

PHARMACY POLICY STATEMENT

Marketplace

DRUG NAME	Agamree (vamorolone)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Agamree, approved by the FDA in 2023, is a corticosteroid indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older.

DMD is an X-linked, progressive disease characterized by muscle wasting, weakness, loss of walking ability, and reduced life expectancy. It is caused by mutations in the dystrophin gene resulting in reduced or near absence of dystrophin, a protein that helps keep muscle cells intact.

Delaying loss of ambulation is a major goal of treatment. Corticosteroids are standard of care to improve muscle strength and function.

DATE	ACTION/DESCRIPTION
10/31/2023	New policy for Agamree created.

References:

1. Agamree [prescribing information]. Santhera Pharmaceuticals (USA), Inc.; 2023.
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):1005-1014. doi:10.1001/jamaneurol.2022.2480
3. Mah JK, Clemens PR, Guglieri M, et al. Efficacy and Safety of Vamorolone in Duchenne Muscular Dystrophy: A 30-Month Nonrandomized Controlled Open-Label Extension Trial. *JAMA Netw Open.* 2022;5(1):e2144178. Published 2022 Jan 4. doi:10.1001/jamanetworkopen.2021.44178
4. Matthews E, Brassington R, Kuntzer T, Jichi F, Manzur AY. Corticosteroids for the treatment of Duchenne muscular dystrophy. *Cochrane Database Syst Rev.* 2016;2016(5):CD003725. Published 2016 May 5. doi:10.1002/14651858.CD003725.pub4
5. 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;86(5):465-472. doi:10.1212/WNL.0000000000002337
6. Birnkrant DJ, Bushby K, Bann CM, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: