

### Clinical Pharmacy Program Guidelines for Entocort

Program	Prior Authorization
Medication	Entocort EC (budesonide)
Issue Date	9/2010
Pharmacy and Therapeutics Approval Date	10/2017
Effective Date	11/2017

**1. Background:**

**A. FDA Approved Indications**

**1. Active Crohn’s Disease**

Entocort EC is indicated for the treatment of mild to moderate active Crohn’s disease involving the ileum and/or the ascending colon.

**2. Remission of Crohn’s Disease**

Entocort EC is indicated 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.

**2. Coverage Criteria:**

<p><b>A. <u>Crohn’s Disease</u></b></p> <p>1. Entocort EC is being used for the treatment of Crohn’s disease</p> <p><b>Authorization will be issued for 12 months.</b></p>
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**3. References:**

1. Entocort EC® [package insert]. Wilmington, DE: AstraZeneca; December 2011.
2. Lichtenstein GR, Abreu MT, Cohen R, et al. American Gastroenterological Association Institute Technical Review on Corticosteroids, Immunomodulators, and Infliximab in Inflammatory Bowel Disease. *Gastroenterology*. 2006; 130: 940-87.
3. Lichtenstein GR, Hanauer SB, Sandborn WJ, et al. Management of Crohn’s Disease in Adults. *Am J Gastroenterol*. 2009; 104 (2): 465-83.4. Feldman PA, Wolfson D, Barkin JS, et al. Medical Management of Crohn’s Disease. *Clin Colon Rectal Surg*. 2007; 20(4): 269-281.

5. Sandborn WJ, Feagan BG. Review article: mild to moderate Crohn's disease – defining the basis for a new treatment algorithm. *Aliment Pharmacol Ther.* 2003; 18: 263-77.
6. Dignass A, Van Assche G, Lindsay JO, et al. The second European evidence-based consensus on the diagnosis and management of Crohn's disease: Current Management. *Journal of Crohn's and Colitis.* 2010; 4: 28-62.
7. Hofer KN. Oral Budesonide in the Management of Crohn's Disease. *Ann Pharmacother.* 2003; 37: 1457-64.
8. *Clinical Pharmacology Gold Standard.* 2017.
9. *Facts and Comparisons 4.0;* 2017.

Program	Prior Authorization- Entocort EC (budesonide)
<b>Change Control</b>	
Date	Change
Sept 2010	New drug policy
Sept 2011	Annual Review
Sept 2012	Annual Review
Dec 2012	Annual Review
October 2016	Updated policy template. Removed dosing paragraph from clinical criteria section.
August 2017	Annual review. Updated references.
September 2017	Updated authorization duration to 12 months and removed additional language surrounding the diagnosis to allow for Dx to Rx implementation