Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCGAS012.1225	**GASTROINTESTINAL AGENTS** **BUDESONIDE TABLET** (Uceris®) **UCERIS FOAM®** (budesonide foam)
Effective Date: 2/1/2026	**Review/Revised Date**: 06/13, 12/13, 12/14, 12/15, 10/16, 10/17, 11/18, 11/19, 10/20, 10/21, 10/22, 11/23, 10/24 , 10/25 (KN)
Original Effective Date: 08/13	**P&T Committee Meeting Date**: 06/13, 12/13, 12/14, 12/15, 12/16, 12/17, 12/18, 12/19, 12/20, 12/21, 12/22, 12/23, 12/24, 12/25
Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan and Providence Health Assurance as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:
Commercial
Medicaid

POLICY CRITERIA:

COVERED USES:
All Food and Drug Administration (FDA) Approved Indications, Some Medically-Accepted Indications not otherwise excluded from the benefit.

The following off-label indications may be covered subject to criteria below:
microscopic colitis

REQUIRED MEDICAL INFORMATION:

1. **For budesonide extended-release tablets (Uceris®)**
    a. **For mild to moderate, active ulcerative colitis:**
        i. Confirmed diagnosis of mild to moderate, active ulcerative colitis
        AND
        ii. Documented trial, failure, intolerance or contraindication to treatment with an aminosalicylate (e.g., sulfasalazine, mesalamine)
        AND
        iii. Documented trial, failure, intolerance or contraindication to one of the following oral corticosteroids: dexamethasone, hydrocortisone, methylprednisolone, prednisone or budesonide extended-release capsule
    b. **For microscopic colitis:**
        i. Confirmed diagnosis of active, microscopic colitis
2. **For budesonide foam (Uceris®):**
    a. **For mild to moderate, active ulcerative colitis:**

i. Documented trial, failure, intolerance or contraindication to a rectal mesalamine product

AND

ii. Documented trial, failure, intolerance or contraindication to a rectal steroid product, specifically hydrocortisone rectal enema

The initial approval will allow for an eight-week treatment course. Further approval for Uceris® requires medical rationale why additional treatment is warranted for ulcerative colitis and microscopic colitis and if patient is not on maintenance therapy for ulcerative colitis why it is not appropriate.

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Approved for patients 18 years and older.

PRESCRIBER RESTRICTIONS: N/A

COVERAGE DURATION:
Initial authorization and reauthorization will be approved for eight weeks.

QUANTITY LIMITS:
Budesonide (Uceris) 9 mg tablets: one tablet per day

Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:
Budesonide is a synthetic corticosteroid with a strong affinity for glucocorticoid receptors and a high ratio of local anti-inflammatory to systemic effects. It is

currently available for treatment of Crohn's disease in a generic, enteric-coated formulation that releases the drug in the ileum and ascending colon.
Uceris® is an extended-release tablet with an enteric coating that dissolves at a pH greater than or equal to 7, usually in the terminal ileum. The tablet core then forms a hydrogel that extends release of the drug throughout the entire colon.

FDA APPROVED INDICATIONS:
Budesonide extended-release tablet (Uceris® tablet): for the induction of remission in patients with active, mild to moderate ulcerative colitis.

Budesonide rectal foam (Uceris® foam): with active mild to moderate distal ulcerative colitis extending up to 40 cm from the anal verge.

POSITION STATEMENT:
Uceris® has been evaluated in two eight-week, placebo controlled studies comparing the results of treatment with 9 mg (n=255) or 6 mg (n=254) budesonide or placebo (n=258). A third study evaluated 60 patients who had previously completed the eight-week induction study but who had not achieved remission. A fourth study evaluated long-term treatment with Uceris® 6 mg in a placebo-controlled 12-month maintenance study (n=123). The glucocorticoid related effects were similar in patients with up to 12 months of therapy with Uceris® 6 mg and placebo.

Uceris® is not approved for Crohn's disease. Enterocort®/Ortikos® is an enteric coated version approved Crohn's disease and is generically available and on formulary.

