budesonide (Entocort EC®)

Commercial Pharmacy Benefit Drug Policy

Drug Details

USP Category: INFLAMMATORY BOWEL DISEASE AGENTS
Mechanism of Action: Glucocorticoid

Label Name	Quantity Limit
Budesonide 3 MG CP DR PART	3 caps/day
Entocort EC 3 MG CP DR PART	3 caps/day

Condition(s) listed in policy *(see coverage criteria for details)*

- AUTOIMMUNE HEPATITIS
- CROHN'S DISEASE; induction of remission in mild to moderate active disease
- CROHN'S DISEASE; maintenance of remission
- GRAFT VS HOST DISEASE (GvHD)
- MICROSCOPIC COLITIS

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

The following condition(s) require Prior Authorization/Preservice:

AUTOIMMUNE HEPATITIS

1. Recommended by a hepatitis specialist (hepatologist, a gastroenterologist, or an infectious disease specialist), **and**
2. Being used in combination with azathioprine, **and**
3. Intolerance or contraindication to prednisone and prednisolone, **and**
4. Dose does not exceed FDA approved maximum

Coverage Period:
one year

CROHN'S DISEASE; induction of remission in mild to moderate active disease

1. Being used for induction of remission, **and**
2. Dose does not exceed FDA approved maximum.

Coverage Period:
8 weeks

CROHN'S DISEASE; maintenance of remission

1. Being used for maintenance of remission, **and**
2. Patient responded to induction of remission therapy, **and**
3. Patient is unable to use all guideline-supported therapies (e.g., azathioprine, mercaptopurine, methotrexate, anti-TNF's) for maintaining remission of active mild to moderate Crohn's disease, **and**
4. Dose does not exceed FDA approved maximum.

Coverage Period:
one year

GRAFT VS HOST DISEASE (GvHD)

1. Patient has GI or liver involvement, **and**
2. Dose does not exceed FDA label maximum.

Coverage Period:
one year

MICROSCOPIC COLITIS

Induction of remission
1. Recommended by gastroenterologist or infectious disease, **and** 2. Dose does not exceed FDA approved maximum.
Maintenance of remission
1. Recurrence of symptoms (i.e. persistent diarrhea, abdominal bloating/cramping/pain) following completion of induction therapy, **and** 2. Dose does not exceed FDA approved maximum.

Coverage Period:
Induction of remission: 8 weeks
Maintenance of remission: one year

Additional Information

- **Immunotherapy-related colitis or diarrhea:** Entocort is supported NCCN guidelines with off-label support category 2A when treating immunotherapy-related colitis or diarrhea.
- **Dosing:**
  - Induction of remission of Crohn's disease (FDA approved indication): Patients not currently receiving corticosteroids are dosed at 9 mg once daily in the morning for up to 8 weeks. Dosing may be tapered to 6 mg once daily for 2 weeks prior to treatment cessation to minimize the risk of adrenal insufficiency. A repeat 8 week course of oral budesonide may be given for recurring episodes of active Crohn's disease. A Crohn's Disease Activity Index (CDAI) < 150 after 8 weeks of treatment for active disease is recommended before maintenance treatment is initiated
  - Induction of remission of Crohn's disease in pediatric patients at least 8 years old (FDA approved indication): Entocort EC is dosed at 9 mg once daily for up to 8 weeks, followed by 6 mg once daily in the morning for 2 weeks
  - Maintenance of clinical remission of Crohn's disease (FDA indication): Entocort EC is dosed at 6 mg once daily in the morning for up to 3 months. Consider dosage taper to complete drug cessation if symptom control is maintained at month 3. Treatment beyond 3 months has not been shown to provide substantial clinical benefit.
- **Ulcerative colitis** affects the colon and rectum, leaving the rest of the gastrointestinal tract unaffected, while Crohn's disease can affect the whole GI tract from mouth to anus. Entocort EC has an enteric coating that prevents dissolution until present in the small intestine where the active budesonide works primarily within the ileum and ascending colon. There is insufficient evidence to support the use of Entocort EC for the use in ulcerative colitis.
- **Auto-immune hepatitis without cirrhosis:** Micromedex supports (IIb) offlabel use of budesonide plus azathioprine as induction therapy in auto-immune hepatitis patients without cirrhosis and may be considered for patients with comorbidities that may be exacerbated by treatment with prednisone or prednisolone. Long-term data on budesonide safety and efficacy in autoimmune hepatitis are lacking. In patients who responded to prednisone or prednisolone and have severe steroid side effects, a switch from prednisone or prednisolone to budesonide may be considered if remission is not maintained with adequately dosed azathioprine. In patients with an incomplete response on a budesonide-based regimen, replacement of budesonide with prednisone or prednisolone (more than 20 mg per day initially) should be considered. Most people need to continue taking the prednisone for at least 18 to 24 months, and many remain on it for life. Although you may experience remission a few years after starting treatment, the disease often returns if the drug is discontinue
- **GVHD:** Although there is limited or lack of good quality supporting literature, it appears use of non- absorbable, oral steroid therapy for mild-moderate GI -GVHD may be an accepted strategy based on experience from blood and marrow transplantation experts and centers. The American Society for Blood and Marrow Transplantation

(ASBMT) has endorsed this approach in a consensus statement based on European expert practice.

- The American Society for Blood and Marrow Transplantation (ASBMT) published a graded consensus report for chronic GvHD, and a similar ungraded report is available from the EBMT–ELN addressing acute GvHD. These reports were based on European practice in expert centers. Both panels suggest budesonide or beclomethasone dipropionate are justified as a first line option for topical therapy of GI-GvHD1, 2, despite limitations of the data. [Level C-I]
- The Leukemia and Lymphoma Society mentions adjunct use of non-absorbable CS on their website as a potential approach for GI-GvHD3. Up to Date4 provides a "weak" (2B) recommendation for the use non-absorbable corticosteroids along with systemic steroids in patients as a steroid sparing option in patients who develop mild to moderate gastrointestinal GvHD.

References

1. Prescribing Information. Entocort EC. Paddock Labs. 2020

Review History

Date of Last Annual Review: 1Q2024
Date of last revision: 01/31/2024
Changes from previous policy version:

- no clinical changes following annual review

Blue Shield of California Medication Policy to Determine Medical Necessity Reviewed by P&T Committee