Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

AGAMREE® (*vamorolone*) PA CRITERIA:

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

Prior authorization is required for AGAMREE® (*vamorolone*). Prior authorization approval will be considered when the following criteria are met. Along with the Universal PA Form, please submit any supporting clinical documentation.

Initial Authorization: 12 Months

1. Age of the patient is within the age range as recommended by the FDA label; **AND**

2. Diagnosis of Duchenne muscular dystrophy (DMD) confirmed by one of the following:
    a. Genetic testing (e.g., dystrophin deletion or duplication mutation found); **OR**
    b. If genetic studies are negative (i.e., no mutation identified), positive muscle biopsy (e.g., absence of dystrophin protein); **AND**

3. Patient meets one of the following scenarios:
    a. An inadequate response to separate trials of prednisone AND deflazacort; **OR**
    b. Prescriber provides detailed clinical justification to why separate trials of prednisone AND deflazacort are inadvisable with supporting documentation (e.g., intolerance, contraindication, etc.).

Re-Authorization: 12 Months

1. Documentation of clinical benefit as supported by medical records (e.g., improvement or stabilization of strength, motor function, pulmonary function, etc.)

AGAMREE® (*vamorolone*) Dosing:

- The recommended dosage is 6 mg/kg taken orally once daily, up to a maximum daily dosage of 300 mg for patients weighing more than 50 kg. Please see the full prescribing information for dosing in hepatic impairment and concomitant use with strong CYP3A4 inhibitors.

Formulation:

- AGAMREE® is available as a 40 mg/mL oral suspension.