PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Fotivda Prior Authorization Policy
- Fotivda® (tivozanib tablets – AVEO)

REVIEW DATE: 04/19/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Fotivda, a kinase inhibitor, is indicated for the treatment of relapsed or refractory advanced **renal cell carcinoma (RCC)** following two or more prior systemic therapies in adults.[1]

Guidelines

In the National Comprehensive Cancer Network (NCCN) clinical practice guidelines for kidney cancer (version 4.2023 – January 18, 2023), Fotivda is given a category 2A recommendation as "useful in certain circumstances" for subsequent therapy for clear cell histology, with a footnote that states this recommendation applies to patients who have received ≥ two systemic therapies. It is also recommended under "Other recommended regimens" for subsequent therapy for clear cell histology in patients who have had prior immune-oncology therapy.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Fotivda. All approvals are provided for the duration noted below.

Fotivda® (tivozanib tablets (AVEO)
is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Renal Cell Carcinoma.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has relapsed or Stage IV disease; AND
   C) Patient has tried at least two other systemic regimens.
   Note: Examples of systemic regimens for renal cell carcinoma include Inlyta (axitinib tablets) + Keytruda (pembrolizumab intravenous infusion), Cabometyx (cabozantinib tablets) + Opdivo (nivolumab intravenous infusion), Lenvima (lenvatinib capsules) + Keytruda, Yervoy (ipilimumab intravenous infusion) + Opdivo, sunitinib, Votrient (pazopanib tablets), and Lenvima+ everolimus.

CONDITIONS NOT COVERED

Fotivda® (tivozanib tablets (AVEO)
is(are) considered experimental, investigational, or unproven for ANY other use(s).

REFERENCES

1. Fotivda® tablets [prescribing information]. Boston, MA: AVEO; March 2021.
2. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 4.2023 – January 18, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed April 18, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	04/13/2022
Selected Revision	**Renal Cell Carcinoma:** The duration of approval was changed from 3 years to 1 year.	06/22/2022
Annual Revision	No criteria changes	04/19/2023