ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Urgent**[1] ☐ **Non-Urgent**

Requested Drug Name: Uceris® (budesonide extended release)

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit: ☐ New Request ☐ Reauthorization

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Uceris® (budesonide extended release)

Diagnosis (documentation supportive of diagnosis is required)

☐ Mild to Moderate Ulcerative Colitis (UC) for the ***induction of remission*** in patients with active disease
☐ Other (please state): _____

Clinical Consideration (for approval, documentation is required of the following):

☐ Patient had failure, incomplete response, or intolerance to one or more 5-ASA medications (e.g. topical 5-ASA [Canasa, Rowasa]; oral 5-ASA [Asacol, Asacol HD, Lialda, Apriso, Balsalazide])

☐ Patient is not a candidate for 5-ASA medication due to hypersensitivity to mesalamine, other salicylates (including aspirin) or aminosalicylates

Physician Specialty

☐ Gastroenterologist
☐ Other (please state): _____

☐ For use in clinical trial? (If yes, provide trial name and registration number):

Drug Name (Brand Name and Scientific Name)/Strength:

Dose:	Route:	Frequency:
Quantity:	Number of Refills:	
Product will be delivered to: ☐ Patient's Home ☐ Physician Office		Other:
Prescriber or Authorized Signature:		Date:

Dispensing Pharmacy Name and Phone Number:

☐ **Approved** ☐ **Denied**

If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:

1. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request

Uceris® (budesonide)

CLASSIFICATION

- Adrenal Glucocorticoid
- Anti-Inflammatory
- Endocrine-Metabolic Agent
- Gastrointestinal Agent

DESCRIPTION

- Budesonide is an anti-inflammatory synthetic corticosteroid with high glucocorticosteroid activity and substantial first-pass elimination.
- Uceris uses the company's MMX® multi-matrix system to deliver the corticosteroid through the length of the colon rather than through the entire GI tract.
- The formulation contains budesonide in an ER tablet core that is enteric coated to protect dissolution in gastric juice which delays budesonide release until exposure to a pH≥7 in the small intestine at the terminal ileum. Upon disintegration of the coating, the core matrix provides extended release of budesonide in a time dependent manner slowly releasing medicine to the full length of the colon.
- Systemic side effects are seen to a lesser extent with budesonide than with conventional glucocorticoids because budesonide is subject to high first-pass metabolism (80-90%).
- Efficacy and safety established in two similarly-designed trials conducted in patients with an Ulcerative Colitis Disease Activity Index (UCDAI) score between 4 and 10 and histology consistent with active ulcerative colitis. Remission at 8 weeks (primary outcome) was defined as UCDAI score 1 or lower, with subscores of 0 for the clinical assessments for rectal bleeding, stool frequency, and mucosal appearance, along with a reduction of 1 point or more in an endoscopy-only score. Participants in both trials had a median baseline UCDAI score of 7 out of 12 possible points.
- CORE I: 8-week, R, DB, PC and AC trial (n=489), in patients with active, mild to moderate UC were randomized to receive oral budesonide MMX 6 mg (n=121) or 9 mg (n=123) once daily, placebo (n=121), or Asacol®(mesalamine delayed-release) 2.4 g once daily (n=124) with 13.2%, 17.9%, 7.4% and 12.1% obtaining remission at 8 weeks, respectively. The treatment difference between the budesonide MMX 9 mg and placebo group was 10.4% (95% CI, 2.2% to 18.7%; $p<0.025$). Comparisons between other treatment arms were not presented.
- CORE II: 8-week, R, DB, PC and AC trial (n=410), patients with active, mild to moderate ulcerative colitis were randomized to receive oral budesonide MMX 6 mg (n=109) or 9 mg (n=109), placebo (n=89), or Entocort EC 9mg that was not indicated for UC (n=103). Combined clinical and endoscopic remission rates with budesonide MMX 9m or 6mg, Entocort EC and placebo at 8 weeks were 17.4%, 8.3%, 12.6%, and 4.5%, respectively with the treatment difference of 12.9% (95% CI, 4.6% to 21.3%; $p<0.025$) between the budesonide 9 mg and placebo group. Trial was not powered for statistical comparison with Entocort EC. The 6mg was not statistically different from placebo for any endpoint. The budesonide MMX 9mg was associated with numerically higher rates but was not statistically significant vs. placebo for clinical (42.2% vs. 33.7%) and endoscopic improvement (42.2% vs. 31.5%).
- For treatment of ulcerative colitis, aminosalicylates (e.g. mesalamine, balsalazide, sulfasalazine) are generally considered first-line medications. Steroids and immunomodulators, and in certain cases, Remicade® (infliximab infusion) or Humira® (adalimumab injection), are considered for intensification of therapy. Oral budesonide ER capsules, indicated in Crohn's disease, release active drug in the ileum and/or the ascending colon and are not optimally designed or indicated for UC.
- Treatment strategies are different if ulcerative proctitis or proctosigmoiditis vs. left-sided colitis, extensive colitis, and pancolits. One of the goals of therapy is rapid induction of a steroid-free remission.

