

Generic Name: vamorolone

Therapeutic Class or Brand Name: Agamree®

Applicable Drugs: N/A

Preferred: Prednisone

Non-preferred: Deflazacort

Date of Origin: 8/26/2024

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

- I. Documented diagnosis of Duchenne Muscular Dystrophy (genetic testing or muscle biopsy documented)
 - A. Trial of BOTH of the following: corticosteroid (ie prednisone) and deflazocort
- II. Documentation of inadequate treatment response, contraindication or intolerance of corticosteroid (ie prednisone) AND deflazacort
- III. The medication is prescribed by or in consultation with neurologist or Duchenne Muscular Dystrophy specialist
- IV. Patients must be 2 years of age or older

EXCLUSION CRITERIA

- Severe behavioral or cognitive problem concerns
- Evidence of symptomatic cardiomyopathy
- History of primary hyperaldosteronism
- Concurrent use of mineralocorticoid receptor agent
- Current or history of chronic systemic fungal or viral infections

OTHER CRITERIA

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 40 mg/ml suspension of 100 ml/vial; max of 300 mg/day

APPROVAL LENGTH

- **Authorization:** 1 year
- **Re-Authorization:** An updated letter of medical necessity or progress notes confirming the current medical necessity criteria are met and showing the medication is effective

APPENDIX

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REFERENCES

1. Agamree (vamorolone) [package insert]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc; June 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;79(10):1005–14.
3. Gloss D, Moxley RT III, 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;86(5):465-472.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.