UnitedHealthcare Community Plan

# Clinical Pharmacy Program Guidelines for Entocort

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| 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:

**A. Crohn's Disease**

1. Entocort EC is being used for the treatment of Crohn's disease

**Authorization will be issued for12 months.**

## 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.

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| **Change Control** | |
| 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 |