

Clinical Policy: Budesonide (Uceris)

Reference Number: CP.PCH.11

Effective Date: 08.14.18

Last Review Date: 02.22

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 the induction of remission in patients with active mild to moderate distal UC extending up to 40 cm from the anal verge (rectal foam).

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 \geq 18 years;
4. Failure of a 4-week trial of aminosalicylates (e.g., sulfasalazine, mesalamine; *see Appendix B*), unless clinically significant adverse effects are experienced or all are contraindicated;
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

Commercial – 12 months or duration of request, whichever is less

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 \geq 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 – 12 months for tablets

Commercial – 12 months or duration of request, whichever is less

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.PA.154 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

Commercial – 12 months or duration of request, whichever is less

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.PA.154 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.PA.154 for health insurance marketplace, or evidence of coverage documents.

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®, Giazol®)	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 <u>Adults:</u> 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) <u>Children 6 years and older:</u> 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 or foam
- 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.	9 mg/day
	Rectal foam: 2 mg (1 metered dose) PR BID for 2 weeks, followed by 2 mg (1 metered dose) PR QD for 4 weeks.	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; April 2020. Available at: <http://shared.salix.com/shared/pi/uceris-pi.pdf>. Accessed June 28, 2021.
2. Uceris Rectal Foam Prescribing Information. Bridgewater, NJ: Salix Pharmaceuticals, Inc.; April 2020. Available at: <https://www.bauschhealth.com/Portals/25/Pdf/PI/UCERIS-PI.pdf>. Accessed June 28, 2021.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed June 28, 2021.
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
4Q 2020: no significant changes; removed references to HIM non-formulary policy for tablet requests; references reviewed and updated.	08.04.20	11.20

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2021: no significant changes; HIM.PHAR.21 changed to HIM.PA.154; references reviewed and updated.	06.28.21	11.21
Revised approval duration for Commercial line of business from length of benefit to 12 months or duration of request, whichever is less	09.27.21	02.22

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.

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