

Clinical Policy Title:	tivozanib
Policy Number:	RxA.683
Drug(s) Applied:	Fotivda®
Original Policy Date:	06/10/2021
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Relapsed, Refractory Advanced Renal Cell Carcinoma (must meet all):

1. Diagnosis of relapsed or refractory advanced renal cell carcinoma with clear cell histology;
2. Trial and failure of at least two (2) prior systemic therapies unless contraindicated or clinically significant adverse effects are experienced (e.g., Inlyta, Keytruda, Cabometyx, Opdivo, Sutent, Votrient, Nexavar, Lenvima);
3. Prescribed as a single agent;
4. Member has not had a surgical procedure within the preceding 24 days or have a surgical wound that has not fully healed;
5. Member does not have unstable or untreated central nervous system (CNS) metastases.

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. Relapsed, Refractory Advanced Renal Cell Carcinoma (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Kidney Cancer Version 1.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed August 28, 2024.
2. AVEO Pharmaceuticals, Inc. A Phase 3, Randomized, Controlled, Multi-Center, Open-Label Study to compare Tivozanib Hydrochloride to Sorafenib in Subjects with Refractory Advanced Renal Cell Carcinoma. Available at: <https://clinicaltrials.gov/ct2/show/NCT02627963>. NLM identifier: NCT02627963. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	06/10/2021	06/10/2021
Policy was reviewed: 1. Initial Approval Criteria I.A.2: Updated from Failure of at least	02/01/2022	04/18/2022

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<p>2 prior systemic therapies at up to maximally indicated doses within the past 12 months, 1 of which includes a VEGF TKI (e.g. Sutent®, Nexavar®, Inlyta®), unless contraindicated or clinically significant adverse effects are experienced to Failure of at least two (2) prior systemic therapies unless contraindicated or clinically significant adverse effects are experienced (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);</p> <p>2. References were reviewed and updated.</p>		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from diagnosis of advanced renal cell carcinoma to Diagnosis of relapsed or refractory advanced renal cell carcinoma with clear cell histology. 2. Initial Approval Criteria, I.A.5: Updated to include new prescribing criteria Fotivda® will be prescribed as single agent. 3. Initial Approval Criteria, I.A.6: Updated to include new criteria pertaining to indication Relapsed, Refractory Advanced Renal Cell Carcinoma, Member must not have had a surgical procedure within the preceding 	<p>02/01/2023</p>	<p>04/13/2023</p>

<p>24 days or have a surgical wound that has not fully healed.</p> <p>4. Initial Approval Criteria, I.A.7: Updated to include new disease progression criteria Member does not have unstable or untreated central nervous system (CNS) metastases.</p> <p>5. References were reviewed and updated.</p>		
Policy was reviewed.	10/19/2023	10/19/2023
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated. 	08/28/2024	9/13/2024
Policy was reviewed.	12/05/2024	N/A
Policy reviewed.	12/11/2025	12/11/2025