JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS104
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	Subject **Emflaza**	*Revision Date*	07/13/2021
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: emflaza

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I. POLICY

Emflaza (deflazacort) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

- PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
- USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. Emflaza may be approved for patients who meet all of the following criteria:
   1. Patient is male and 2 years of age or older
   2. Diagnosis of Duchenne Muscular Dystrophy(DMD) has been determined by one of the following:
      a. A neurologist with expertise in the diagnosis of DMD
      b. A physician in consultation with a neurologist with expertise in the diagnosis of DMD
   3. Submission of medical records (e.g., chart notes) confirming that the patient has a 6- Minute Walk Time (6MWT)
   4. Documentation of serum creatinine kinase activity at least 10 times the upper limit of normal (ULN)
   5. Trial and failure of at least 3 months of oral prednisone

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval may be granted for up to 6 months of therapy.
B. Approval for continuation of therapy can be extended in 12-month intervals with documentation showing a clinical improvement as a result of treatment.

IV. EXCLUSIONS

A. Emflaza will not be approved for any non-FDA approved indications, including, but not limited to the following:

1. Inflammatory arthropathies (not otherwise specified)
2. Idiopathic (autoimmune) thrombocytopenic purpura (ITP)
3. Juvenile rheumatoid (idiopathic) arthritis (JRA, JIA)
4. Nephrotic syndrome
5. Polymyalgia rheumatica (PMR)
6. Rheumatoid arthritis (RA)
7. Sarcoidosis
8. Solid organ transplant (such as kidney, heart transplant)
9. Systemic lupus erythematosus (SLE)

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Emflaza. Prescribing Information. Northbrook, ILMarathon Pharmaceuticals, LLC. July 2020

VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
07/19/2017	Policy Creation
07/27/2017	Updated Exclusion section regarding physician samples
07/01/2018	Removed EHP Line of Business
07/13/2021	Updated applicable coverage age based on FDA PI update

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