Budesonide 3mg Delayed-Release Capsule (Entocort EC)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Budesonide 3mg Oral capsule (Brand Name, Entocort EC 3mg Capsule) is a medication belonging to a group called steroids. Budesonide 3mg Oral capsule is approved for the treatment or maintenance of clinical remission for certain patients with mild to moderate active Crohn's disease. Budesonide is also available in several other products and formulations, including intranasal inhalation, oral inhalation, rectally, or orally. The other budesonide products are indicated and used for conditions including Crohn's disease, ulcerative colitis, certain kidney conditions to lower the risk of worsening kidney problems, and sometimes may be used for other purposes. Depending on the specific product or formulation, the use and effectiveness of budesonide varies. Please refer to Table 1 below for a list of available budesonide oral tablets & capsules, and their approved indications and usage.

Table 1: Budesonide Oral Tablet & Capsules for Inflammatory Bowel Disease

Product	Generic Availability	FDA-approved Indications and Usage

Entocort 3mg EC Capsule Delayed Release Particles, Oral	Yes	1. the treatment of mild to moderate active Crohn's disease involving the ileum and/or the ascending colon 2. 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.
Ortikos 6mg & 9mg Capsule Extended Release 24 Hour, Oral	No	1. the treatment of mild to moderate active Crohn's disease involving the ileum and/or the ascending colon in patients 8 years of age and older 2. 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 9mg Tablet Extended Release 24 Hour, Oral	Yes	1. the induction of remission in patients with active, mild to moderate ulcerative colitis

Definitions

"Autoimmune Hepatitis" refers to a condition in which the liver is attacked by the body's immune system and causes it to become inflamed, potentially causing cirrhosis (scarring of the liver) and liver failure.

"**Crohn's Disease**" refers to a chronic inflammatory condition that affects the gastrointestinal (GI) tract. The symptoms can come and go, and can affect any part of the GI tract, but usually in the small intestine and the beginning of the large intestine. It is among a group of diseases commonly referred to as inflammatory bowel disease (IBD).

"Microscopic Colitis" refers to conditions, known as lymphocytic colitis and collagenous colitis, which causes watery diarrhea.

"Ulcerative Colitis" refers to a chronic inflammatory condition that affects the colon (large intestine) and rectum. It is among a group of diseases commonly referred to as inflammatory bowel disease (IBD).

Clinical Indications

Medical Necessity Criteria for Initial Authorization

The Plan considers **Budesonide 3mg Oral capsule** medically necessary when **ALL** the following criteria are met for the applicable indication listed below:

Crohn's Disease

1. The member is 8 years or older; ***AND***
2. The member has a documented diagnosis mildly to moderately active Crohn's disease; ***AND***
3. Chart documentation and supporting laboratory test results are provided for review to substantiate the above listed requirements.

Autoimmune Hepatitis

1. The requested medication is prescribed by or in consultation with a hepatologist; ***AND***
2. The member has a documented diagnosis of autoimmune hepatitis; ***AND***
3. The member does **NOT** have ONE (1) of the following:
    a. acute severe autoimmune hepatitis; ***or***
    b. acute liver failure; ***or***
    c. cirrhosis; ***AND***
4. The member is unable to use or has tried and failed prednisone/prednisolone; ***AND***
5. Chart documentation and supporting laboratory test results are provided for review to substantiate the above listed requirements.

Microscopic (lymphocytic and collagenous) Colitis

1. The member has a documented diagnosis of microscopic colitis, defined as **ONE** (1) of the following:
    a. greater than or equal to 3 stools daily***; or***
    b. greater than equal to 1 watery stool daily; ***AND***
2. The member is unable to use or has tried and failed antidiarrheal agents, such as loperamide or bismuth subsalicylate; ***AND***
3. Chart documentation is provided for review to substantiate the above listed requirements.

If the above prior authorization criteria is met, Budesonide 3mg capsules will be approved for 16 weeks.

Medical Necessity Criteria for Reauthorization

Crohn's Disease

Reauthorization for 3-months will be granted if the member has recent chart documentation (within the last 3 months) demonstrating a clinical improvement (e.g., clinical remission, Crohn's Disease Activity Index (CDAI) score of 150 or less, quality of life improvement) in symptoms from the previous course of therapy with the requested medication.

