



Prior Authorization Criteria

KYMBEE™ (deflazacort) PA CRITERIA:

KYMBEE™ (deflazacort) is a corticosteroid indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 5 years of age and older.

Prior authorization is required for KYMBEE™ (deflazacort). Prior authorization approval will be considered when the following criteria are met. Along with the Universal PA Form, please submit any supporting clinical documentation.

Initial Authorization: 12 Months

1. The patient is 5 years of age or older; **AND**
2. The patient has a diagnosis of Duchenne muscular dystrophy (DMD) confirmed by genetic testing (e.g., dystrophin deletion or duplication mutation found), or positive muscle biopsy (e.g., absence of dystrophin protein); **AND**
3. The patient had at least a six-month trial and had an inadequate response, allergy, or intolerable adverse effects to prednisone (e.g. cushingoid appearance, central (truncal) obesity, undesirable weight gain defined as a $\geq 10\%$ of body weight gain increase over a 6-month period, diabetes and/or hypertension that is difficult to manage per the prescribing physician, or severe behavioral/psychiatric effects that require a dosage reduction) unless contraindicated; **AND**
4. The patient had at least a six-month trial and had an inadequate response to EMFLAZA® (deflazacort); **AND**
5. The prescribed dose does not exceed 0.9 mg/kg/day.

Re-Authorization: 12 Months

1. The prescribed dose does not exceed 0.9 mg/kg/day; **AND**
2. Submitted documentation showing positive clinical response to therapy, such as:
 - a. Stabilization, maintenance or improvement of muscle strength or pulmonary function; **OR**
 - b. Improvement in motor milestone assessment scores from baseline testing; **OR**
 - c. Improvement of motor function must be superior relative to that projected for the natural course of Duchenne Muscular Dystrophy (slowing of decline or slowing of progression).

KYMBEE™ Dosing: 0.9 mg/kg orally once daily, round up to the nearest possible dose

Formulation: Oral Tablet: 6 mg, 18 mg, 30 mg, 36 mg.