BlueCross BlueShield
Federal Employee Program

ZYMFENTRA
(infliximab-dyyb)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Zymfentra (infliximab-dyyb) is a tumor necrosis factor (TNF) blocker and is a chimeric IgG1κ monocloncal antibody. Zymfentra neutralizes the biological activity of TNFα by binding with high affinity to the soluble and transmembrane forms of TNFα and inhibit binding of TNFα with its receptors. Zymfentra has shown biological activities, such as TNFα neutralization activity and TNFα binding affinities, complement component 1q binding affinity and crystallizable fragment receptor binding affinities in a wide variety of in vitro bioassays (1).

Regulatory Status

FDA-approved indications: Zymfentra is a tumor necrosis factor (TNF) blocker indicated in adults for maintenance treatment of: (1)

- 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.

Zymfentra carries a boxed warning regarding the increased risk of serious infections and malignancies. Patients treated with Zymfentra are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including infliximab products (1).

Zymfentra also has warnings regarding Hepatitis B virus reactivation, hepatotoxicity, congestive heart failure, hematologic reactions, hypersensitivity, neurologic reactions, and risk of additive immunosuppressive effects from prior biological products (1).

It is recommended that live vaccines not be given concurrently. At least a 6-month waiting period following birth is recommended before the administration of live vaccines to infants born to female patients treated with infliximab (1).

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The safety and effectiveness of Zymfentra in pediatric patients less than 18 years of age have not been established (1).

Summary

Zymfentra is a tumor necrosis factor (TNFα) blocker indicated for use in ulcerative colitis and Crohn's disease. It carries a boxed warning regarding the increased risk of serious infections and malignancies. It is recommended that live vaccines not be given concurrently. The safety and effectiveness of Zymfentra in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Zymfentra while maintaining optimal therapeutic outcomes.

References

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