Clinical Policy: Tivozanib (Fotivda)

Reference Number: ERX.SPA.438
Effective Date: 06.01.21
Last Review Date: 05.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Tivozanib (Fotivda®) is a tyrosine kinase inhibitor.

FDA Approved Indication(s)
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.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Fotivda is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Renal Cell Carcinoma (must meet all)**:**

1. Diagnosis of advanced RCC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is relapsed or refractory following at least 2 prior systemic therapies (*see Appendix B*);
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 1.34 mg per day for 21 days, followed by 7 days off treatment, for every 28-day cycle;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid – 6 months
Commercial – Length of Benefit

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Renal Cell Carcinoma (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Fotivda for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*

a. New dose does not exceed 1.34 mg per day for 21 days, followed by 7 days off treatment, for every 28-day cycle;
b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid – 12 months
Commercial – Length of Benefit

A. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
RCC: renal cell carcinoma

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Regimens for clear cell histology: • Inlyta® (axitinib) + Keytruda® (pembrolizumab) • Cabometyx® (cabozanitinib) + Opdivo® (nivolumab) • Votrient® (pazopanib) • Sutent® (sunitinib) • Yervoy® (ipilumab) + Opdivo (nivolumab) • Cabometyx (cabozanitinib) • Inlyta (axitinib) + Bavencio® (avelumab) • Proleukin® (aldesleukin) • Torisel® (temsirolimus) • Opdivo (nivolumab) • Lenvima® (lenvatinib) + Afinitor® (everolimus) • Avastin® (bevacizumab) • Nexavar® (sorafenib)	Varies	Varies
Regimens for non-clear cell histology: • Sutent (sunitinib) • Cabometyx (cabozanitinib) • Afinitor (everolimus) • Lenvima (lenvatinib) + Afinitor (everolimus) • Inlyta (axitinib) • Avastin (bevacizumab) • Tarceva® (erlotinib) • Opdivo (nivolumab)	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
• Votrient (pazopanib) • Avastin (bevacizumab) + Tarceva (erlotinib) • Avastin (bevacizumab) + Afinitor (everlimus) • Torisel (temsirolimus)		

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
RCC	1.34 mg PO QD for 21 days on treatment followed by 7 days off treatment (28-day cycle) until disease progression or unacceptable toxicity Reduce the dose to 0.89 mg/day for patients with moderate hepatic impairment	1.34 mg/day

VI. Product Availability
Capsules: 1.34 mg, 0.89 mg

VII. References
1. Fotivda Prescribing Information. Boston, MA: AVEO Pharmaceuticals, Inc.; March 2021. Available at: https://www.aveooncology.com/fotivdapi.pdf. Accessed March 16, 2021.
2. National Comprehensive Cancer Network. Kidney Cancer Version 2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed March 16, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	03.16.21	05.21

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.