Pharmacy Benefit Coverage Criteria

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Coverage Policy Number P0084

Budesonide

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Related Coverage Resources

Quantity Limitations

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Medical Necessity Criteria

This policy addresses coverage criteria only for the following budesonide products:

- Budesonide extended release tablets - 9mg
- **Ortikos**™ (budesonide 6 mg and 9 mg extended release tablets)
- **Uceris**® (budesonide extended release tablets - 9 mg)
- **Uceris**® (budesonide rectal foam)

Coverage for budesonide 9 mg extended release tablets, Ortikos™, Uceris® tablets and Uceris® rectal foam varies across plans. Refer to the customer's benefit plan document for coverage details.

Budesonide products are considered medically necessary when the following criteria are met:

For Employer Group Plans:

	Legacy Drug List Plan Standard Drug List Plan / Performance Drug List Plan Value Drug List Plan / Advantage Drug List Plan
budesonide extended	BOTH of the following: • Age 18 years of age and older • Induction of remission in active, mild to moderate ulcerative colitis

	Legacy Drug List Plan Standard Drug List Plan / Performance Drug List Plan Value Drug List Plan / Advantage Drug List Plan
release tablets-9mg	
Ortikos™ (budesonide 6 mg and 9 mg extended release tablets)	ALL of the following: • Individual is 8 years of age or older • ONE of the following: o Treatment of mild to moderate active Crohn's disease o Maintenance of remission of mild to moderate Crohn's disease • Documented intolerance to or inability to use budesonide 3 mg capsules
Uceris® (budesonide extended release tablets-9mg)	ALL of the following: • Age 18 years of age and older • Induction of remission in active, mild to moderate ulcerative colitis • Documented intolerance to 1 generic formulation of Uceris (budesonide 9 mg extended release tablet)
Uceris® (budesonide rectal foam)	ALL of the following: • Age 18 years of age and older • Induction of remission in active, mild to moderate distal ulcerative colitis extending up to 40 cm from the anal verge • Documented failure/inadequate response, contraindication per FDA label, or intolerance to or not a candidate for (for example, experiencing steroid side effects) for **ONE** of the following: hydrocortisone 100 mg / 60 ml rectal enema OR hydrocortisone acetate 10% rectal foam

Initial and reauthorization of Ortikos is up to 3 months.

Authorization for Uceris and budesonide extended release tablets- 9mg is for a single course of therapy (1 tablet per day for 8 weeks) with a limit of one course of therapy every 6 months.

Authorization for Uceris rectal foam is for a single course of therapy (2 kits per 56 days) with a limit of one course of therapy every 6 months.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Budesonide extended release tablets - 9mg, Ortikos, Uceris extended-release tablets and Uceris rectal foam are considered experimental, investigational or unproven for ANY other use.

Note: Receipt of sample product does not satisfy any criteria requirements for coverage.

FDA Approved Indications

FDA Approved Indication

Ortikos is indicated for the treatment of mild to moderate active Crohn’s disease involving the ileum and/or the ascending colon, in patients 8 years and older and 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.

Uceris (budesonide) extended release tablets are indicated for the induction of remission in patients with active, mild to moderate ulcerative colitis.

Uceris rectal foam 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.

Recommended Dosing

FDA Recommended Dosing

Ortikos extended-release tablets:
The recommended dosage for Mild to moderate active Crohn's disease

- Adults: 9 mg once daily for up to 8 weeks; repeat 8 week treatment courses recurring episodes of active disease.
- Pediatric patients 8 to 17 years who weigh more than 25 kg: 9 mg once daily for up to 8 weeks, followed by 6 mg once daily in the morning for 2 weeks.

The recommended dosage for Maintenance of clinical remission of mild to moderate Crohn's disease:

- Adults: 6 mg once daily for up to 3 months; taper to complete cessation after 3 months. Continued treatment for more than 3 months has not been shown to provide substantial clinical benefit.
- When switching from oral prednisolone, begin tapering prednisolone concomitantly with initiating Ortikos.

Uceris extended release tablets:
The recommended dosage for the induction of remission in adult patients with active, mild to moderate ulcerative colitis is one 9 mg tablet to be taken once daily in the morning with or without food for up to 8 weeks.

Uceris rectal foam:
The recommended dosage is 1 metered dose administered twice daily for 2 weeks followed by 1 metered dose administered once daily for 4 weeks.

