

Prior Authorization DRUG Guidelines

**FOTIVDA® (Tivozanib)**

Effective Date: Q1-25 UMC date

Date Developed: 11/26/24 by Howard Taekman MD

Date Approved by P&T Committee: 2/18/25

Fotivda is an Antineoplastic Agent. It is a Tyrosine Kinase Inhibitor which targets the Vascular Endothelial Growth Factor (VEGF) receptors thereby inhibiting tumor angiogenesis.

**Authorization Criteria:**

**Treatment of relapsed or refractory advanced renal cell carcinoma in adults following  $\geq 2$  prior systemic therapies (including a VEGFR tyrosine kinase inhibitor and may be an option in patients who have progressed on both immunotherapy and a VEGFR inhibitor)**

**DOSING:**

**ADULTS** - Oral: 1.34 mg capsule once daily for 21 days and 7 days off (28-day cycle) until disease progression or unacceptable toxicity.

**NOTE:** Reduce dose to 0.89 mg if patient has hepatic impairment (total bilirubin  $>1.5$  to 3 times ULN), or moderate to severe proteinuria ( $\geq 2$  g per 24 hours).

**Coverage Duration:** one year

**PEDIATRIC-** Not available.

**CONTRAINDICATIONS**

Fotivda is contraindicated in patients with uncontrolled hypertension, severe or Grade 3-4 hypertension, hypertensive crisis, Grade 3-4 cardiac failure, arterial thromboembolic event (such as stroke, heart attack, arterial embolic limb occlusion), hemorrhagic events, reverse posterior leukoencephalopathy syndrome, nephrotic syndrome, pregnancy.

**NOTE:** Tivozanib is metabolized by CYP3A4. Use caution with potent inducers of this enzyme (e.g. rifampicin, St. John's Wort) or inhibitors (e.g. erythromycin, ritonavir, diltiazem)

## REFERENCES

Beckermann, Kathryn E and Asnis-Alibozek, Aviva G and Atkins, Michael B and Escudier, Bernard and Hutson, Thomas E and Kasturi, Vijay and McDermott, David F and Pal, Sumanta K and Porta, Camillo and Rini, Brian I and Verzoni, Elena, Long-Term Survival in Patients With Relapsed/Refractory Advanced Renal Cell Carcinoma Treated With Tivozanib: Analysis of the Phase III TIVO-3 Trial, *The Oncologist*, Volume 29, Issue 3, March 2024, Pages 254–262, <https://doi.org/10.1093/oncolo/oyad348>

FOTIVDA (tivozanib) [prescribing information]. Otsuka America Pharmaceutical, Inc; November 2023. <https://fotivda.com/>

Rini, B. I., Pal, S. K., Escudier, B. J., Atkins, M. B., Hutson, T. E., Porta, C., Verzoni, E., Needle, M. N., & McDermott, D. F. (2020). Tivozanib versus sorafenib in patients with advanced renal cell carcinoma (TIVO-3): a phase 3, multicentre, randomised, controlled, open-label study. *The Lancet. Oncology*, 21(1), 95–104. [https://doi.org/10.1016/S1470-2045\(19\)30735-1](https://doi.org/10.1016/S1470-2045(19)30735-1)

### A. Attachments: None

### B. History:

Policy created by Howard Taekman, MD; Robert Sterling MD

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Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes