Reference number(s)
4619-A

SPECIALTY GUIDELINE MANAGEMENT

FOTIVDA (tivozanib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication[1]
Fotivda is indicated for the treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Renal Cell Carcinoma (RCC)
Authorization of 12 months may be granted for treatment of renal cell carcinoma of clear cell histology when all the following criteria are met:
1. The disease is relapsed, refractory, advanced, or stage IV
2. Member has received at least two prior systemic therapies
3. The requested medication will be used as a single agent

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Fotivda [package insert]. Boston, MA: AVEO Pharmaceuticals, Inc.; March 2021.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed May 3, 2023.