Pharmacy Medical Necessity Guidelines:
Uceris® (budesonide) Rectal Foam

Effective: April 14, 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

Budesonide rectal foam **(Uceris®)** is indicated for the induction of remission in patients with active mild to moderate distal ulcerative colitis extending up to 40 cm from the anal verge.

COVERAGE GUIDELINES

The plan may authorize coverage of **Uceris (budesonide) rectal foam** for members when the following criteria are met:

1. The Member is diagnosed with distal ulcerative colitis

AND

2. The Member tried and failed therapy with, or the provider indicates clinical inappropriateness of therapy with, one mesalamine product (oral or rectal [suppository, enema])

AND

3. The Member has tried and failed therapy with, or the provider indicates clinical inappropriateness of therapy with, one generic corticosteroid product (topical or oral)

LIMITATIONS

1. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.

CODES

None

REFERENCES

1. Hashasah JAI, Reguiero M. Medical management of low-risk adult patients with mild to moderate ulcerative colitis. UpToDate. Available at: www.uptodate.com. Accessed 26 March 2024.
2. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J* Gastroenterol. 2019;114:382-413.
3. Uceris (budesonide) rectal foam [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals; April 2020.

APPROVAL HISTORY

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

Subsequent endorsement date(s) and changes made:

1. July 11, 2023: Effective August 1, 2023, updated mesalamine step through requirement to allow formulation to be either oral or rectal.
2. April 9, 2024: Effective May 1, 2024, administrative update: added language regarding requests for brand-name products with AB-rated generics. Updated RxUM fax number.
3. April 8, 2025: No changes
4. April 14, 2026: No changes.

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