

PHARMACY COVERAGE GUIDELINE

FOTIVDA™ (tivozanib) Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively “Service”) is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider’s judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member’s benefit plan; and
- Is subject to change as new information becomes available.

Scope

- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance

- To determine whether a member is eligible for the Service, read the entire PCG.
 - This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
 - Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
 - The “Criteria” section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member’s benefit plan.
 - The “Description” section describes the Service.
 - The “Definition” section defines certain words, terms or items within the policy and may include tables and charts.
 - The “Resources” section lists the information and materials we considered in developing this PCG
 - **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
 - Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the [request form](#) and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.
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Medical Necessity Requirements for FOTIVDA (tivozanib)

Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by a physician specializing in the diagnosis or in consultation with an Oncologist

Indication

- Relapsed or refractory advanced renal cell carcinoma (renal cell carcinoma) following two or more prior systemic therapies
- Other oncologic direct treatment use listed in the National Comprehensive Cancer Network (National Comprehensive Cancer Network) Guidelines with Categories of Evidence and Consensus of 1 and 2A

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Age Requirement

- 18 years or older

Baseline Clinical Evaluation

- Systolic blood pressure is less than 150 mmHg or diastolic blood pressure is less than 100 mmHg
- Thyroid function tests completed
- Negative pregnancy test in a woman of childbearing potential
- Eastern Cooperative Oncology Group (Eastern Cooperative Oncology Group) Performance Status of 0–1

Brand Specific Criteria

- Have failure, contraindication, or intolerance with **THREE** generic equivalents (when available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the United States Food and Drug Administration (United States Food and Drug Administration)

Safety

- No symptomatic cardiac failure within the preceding six months
- No arterial thrombotic event within the preceding six months
- No concomitant drug use with strong CYP3A inducers (e.g., rifampin, rifabutin, phenobarbital, carbamazepine)
- Does not have end-stage renal disease (creatinine clearance less than 15 mL/min)
- Does not have severe hepatic impairment (total bilirubin greater than 3–10 times the upper limit of normal and any aspartate aminotransferase)

Documentation Requirements

- A completed request form must be submitted, including:
 - Chart notes
 - Lab results (blood pressure, thyroid function, pregnancy test, Eastern Cooperative Oncology Group status)
 - Supporting clinical documentation

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year
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Criteria for Continuation of Therapy (renewal therapy)

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Prescriber Qualifications

- Continues to be seen by a physician specializing in or is in consultation with an Oncologist

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Clinical Response

- No evidence of disease progression or unacceptable toxicity

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication, or intolerance with three generic equivalents (when available) for at least three months each. Note: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- No significant adverse drug effects such as:
 - Severe hypertension despite optimal antihypertensive therapy or hypertensive crisis
 - Life-threatening cardiac failure
 - Cardiac ischemia or arterial thromboembolic event (e.g., myocardial infarction, stroke)
 - Severe or life-threatening venous thromboembolic event
 - Severe or life-threatening hemorrhagic event
 - Proteinuria or nephrotic syndrome Reverse Posterior Leukoencephalopathy Syndrome
 - Severe or life-threatening gastrointestinal perforation
 - Any other life-threatening adverse reaction
- No concomitant drug use with strong CYP3A inducers (e.g., rifampin, rifabutin, phenobarbital, carbamazepine, etc.)
- Does not have end-stage renal disease (creatinine clearance less than 15 mL/min)
- Does not have severe hepatic impairment (total bilirubin greater than 3–10 times the upper limit of normal and any aspartate aminotransferase)

Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement in given indication
- Lab values that confirm safe use from above criteria

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year
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Criteria for Off-Label Use Requests:

Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. Off-Label Use of Non-Cancer Medications

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2. Off-Label Use of Cancer Medications

Description:

Fotivda (tivozanib) 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.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
[MedWatch Forms for FDA Safety Reporting | FDA](#)

ECOG Performance status:

Eastern Co-operative Oncology Group (ECOG) Performance Status	
Grade	ECOG description
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
5	Dead

Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., Carbone, P.P.: Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982

NCCN recommendation definitions:

Category 1:

Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

Category 2A:

Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

Category 2B:

Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.

Category 3:

Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate

Resources:

Fotivda (tivozanib) product information, revised by AVEO Pharmaceuticals, Inc. 08-2024. Available at DailyMed
<http://dailymed.nlm.nih.gov>. Accessed February 21, 2025.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Kidney Cancer
Version 3.2025 – Updated January 09, 2025. Available at <https://www.nccn.org>. Accessed April 17, 2025.

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Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.

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