

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2024 P 3186-2 |
| Program | Step Therapy |
| Medication | Agamree® (vamorolone)* |
| P&T Approval Date | 10/2024 |
| Effective Date | 2/1/2025 |

1. Background:

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

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:

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| <p>A. <u>Duchenne Muscular Dystrophy</u></p> <p>1. Agamree* will be approved based on both of the following criterion:</p> <p style="margin-left: 40px;">a. Diagnosis of Duchenne muscular dystrophy</p> <p style="text-align: center;">-AND-</p> <p style="margin-left: 40px;">b. Patient has a history of failure, contraindication, or intolerance to prednisone or prednisolone</p> <p style="text-align: center;">Authorization will be issued for 12 months</p> <p>B. <u>Other Diagnoses</u></p> <p>1. Agamree* will be approved.</p> <p style="text-align: center;">Authorization will be issued for 12 months</p> <p>^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.</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.
- Supply limits, Medical Necessity and/or Notification may apply

4. References:

1. Agamree [package insert]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc.; June 2024.
2. 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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| Program | Step Therapy – Agamree (vamorolone) |
| Change Control | |
| Date | Change |
| 7/2024 | New program. |
| 10/2024 | Removed reauthorization section and replaced with section for other diagnoses. Removed reauthorization criteria and replaced with section for diagnosis other than DMD. Added exclusion footnote and updated references. |