



UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2025 P 2345-3
Program	Prior Authorization/Medical Necessity
Medication	Agamree® (vamorolone)*
P&T Approval Date	7/2024, 10/2024, 10/2025
Effective Date	1/17/2026

**1. Background:**

Agamree (vamorolone)\* is a corticosteroid indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older.<sup>1</sup>

The UnitedHealthcare Pharmacy and Therapeutics Committee has determined that Agamree is Therapeutically Equivalent to prednisone in the treatment of DMD. While adverse effect profiles may differ among glucocorticoids, vamorolone does not offer a clear advantage over other glucocorticoids for DMD with respect to efficacy and overall safety.<sup>2-5</sup>

**2. Coverage Criteria<sup>a</sup>:**

**A. Duchenne Muscular Dystrophy**

1. Published clinical evidence shows Agamree\* is likely to produce equivalent therapeutic results as other available corticosteroids (e.g., prednisone); therefore, Agamree is **not medically necessary** for treatment of Duchenne muscular dystrophy.

<sup>a</sup> State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

\*Agamree is typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

**4. References:**

1. Agamree [package insert]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc.; June 2024.
2. Dang UJ, Damsker JM, Guglieri M, et al. Efficacy and Safety of Vamorolone Over 48 Weeks in Boys With Duchenne Muscular Dystrophy: A Randomized Controlled Trial. *Neurology*. 2024;102(5):e208112.
3. 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):1005-1014.



4. Birnkrant DJ, Bushby K, Bann CM, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management. *Lancet Neurol*. 2018;17(3):251-267.

Program	Prior Authorization/Medical Necessity - Agamree (vamorolone)
<b>Change Control</b>	
7/2024	New program
10/2024	Added exclusion footnote and updated reference.
10/2025	Annual review with no changes to criteria. Updated background and references.