BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
750 9th St NW
Washington, D.C. 20001
202.942.1000
Fax 202.942.1125

5.21.172

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	April 9, 2021
Subject:	Fotivda	**Page:**	1 of 5

Last Review Date: March 8, 2024

Fotivda

Description

Fotivda (tivozanib)

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).

Related policies
Cabometyx, Inlyta, Lenvima, Nexavar, Sutent, Votrient

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Fotivda may be considered **medically necessary** if the conditions indicated below are met.

Fotivda may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Relapsed or refractory advanced renal cell carcinoma (RCC)
    a. Patient has had **TWO** or more prior systemic therapies
    b. Patient has clear cell histology

AND ALL of the following:

a. Prescriber agrees to monitor and control blood pressure using anti-hypertensive therapy when indicated

b. Prescriber agrees to monitor for cardiac failure and thromboembolic events
c. Prescriber agrees to discontinue if the patient develops reversible posterior leukoencephalopathy syndrome (RPLS)
d. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Fotivda and for 1 month after the last dose
e. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Fotivda and for 1 month after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Relapsed or refractory advanced renal cell carcinoma (RCC)

AND ALL of the following:

a. **NO** disease progression or unacceptable toxicity
b. Prescriber agrees to monitor and control blood pressure using anti-hypertensive therapy when indicated
c. Prescriber agrees to monitor for cardiac failure and thromboembolic events
d. Prescriber agrees to discontinue if the patient develops reversible posterior leukoencephalopathy syndrome (RPLS)
e. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Fotivda and for 1 month after the last dose
f. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Fotivda and for 1 month after the last dose

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Quantity 63 capsules per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits
Same as above

Rationale

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.; March 2021.
2. NCCN Drugs & Biologics Compendium® Tivozanib 2024. National Comprehensive Cancer Network, Inc. Accessed on January 24, 2024.

Policy History

Date	Action
April 2021	Addition to PA

June 2021	Annual review and reference update. Added initiation requirement that patient has clear cell histology per SME
March 2022	Annual review and reference update
March 2023	Annual review and reference update
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.