

Policy Name:	Emflaza (deflazacort)	Policy #:	2607P
---------------------	------------------------------	------------------	--------------

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Emflaza.

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Emflaza under the Specialty Pharmacy benefit when the following criteria have been met.

Criteria

1. Coverage Criteria

- 1.1 Diagnosis of Duchenne Muscular Dystrophy with a documented mutation of the dystrophin gene
- 1.2 Age 2 years of age or older
- 1.3 Prescribed by or in consultation with a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders
- 1.4 Documented trial of prednisone for 6 months and documentation that the member experienced at least one of the following significant intolerable adverse effects (AE)
 - Cushingoid appearance
 - Central (truncal) obesity
 - Undesirable weight gain defined as a 10% of body weight gain increase over a 6-month period
 - Diabetes and/or hypertension that is difficult to manage
 - Severe behavioral adverse effects that would require a prednisone dose reduction
- 1.5 Obtain a baseline motor milestone score from one of the following assessments:
 - 6-Minute Walk Test (6MWT)
 - North Star Ambulatory Assessment (NSAA)
 - Motor Function Measure (MFM)
 - Hammersmith Functional Motor Scale (HFMS)

2. Approval Period

- 2.1 Initial: 12 months
- 2.2 Reapproval: 12 months with documentation of improvement in one of the following motor milestone scores:
 - 6-Minute Walk Test (6MWT)
 - North Star Ambulatory Assessment (NSAA)
 - Motor Function Measure (MFM)
 - Hammersmith Functional Motor Scale (HFMS)

CPT Codes

--	--

HCPCS Codes

--	--

References

1. DJ Birnkrant, K Bushby, CM Bann, et al. Diagnosis and management of Duchenne muscular dystrophy, part 2: respiratory, cardiac, bone health, and orthopaedic management. *Lancet Neurol* 2018, 17;4:347-61.
2. DJ Birnkrant, K Bushby, CM Bann, et al. Diagnosis and management of Duchenne muscular dystrophy, part 3: primary care, emergency management, psychosocial care, and transitions of care across the lifespan. *Lancet Neurol* 2018; 17:445.
3. Emflaza (deflazacort) [prescribing information]. Northbrook, IL: Marathon Pharmaceuticals; June 2021.
4. Gloss D, Moxley RT, Ashwal S, Oskoui M. Practice guideline update summary: corticosteroid treatment of Duchenne muscular dystrophy. *American Academy of Neurology*. 2016.
5. Kang PB, Morrison L, Iannaccone ST, et al; Guideline Development Subcommittee of the American Academy of Neurology and the Practice Issues Review Panel of the American Association of Neuromuscular & Electrodiagnostic Medicine. Evidence-based guideline summary: evaluation, diagnosis, and management of congenital muscular dystrophy. *Neurology*. 2015 Mar 31;84(13):1369-78.

Created Date: 10/04/17

Effective Date: 10/04/17

Posted to Website: 01/01/2022

Revision Date: 10/05/2023

DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.