Effective Date: 12/2017
Revised: 7/2018, 10/2019 Reviewed: 12/2017, 7/2018, 10/2019, 8/2020, 4/2021, 3/2022 Scope: Medicaid

UCERIS (budesonide) rectal foam

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

A. Budesonide rectal foam is indicated for induction of remission of active mild to moderate distal ulcerative colitis that extends up to 40 cm from the anal verge.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR APPROVAL

An authorization may be granted when all the following criteria are met:

- Member is 18 years of age or older
- Member has a diagnosis of active, mild to moderate distal ulcerative colitis
- The requested drug is being prescribed for the induction of remission only
- Member has failed a recent 4-week trial of an oral aminosalicylate product (e.g. sulfasalazine, mesalamine)
- Member has failed, is intolerant to with significant side effect/toxicity, or contraindicated to formulary mesalamine enema or hydrocortisone enema
- Dose does not exceed the following:
    - Initial: 2 canisters for 2 weeks;
    - Maintenance: 2 canisters every 4 weeks.

Note: Uceris is not approvable for chronic use or maintenance use.

III. COVERAGE DURATION

- 2 months

IV. REFERENCES

1. Uceris rectal foam [package insert]. Bridgewater, NJ: Salix Pharmaceuticals; April 2020.
2. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. *American Journal of Gastroenterology* March 2019; 114(3): 384-413.