PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Muscular Dystrophy – Deflazacort Preferred Specialty Management Policy

- Emflaza® (deflazacort tablets and oral suspension – PTC Therapeutics, generic for tablets only)

REVIEW DATE: 03/06/2024; Effective 05/20/2024

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 AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.

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 the Preferred Product 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 use of Emflaza tablets or oral suspension 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.

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

Muscular Dystrophy – Deflazacort 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	**1.** Approve for 1 year if the patient meets ALL of the following (A, B, and C): **A)** Patient meets the standard *Muscular Dystrophy – Deflazacort Prior Authorization Policy* criteria; AND **B)** Patient has tried generic deflazacort tablets **[documentation required]**; AND **C)** Patient cannot take deflazacort tablets 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 *Muscular Dystrophy – Deflazacort Prior Authorization Policy* criteria (1A), but has not met exception criteria (1B) and/or (1C) above for brand Emflaza tablets: approve generic deflazacort tablets.
Emflaza Oral Suspension	**1.** Approve for 1 year if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Muscular Dystrophy – Deflazacort Prior Authorization Policy* criteria; AND **B)** Patient meets ONE of the following (i or ii): **i.** Patient has tried generic deflazacort tablets **[documentation required]**; OR **ii.** Patient cannot swallow or has difficulty swallowing tablets. **2.** If the patient has met the standard Muscular Dystrophy – Deflazacort Prior Authorization Policy criteria (1A), but has not met exception criteria (1B) above for brand Emflaza Oral Suspension: approve generic deflazacort tablets.

REFERENCES

1. Emflaza™ tablets [prescribing information]. South Plainfield, NJ: PTC Therapeutics; June 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	Effective 05/20/2024	03/06/2024