PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 05/08/2024

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 3.2024 – March 11, 2024), Fotivda is given a category 2A recommendation as "useful in certain circumstances" for subsequent therapy for clear cell histology in immune-oncology therapy naïve patients, with a footnote that states this recommendation applies to patients who have received \geq 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Fotivda is recommended in those who meet the following criteria:

FDA-Approved Indication

- 1. Renal Cell Carcinoma. Approve for 1 year if the patient meets the following (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, pazopanib, and Lenvima+ everolimus.

Oncology – Fotivda PA Policy Page 2

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Fotivda is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

- 1. Fotivda® tablets [prescribing information]. Boston, MA: AVEO; March 2021.
- The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 3.2024 March 11, 2024). © 2024 National Comprehensive Cancer Network. Available at: <u>http://www.nccn.org</u>. Accessed May 5, 2024.