

**Policy Name:** Agamree (vamorolone)

**Policy#:** 3258P

## Purpose of the Policy

The purpose of this policy is to define coverage criteria for Agamree (vamorolone)

## Statement of the Policy

Health Alliance Medical Plans will approve the use of Agamree (vamorolone) under the specialty pharmacy benefit if the following criteria are met.

## Criteria

### 1. Coverage Criteria

- 1.1 Diagnosis of Duchenne Muscular Dystrophy confirmed by one of the following:
  - Genetic testing documenting a mutation in the dystrophin (DMD) gene
  - Muscle biopsy documenting lack of muscle dystrophin
- 1.2 Age 2 years or older
- 1.3 Prescribed by or in consultation with a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders
- 1.4 Patient is currently ambulatory (able to walk independently)
- 1.5 Documented trial of prednisone for 6 months and documentation that the member experienced at least one of the following significant intolerable adverse effects (AE)
  - Cushingoid appearance
  - Central (truncal) obesity
  - Undesirable weight gain defined as a 10% of body weight gain increase over a 6-month period
  - Diabetes and/or hypertension that is difficult to manage
  - Severe behavioral AE that would require a prednisone dose reduction
  - Clinically significant growth stunting as evidenced by decline in mean height percentile from baseline, decrease in growth velocity or decrease in serum bone formation biomarkers
- 1.6 Documented trial and failure, intolerance or contraindication to generic deflazacort
- 1.7 Documentation of a baseline motor milestone score from one of the following assessments:
  - 6-minute walk test (6MWT)
  - Time to stand test (TTSTAND)
  - Time to run/walk test (TTRW)

### 2. Managed Dose Limit

- 2.1 3 bottles (300mL) per 30 days

### 3. Approval Period

- 3.1 Initial: 12 months
- 3.2 Reauthorization: 12 months with documentation of improvement in one of the following motor milestone scores:
  - 6-minute walk test (6MWT)
  - Time to stand test (TTSTAND)
  - Time to run/walk test (TTRW)

**CPT Codes****HCPCS Codes****References**

1. Agamree (vamorolone) [prescribing information]. Burlington, CA: Santhera Pharmaceuticals (USA) Inc; March 2024.
2. Guglieri M, Clemens PR, Perlman SJ, et al. Efficacy and Safety of Vamorolone vs Placebo and Prednisone Among Boys With Duchenne Muscular Dystrophy: A Randomized Clinical Trial. *JAMA Neurol.* 2022 Oct 1;79(10):1005-1014.
3. Birnkrant DJ, Bushby K, Bann CM, et al; DMD Care Considerations Working Group. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management. *Lancet Neurol.* 2018 Mar;17(3):251-267.
4. Gloss D, Moxley RT 3rd, Ashwal S, Oskoui M. Practice guideline update summary: Corticosteroid treatment of Duchenne muscular dystrophy: Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology.* 2016 Feb 2;86(5):465-72.

**Created Date:** 08/07/24

**Effective Date:** 08/07/24

**Posted to Website:** 08/07/24

**Revision Date:**

**DISCLAIMER**

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.