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|---|---|
| **Clinical Policy Title:** | budesonide |
| **Policy Number:** | RxA.286 |
| **Drug(s) Applied:** | Uceris®, Entocort® EC, Ortikos™ |
| **Original Policy Date:** | 02/07/2020 |
| **Last Review Date:** | 06/10/2021 |
| **Line of Business Policy Applies to:** | All lines of business |

## Background

Uceris® is a glucocorticosteroid. It is indicated:

- For the induction of remission in adult patients with active, mild to moderate ulcerative colitis (UC) (extended-release tablet).
- For the induction of remission in adult patients with active mild to moderate distal UC extending up to 40 cm from the anal verge (rectal foam).

Entocort® EC is a corticosteroid. It is indicated:

- For treatment of mild to moderate active Crohn's disease involving the ileum and/or the ascending colon, in patients 8 years and older.
- For maintenance of clinical remission of mild to moderate Crohn's disease involving the ileum and/or the ascending colon for up to 3 months in adults.

Ortikos™ is a corticosteroid. It is indicated:

- For treatment of mild to moderate active Crohn's disease involving the ileum and/or the ascending colon, in patients 8 years and older.
- For maintenance of clinical remission of mild to moderate Crohn's disease involving the ileum and/or the ascending colon for up to 3 months in adults

## Dosing Information

| Drug Name | Indication | Dosing Regimen | Maximum Dose |
|---|---|---|---|
| budesonide (Uceris®) | Ulcerative Colitis | • Tablet, extended-release: 9 mg by mouth in the morning for up to 8 weeks.<br>• Rectal foam: 2 mg (1 metered dose) Per Rectum twice daily for 2 weeks, followed by 2 mg (1 metered dose) Per Rectum once daily for 4 weeks. | 9 mg/day |
| budesonide (Entocort® EC) | Mild to moderate active Crohn's disease | • For adults (Age≥ 18) 9 mg once daily for up to 8 weeks; repeat 8 week treatment courses recurring episodes of active disease | 9 mg/day |

## Dosing Information

| Drug Name | Indication | Dosing Regimen | Maximum Dose |
|---|---|---|---|
| | | • Pediatric patients (8 to 17 years) who weigh more than 25 kg: 9 mg once daily for up to 8 weeks, followed by 6 mg once daily in the morning for 2 weeks | |
| | Maintenance of clinical remission of mild to moderate Crohn's disease. | • Adults: 6 mg once daily for up to 3 months; taper to complete cessation after 3 months. Continued treatment for more than 3 months has not been shown to provide substantial clinical benefit. | 6 mg/day |
| budesonide (Ortikos™) | Mild to moderate active Crohn's disease | • For adults (Age≥ 18) 9 mg once daily for up to 8 weeks; repeat 8 week treatment courses recurring episodes of active disease<br>• Pediatric patients (8 to 17 years) who weigh more than 25 kg: 9 mg once daily for up to 8 weeks, followed by 6 mg once daily in the morning for 2 weeks | 9 mg/day |
| | Maintenance of clinical remission of mild to moderate Crohn's disease | • Adults: 6 mg once daily for up to 3 months; taper to complete cessation after 3 months. Continued treatment for more than 3 months has not been shown to provide substantial clinical benefit. | 6 mg/day |

## Dosage Forms

Uceris®
- Tablets, extended-release: 9 mg
- Rectal foam: 1 kit of 2 canisters (14 doses per canister, 2 mg per metered dose)

Entocort® EC
- Delayed-Release Capsules: 3 mg

Ortikos™
- Extended-Release Capsules: 6 mg and 9 mg

## Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

**I. Initial Approval Criteria**

**A. Ulcerative Colitis** (must meet all):

1. Diagnosis of Ulcerative Colitis (UC);
2. Prescribed by or in consultation with a gastroenterologist;
3. Age 18 years or older;
4. Failure of a 4-week trial of aminosalicylates (e.g., sulfasalazine, mesalamine; Appendix B), unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed one of the following (a or b):
   a. Oral: 9 mg (1 tablet) per day;
   b. Rectal:
      i. Initial: 2 canisters for 2 weeks;
      ii. Maintenance: 2 canisters every 4 weeks.

**Approval Duration**
**Commercial:** 12 months
**Medicaid:** 12 months

**B. Microscopic Colitis (off-label)** (must meet all):

1. Diagnosis of microscopic colitis, including collagenous colitis or lymphocytic colitis;
2. Prescribed by or in consultation with a GI specialist;
3. Age 18 years or older;
4. Request is for tablets;
5. Medical justification supports inability to use budesonide capsules;
6. Dose does not exceed 9 mg (1 tablet) per day.

**Approval Duration**
**Commercial:** 12 months
**Medicaid:** 12 months

**C. Crohn's disease** (must meet all):

1. Diagnosis of Crohn's disease;
2. Prescribed by or in consultation with a GI specialist;
3. Age 8 years or older;
4. Request is for Ortikos™ or Entocort® EC;
5. Medical justification supports inability to use budesonide tablets;
6. Dosing does not exceed (a or b):
   a. For Ortikos™
      i. Initial: Dose does not exceed 9 mg (1 capsule) per day;
      ii. Maintenance: Dose does not exceed 6 mg (1 capsule) per day
   b. For Entocort® EC
      i. Initial: Dose does not exceed 9 mg (3 capsule) per day;
      ii. Maintenance: Dose does not exceed 6 mg (2 capsule) per day.

