

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3186-1
Program	Step Therapy
Medication	Agamree® (vamorolone)
P&T Approval Date	7/2024
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.

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try prednisone prior to receiving coverage for Agamree.

2. Coverage Criteria^a:

A. Initial Authorization

1. Agamree will be approved based on **both** of the following criterion:

a. Diagnosis of Duchenne muscular dystrophy

-AND-

b. Patient has a history of failure, contraindication, or intolerance to prednisone or prednisolone

Authorization will be issued for 12 months

B. Reauthorization

1. Agamree will be approved based on the following criterion:

a. Documentation of positive clinical response to Agamree therapy

Authorization will be issued for 12 months

^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.

- Supply limits, Medical Necessity and/or Notification may apply

4. References:

1. Agamree [package insert]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc.; March 2024.

Program	Step Therapy – Agamree (vamorolone)
Change Control	
Date	Change
7/2024	New program.