Reference number(s)
3215-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☑
Standard Control – Choice (SCCF)	☑
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☑
Advanced Control Specialty – Choice (ACSCF)	☑
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☑

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☑
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☑
Value Formulary Chart (VFC)	☑
Medical Benefit	☐
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Duchenne Muscular Dystrophy

This document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

These criteria were developed to align with the following: Standard Control Formulary (SF), Standard Control Choice Formulary (SCCF), Advanced Control Specialty Formulary (ACSF), Advanced Control Specialty – Choice Formulary (ACSCF), Value Formulary (VF), Advanced Control Specialty Formulary Chart (ACSFC), Standard Formulary Chart (SFC), and Value Formulary CHART (VFC).

Plan Design Summary

This program applies to the Duchenne muscular dystrophy product(s) specified in this document. Coverage for targeted product(s) is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) criteria implemented for the client.

Table. Duchenne Muscular Dystrophy

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

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	Products
Preferred	• deflazacort • prednisolone • prednisone
Targeted	• Emflaza (deflazacort)

Exception Criteria

Coverage for the targeted product is provided when both of the following criteria are met:

- Member has experienced documented unmanageable and clinically significant weight gain/obesity or psychiatric/behavioral issues (e.g., abnormal behavior, aggression, irritability) with prednisolone or prednisone.
    - For weight gain/obesity: body mass index is in the overweight or obese category while receiving treatment with prednisone or prednisolone (refer to Appendix for weight status categories for children and adults).
- Member has had a documented intolerable adverse event to generic deflazacort, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

Appendix

Body Mass Index Percentile and Weight Status Category for Children 2 Through 19 Years of Age

Body Mass Index Percentile Range	**Weight Status**
Less than the 5th percentile	Underweight
5th percentile to less than the 85th percentile	Healthy Weight
85th to less than the 95th percentile	Overweight
Equal to or greater than the 95th percentile	Obese

Body Mass Index and Weight Status Category for Adults (20 Years of Age and Older)

Body Mass Index	**Weight Status**
Below 18.5	Underweight
18.5 – 24.9	Healthy Weight

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Body Mass Index	Weight Status
25.0 – 29.9	Overweight
30.0 and Above	Obese

References

1. Emflaza [package insert]. South Plainfield, NJ: PTC Therapeutics, Inc.; May 2024.
2. Deflazacort tablet [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; June 2024.
3. Deflazacort oral suspension [package insert]. Monmouth Junction, NJ: Tris Pharma, Inc.; June 2024.
4. Centers for Disease Control and Prevention. Assessing Your Weight. https://www.cdc.gov/healthyweight/assessing/bmi/ Accessed: September 20, 2024.

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