STATE OF WEST VIRGINIA
DEPARTMENT OF HUMAN SERVICES
BUREAU FOR MEDICAL SERVICES

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Office of Pharmacy Services
Prior Authorization Criteria
Agamree® (vamorolone)
Effective 1/01/2026

Prior Authorization Forms

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

Criteria for Approval:

1. Diagnosis of Duchenne muscular dystrophy (DMD); **AND**
2. Patient is two years of age or older; **AND**
3. Prescribed by, or in consultation with, a neurologist or a specialist in Duchenne muscular dystrophy (DMD) or neuromuscular disorders; **AND**
4. Patient must have a documented history of at least six months continuous therapy with prednisone; **AND**
5. Documentation must be submitted indicating that the patient has experienced significant adverse effects associated with prednisone therapy. Documentation must include a detailed description of the adverse effect; as the side effect profiles are similar between Agamree and prednisone, prior authorization shall only be granted for those patients experiencing side effects where Agamree shows an improved profile. Significant adverse effects are defined as:
    a. Patient has manifested significant psychiatric or behavioral changes negatively impacting function at school, daycare, etc; OR
    b. Patient has experienced Cushingoid effects or significant weight gain (crossing two percentiles and/or reaching 98th percentile for age and sex); AND
6. Request must be accompanied by baseline clinical criteria used to assess the patient by at least one of the following tests:
    a. Muscle strength tests (such as, Medical Research Council [MRC] scale for muscle strength with 0 being no movement and five being normal strength), or
    b. Motor (walk) tests (such as six-minute walk test [6MWT] distance), or
    c. Pulmonary function tests (such as forced vital capacity [FVC] and maximal expiratory pressure), or
    d. Timed functional tests (such as, standing from lying position; climbing four stairs; running/walking 30 feet; propelling a wheelchair 30 feet).

Approval Duration:

Initial approval: will be for six months.

Criteria for reauthorization:

1. Patient must continue to meet initial approval criteria; **AND**

2. Demonstrate continued documented compliance; **AND**

3. Documentation that adverse events associated with prednisone therapy were resolved through treatment with Agamree; OR

4. Documented evidence with the most recent results (≤ six months prior to request) must be submitted showing clinically significant improvement in DMD associated symptoms, stabilization or lack of progression as compared to the natural history trajectory of the disease demonstrated by at least one of the following from pre-treatment baseline status:

    1. Muscle strength tests (such as, Medical Research Council [MRC] scale for muscle strength with 0 being no movement and five being normal strength), or
    2. Motor (walk) tests (such as six-minute walk test [6MWT] distance), or
    3. Pulmonary function tests (such as, forced vital capacity [FVC] and maximal expiratory pressure), or
    4. Timed functional tests (such as, standing from lying position; climbing four stairs; running/walking 30 feet; propelling a wheelchair 30 feet).

Continuation of therapy approvals will be granted for 12 months.