HIGHMARK HEALTH OPTIONS

Updated: 10/2025
DMMA Approved: 11/2025

Request for Prior Authorization for Emflaza (deflazacort) and Agamree (vamorolone)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

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

Emflaza (deflazacort) and Agamree (vamorolone) Prior Authorization Criteria:

Coverage may be provided when the member is 2 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)
- Prescribed by or in consultation with a neurologist who has experience treating and managing DMD

For Emflaza requests:

- The member 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
    - ii. Central (truncal) obesity
    - iii. Undesirable weight gain defined as a ≥ 10% of body weight gain increase over a 6-month period
  - 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
    - ii. A dose reduction (e.g.0.3mg/kg/day) was trialed and did not result in an improvement of intolerable adverse effects
    - iii. A change in timing of prednisone administration (eg, afternoon or evening) has been attempted but was unsuccessful

For Agamree requests:

- The member has tried and failed prednisone for ≥ 3 months AND Emflaza for ≥ 3 months (documentation required) and has experienced clinically significant adverse effects such as one of the following:
  - Cushingoid appearance
  - Central (truncal) obesity
  - Undesirable weight gain defined as a ≥ 10% of body weight gain increase over a 6-month period
- 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:** 6 months

- **Reauthorization criteria**
  - Documentation the member is receiving a clinical benefit from therapy, such as improvement or stabilization of muscle strength or pulmonary function
- **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.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

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EMFLAZA (DEFLAZACORT) AND AGAMREE (VAMOROLONE) PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (844) 325-6251 Monday through Friday 8:00am to 7:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	
Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No		

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____
Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis: **ICD-10:** _____
Is there appropriate documentation of a confirmed diagnosis of DMD attached such as dystrophin gene mutation and onset of weakness before 5 years of age? ☐ Yes ☐ No
For Emflaza requests: Please mark which applies, A or B, to the member:
A. Has the member tried prednisone for ≥ 6 months (documentation required) AND experienced at least one clinically significant adverse effects (documentation required for any that apply)? ☐ Yes ☐ No
B. Has the member experienced behavioral issues (abnormal behavior, aggression) while on prednisone therapy with one of the following: the behavioral issues persisted beyond the first 6 weeks of treatment with prednisone OR a dose reduction was trialed and did not result in an improvement of intolerable adverse effects OR a change in timing of prednisone administration (eg, afternoon or evening) has been attempted but was unsuccessful? ☐ Yes ☐ No
For Agamree requests:
Has the member tried and failed ≥ 3 months of BOTH prednisone and Emflaza therapy (documentation submitted)? ☐ Yes ☐ No
Has the member experienced clinically significant adverse effects such as cushingoid appearance, central (truncal) obesity, undesirable weight gain defined as a ≥ 10% of body weight gain increase over a 6-month period while on both prednisone and Emflaza? ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why / Current)

SUPPORTING INFORMATION or CLINICAL RATIONALE

REAUTHORIZATION

Is there documentation the member is receiving a clinical benefit from therapy such as improvement or stabilization of muscle strength or pulmonary function? ☐ Yes ☐ No	
Prescribing Provider Signature	Date