Clinical Policy: Budesonide (Uceris)

Reference Number: CP.PCH.11
Effective Date: 08.14.18
Last Review Date: 11.19
Line of Business: Commercial, HIM* Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Budesonide (Uceris®) is a glucocorticosteroid.

FDA Approved Indication(s)
Uceris is indicated:

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

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***For Health Insurance Marketplace (HIM),** Uceris extended-release tablet is non-formulary and cannot be approved using these criteria; refer to the formulary exception policy, HIM.PA.103.*

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Uceris is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of UC;
2. Prescribed by or in consultation with a gastroenterologist;
3. Age ≥ 18 years;
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:
HIM – 6 months for rectal foam (*refer to HIM.PA.103 for extended-release tablet)*
Commercial – Length of Benefit

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;
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:
HIM – *refer to HIM.PA.103 for extended-release tablet*
Commercial – Length of Benefit

C. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and HIM.PHAR.21 for health insurance marketplace.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. For microscopic colitis, request is for tablets;
4. Dose does not exceed one of the following (a or b):
   a. UC or microscopic colitis: Oral: 9 mg (1 tablet) per day;
   b. UC: Rectal: 2 canisters every 4 weeks.

Approval duration:
HIM – 6 months for rectal foam (*refer to HIM.PA.103 for extended-release tablet)*
Commercial – Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and HIM.PHAR.21 for health insurance marketplace.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial and HIM.PHAR.21 for health insurance marketplace.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
UC: ulcerative colitis

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Pentasa® (mesalamine extended-release capsule)	**UC** 1 g PO QID for up to 8 weeks or 500 mg PR BID to TID	4 g/day
Delzicol® (mesalamine delayed-release capsule)	**UC** 800 mg PO TID for 6 weeks	2.4 g/day
mesalamine delayed-release tablet (Lialda®, Asacol® HD)	**UC** Lialda: 2.4 g to 4.8 g PO QD for up to 8 weeks Asacol HD: 1600 mg PO TID for 6 weeks	4.8 g/day
balsalazide (Colazal®, Giazo®)	**UC** 2.25 g (capsule) PO TID for 8 to 12 weeks or 3.3 g (tablet) PO BID for up to 8 weeks	6.75 g/day
sulfasalazine (Azulfidine®, Azulfidine-EN tabs®)	**UC** Adults: Initial: 3 to 4 g/day (enteric coated) PO in evenly divided doses with dosage interval not exceeding 8 hours, or 1 g (uncoated) PO Q6-8 hrs Maintenance: 2 g/day (enteric coated) or 500 mg PO Q6H (uncoated) Children 6 years and older: 40 to 60 mg/kg of body weight/day PO divided into 3 to 6 doses	Adults: 4 g/day Children: 2 g/day

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
- 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.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
UC	Tablet, extended-release: 9 mg PO in the morning for up to 8 weeks. Rectal foam: 2 mg (1 metered dose) PR BID for 2 weeks, followed by 2 mg (1 metered dose) PR QD for 4 weeks.	9 mg/day 4 canisters over 6 weeks

VI. Product Availability

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

VII. References

1. Uceris Extended Release Tablet Prescribing Information. Bridgewater, NJ: Salix Pharmaceuticals; November 2016. Available at: http://shared.salix.com/shared/pi/uceris-pi.pdf. Accessed August 15, 2019.
2. Uceris Rectal Foam Prescribing Information. Bridgewater, NJ: Salix Pharmaceuticals, Inc.; September 2016. Available at: https://www.bauschhealth.com/Portals/25/Pdf/PI/UCERIS-PI.pdf. Accessed August 15, 2019.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: http://www.clinicalpharmacology-ip.com/. August 15, 2019.
4. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. American College of Gastroenterology (ACG) Clinical Guidelines; Ulcerative Colitis in Adults. Am J Gastroenterol 2019;114:384 – 413.
5. Ko CW, Singh S, Feuerstein JD, et al. American Gastroenterological Association (AGA) Clinical Practice Guidelines on the Management of Mild-to-Moderate Ulcerative Colitis. Gastroenterology 2019; 156(3):748-764.
6. Nguyen GC, Smalley WE, Vege SS, et al. American Gastroenterological Association institute guideline on medical management of microscopic colitis. Gastroenterology 2016; 150(1):242-246.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from previously approved policy CP.CPA.165 (retired) and added new line of business - HIM; removed modifier from diagnosis of UC; added prescriber specialist requirement; added age requirement; specified maximum dose requirement for initial v. maintenance treatment of UC for rectal formulation; added criteria for off-label use in microscopic colitis; references reviewed and updated.	08.14.18	11.18
4Q 2019: no significant changes; references reviewed and updated.	08.15.19	11.19

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members

and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the non-formulary policy; HIM.PA.103.