BlueCross BlueShield
Federal Employee Program

OJEMDA
(tovorafenib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Ojemda (tovorafenib) is a Type II RAF kinase inhibitor of mutant BRAF V600E, wild-type BRAF, and wild-type CRAF kinases. Ojemda exhibited antitumor activity in cultured cells and xenograft tumor models harboring BRAF V600 and V600D mutations, and in a xenograft model harboring a BRAF fusion (1).

Regulatory Status

FDA-approved indications: Ojemda is a kinase inhibitor indicated for the treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (LGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation (1).

Prior to initiation of therapy, the presence of BRAF fusion or rearrangement, or BRAF V600 mutation must be confirmed (1).

Hemorrhages, skin toxicity including photosensitivity, hepatotoxicity, and reductions in growth velocity may occur with Ojemda use. Monitor for signs and symptoms of hemorrhage, new or worsening skin reactions, liver function tests, and patient growth during treatment with Ojemda. Depending on severity, treatment should be withheld and resumed at the same or reduced dose upon improvement, or permanently discontinued (1).

Ojemda may promote tumor growth in patients with NF1 tumors. Confirm evidence of a BRAF alteration prior to initiation of treatment with Ojemda (1).

Ojemda may cause fetal harm when administered to a pregnant woman. Advise female patients of reproductive potential to use effective non-hormonal contraception during treatment with Ojemda and for 28 days after the last dose. Advise male patients with female partners of reproductive potential to use effective nonhormonal contraception during treatment with Ojemda and for 2 weeks after the last dose (1).

The safety and effectiveness of Ojemda for pediatric patients less than 6 months of age have not been established (1).

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Summary

Ojemda (tovorafenib) is indicated for the treatment of relapsed or refractory pediatric low-grade glioma (LGG). Ojemda has warnings for hemorrhage, skin toxicity, hepatotoxicity, reductions in growth velocity, embryo-fetal toxicity, and NF1 associated tumors. The safety and effectiveness of Ojemda for pediatric patients less than 6 months of age have not been established (1).

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

References

1. Ojemda [package insert]. Brisbane, CA: Day One Biopharmaceuticals, Inc.; June 2024.
2. NCCN Drugs & Biologics Compendium® Tovorafenib 2024. National Comprehensive Cancer Network, Inc. Accessed on October 24, 2024.