

## Commercial/Healthcare Exchange PA Criteria *Effective: August 3, 2020*

**Prior Authorization:** Ortikos

**Products Affected:** Ortikos (budesonide) oral capsules

**Medication Description:** Budesonide is an anti-inflammatory corticosteroid and has a high glucocorticoid effect and a weak mineralocorticoid effect, and the affinity of budesonide to glucocorticoid receptors, which reflects the intrinsic potency of the drug, is about 200-fold that of cortisol and 15-fold that of prednisolone.

**Covered Uses:**

1. Treatment of Mild to Moderate Active Crohn's Disease
2. Maintenance of Clinical Remission of Mild to Moderate Crohn's Disease

**Exclusion Criteria:**

1. Hypersensitivity to budesonide

**Required Medical Information:**

1. Diagnosis
2. Previous therapies tried and failed

**Age Restrictions:**

Treatment of Mild to Moderate Active Crohn's Disease: 8 years of age and older

Maintenance of Clinical Remission of Mild to Moderate Crohn's Disease: 18 years of age and older

**Prescriber Restrictions:** Prescribed by, or in consultation with, a gastroenterologist.

**Coverage Duration:** 12 months

**Other Criteria:**

Coverage of Ortikos is recommended in those who meet the following criteria:

- A. Patient has a diagnosis of Mild to Moderate Active Crohn's Disease; AND
- B. Patient has had a trial and failure, intolerance, or contraindication to, generic budesonide delayed-release 3mg capsules.

**References:**

1. Ortikos [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc. June 2019.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	08/06/2020

