Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: **Uceris (*budesonide ER tablet and budesonide rectal foam)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***September 2013 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Uceris (budesonide ER tablet and budesonide rectal foam).

Uceris (Budesonide ER tablet) is a glucocorticosteroid indicated for the induction of remission in patients with active, mild to moderate ulcerative colitis.

Budesonide rectal foam is a glucocorticosteroid 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.

DEFINITIONS

Distal ulcerative colitis (UC)- limited to below the descending colon and thus within reach of topical therapy.

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Uceris (budesonide ER tablet and budesonide rectal foam), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective product:

1. **Budesonide ER tablet:**
   - Must be prescribed by or in consultation with a gastroenterologist
   - Must be age 18 years or older
   - Must have a diagnosis of active, mild to moderate ulcerative colitis
   - Must be used to induce remission of active disease
   - Must have an adequate trial of one of the following with an inadequate response or significant side effect/toxicity or have a contraindication to these therapies:
     - Oral sulfasalazine or balsalazide
     - Oral corticosteroid
   - Must not have current evidence of infection

2. **Budesonide rectal foam:**
   - Must be prescribed by or in consultation with a gastroenterologist
   - Must be age 18 years or older
   - Must have a diagnosis of active, mild to moderate ulcerative colitis
   - Must be used to induce remission of active disease
   - Must have an adequate trial of one of the following with an inadequate response or significant side effect/toxicity or have a contraindication to these therapies:
     - Topical mesalamine (i.e. Canasa® rectal suppository, mesalamine enema)
     - Topical steroids (i.e. hydrocortisone enema, hydrocortisone foam, hydrocortisone suppositories)

- Must not have current evidence of infection

Reauthorization Criteria:

All prior authorization renewals are reviewed on a case-by-case basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended based upon either one of the following:

- Clinical rationale from the prescriber for continuation of treatment beyond:
  - 8 weeks for budesonide ER tablets
  - 6 weeks for budesonide rectal foam
- Documentation that the member is experiencing a subsequent flare-up and experienced improvement in the condition as a result of treatment with Uceris (budesonide) during a previous flare-up

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	• ER tablet: 8 weeks • Foam: 6 weeks
Reauthorization	• ER tablet: 8 weeks • Foam: 6 weeks

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Uceris [prescribing information]. San Diego, CA: Santarus, Inc.; January 2013.
2. Uceris Rectal Foam [prescribing information]. Raleigh, NC: Salix Pharmaceuticals, Inc. October 2014.
3. Kornbluth A, Sachar D, and The Practice Committee of the American College of Gastroenterology. Erratum: Ulcerative Colitis Practice Guidelines in Adults: American College of Gastroenterology, Practice Parameeters Committee. The American Journal of Gastroenterology 2010;105:500-523.
4. Sanborn W, Travis S, Moro L, et.al. Once-Daily Budesonide MMX® Extended-Release Tablets Induce Remission in Patients with Mild to Moderate Ulcerative Colitis: Results from the CORE I Study. Gastroenterology 2012;143:1218-1226.
5. Travis S, Danese S, Kupcinkskas L, et.al. Once-Daily Budesonide MMX in Active Mild-to- Moderate Ulcerative Colitis: Results from the Randomized CORE II Study. Gut Online First, published on February 22, 2013. Accessed September 9, 2013.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided

within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*