Mass General Brigham
Health Plan

# Agamree (vamorolone)
# Effective 11/01/2024

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| **Plan** | ☐ MassHealth UPPL<br>☒Commercial/Exchange | **Program Type** | ☒ Prior Authorization<br>☐ Quantity Limit<br>☐ Step Therapy |
| **Benefit** | ☒ Pharmacy Benefit<br>☐ Medical Benefit | | |
| **Specialty Limitations** | This medication has been designated specialty and must be filled at a contracted specialty pharmacy. | | |
| **Contact Information** | **Medical and Specialty Medications**<br>All Plans \| Phone: 877-519-1908 \| Fax: 855-540-3693 | | |
| | **Non-Specialty Medications**<br>All Plans \| Phone: 800-711-4555 \| Fax: 844-403-1029 | | |
| **Exceptions** | N/A | | |

**Overview**
Agamree (vamorolone) is a corticosteroid indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older.

**Coverage Guidelines**
Authorization may be reviewed for members new to the plan within the last 90 days who are currently receiving treatment with the requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
**OR**
Authorization may be granted for members when ALL the following criteria are met:

1. Member has a diagnosis of Duchenne muscular dystrophy (DMD) that has been confirmed by genetic testing demonstrating a mutation in the DMD gene. Laboratory confirmation of genetic testing is required.
2. Member is 2 years of age or older.
3. Member meets one of the following:
    a. Member had a clinically significant adverse reaction to treatment with prednisone or prednisolone (e.g., clinically significant weight gain, Cushingoid appearance, psychiatric/behavioral issues persisted beyond the first 6 weeks of therapy, etc)
    b. Treatment with prednisone or prednisolone is clinically inappropriate for the member
4. Member has had an inadequate response, adverse reaction, or contraindication to deflazacort
5. Requested medication is prescribed by or in consultation with a specialist with experience treating DMD

**<u>Continuation of Therapy</u>**
Requests for reauthorization will be approved when the following criteria are met:

1. Member meets initial criteria

2. Documentation the member has responded to treatment with vamorolone. Examples include motor function tests (e.g., 6 minute walk test [6MWT], time to stand test [TTSDT], time to walk/run [TTWR]) or pulmonary function tests.

**Limitations**

1. Initial approvals will be granted for 6 months.
2. Reauthorization approvals will be granted for 12 months.
3. The following quantity limitations apply:

| Drug Name and Dosage Form | Quantity Limit |
|---|---|
| Agamree oral suspension | 7.5 mL per day |

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**Review History**
09/11/2024 – Reviewed at September P&T. Effective 11/01/2024.