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

Effective: November 16, 2020

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:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

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.

Ortikos™ (budesonide) extended-release capsule is indicated for the treatment of mild to moderately active Crohn's disease involving the ileum and/or ascending colon in patients who are 8 years of age or older. It is also approved for maintenance of clinical remission of milder to moderate Crohn's disease involving the ileum and/or ascending colon for up to 3 months in adults.

Budesonide 24 hour extended-release 3 mg capsules (Entocort EC, generic) for the treatment of mild to moderate Crohn's disease involving the ileum and/or the ascending colon in patients 8 years and older. It is also approved for the maintenance of clinical remission of mild to moderate Crohn's disease involving the ileum and/or the ascending colon for up to 3 months in adults.

COVERAGE GUIDELINES

The plan may authorize coverage of Uceris or Ortikos 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 mesalamine product (for example, generic Lialda, generic Asacol HD)

Ortikos (budesonide) Extended-Release Capsules

1. The Member has tried and failed therapy with, or the provider indicates clinical inappropriateness of therapy with generic Entocort EC capsules

LIMITATIONS

None

CODES

None

REFERENCES

1. Uceris (budesonide) extended-release tablets [prescribing information]. Bridgewater, NJC: Salix Pharmaceuticals; April 2020.
2. Entocort EC (budesonide) [prescribing information]. Allegan, MI: Perrigo; October 2017.

3. Lialda (mesalamine) [prescribing information]. Lexington, MA: Shire US Inc.; July 2019.
4. 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.
5. Ortikos (budesonide) extended-release capsule [prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals, Inc; October 2019.

APPROVAL HISTORY

February 10, 2015: Reviewed by Pharmacy & Therapeutics Committee; clarified criteria is specific to budesonide oral therapy; approval duration is limited to one year.

Subsequent endorsement date(s) and changes made:
1. September 16, 2015: Approval duration approved for life of plan.
2. January 1, 2016: Administrative change to rebranded template.
3. January 12, 2016: No changes.
4. January 10, 2017: No changes.
5. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether. Updated criteria to require a trial and failure with a generic steroid product.
6. April 10, 2018: No changes.
7. December 11, 2018: Added examples of mesalamine products to the criteria. Administrative changes made to template.
8. October 15, 2019: Removed Apriso as an example of a covered mesalamine product and replaced it with generic Lialda.
9. July 14, 2020: Effective 7/20/20, updated criteria to remove requirement that member must try and fail therapy with a corticosteroid.
10. November 10, 2020: Added criteria for Ortikos to the MNG. Updated title of the MNG to "Budesonide extended-release tablets and capsules"

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.