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| <b>Reference number(s)</b> |
| 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 Indications

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 relapsed or refractory advanced renal cell carcinoma in members who have received two or more prior systemic therapies, when the requested medication is 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.