BlueCross BlueShield Federal Employee Program

ELREXFIO
(elranatamab-bcmm)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Elrexfio (elranatamab-bcmm) is a bispecific B-cell maturation antigen (BCMA)-directed T-cell engaging antibody that binds BCMA on plasma cells, plasmablasts, and multiple myeloma cells and CD3 on T-cells leading to cytolysis of the BCMA-expressing cells. Elrexfio activated T-cells, caused proinflammatory cytokine release, and resulted in multiple myeloma cell lysis (1).

Regulatory Status

FDA-approved indication: Elrexfio is a bispecific BCMA-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody (1).

Elrexfio has a boxed warning regarding cytokine release syndrome (CRS) and neurotoxicity. Initiate treatment with Elrexfio step-up dosing schedule to reduce risk of CRS. Withold dose until CRS resolves or permanently discontinue based on severity. Neurotoxicity, including immune effector cell-associated neurotoxcitiy syndrome (ICANS), and serious and life-threatening reactions, can occur. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment. Withold dose until neurologic toxicity resolves or permanently discontinue based on severity. Elrexfio is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS), called the Elrexfio REMS (1).

Elrexfio may cause hepatotoxicity, neutropenia, and infections. Monitor liver enzymes, bilirubin, and complete blood count (CBC) at baseline and during treatment as clinically indicated. Signs and symptoms of infection should be monitored and treated appropriately. Do not initiate treatment in patients with active infections (1).

Elrexfio can cause fetal harm when administerd to a pregnant woman. Pregnant women should be advised of the potential risk to a fetus. Females of reproductive potential should be advised to use effective contraception during treatment with Elrexfio and for 4 months after the last dose (1).

The safety and effectiveness of Elrexfio in pediatric patients have not been established (1).

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Summary

Elrexfio (elranatamab-bcmm) is indicated for the treatment of relapsed or refractory multiple myeloma who have received at least four prior lines of therapy. Elrexfio has a boxed warning for cytokine release syndrome and neurologic toxicity. Hepatotoxicity, neutropenia, and infections can occur in patients treated with Elrexfio; therefore liver enzymes, bilirubin, complete blood cell counts, and signs and symptoms of infections must be monitored. The safety and effectiveness of Elrexfio in pediatric patients have not been established (1).

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

References

1. Elrexfio [package insert]. New York, NY: Pfizer Inc.; August 2023.
2. NCCN Drugs & Biologics Compendium® Elranatamab-bcmm 2023. National Comprehensive Cancer Network, Inc. Accessed on October 3, 2023.