ALASKA MEDICAID
Prior Authorization Criteria

Zymfentra
(infliximab-dyyb)

FDA INDICATIONS AND USAGE[1]

Zymfentra 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.
- moderately to severely active Crohn's disease following treatment with an infliximab product administered intravenously.

APPROVAL CRITERIA[1,2,3]

1. Patient meets FDA labeled age **AND**;
2. Prescribed by or in consultation with a gastroenterologist **AND**;
3. Patient has the diagnosis of one of the following:
    a. Moderate or severe ulcerative colitis
    b. Moderate or severe Crohn's disease **AND**;
4. Patient has received treatment with an infliximab product administered intravenously for ≥ 10 weeks and has demonstrated a positive clinical response to infliximab **AND**;
5. Patient is not and will not be on concurrent treatment with another biologic agent (e.g. TNF-inhibitory, interleukin inhibitor, biologic response modifier, etc.) **AND**;
6. Patient has been evaluated and screened for latent tuberculosis and hepatitis B virus infection prior to initiating treatment

DENIAL CRITERIA [1]

1. Failure to meet approval criteria **OR**;
2. Patient has a clinically significant infection **OR**;
3. Patient has a history of malignancy **OR**;
4. Patient has a history of moderate to severe chronic obstructive pulmonary disease (COPD) **OR**;
5. Patient has a history of congestive heart failure (CHF)

CAUTIONS[1]

- An increased risk of malignancies, including lymphoma, has been observed in patients receiving TNF blockers
- Monitor hepatic enzymes and liver function tests every 3 to 4 months during treatment due to risk of severe hepatic reactions
- Patients treated with Zymfentra are at increased risk of developing severe infections.
- Live vaccines should be avoided while receiving Zymfentra

DURATION OF APPROVAL

- Authorization Approval: up to 12 months

QUANTITY LIMIT

- 2 prefilled pens or syringes every 28 days
    - Max dose 120mg every 14 days

REFERENCES / FOOTNOTES:

1. Zymfentra (infliximab-dyyb) [prescribing information]. Jersey City, NJ: Celltrion; February 2024
2. Sands BE, Hanauer SB, Colombel JF, et al. P492 subcutaneous infliximab (CT-P13 SC) as maintenance therapy for ulcerative colitis: a phase 3, randomized, placebo-controlled study: results of the LIBERTY-UC study. Journal of Crohn's and Colitis. 2023;17(supp 1):i623-i624.
3. Colombel JF, Hanauer SB, Sandborn W, et al. DOP86 subcutaneous infliximab (CT-P13 SC) as maintenance therapy for Crohn's disease: a phase 3, randomized, placebo-controlled study (LIBERTY-CD). Journal of Crohn's and Colitis. 2023;17(supp 1):i161-i162.