The 2025 American College of Gastroenterology (ACG) Ulcerative Colitis Guidelines in Adults Provide the Following Recommendations:

Induction of remission in mildly to moderately active UC:
- Rectal 5-aminosalicylate therapies at a dose of 1 g/d preferred over rectal steroids (strong recommendation, moderate quality evidence)
- If not responsive to topical 5-ASA, tacrolimus or betamethasone suppository over no treatment (conditional recommendation, low quality of evidence)
- Topical corticosteroids (suppository, foam, enema), over no treatment (Conditional recommendation, very low quality of evidence)
- Rectal 5-ASA enemas at a dose of at least 1 g/daily combined with oral 5-ASA at a dose of at least 2.0 g/daily compared with oral 5-ASA therapy alone (Conditional recommendation, low quality of evidence) Intolerant or nonresponsive to oral and rectal 5-ASA at appropriate doses (oral at least 2.0 g daily and rectal at least 1 g daily), oral budesonide Multi Matrix System (MMX) 9

mg/d for induction of remission (Strong recommendation, moderate quality of evidence)

Maintenance of remission in patients with previously mildly active UC
- In patients with mildly active ulcerative proctitis, we recommend rectal 5-ASA at a dose of 1 g/d (strong recommendation, moderate quality of evidence)
- In patients with mildly active left-sided or extensive UC, we recommend oral 5-ASA therapy (at least 1.5 g/d) (strong recommendation, moderate quality of evidence).
- Recommend against systemic, budesonide, or topical corticosteroids (strong recommendation, moderate quality of evidence).

Management of moderately to severely active UC
- In patients with moderately active UC, oral budesonide MMX for induction of remission (strong recommendation, moderate quality of evidence)
- In patients with moderately to severely active UC of any extent, oral systemic corticosteroids to induce remission (strong recommendation, moderate quality of evidence)
- Recommend against systemic corticosteroids for maintenance of remission (Strong recommendation, moderate quality of evidence)
- Budesonide MMX has not been studied for maintenance of remission of prior moderately to severely active UC

Microscopic Colitis

Uceris®, although not FDA approved for this indication, is supported by compendia and the American Gastroenterological Association for the use in the treatment of microscopic colitis. The 2015 American Gastroenterological Association Institute Guideline on the Medical Management of Microscopic Colitis recommends budesonide over no treatment for the induction of clinical remission in patients with symptomatic microscopic colitis (strong recommendation, high quality of evidence). They also recommend treatment with budesonide over mesalamine for the induction of clinical remission in patients with symptomatic microscopic colitis (strong recommendation, high quality of evidence). Studies demonstrated that patients treated with 9 mg of budesonide daily were more than twice as likely to achieve clinical remission over an average of 7 to 12 days when compared with no treatment (relative risk, 2.52; 95% confidence interval, 1.45-4.4). Guidelines also state that cessation of budesonide can be considered after 8 weeks of therapy and that one-third of patients will remain symptoms-free after therapy and not require maintenance therapy.

REFERENCE/RESOURCES:

1. Sandborn WJ, et al. Once-daily budesonide MMX extended release tablets induce remission in patients with mild to moderate ulcerative colitis: results from the CORE I study. Gastroenterol 2012;143:1218.
2. Teavis, SP, et al. Once-daily budesonide MMX in active, mild-to-moderate ulcerative colitis: results from the randomized CORE II study. Gut 2013:Feb 22 (e pub).
3. Uceris® package insert. San Diego, CA: Santarus, Inc.; 2020 April.
4. Rubin, David T. MD, FACG[1]; Ananthakrishnan, Ashwin N. MBBS, MPH, FACG[2]; Siegel, Corey A. MD, MS[3]; Barnes, Edward L. MD, MPH, FACG[4]; Long, Millie D. MD, MPH, FACG[4]. ACG Clinical Guideline Update: Ulcerative Colitis in Adults. The American Journal of Gastroenterology 120(6):p 1187-1224, June 2025. | DOI: 10.14309/ajg.0000000000003463
5. Nguyen, GC, Smalley WE, Vege SS, et al. American gastroenterological association institute guideline on the medical management of microscopic colitis. Gastroenterology 2016, 150(1): 242-246. Available at: https://www.sciencedirect.com/science/article/pii/S001650851501625X?via%3Dihub.