

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2353-2
Program	Prior Authorization/Medical Necessity
Medication	*Zymfentra (infliximab-dyyb) *Zymfentra is excluded from coverage for the majority of our benefits
P&T Approval Date	10/2024, 10/2025
Effective Date	12/1/2025

1. Background:

Zymfentra (infliximab-dyyb) is a tumor necrosis factor (TNF) blocker indicated in adults for maintenance treatment of moderately to severely active ulcerative colitis following treatment with an infliximab product administered intravenously and moderately to severely active Crohn's disease following treatment with an infliximab product administered intravenously.

2. Coverage Criteria^a:

A. Ulcerative Colitis

1. **Zymfentra*** provides similar efficacy as intravenous administration of infliximab products; therefore, Zymfentra is not medically necessary for treatment of ulcerative colitis since its use is mainly for convenience as compared to intravenous administration of infliximab.

All requests for authorization will be denied.

B. Crohn's Disease

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

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.
- Exclusion: Zymfentra is excluded from coverage for the majority of our benefits
- Supply limits may be in place.

4. References:

1. Zymfentra [package insert]. Jersey City, NJ: Celltrion USA, Inc.; February 2024.

Program	Prior Authorization/Medical Necessity – Zymfentra (infliximab-dyyb)
Change Control	
10/2024	New program.
10/2025	Annual review with no change to coverage criteria.