

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

1. Background:

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

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.²⁻⁵

2. Coverage Criteria^a:**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.

^a 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.

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.; March 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.

Program	Prior Authorization/Medical Necessity - Agamree (vamorolone)
Change Control	
7/2024	New program