UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1458-2
Program	Prior Authorization/Notification
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	1/17/2026

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. **Initial Authorization**

a. **Zymfentra*** 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 Zymfentra in combination with a systemic targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), 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.

2. **Reauthorization**

a. **Zymfentra*** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Zymfentra therapy

-AND-

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

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Zymfentra*** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Zymfentra therapy

-AND-

(2) Patient is not receiving Zymfentra in combination with a systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), 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.
- Exclusion: Zymfentra is excluded from coverage for the majority of our benefits
- Supply limits and/or Medical Necessity may be in place.

4. References:

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

Program	Prior Authorization/Notification – Zymfentra (infliximab-dyyb)
Change Control	
10/2024	New program.
10/2025	Annual review. Updated combination examples and language with no change to clinical intent.