ConnectiCare

Commercial PA Criteria

Effective: February 8, 2024

Prior Authorization: Agamree

Products Affected: Agamree (Vamorolone) oral capsules

Medication Description: Vamorolone is a corticosteroid that acts through the glucocorticoid receptor to exert anti-inflammatory and immunosuppressive effects. The precise mechanism by which vamorolone exerts its effect in patients with DMD is unknown.

Covered Uses:

1. Treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older.

Exclusion Criteria: None

Required Medical Information:

1. Diagnosis
2. Previous therapies tried and failed

Prescriber Restriction: a physician who specializes in the treatment of Duchenne muscular dystrophy and/or neuromuscular disorders.

Age Restriction: 2 years of age and older.

Coverage Duration: 12 months

Other Criteria:

Initial Approval Criteria

1. Duchenne Muscular Dystrophy. Approve if the patient meets one of the following (A **OR** B):

A. Approve if the patient meets the following (i, ii, iii, **AND** iv):
   i. Patient is ≥ 2 years of age; **AND**
   ii. Patient's diagnosis of Duchenne Muscular Dystrophy is confirmed by one of the following (a **OR** b)
      a. Genetic testing with a confirmed pathogenic variant in the dystrophin gene; **OR**
      b. Muscle biopsy showing the absence of, or marked decrease in, dystrophin protein; **AND**
   iii. Patient meets ONE of the following (a **OR** b):
      a. Patient has tried prednisone or prednisolone for ≥ 6 months AND according to the prescriber, the patient has had at least one of the following significant intolerable adverse effects [1, 2, 3, or 4]:
         1) Cushingoid appearance; **OR**
         2) Central (truncal) obesity; **OR**
         3) Undesirable weight gain defined as ≥ 10% body weight increase over a 6-month period: **OR**

4) Diabetes and/or hypertension that is difficult to manage according to the prescriber, **OR**

b. According to the prescriber, the patient has experienced a severe behavioral adverse event while on prednisone or prednisolone therapy that has or would require a prednisone or prednisolone dose reduction,

iv. The medication is prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy and/or neuromuscular disorders.

Continuation:

1. **Duchenne Muscular Dystrophy.** Approve if the patient meets one of the following (i, ii, iii, **AND** iv):

i. Patient is ≥ 2 years of age; **AND**

ii. Patient has tried prednisone or prednisolone; **AND**

iii. According to the prescriber, the patient has responded to or continues to have improvement or benefit from Agamree therapy; **AND**

Note: Examples of improvement or benefit from Agamree therapy would include improvements in motor function (e.g., time from supine to standing, time to climb four stairs, time to run or walk 10 meters, 6-minute walk test), improvement in muscle strength, and improved pulmonary function.

iv. The medication is prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy and/or neuromuscular disorders.

References:

1. Agamree® oral suspension [prescribing information]. Burlington, MA: Santhera/Catalyst; October 2023.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	02/08/2024