Pharmacy Medical Necessity Guidelines:
Budesonide Extended-Release Tablets and Capsules

Effective: January 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATIONS

Uceris® (budesonide) 24 hour extended-release 9 mg tablet is a glucocorticoid indicated for the induction of remission in patients with active, mild to moderate ulcerative colitis.

COVERAGE GUIDELINES

The plan may authorize coverage of Uceris for Members when the following criteria are met and limitations do not apply:

Uceris (budesonide) Extended-Release Tablets

1. The Member is diagnosed with ulcerative colitis

AND

2. The Member tried and failed therapy with, or the provider indicates clinical inappropriateness of therapy with a 5-aminosalicylic acid (5-ASA) derivative, such as mesalamine (for example, generic Lialda, generic Asacol HD), sulfasalazine, or balsalazide

LIMITATIONS

1. Requests for brand-name products, which have AB-rated generics, will be reviewed according to the Non-covered Medications criteria.

CODES

None

REFERENCES

1. Entocort EC (budesonide) [prescribing information]. Allegan, MI: Perrigo; October 2017.
2. Hashash JA, Regueiro M. Medical management of low-risk adult patients with mild to moderate ulcerative colitis. Available at: www.uptodate.com. Accessed 26 March 2024.
3. Ko CW, Singh S, Feuerstein JD, et al. American Gastroenterological Association Institute Guideline on the Management of Mild-Moderate Ulcerative Colitis. *Gastroenterology*. 2019; 156: 748-764.
4. Lialda (mesalamine) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; November 2023.
5. Regueiro M, Hashash JA. Overview of the medical management of mild (low risk) Crohn disease in adults. Available at: www.uptodate.com. Accessed 22 June 2023.
6. Uceris (budesonide) extended-release tablets [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals; June 2024.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. July 11, 2023: No changes.
2. April 9, 2024: Effective May 1, 2024, updated RxUM fax number.
3. December 2025 E-Vote: Effective January 1, 2026, removed Ortikos approval criteria from MNG due to product discontinuation.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are

medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services