ConnectiCare

Commercial PA Criteria

Effective: 6/23/2020

Prior Authorization: Entyvio

Products Affected: Entyvio (vedolizumab subcutaneous and intravenous solution)

Medication Description: Entyvio subcutaneous, an integrin receptor antagonist, is indicated for treatment of ulcerative colitis, in adults with moderate to severe active disease who have received two induction doses with Entyvio intravenous

Covered Uses:

1. Moderate to severe ulcerative colitis

Required Medical Information:

1. Diagnosis
2. Previous therapies tried/failed

Age Restrictions: 18 years of age or older

Prescriber Restrictions: Must be prescribed by, or in consultation with a gastroenterologist.

Coverage Duration:
Initial: 6 months
Continuation: 1 year

Other Criteria:

1. Ulcerative Colitis (Subcutaneous) Approve for the duration noted if the patient meets the following:
Initial Therapy - Approve for 6 months if the patient meets ALL of the following (A **AND**, B):

A. According to the prescriber, the patient is currently receiving Entyvio intravenous or will receive induction dosing with Entyvio intravenous within 2 months of initiating therapy with Entyvio subcutaneous; **AND**

B. Patient meets ONE of the following (i **OR** ii):

i. Patient has had a trial of ONE systemic therapy; **OR**

Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone or methylprednisolone. A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis. A trial of a biologic also counts as a trial of one systemic agent for ulcerative colitis.

ii. Patient meets BOTH of the following [(1) **AND** (2)]:

1. Patient has pouchitis; **AND**

2. Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema;

Note: Examples of antibiotics include metronidazole and ciprofloxacin. Examples of corticosteroid enemas include hydrocortisone enema.

2. **Crohn's disease (Intravenous)** Approve for the duration noted if the patient meets the following:
   Initial Therapy. Approve for 6 months if the patient meets the following
   A. Documented moderate to severe disease; **AND**
   B. Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of corticosteroids or immunomodulators (e.g. azathioprine, 6-mercaptopurine, or methotrexate, etc.); **OR**
   C. Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial on previous therapy with a TNF modifier such as adalimumab, golimumab, or infliximab

3. **Ulcerative Colitis (Intravenous)** Approve for the duration noted if the patient meets the following:
   A. Documented moderate to severe disease; **AND**
   B. Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of corticosteroids or immunomodulators (e.g. azathioprine, 6-mercaptopurine, or methotrexate); **OR**
   C. Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial on previous therapy with a TNF modifier such as adalimumab, golimumab, or infliximab

Renewal

Patient is Currently Receiving Entyvio (Subcutaneous or Intravenous). Approve for 1 year if the patient meets BOTH of the following (1 **AND** 2):

1. Patient has been established on Entyvio subcutaneous or intravenous for at least 6 months;
   *Note: A patient who has received < 6 months of **AND** therapy or who is restarting therapy with Entyvio subcutaneous or intravenous is reviewed under Initial Therapy*
2. Patient meets at least one of the following (a **OR** b):
   a. When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); **OR**
   Note: Examples of assessment for inflammatory response include fecal markers (e.g., fecal calprotectin), serum markers (e.g., C-reactive protein), endoscopic assessment, and/or reduced dose of corticosteroids.
   b. Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or decreased rectal bleeding.

References:

1. Entyvio intravenous infusion [prescribing information]. Deerfield, IL: Takeda; June 2022.
2. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114(3):384-413.
3. Bressler B, Marshall JK, Bernstein CN, et al. Clinical practice guidelines for the medical management of nonhospitalized ulcerative colitis: the Toronto consensus. Gastroenterology. 2015;148(5):1035-1058.
4. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology. 2020;158(5):1450-1461.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	6/23/2020
2	Update	Clinical Criteria	Updated clinical criteria for Crohn's disease and Ulcerative Colitis to include trials with corticosteroids, immunomodulators (e.g. azathioprine, 6-mercaptopurine, or methotrexate, etc.) OR a TNF modifier such as adalimumab, certolizumab, or infliximab.	6/23/2020
3	Update	Transferred policy to new template	All	4/1/2022
4	Update	Annual Review	Updated Length of Authorization: Removed "Coverage is provided for 12 months and may be renewed." Added "Coverage will be provided for 14 weeks initially and may be renewed every 6 months thereafter" Management of Immune Checkpoint Inhibitor related diarrhea/colitis ‡ Initial Criteria: Removed "Patient has diarrhea or colitis related to their immunotherapy; AND 4. Documented moderate or severe disease; AND" Added "Patient has moderate (grade 2) to severe (grade 3-4) diarrhea or colitis related to their immunotherapy"	7/5/2023
5	Update	Transfer to Pharmacy PA template (from medical template)	ALL	12/12/2023
6	Update	New Criteria and Renewal for Ulcerative Colitis Subcutaneous Injection	ALL	12/12/2023