

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Fotivda Prior Authorization Policy

• Fotivda® (tivozanib tablets – AVEO Pharmaceuticals)

REVIEW DATE: 03/24/2021

OVERVIEW

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

Guidelines

In the National Comprehensive Cancer Network (NCCN) clinical practice guidelines for kidney cancer (version 3.2021 – March 23, 2021), Fotivda is given a category 2A recommendation as an "other recommended regimen" for subsequent therapy for clear cell histology, with a footnote that this recommendation applies to patients who have received at least two systemic therapies. Preferred regimens for subsequent therapy include Cabometyx® (cabozantinib tablets) [category 1], Opdivo® (nivolumab injection) [category 1], or Yervoy® (ipilimumab injection) + Opdivo (category 2A). Additional other recommended regimens include Inlyta® (axitinib tablets) [category 1], Lenvima® (lenvatinib capsules) + everolimus (category 1), Inlyta + Keytruda® (pembrolizumab injection) [category 2A], everolimus (category 2A), Votrient® (pazopanib tablets), Sutent® (sunitinib malate capsules) [category 2A], and Inlyta + Bavencio® (avelumab injection) [category 3]. Fotivda is not among the recommendations for use in the first-line setting.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Fotivda. All approvals are provided for 3 years in duration unless otherwise 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 (RCC). Approve for 3 years 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.

<u>Note</u>: Examples of systemic regimens for renal cell carcinoma include Inlyta (axitinib tablets), Inlyta + Keytruda (pembrolizumab injection), Cabometyx (cabozantinib tablets), Cabometyx + Opdivo (nivolumab injection), Sutent (sunitinib malate capsules), Votrient (pazopanib tablets), Nexavar (sorafenib tablets), and Lenvima (lenvatinib capsules) + everolimus.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Fotivda is not recommended in the following situations:

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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® [prescribing information]. Boston, MA: AVEO Pharmaceuticals; March 2021.
- 2. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 3.2021 March 23, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed March 24, 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy		03/24/2021