**Approval Duration**
**Commercial:** 12 months

**Medicaid:** 12 months

**II. Continued Therapy Approval**

**A. All Indications in Section I** (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. For microscopic colitis, request is for tablets;
4. For UC or microscopic colitis: Dose does not exceed one of the following:
   a. If request is for Uceris®:
      i. Oral: 9 mg (1 tablet) per day;
      ii. Rectal: 2 canisters every 4 weeks.
5. For CD: Dose does not exceed one of the following:
   a. If request is for Ortikos™:
      i. Initial: Dose does not exceed 9 mg (1 capsule) per day;
      ii. Maintenance: Dose does not exceed 6 mg (1 capsule) per day
   b. If request is for Entocort® EC:
      i. Initial: Dose does not exceed 9 (3 capsule) mg per day;
      ii. Maintenance: Dose does not exceed 6 mg (2 capsule) per day.

**Approval Duration**
**Commercial:** 12 months
**Medicaid:** 12 months

**III. Appendices**

**APPENDIX A: Abbreviation/Acronym Key**
FDA: Food and Drug Administration
UC: Ulcerative colitis
PR: Per Rectum
EC: Entocort®
GI: Gastrointestinal

**APPENDIX B: Therapeutic Alternatives**
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| Pentasa® (mesalamine extended-release capsule) | **UC**<br>1 g by mouth four times a day for up to 8 weeks or 500 mg PR twice daily to three times a day | 4 g/day |
| | **CD**<br>1,000 mg by mouth four times a day | 4 mg per day |
| Delzicol® (mesalamine delayed-release capsule) | **UC**<br>800 mg by mouth three times a day for 6 weeks | 2.4 g/day |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| mesalamine delayed-release tablet (Lialda®, Asacol® HD) | **UC**<br>Lialda: 2.4 g to 4.8 g by mouth once daily for up to 8 weeks<br>Asacol HD: 1600 mg by mouth three times a day for 6 weeks | 4.8 g/day |
| balsalazide (Colazal®, Giazo®) | **UC**<br>2.25 g (capsule) by mouth three times a day for 8 to 12 weeks or 3.3 g<br>(tablet) by mouth twice daily for up to 8 weeks | 6.75 g/day |
| sulfasalazine (Azulfidine®, Azulfidine-EN tabs®) | **UC**<br>Adults:<br>Initial: 3 to 4 g/day (enteric coated) by mouth in evenly divided doses with dosage interval not exceeding 8 hours, or 1 g (uncoated) by mouth Every 6-8 hrs<br>Maintenance: 2 g/day (enteric coated) or 500 mg by mouth every 6H (uncoated)<br>Children 6 years and older:<br>40 to 60 mg/kg of body weight/day by mouth divided into 3 to 6 doses | Adults:<br>4 g/day<br><br>Children:<br>2 g/day |
| 6-mercaptopurine (Purixan®) | **CD**<br>50 mg by mouth once daily or 1 – 2 mg/kg/day by mouth 2 mg/kg/day | 2 mg/kg/day |
| Rheumatrex® (methotrexate) | **CD**<br>15 – 25 mg/week Intramuscular or Subcutaneous | 30 mg/week |
| Prograf® (Tacrolimus) | **CD**<br>0.27 mg/kg/day by mouth in divided doses or 0.15 – 0.29 mg/kg/day by mouth | N/A |

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

**APPENDIX C: Contraindications/Boxed Warnings**

- Contraindication(s):
  - Hypersensitivity to budesonide or any of the ingredients in Uceris® (tablets or rectal foam) or Ortikos™ Or Entocort® EC.
- Boxed Warning(s):
  - None reported.

**APPENDIX D: General Information**

- Per the 2016 American Gastroenterological Association guidelines, budesonide 9 mg daily for 6 weeks is the

preferred treatment option for microscopic colitis which includes lymphocytic colitis and collagenous colitis.
- Avoid consumption of grapefruit juice for the duration of therapy with Ortikos™ or Entocort® EC.

**References**


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| Review/Revision History | Review/Revised Date | P&T Approval Date |
|---|---|---|
| Policy established. | 01/2020 | 02/07/2020 |
| Policy was reviewed:<br>1. Clinical policy title updated<br>2. Line of Business Policy Applies to was updated to all lines of business.<br>3. Added alternative authorized brand (Entocort® EC, Ortikos™) and indication for both brand<br>4. Initial approval criteria I.B.4- one criteria added.<br>5. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..."<br>6. Reference reviewed and updated | 08/25/2020 | 09/14/2020 |
| Policy was reviewed:<br>1. Clinical policy title updated. | 04/07/2021 | 06/10/2021 |

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|---|---|---|
| 2. Dosing Information abbreviated forms changed to full form.<br>3. Appendix A: Abbreviation/Acronym Key added for PR, EC, GI.<br>4. Reference reviewed and updated. | | |