

## Louisiana Medicaid Oral Glucocorticoids

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The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request authorization for non-preferred oral glucocorticoids **OR** to request clinical authorization for deflazacort (Emflaza®).

Additional Point-of-Sale edits may apply.

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### Deflazacort (Emflaza®)

#### Approval Criteria

- The recipient has a documented diagnosis of Duchenne muscular dystrophy (DMD); **AND**
- The recipient is 2 years of age or older on the date of the request; **AND**
- The medication is prescribed by, or in consultation with, a neurologist; **AND**
- Previous use of a preferred product - **ONE** of the following is required:
  - The recipient has had a *treatment failure* with at least one preferred product; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- **ONE** of the following:
  - The recipient had an inadequate response to a preferred prednisone / prednisolone product after 6 months or more of treatment (**medication name with begin and end dates of treatment are stated on the request**); **OR**
  - The recipient has a documented adverse reaction, intolerance, or contraindication to treatment with generic prednisone / prednisolone that is not expected to occur with the requested medication (explanation of why it is not expected to occur with the requested medication is required and **is stated on the request**); **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The recommended oral dosage of 0.9 mg/kg/day will not be exceeded; **AND**
  - The requested medication will not be given concurrently with live-attenuated or live vaccines; **AND**
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

\*\*\*Duration of initial approval: **6 months**\*\*\*

## Reauthorization Criteria

- The recipient continues to meet all initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is receiving clinical benefit from deflazacort therapy, such as stabilization, maintenance, or improvement of muscle strength or pulmonary function, indicating a slowing of disease progression relative to the projected natural course of DMD.

\*\*\*Duration of reauthorization approval: **12 months**\*\*\*

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## Non-Preferred Oral Glucocorticoids (Except Deflazacort [Emflaza®])

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### Initial and Reauthorization Approval ~~ALL of the following are required~~ Criteria for both initial and reauthorization requests for oral glucocorticoids

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- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- Previous use of a preferred product - **ONE** of the following is required:
  - The recipient has had a *treatment failure* with at least one preferred product; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no inappropriate concomitant drug therapies or disease states.

\*\*\*Duration of authorization approval for non-preferred oral glucocorticoids, both initial and reauthorization: **Up to 12 months based upon patient-specific factors and the condition being treated**\*\*\*

### References

American Academy of Neurology. (2016). Practice Guideline Update Summary: Corticosteroid Treatment of Duchenne Muscular Dystrophy. Retrieved from <https://n.neurology.org/content/86/5/465.full>

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; Retrieved from <https://www.clinicalkey.com/pharmacology/>

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach, 10e* New York, NY: McGraw-Hill; Retrieved from <https://accesspharmacy.mhmedical.com/book.aspx?bookid=1861m>

Emflaza (deflazacort) [package insert]. South Plainfield, NJ: PTC Therapeutics, Inc.; June 2019. <http://hcp.emflaza.com/wp-content/themes/emflaza-hcp/pdf/prescribing-information.pdf>

Revision	Date
Policy created	January 2020
Policy implemented and combined with Oral Glucocorticoid non-preferred criteria document	May 2020