Updated: 03/2019
PARP Approved: 04/2019

Gateway Health
Prior Authorization Criteria
Emflaza (deflazacort)

All requests for Emflaza (deflazacort) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Emflaza (deflazacort) Prior Authorization Criteria:

Coverage may be provided when the member is 5 years of age or older with a diagnosis of Duchenne Muscular Dystrophy (DMD) and the following criteria is met:

- A confirmed diagnosis of DMD with documentation of the following:
  - Documented mutation of the dystrophin gene (required);
  - Chart documentation of onset of weakness before 5 years of age (required);
  - Serum creatinine kinase activity at least 10 times the upper limit of normal (ULN) at some stage in their illness (recommended if available);
- Prescribed by or in consultation with a neurologist who has experience treating DMD;
- The patient meets ONE of the following conditions (A or B):
  - A) The member has tried prednisone for ≥ 6 months (documentation required) AND experienced at least one of the following clinically significant adverse effects (documentation required for any that apply):
    - i. Cushingoid appearance; **OR**
    - ii. Central (truncal) obesity; **OR**
    - iii. Undesirable weight gain defined as a ≥ 10% of body weight gain increase over a 6-month period; **OR**
  - B) The member has experienced behavioral issues (abnormal behavior, aggression) while on prednisone therapy with one of the following:
    - i. The behavioral issues persisted beyond the first 6 weeks of treatment with prednisone; **OR**
    - ii. A dose reduction (e.g.0.3mg/kg/day) was trialed and did not result in an improvement of intolerable adverse effects; **OR**
    - iii. A change in timing of prednisone administration (eg, afternoon or evening) has been attempted but was unsuccessful;
- Documentation Emflaza will NOT be given concurrently with live vaccinations;
- Documentation of the absence of active infection (including tuberculosis and Hepatitis B virus (HBV)
  - If the patient has a history of HBV infection, the prescriber agrees to monitor for HBV reinfection;
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
  - Documentation the member is receiving a clinical benefit from therapy, such as improvement or stabilization of muscle strength or pulmonary function;

    - Documentation of ongoing monitoring of active infection (including tuberculosis and HBV)
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.