Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	August 4, 2021

ORTIKOS™ (budesonide) extended-release

LENGTH OF AUTHORIZATION: Up to 3 months

INITIAL REVIEW CRITERIA:

- Patient has a documented diagnosis of Crohn's disease.
  - For treatment of mild to moderate active Crohn's disease: Patient must be ≥ 8 years of age.
  - For maintenance of clinical remission of mild to moderate Crohn's disease: Patient must be ≥ 18 years of age.
- Patient must have documentation of disease involving the ileum and/or the ascending colon.
- Trial and failure of preferred Budesonide EC 3 mg capsule.

CONTINUATION OF THERAPY:

- Patient met initial review criteria.
- Documentation of positive clinical response.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Dosage Forms: 6 mg and 9 mg extended-release capsules