UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1436-2
Program	Prior Authorization/Notification
Medication	*Entyvio® (vedolizumab) *This program applies to the subcutaneous formulation of vedolizumab
P&T Approval Date	4/2024, 5/2024
Effective Date	7/1/2024

1. Background:
Entyvio (vedolizumab) for subcutaneous use is an integrin receptor antagonist indicated in adults for the treatment of moderately to severely active ulcerative colitis (UC) and Crohn's disease (CD).

2. Coverage Criteria[a]:

A. Ulcerative Colitis

1. **Initial Authorization**

a. **Entyvio** for subcutaneous use will be approved based on **both** of the following criteria:

(1) Diagnosis of moderately to severely active ulcerative colitis

-AND-

(2) Patient is not receiving Entyvio in combination with a targeted immunomodulator [e.g., Simponi (golimumab), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Stelara (ustekinumab), Skyrizi (risankizumab)]

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Entyvio** for subcutaneous use will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Entyvio therapy

-AND-

(2) Patient is not receiving Entyvio in combination with a targeted immunomodulator [e.g., Simponi (golimumab), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Stelara (ustekinumab), Skyrizi (risankizumab)]

Authorization will be issued for 12 months.

B. Crohn's Disease

1. **Initial Authorization**

   a. **Entyvio** for subcutaneous use will be approved based on **both** of the following criteria:

      (1) Diagnosis of moderately to severely active Crohn's disease

      -AND-

      (2) Patient is not receiving Entyvio in combination with a targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Stelara (ustekinumab), Skyrizi (risankizumab)]

      Authorization will be issued for 12 months.

2. **Reauthorization**

   a. **Entyvio** for subcutaneous use will be approved based on **both** of the following criteria:

      (1) Documentation of positive clinical response to Entyvio therapy

      -AND-

      (2) Patient is not receiving Entyvio in combination with a targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Stelara (ustekinumab), Skyrizi (risankizumab)]

      Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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. Entyvio [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; April 2024.

Program	Prior Authorization/Notification – Entyvio (vedolizumab)
Change Control	
4/2024	New program.
5/2024	Added coverage criteria for Crohn's disease. Updated background and reference.