UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2332-4
Program	Prior Authorization/Medical Necessity
Medication	*Entyvio® (vedolizumab) *This program applies to the subcutaneous formulation of vedolizumab
P&T Approval Date	4/2024, 5/2024, 10/2024, 10/2025
Effective Date	1/17/2026

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 **all** of the following criteria:

(1) Diagnosis of moderately to severely active ulcerative colitis

-AND-

(2) **One** of the following:

(a) Patient has been established on therapy with Entyvio under an active UnitedHealthcare medical benefit prior authorization for the treatment of moderately to severely active ulcerative colitis

-OR-

(b) **Both** of the following:

i. Patient is currently on Entyvio for subcutaneous use therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Entyvio*

-AND-

(3) Patient is not receiving Entyvio for subcutaneous use in combination with another systemic targeted immunomodulator [e.g., adalimumab, Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab, Zeposia (ozanimod)] for treatment of the same indication

-AND-

(4) Prescribed by or in consultation with a gastroenterologist

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a manufacturer sponsored program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Entyvio for subcutaneous use therapy

-AND-

(2) Patient is not receiving Entyvio for subcutaneous use in combination with another systemic targeted immunomodulator [e.g., adalimumab, Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab, Zeposia (ozanimod)] for treatment of the same indication

Authorization will be issued for 12 months.

B. Crohn's Disease

1. **Initial Authorization**

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

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

-AND-

(2) **One** of the following:

(a) Patient has been established on therapy with Entyvio under an active UnitedHealthcare medical benefit prior authorization for the treatment of moderately to severely active Crohn's disease

-OR-

(b) **Both** of the following:

i. Patient is currently on Entyvio for subcutaneous use therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Entyvio*

-AND-

(3) Patient is not receiving Entyvio for subcutaneous use in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication

-AND-

(4) Prescribed by or in consultation with a gastroenterologist

***** Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a manufacturer sponsored program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Entyvio for subcutaneous use therapy

-AND-

(2) Patient is not receiving Entyvio for subcutaneous use in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication

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/Medical Necessity – Entyvio (vedolizumab)
Change Control	
4/2024	New program.
5/2024	Added coverage criteria for Crohn's disease. Updated background and reference.
10/2024	Updated coverage criteria for ulcerative colitis and Crohn's disease.
10/2025	Annual review. Updated combination examples and language with no change to clinical intent.