UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2332-2
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
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. Entyvio for subcutaneous use provides similar efficacy as intravenous administration of Entyvio; therefore, Entyvio for subcutaneous use is not medically necessary for treatment of ulcerative colitis since its use is mainly for convenience as compared to intravenous administration of Entyvio.

   All requests for authorization will be denied.

B. Crohn's Disease

1. Entyvio for subcutaneous use provides similar efficacy as intravenous administration of Entyvio; therefore, Entyvio for subcutaneous use is not medically necessary for treatment of Crohn's disease since its use is mainly for convenience as compared to intravenous administration of Entyvio.

   All requests for authorization will be denied.

[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.