Autoimmune Hepatitis

Reauthorization for 6-months will be granted if the member has recent chart documentation (within the last 3 months) demonstrating a clinical improvement (e.g., clinical remission, prevented further progression of liver damage) in symptoms from the previous course of therapy with the requested medication.

Microscopic (lymphocytic and collagenous) Colitis

Reauthorization for 12-months will be granted if the member has recent chart documentation (within the last 3 months) demonstrating a clinical improvement (e.g., clinical remission, histological improvement, quality of life improvement) in symptoms from the previous course of therapy with the requested medication.

Table 2: Common Treatment Regimens using Budesonide 3mg Delayed-Release Capsule (Entocort EC)

Condition	Induction	Maintenance
Crohn's Disease	9 mg once daily in the morning for up to 8 weeks; a second 8-week (16 weeks of continuous therapy) course with the drug may be beneficial in some patients	6 mg once daily for up to 3 months
Autoimmune hepatitis	3 mg three times daily	may reduce to 3 mg twice daily after remission, then slowly taper over 6 months to maintenance dose of 3 mg daily

Lymphocytic Colitis	9 mg once daily for 6 to 8 weeks	6 mg once daily, then taper to the lowest effective dose and continue for 6 to 12 months OR 3 mg/day alternating with 6 mg/day over 12 months

Experimental or Investigational / Not Medically Necessary

Budesonide 3mg Oral capsule for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

References

1. Abdalla MI, Herfarth H. Budesonide for the treatment of ulcerative colitis. Expert Opin Pharmacother. 2016;17(11):1549-1559. doi:10.1080/14656566.2016.1183648
2. Dietrich CF. Microscopic (lymphocytic and collagenous) colitis: Clinical manifestations, diagnosis, and management. Post, TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed July 29, 2022.
3. Entocort EC (budesonide) extended-release capsules [prescribing information]. Allegan, MI: Perrigo; July 2020.
4. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 clinical practice guideline for the management of glomerular diseases. Kidney Int. 2021;100(4S):S1-S276. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 clinical practice guideline for the management of glomerular diseases. Kidney Int. 2021;100(4S):S1-S276. https://kdigo.org/wp-content/uploads/2017/02/KDIGO-Glomerular-Diseases-Guideline-2021-English.pdf.
5. Mack CL, Adams D, Assis DN, et al. Diagnosis and management of autoimmune hepatitis in adults and children: 2019 practice guidance and guidelines from the American Association for the Study of Liver Diseases (AASLD). Hepatology. 2020;72(2):671-722. doi:10.1002/hep.31065
6. Miehlke S, Aust D, Mihaly E, et al.; BUG-1/LMC Study Group. Efficacy and Safety of Budesonide, vs Mesalazine or Placebo, as Induction Therapy for Lymphocytic Colitis. Gastroenterology. 2018;155(6):1795-1804.e3. doi:10.1053/j.gastro.2018.08.042
7. Miehlke S, Madisch A, Karimi D, et al. Budesonide is effective in treating lymphocytic colitis: a randomized double-blind placebo-controlled study. Gastroenterology. 2009;136(7):2092-2100. doi:10.1053/j.gastro.2009.02.078

8. Nguyen GC, Smalley WE, Vege SS, Carrasco-Labra A; Clinical Guidelines Committee. American Gastroenterological Association Institute Guideline on the Medical Management of Microscopic Colitis. Gastroenterology. 2016;150(1):242-246. doi:10.1053/j.gastro.2015.11.008
9. Ortikos (budesonide) ER capsule [prescribing information]. Cranbury, NJ: Sun Pharmaceuticals Inc; June 2019.
10. Tarpeyo (budesonide) [prescribing information]. Stockholm Sweden: Colliditas Therapeutics AB; December 2021.
11. Uceris (budesonide tablet, extended release) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals; April 2020.
12. van Rheenen PF, Aloi M, Assa A, et al. The medical management of paediatric Crohn's disease: an ECCO-ESPGHAN guideline update. J Crohns Colitis. 2020;jjaa161. doi:10.1093/ecco-jcc/jjaa161.

Clinical Guideline Revision / History Information

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