

## PHARMACY POLICY STATEMENT

### North Carolina Marketplace

|                  |                              |
|------------------|------------------------------|
| <b>DRUG NAME</b> | <b>Agamree (vamorolone)</b>  |
| BENEFIT TYPE     | Pharmacy                     |
| STATUS           | Prior Authorization Required |

Agamree, approved by the FDA in 2023, is a corticosteroid indicated for the

| 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: