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

Effective: January 10, 2017

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<th>Type of Review – Care Management</th>
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Pharmacy (RX) or Medical (MED) Benefit  

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This pharmacy medical necessity guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan - large group plans
- Tufts Health Freedom Plan - small group plans

Fax Numbers:

| RXUM: 617-673-0988 |

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 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 a mesalamine rectal (suppository or enema) product

LIMITATIONS
None

CODES
None

REFERENCES
1. Uceris (budesonide) [prescribing information]. Raleigh, NC: Salix Pharmaceuticals; September 2016.
2. Canasa (mesalamine) [prescribing information]. Birmingham, AL: Axcan Pharma Inc; July 2013.

APPROVAL HISTORY
February 10, 2015: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- September 16, 2015: Approval duration approved for life of plan.
- January 1, 2016: Administrative change to rebranded template.
- January 12, 2016: No changes.
- January 10, 2017: No changes.
April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template

**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. They are used in conjunction with a member’s benefit document and in coordination with the member’s physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan members or to certain delegated service arrangements. Unless otherwise noted in the member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.