

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)

<input type="checkbox"/> Agamree[®] (vamorolone)	<input type="checkbox"/> deflazacort (Emflaza [®])
<input type="checkbox"/> Jaythari (deflazacort)	<input type="checkbox"/> Pyquvi (deflazacort) oral suspension

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: _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight (if applicable): _____ Date weight obtained: _____

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 [®]) & Jaythari (deflazacort)	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 ($\geq 10\%$ 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 pharmacy paid claims or submitted chart notes.****