

Clinical Policy Title:	axitinib
Policy Number:	RxA.167
Drug(s) Applied:	Inlyta®
Original Policy Date:	03/06/2020
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business

Clinical Policy

I. Initial Approval Criteria (Prescribed regimen must be FDA-approved or recommended by NCCN)

A. Renal Cell Carcinoma (must meet all):

1. Diagnosis of advanced renal cell carcinoma;
2. One of the following (a or b):
 - a. Prescribed as a single agent after failure of one prior systemic therapy;
 - b. Prescribed as first-line therapy in combination with avelumab or pembrolizumab.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications in Section I (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 Guidelines. Kidney Cancer Version 3.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed March 20, 2025.
2. National Comprehensive Cancer Network Guidelines. Thyroid Carcinoma Version 5.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed March 20, 2025.
3. National Comprehensive Cancer Network Guidelines. Soft Tissue sarcoma Version 5.2024. available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed March 20, 2025.
4. PhD JT MD. A Phase II Trial of Concurrent Axitinib and Pembrolizumab in Subjects with Advanced Alveolar Soft Part Sarcoma (Asps) and Other Soft Tissue Sarcomas(Sts). clinicaltrials.gov; 2022. Available at: <https://clinicaltrials.gov/ct2/show/NCT02636725>. Accessed March 20, 2025.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	02/2020	03/06/2020
Policy was reviewed:	06/14/2020	09/14/2020

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.

<ol style="list-style-type: none"> 1. Policy title table was updated. 2. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance...”. 3. References were updated. 		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Continuation approval therapy rephrased to: Member is currently receiving medication that has been authorized by RxAdvance or documentation supports that member has met initial approval criteria for the covered indications and has received this medication for at least 30 days..” 2. Initial therapy criteria was updated to clarify prescribing criteria under section I.A.2 and I.A.3 3. Updated dosing criteria based on NCCN evidence under section I.B.6. 4. References were updated. 	03/19/2021	06/10/2021
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.2.a: Updated to remove prior 2B NCCN criteria "First-line single agent therapy, useful in certain circumstances". 2. Initial Approval Criteria I.A.2.c.i and I.A.2.c.ii were removed and modified to I.A.2.b, as first line therapy for favourable risk, poor/intermediate risk in combination therapy with pembrolizumab or avelumab and I.A.2 .c , as subsequent therapy in combination with pembrolizumab. 3. Initial Approval Criteria I.B.6.a was updated from does not exceed 5 mg twice daily to 20 mg daily. 4. References were reviewed and updated. 	01/12/2022	04/18/2022
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.2: Updated prescriber criteria from For clear cell histology, prescribed as (must meet one of the following): <ol style="list-style-type: none"> a. Subsequent single agent therapy (failure of previous therapy, see Appendix B); b. As first line therapy for favourable risk, poor/intermediate risk in combination therapy with pembrolizumab or avelumab; c. As subsequent therapy in combination with pembrolizumab; to Prescribed in one of the following ways (a or b): <ol style="list-style-type: none"> a. As a single agent therapy; b. For clear cell histology, in combination with Keytruda® or Bavencio®; 2. Initial Approval Criteria, I.A.3: Updated to remove prior criteria pertaining to indication Renal Cell 	01/18/2023	04/13/2023

<p>Carcinoma.</p> <ol style="list-style-type: none"> 3. Initial Approval Criteria, I.B.5: Updated to remove prior trial and failure criteria "Failure of lenvatinib (Lenvima®)* or sorafenib (Nexavar®)* unless contraindicated or clinically adverse effects are experienced; *Prior authorization may be required." 4. Initial Approval Criteria, I.B.5.a: Updated to remove prior dosing criteria "Dose does not exceed 20 mg daily". 5. Initial Approval Criteria, I.C: Updated to include approval criteria for off label indication Soft Tissue Sarcoma. 6. Initial Approval Criteria, I.A and I.B: Updated approval duration from 6 months to 12 months. 7. Continued Therapy Approval Criteria, II.A: Updated approval duration from 6 months to 12 months. 8. References were reviewed and updated. 		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Removed age criteria. 2. Removed dose criteria. 3. Updated approval duration. 4. Removed subtypes of disease for indication Thyroid Carcinoma "unresectable, locally advanced, or metastatic". 5. Removed reauthorization requirement for positive response to therapy. 6. References were reviewed and updated. 	12/08/2023	01/01/2024
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Removed Prescriber Criteria. 2. Updated Continuation of therapy language. 3. References were reviewed and updated. 	03/20/2025	04/10/2025
<p>Policy reviewed.</p>	12/11/2025	12/11/2025