UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Entocort

Program	Prior Authorization
Medication	Entocort EC (budesonide)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, New Jersey, Nevada, New York, New York EPP, Pennsylvania CHIP, Rhode Island, South Carolina
Issue Date	9/2010
Pharmacy and Therapeutics Approval Date	12/2020
Effective Date	3/2021

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 in patients 8 years and older.

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 in adults.

2. Coverage Criteria:

A. <u>Crohn's Disease</u>

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

Authorization will be issued for 12 months.

3. Additional Clinical Rules

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

- Supply limits may be in place.

4. References:

1. Entocort EC® [package insert]. Allegan, MI: Perrigo; September 2019.

Program	Prior Authorization- Entocort EC (budesonide)
Change Control	
Date	Change
9/2010	New drug policy
9/2011	Annual Review
12/2012	Annual Review
12/2012	Annual Review
10/2016	Updated policy template. Removed dosing paragraph from clinical criteria section.
8/2017	Annual review. Updated references.
9/2017	Updated authorization duration to 12 months and removed additional language surrounding the diagnosis to allow for Dx to Rx implementation
10/2018	Annual review. Updated references.
12/2019	Annual review. Updated Background. Updated references.
12/2020	Annual review, no updates.