BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

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.

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 (RCC) 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

ORIGINAL EFFECTIVE DATE: 05/20/2021 | ARCHIVE DATE: | LAST REVIEW DATE: 05/21/2026 | LAST CRITERIA REVISION DATE: 05/15/2025

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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 to 1

Brand Specific Criteria
- Have failure, contraindication or intolerance with **THREE** generic equivalents (if 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 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 to 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

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 (if 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 to 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

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:

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1. Off-Label Use of Non-Cancer Medications
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. 01-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed January 29, 2026.

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National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Kidney Cancer Version 1.2026 – Updated July 24, 2025. Available at https://www.nccn.org. Accessed March 10, 2026.

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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