Tivozanib (FOTIVDA)
Criteria for Use
June 2022

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information. See the VA National PBM-MAP-VPE Monograph on this drug at the *PBM INTERnet* or *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive tivozanib: ^1

- ☐ Active or untreated central nervous system metastases
- ☐ Hepatic insufficiency (i.e., total bilirubin > 3 to 10 x ULN with any AST)
- ☐ Significant cardiovascular disease (i.e., symptomatic left ventricular heart failure, uncontrolled hypertension with systolic blood pressure >150 mmHg or diastolic blood pressure >100 mmHg, acute coronary syndrome within past 6 months)
- ☐ Pregnancy (i.e., known pregnancy or positive pregnancy test) or lactating
- ☐ Concomitant CYP3A4 inducers (strong)

^1 Tivozanib contains tartrazine yellow dye (FD&C Yellow No. 5) which may cause allergic-type reactions

Inclusion Criteria

The answers to the following must be fulfilled to meet criteria:

- ☐ Care provided by a VA/VA Community Care hematology or oncology provider
- ☐ Goals of care and role of Palliative Care consult have been discussed and documented
- ☐ Eastern Cooperative Oncology Group (ECOG) Performance Status 0 to 1

Additional Inclusion Criteria (select if applicable)

- ☐ For patients who can become pregnant and patients with partners who can become pregnant: Counseling provided on potential risks vs. benefits of treatment and the use of effective contraception during therapy and for one month after stopping treatment

Additional Inclusion Criteria

The answers to the following must be fulfilled to meet criteria:

- ☐ Metastatic renal cell carcinoma with a clear cell component
- ☐ Previously unsuccessful treatment with 2 or 3 systemic therapy regimens, 1 of which were vascular endothelial growth factor receptor inhibitors other than tivozanib

Other Justification

- ☐ _____

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