PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 5/20/2021
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ARCHIVE DATE:

FOTIVDA™ (tivozanib)

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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Criteria:

- **Criteria for initial therapy:** Fotivda (tivozanib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Oncologist

  2. Individual is 18 years of age or older

  3. A confirmed diagnosis of **ONE** of the following:
     a. Relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies

     b. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

  4. **ALL** of the following **baseline tests** have been completed before initiation of treatment with continued monitoring as clinically appropriate:
     a. Systolic blood pressure is less than 150 mmHg or diastolic blood pressure is less than 100 mmHg
     b. Thyroid function tests
     c. Negative pregnancy test in a woman of child bearing potential
     d. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0-1

  5. Individual has not had symptomatic cardiac failure within the preceding 6-months

  6. Individual has not had an arterial thrombotic event within the preceding 6-months

  7. Individual does not have end-stage renal disease (CLcr less than 15 mL/min)

  8. Individual does not have severe hepatic impairment (total bilirubin greater than 3-10 times the upper limit of normal and any aspartate aminotransferase)

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Fotivda (tivozanib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist

  2. Individual's condition has responded while on therapy
     a. Response is defined as:
        i. No evidence of disease progression
        ii. Documented evidence of efficacy, disease stability and/or improvement

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3. Individual has been adherent with the medication

4. Individual has not developed any significant adverse drug effects that may exclude continued use
    a. Significant adverse effect such as:
        i. Severe hypertension despite use of optimal antihypertensive therapy or experienced hypertensive crisis episode
        ii. Life-threatening cardiac failure
        iii. Cardiac ischemia or arterial thromboembolic event such as myocardial infarction and stroke
        iv. Severe or life-threatening venous thromboembolic event
        v. Severe or life-threatening hemorrhagic event
        vi. Proteinuria or nephrotic syndrome
        vii. Reverse Posterior Leukoencephalopathy Syndrome
        viii. Any other life-threatening adverse reaction

5. There are no significant interacting drugs

6. Individual does not have end-stage renal disease (CLcr less than 15 mL/min)

7. Individual does not have severe hepatic impairment (total bilirubin greater than 3-10 times the upper limit of normal and any aspartate aminotransferase)

Renewal duration: 12 months

- 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 a Non-Cancer Medications**

2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

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.

Resources:

Fotivda (tivozanib) product information, revised by AVEO Pharmaceuticals, Inc. 03-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed on April 26, 2021.

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National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Kidney Cancer Version 4.2021 – Updated April 19, 2021. Available at https://www.nccn.org. Accessed on April 26, 2021.

National Comprehensive Cancer Network (NCCN) Compendium: Fotivda. National Comprehensive Cancer Network (NCCN). NCCN Drugs & Biologics Compendium. 2021(c); Available at: http://www.nccn.org. Accessed on April 26, 2021.

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.