Background

Therapeutic Alternatives

Ortikos is available as oral extended-release tablets.
Uceris (budesonide) is available in oral and rectal formulations.
Considering specific route of administration, therapeutic alternatives include corticosteroids, balsalazide, mesalamine, osalazine, sulfasalazine, and rectal 5-ASA products.

Professional Societies/Organizations

American College of Gastroenterology (ACG)
The American College of Gastroenterology (ACG) has guidelines for treatment of UC in adults (2019). Among the goals of the treatment recommendations are induction and maintenance of a sustained and durable period of steroid-free remission, improved quality of life, and minimization of cancer risk. Topical corticosteroid therapy may be helpful for patients with symptoms of distal involvement, including use in patients who are taking systemic corticosteroids. When selecting therapies, there should be a balance of safety and efficacy; this could support an approach of starting topical rectal therapy prior to a trial of systemic therapy in patients with distal colitis. (Rubin, 2019)

American Gastroenterological Association (AGA)
Guidelines from the AGA (2019) address the medical management of patients with mild to moderate UC. The mainstay of therapy for mild to moderate UC is oral 5-ASA medications. Therapeutic efficacy, systemic exposure, and safety are recognized as similar between the different 5-ASA formulations. In patients with extensive mild to moderate UC, use standard-dose mesalamine (2–3 g/day), balsalazide, or Dipentum rather than low-dose mesalamine, sulfasalazine, or no treatment. Patients with extensive or left-sided mild to moderate UC can add rectal mesalamine to oral 5-ASA if necessary. Suboptimal response to standard-dose therapies should move to high-dose mesalamine (> 3 g/day) with rectal mesalamine. The AGA advises using once-daily dosing rather than multiple times per day dosing. Patients with left-sided mild to moderate ulcerative proctosigmoiditis or proctitis, the AGA recommends rectal mesalamine rather than oral mesalamine. Patients

with inadequate response to optimized 5-ASA require escalation of therapy to oral prednisone or Uceris. (Ko, 2019)

European Crohn's and Colitis Organization
The European Crohn's and Colitis Organization has guidelines for the management of UC (2017) which note that for mild or moderately active proctitis, mesalamine 1 g suppository once daily is the preferred initial treatment and mesalamine foam enema is an alternative. Combining topical mesalamine with oral mesalamine or topical steroid (no distinction between GCSs) is more effective than either treatment alone and should be considered for escalation of treatment. Refractory proctitis may require treatment with systemic steroids, immunosuppressants and/or biologics. For left-sided UC of mild to moderate severity, treat initially with an 5-ASA enema (≥ 1 g/day) combined with oral mesalamine ≥ 2.4 g/day. Topical therapy with steroids or 5-ASAs alone as well as monotherapy with oral 5-ASAs is less effective than oral plus topical 5-ASA therapy. Topical mesalamine works as well and may be more effective than a topical steroid (e.g., rectal beclomethasone diproprionate). Systemic steroids are appropriate in disease that is of mild activity, if symptoms of active colitis do not respond to mesalamine, as well as in patients with disease of moderate or severe activity. (Harbord, 2017)

Off Label Uses
AHFS Drug Information 2020 Edition supports no off-label uses of Uceris.

Generics
The FDA's generic drug approval process does not require the drug sponsor to repeat costly animal and clinical research on ingredients or dosage forms already approved for safety and effectiveness. Generic drugs must establish the following for approval:
• contain the same active ingredients as the innovator drug (inactive ingredients may vary)
• be identical in strength, dosage form, and route of administration
• have the same use indications
• be bioequivalent
• meet the same batch requirements for identity, strength, purity, and quality
• be manufactured under the same strict standards of FDA's good manufacturing practice regulations required for innovator products

A generic drug is the same as a brand-name drug in dosage, safety, strength, quality, the way it works, the way it is taken and the way it should be used. FDA requires generic drugs have the same high quality, strength, purity and stability as brand-name drugs. Not every brand-name drug has a generic drug. When new drugs are first made they have drug patents. Most drug patents are protected for 20 years. The patent, which protects the company that made the drug first, doesn't allow anyone else to make and sell the drug. When the patent expires, other drug companies can start selling a generic version of the drug. But, first, they must test the drug and the FDA must approve it.

References

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