AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: (select **ONE** drug below)

❑ **Agamree®** (vamorolone)	❑ **deflazacort** (Emflaza®)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

Drug Name:	**Recommended Dosage:**	**Quantity Limit:**
Agamree® (vamorolone)	6 mg/kg taken orally once daily preferably with a meal, up to a maximum daily dosage of 300 mg for patients weighing more than 50 kg	2 bottles per 26 days
deflazacort (Emflaza®)	0.9 mg/kg administered orally once daily	N/A

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- ❑ Member is 2 years of age or older
- ❑ Member has a diagnosis of Duchenne Muscular Dystrophy (DMD) confirmed by documented presence of abnormal dystrophin or confirmed mutation of dystrophin gene **(submit documentation)**
- ❑ Prescribed by or in consultation with a physician who specializes in the treatment of DMD
- ❑ Serum creatinine kinase activity at least 10 times the upper limit of normal at some stage of the illness prior to initiating therapy **(submit documentation)**
- ❑ Member has had a minimum **THREE (3)** month trial of prednisone **(verified by chart notes or pharmacy paid claims)**
- ❑ **For Agamree requests:** Member has had a minimum **THREE (3)** month trial of generic deflazacort (Emflaza) tablets, unless member is unable to swallow tablets **(verified by chart notes or pharmacy paid claims)**
- ❑ Member had at least **ONE** of the following significant intolerable adverse effect due to prednisone therapy:
  - ❑ Cushingoid appearance
  - ❑ Truncal obesity
  - ❑ Undesirable weight gain (≥ 10% body weight gain increase over a 6-month period)
  - ❑ Diabetes and/or hypertension that is difficult to manage

  OR

  - ❑ Member has experienced a severe behavioral adverse event while on prednisone that required or will require a reduction in prednisone dose with **BOTH** of the following:
    - ❑ Behavioral adverse event persisted beyond the first 6 weeks of prednisone therapy
    - ❑ Change in the time of prednisone administration was attempted and was unsuccessful
- ❑ Baseline motor assessment with milestone score from **ONE** of the following has been performed:
  - ❑ 6-Minute Walk Test (6MWT)
  - ❑ North Star Ambulatory Assessment (NSAA)
  - ❑ Hammersmith Functional Motor Scale (HFMS)
  - ❑ Motor Function Measure (MFM)
- ❑ Therapy will **NOT** be used concurrently with live vaccines
- ❑ Active infection is absent
- ❑ Does the member have a history of HBV Infection? ❑ Yes ❑ No
  - ❑ If **YES**, member will be monitored for reactivation of HBV
- ❑ Requested dosing is in accordance with the United States Food and Drug Administration approved labeling

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Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet all initial authorization criteria
- ❑ Member must have improvement or stabilization from baseline motor assessment milestone score of **ONE** of the following:
  - ❑ 6MWT
  - ❑ NSAA
  - ❑ MFM
  - ❑ HFMS
- ❑ Member must have reduction in intolerable side effects compared to prednisone with documentation of improvement in **ONE** of the following:
  - ❑ Cushingoid appearance
  - ❑ Truncal obesity
  - ❑ Weight gain
  - ❑ Diabetes and/or hypertension management
  - ❑ Behavior

Medication being provided by Specialty Pharmacy – Proprium Rx

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pha rmacy paid claims or submitted chart notes.*