

POLICY NAME	Agamree (vamorolone)	POLICY #	3258P
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Criteria

Coverage Criteria

- ☐ Diagnosis of Duchenne Muscular Dystrophy confirmed by one of the following:
 - Genetic testing documenting a mutation in the dystrophin (DMD) gene
 - Muscle biopsy documenting lack of muscle dystrophin
- ☐ Age 2 years or older
- ☐ Prescribed by or in consultation with a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders
- ☐ Patient is currently ambulatory (able to walk independently)
- ☐ Documented trial of prednisone for 6 months and documentation that the member experienced at least one of the following significant intolerable adverse effects (AE)
 - Cushingoid appearance
 - Central (truncal) obesity
 - Undesirable weight gain defined as a 10% of body weight gain increase over a 6-month period
 - Diabetes and/or hypertension that is difficult to manage
 - Severe behavioral AE that would require a prednisone dose reduction
 - Clinically significant growth stunting as evidenced by decline in mean height percentile from baseline, decrease in growth velocity or decrease in serum bone formation biomarkers
- ☐ Documented trial and failure, intolerance or contraindication to generic deflazacort
- ☐ Documentation of a baseline motor milestone score from one of the following assessments:
 - 6-minute walk test (6MWT)
 - Time to stand test (TTSTAND)
 - Time to run/walk test (TTRW)