ALASKA MEDICAID
Prior Authorization Criteria

Emflaza® (deflazacort)

FDA INDICATIONS AND USAGE[1]

Emflaza® (delazacort) is a corticosteroid indicated for the treatment of patients 2 years of age and older with the diagnosis of Duchenne muscular dystrophy (DMD). DMD is an X-linked recessive disease affecting male infants, which leads to the loss a structural protein of muscle cells called dystrophin.

APPROVAL CRITERIA[1,2,3]

1. Patient is 2 years of age or older **AND**;
2. Patient has a diagnosis of Duchenne muscular dystrophy (DMD) documented by the mutation or absence of the dystrophin gene **AND**;
3. Is being prescribed by or in consultation with a neurologist or a provider that specializes in DMD **AND**;
4. The patient has had an adequate trial and failure, for at least 6 months, of oral prednisone, or has a contraindication to prednisone, or has experienced significant adverse effects from prednisone use.

DENIAL CRITERIA[1,2,3]

1. Patient is less than 2 years of age **OR**;
2. Patient does not have a diagnosis of Duchenne muscular dystrophy (DMD) documented by the mutation or absence of the dystrophin gene **OR;**
3. Is not being prescribed by or in consultation with a neurologist or a physician that specializes in DMD **OR**;
4. The patient has not had an adequate trial and failure, for at least 6 months, of oral prednisone, or has no contraindications to, or has not experienced significant adverse effects from prednisone use.
5. Being given concurrently with live vaccinations.

CAUTIONS[1]

- Monitor for changes in endocrine, cardiovascular, and renal function.
- Increased risk of infection due to immunosuppression and may mask the signs and symptoms of an infection.
- May cause behavioral and mood disturbances.
- Decreases in bone mineral density can occur with chronic use.

DURATION OF APPROVAL

- Initial Approval: up to 30 days

- Reauthorization Approval: up to 12 months

QUANTITY LIMIT

- Up to 0.9mg/kg/day rounded to the nearest tablet dosage strength (6mg, 18mg, 30mg, 36mg, and 22.75mg/ml suspension)

REFERENCES / FOOTNOTES:

1. Emflaza® tablets and oral suspension [prescribing information]. South Plainfield, NJ: PTC Therapeutics, Inc.; June 2019.
2. Gloss D, Moxley RT 3rd, Ashwal S, Oskoui M. Practice guideline update summary: corticosteroid treatment of Duchenne muscular dystrophy: report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016;86(5):465-472
3. Griggs RC, Miller JP, Greenberg CR, et al. Efficacy and safety of Emflaza vs prednisone and placebo for Duchenne muscular dystrophy. Neurology. 2016;87(20):2123-2131.