Fotivda® (tivozanib)
(Oral)

Document Number: IC-0596

Last Review Date: 07/05/2023
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I. Length of Authorization

- Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Fotivda 0.89 mg capsules: 21 capsules every 28 days
- Fotivda 1.34 mg capsules 21 capsules every 28 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- RCC: 1.34 mg daily for 21 days of a 28-day cycle

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Patient blood pressure is controlled prior to initiation of treatment (*Note: do not administer if systolic blood pressure >150 mmHg or diastolic blood pressure >100 mmHg*); **AND**

Universal Criteria [1]

- Patient must not have had a surgical procedure within the preceding 24 days or have a surgical wound that has not fully healed; **AND**
- Patient does not have unstable or untreated central nervous system (CNS) metastases; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Used as a single agent; **AND**

Renal Cell Carcinoma (RCC) † [1-4]

- Patient has relapsed, refractory advanced, or metastatic (stage IV) disease with clear cell histology; **AND**

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- Patient has progressed after at least two prior systemic therapies

† FDA Approved Indication(s); ‡ Compendia Approved Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in Section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypertension and hypertensive crisis, cardiac failure, cardiac ischemia, arterial thrombotic events, myocardial infarction, stroke, venous thromboembolic events, hemorrhagic events, severe proteinuria, thyroid dysfunction, impaired wound healing, reversible posterior leukoencephalopathy syndrome (RPLS), tartrazine hypersensitivity reactions, etc.

V. Dosage/Administration [1]

Indication	Dose
Renal Cell Carcinoma (RCC)	Administer 1.34 mg orally once daily for 21 days on treatment followed by 7 days off treatment for a 28-day cycle. Continue treatment until disease progression or until unacceptable toxicity occurs. Take with or without food.

VI. Billing Code/Availability Information

HCPCS Code:

- J8999 – Prescription drug, oral, chemotherapeutic, NOS
- C9399 – Unclassified drugs or biological

NDC:

- Fotivda 0.89 mg capsules: 45629-0089-xx
- Fotivda 1.34 mg capsules: 45629-0134-xx

VII. References

1. Fotivda [package insert]. Boston, MA; Aveo Pharmaceuticals, Inc; March 2021. Accessed June 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for tivozanib. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL

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3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Kidney Cancer Version 4.2023. National Comprehensive Cancer Network, 2023. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed June 2023.
4. Rini BI, Pal SK, Escudier BJ, Atkins MB, Hutson TE, Porta C, Verzoni E, Needle MN, McDermott DF. Tivozanib versus sorafenib in patients with advanced renal cell carcinoma (TIVO-3): a phase 3, multicentre, randomised, controlled, open-label study. Lancet Oncol. 2020 Jan;21(1):95-104. doi: 10.1016/S1470-2045(19)30735-1. Epub 2019 Dec 3.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.

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Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

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