FORMULARY COVERAGE

Prior authorization: Required
Good Health Formulary: Tier 3
Commercial Formulary: Tier 3
Medicare Part D coverage: Tier 4

COVERAGE CRITERIA

Uceris® (budesonide) meets the definition of **medical necessity** the following:

- Mild to Moderate Ulcerative Colitis: for the induction of remission in patients with active disease (documentation required).
- Documentation of failure, incomplete response or intolerance to one or more of 5-ASA medications (e.g. topical 5-ASA [Canasa, Rowasa]; oral 5-ASA [Asacol, Asacol HD, Lialda, Apriso, Balsalazide]); **OR**
- Documentation of hypersensitivity to mesalamine, other salicylates (including aspirin) or aminosalicylates; thus patient is not a candidate for 5-ASA medication.

Uceris® (budesonide) is considered **experimental** for the following:

- Any condition or diagnosis not FDA approved or Compendia supported

Required Provider Specialty:

- Approval is limited to Gastroenterologists

DOSAGE/ADMINISTRATION

Adult Dosing (safety and efficacy has not been determined for pediatric patients):

- Active, Mild to Moderate Ulcerative Colitis: For induction of remission, the recommended dose is 9mg orally once daily in the morning with or without food for 8 weeks. An additional 8 weeks can be given if UC still active.

PRECAUTIONS

- Contraindicated if hypersensitivity to budesonide or any component of the product.
- Cataracts have been reported; monitoring recommended in patients with vision changes or a history of glaucoma, increased intraocular pressure, or cataracts.
- Concomitant consumption of grapefruit or grapefruit juice should be avoided
- Diabetes mellitus or a family history of diabetes
- Glaucoma or a family history of glaucoma
- Glaucoma has been reported; monitoring recommended in patients with vision changes or a history of glaucoma, increased intraocular pressure, or cataracts.
- Hepatic impairment may result in drug accumulation.
- Moderate to severe hepatic impairment: monitoring is recommended; consider discontinuation
- Hypertension
- Immunosuppression may result in more susceptibility to serious infections and communicable diseases (e.g. chickenpox and measles), possibly resulting in fatalities; avoid exposure.
- Osteoporosis
- Peptic ulcer
- Systemic corticosteroid effects (e.g., hypercorticism and adrenal suppression) may occur; increased risk with higher than recommended doses or recommended doses in susceptible patients; monitoring recommended, particularly in patients exposed to trauma, surgery, infection, or stress.

- Transfer from steroid therapy with higher systemic effects to that with lower systemic effects, or from systemic corticosteroid therapy to inhalation or intranasal therapy; risk of acute adrenal suppression, benign intracranial hypertension, withdrawal effects, and unmasking of suppressed allergic conditions (e.g. rhinitis, eczema); monitoring and slow tapering of systemic corticosteroid recommended
- Use caution or avoid use if active or quiescent tuberculosis.
- If untreated infections (systemic bacterial, fungal, viral, or parasitic infections or ocular herpes simplex), there is risk of worsening of infection; use caution or avoid use.

COST

- AWP (March 2013): Uceris 9mg oral (30): $1,482
- AWP (March 2013): Uceris 9mg oral (30): $1,600

COMMITTEE APPROVAL

- March 2013

GUIDELINE UPDATE INFORMATION

March 2013	Prior Authorization and Coverage Policy created

REFERENCES

- DRUGDEX®, accessed 03/17/2013, 5/10/2014.
- Product Information: Uceris® (budesonide) extended release tablets, for oral use. Santarus, Inc., San Diego, CA, 2013.