BlueCross BlueShield
Federal Employee Program

FOTIVDA
(tivozanib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Fotivda (tivozanib) is a tyrosine kinase inhibitor. Fotivda inhibits phosphorylation of vascular endothelial growth factor receptor (VEGFR)-1, VEGFR-2, and VEGFR-3 and inhibits other kinases including c-kit and PDGFR β. Fotivda inhibits angiogenesis, vascular permeability, and tumor growth of various tumor cell types (1).

Regulatory Status

FDA-approved indication: Fotivda is a kinase inhibitor indicated for the treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies (1).

Fotivda has warnings regarding hypertension and hypertensive crisis; cardiac failure; cardiac ischemia and arterial thromboembolic events; venous thromboembolic events; hemorrhagic events; proteinuria; and thyroid dysfunction. Patients should be monitored closely for these events (1).

Fotivda should be stopped at least 24 days prior to elective surgery due to the risk for impaired wound healing (1).

Fotivda should be discontinued if reversible posterior leukoencephalopathy syndrome (RPLS) occurs (1).

Fotivda can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should be advised to use effective contraception during treatment with Fotivda and for one month after the las dose. Males with female partners of reproductive potential should be advised to use effective contraception during treatment with Fotivda and for one month after the last dose (1).

Most patients enrolled in the Fotivda study had clear cell or clear cell component histology (1).

The safety and efficacy of Fotivda in pediatric patients less than 18 years of age have not been

established (1).

Summary

Fotivda (tivozanib) is a tyrosine kinase inhibitor. Fotivda inhibits phosphorylation of vascular endothelial growth factor receptor (VEGFR)-1, VEGFR-2, and VEGFR-3 and inhibits other kinases including c-kit and PDGFR β. Fotivda inhibits angiogenesis, vascular permeability, and tumor growth of various tumor cell types. Fotivda has warnings regarding hypertension and hypertensive crisis; cardiac failure; cardiac ischemia and arterial thromboembolic events; venous thromboembolic events; hemorrhagic events; proteinuria; thyroid dysfunction; risk of impaired wound healing, reversible posterior leukoencephalopathy syndrome (RPLS); embryo-fetal toxicity; and allergic reactions to Tartrazine. The safety and efficacy of Fotivda in pediatric patients less than 18 years of age have not been established (1).

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

References

1. Fotivda [package insert]. Boston, MA: AVEO Pharmaceuticals, Inc.; August 2024.
2. NCCN Drugs & Biologics Compendium® Tivozanib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 15, 2025.