

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2024 P 2345-2
Program	Prior Authorization/Medical Necessity
Medication	Agamree® (vamorolone)*
P&T Approval Date	10/1/2024
Effective Date	1/1/2025

**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. Data for FDA approval from relatively short-term randomized controlled trials were limited; and 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>:**

<p><b>A. <u>Duchenne Muscular Dystrophy</u></b></p> <p>1. Published clinical evidence shows Agamree* is likely to produce equivalent therapeutic results as other available corticosteroids (e.g., prednisone); therefore, Agamree is <b>not medically necessary</b> for treatment of Duchenne muscular dystrophy.</p> <p><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.</p>
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\*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. Griggs RC, Miller JP, Greenberg CR, et al. Efficacy and safety of deflazacort vs prednisone and placebo for Duchenne muscular dystrophy. *Neurology*. 2016;87(20):2123-2131.
5. Gloss D, Moxley III R, Ashwal S, et. al. 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;465-472.

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<b>Change Control</b>	
7/2024	New program
10/2024	Added exclusion footnote and updated reference.