PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 04/13/2022; selected revision 06/22/2022

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 4.2022 – December 21, 2021), Fotivda is given a category 2A recommendation as an "other recommended regimen" for subsequent therapy for clear cell histology, with a footnote that states this recommendation applies to patients who have received ≥ two systemic therapies. Preferred regimens for subsequent therapy include Cabometyx® (cabozantinib tablets), Opdivo® (nivolumab intravenous infusion), or Lenvima® (lenvatinib capsules) + everolimus (all category 1).

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 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, Sutent (sunitinib capsules), Votrient (pazopanib tablets), and Lenvima+ everolimus.

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.
2. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 4.2022 – December 21, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed April 10, 2022.