# Commercial/Healthcare Exchange PA Criteria

***Effective: August 3, 2020***

***Prior Authorization:*** Budesonide capsules

***Products Affected:*** Ortikos (budesonide) oral capsules, Tarpeyo (budesonide) delayed release 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:***
Ortikos*:* Treatment of Mild to Moderate Active Crohn's Disease and maintenance of Clinical Remission of Mild to Moderate Crohn's Disease
Tarpeyo: Treatment to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression

***Exclusion Criteria:***
Ortikos:
1. Hypersensitivity to budesonide
2. Treatment duration exceeding 3months for Clinical Remission of Mild to Moderate Crohn's Disease

Tarpeyo:
1. Hypersensitivity to budesonide
2. Treatment duration exceeding 9 months

***Required Medical Information:***
1. Diagnosis
2. Previous therapies tried and failed

***Age Restrictions:***
Ortikos
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

Tarpeyo*:* 18 years of age and older

***Prescriber Restrictions:***
Ortikos- Prescribed by, or in consultation with, a gastroenterologist.
Tarpeyo**-** N/A

***Coverage Duration:***
Ortikos:
Mild to Moderate Active Crohn's Disease: 12 months
Clinical Remission of Mild to Moderate Crohn's Disease: 3 months
Tarpeyo: 9 months

***Other Criteria:***

Ortikos: Coverage of Ortikos is recommended in those who meet the following criteria: (A and B)

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

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

A. Patient has a diagnosis of Biopsy-verified primary immunoglobulin A nephropathy (IgAN); AND
B. Patient has a urine protein-to-creatinine ratio UPCR ≥1.5 and eGFR ≥35 mL/min/1.73 m2 **AND**
C. Patient is receiving a stable dose of an RAS inhibitor (ACE inhibitor or ARB) at a maximally tolerated dose; AND
D. Patient is not currently receiving dialysis or has undergone kidney transplant

***References:***

1. Ortikos [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc. June 2019
2. Tarpeyo (budesonide) [prescribing information]. Stockholm Sweden: Colliditas Therapeutics AB; December

Policy Revision history

| Rev # | Type of Change | Summary of Change | Sections Affected | Date |
|---|---|---|---|---|
| 1 | New Policy | New Policy | All | 08/06/2020 |
| 2 | Policy Revision | Added Tarpeyo to account for the new indication | Covered uses, required medical information, Age restrictions, Other criteria | 02/07/2022 |