cannot take the Preferred Products due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and bioequivalent generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction [documentation required]. 2. If the patient has met the standard <i>Muscular Dystrophy – Deflazacort Prior Authorization Policy</i> criteria (1A), but has <u>not</u> met exception criteria (1B) and/or (1C) above for brand Emflaza tablets: approve the Preferred Products.
Emflaza oral suspension, Deflazacort oral suspension (generic), Jaythari oral suspension, Pyquvi oral suspension	<ol style="list-style-type: none"> 1. Approve for 1 year if the patient meets BOTH of the following (A <u>and</u> B): <ol style="list-style-type: none"> A) Patient meets the standard <i>Muscular Dystrophy – Deflazacort Prior Authorization Policy</i> criteria; AND B) Patient meets ONE of the following (i <u>or</u> ii): <ol style="list-style-type: none"> i. Patient has tried one of generic deflazacort tablets, Jaythari tablets, or Kymbee [documentation required]; OR ii. Patient cannot swallow or has difficulty swallowing tablets. 2. If the patient has met the standard <i>Muscular Dystrophy – Deflazacort Prior Authorization Policy</i> criteria (1A), but has <u>not</u> met exception criteria (1B) above: approve the Preferred Products.

REFERENCES

1. Emflaza™ tablets [prescribing information]. South Plainfield, NJ: PTC Therapeutics; June 2024.
2. Jaythari™ tablets [prescribing information]. Pennington, NJ: Zydus Pharmaceuticals; May 2025.
3. Kymbee™ tablets [prescribing information]. Maple Grove, MN: Upsher-Smith Laboratories; July 2025.
4. Pyquvi™ oral suspension [prescribing information]. Piscataway, NJ: Aucta Pharmaceuticals; February 2025.
5. Jaythari™ oral suspension [prescribing information]. Pennington, NJ: Zydus Pharmaceuticals; November 2025

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	Effective 05/20/2024	03/06/2024
Selected Revision	Added generic deflazacort oral suspension to Non-Preferred Products. Added exception criteria as well.	07/03/2024
Annual Revision	No criteria changes.	03/05/2025
Selected Revision	Added Pyquvi oral suspension to Non-Preferred Products and added new exception criteria. Added Jaythari tablets and Kymbee to the Preferred Products. Updated exception criteria to include Jaythari tablets and Kymbee in the Preferred Products.	12/17/2025
Early Annual Revision	Added Jaythari oral suspension to Non-Preferred products with the same exception as the other Non-Preferred oral suspension products.	01/21/2026

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