Clinical Policy Title:	axitinib
Policy Number:	RxA.167
Drug(s) Applied:	Inlyta®
Original Policy Date:	03/06/2020
Last Review Date:	01/01/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

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 relapsed, metastatic or stage IV RCC;
2. Prescribed in one of the following ways (a or b):
   a. As a single agent therapy;
   b. For clear cell histology, in combination with Keytruda® or Bavencio®;
3. Prescribed by or in consultation with an oncologist;

Approval Duration

All Lines of Business (except Medicare): 12 months

B. Thyroid Carcinoma (off-label) (must meet all):

1. Diagnosis of differentiated thyroid carcinoma (i.e., follicular, Hurthle cell or papillary thyroid carcinoma);
2. Prescribed by or in consultation with an oncologist;
3. Refractory to radioactive iodine therapy;

Approval Duration

All Lines of Business (except Medicare): 12 months

C. Soft Tissue Sarcoma (off-label) (must meet all):

1. Diagnosis of alveolar soft part sarcoma (ASPS);
2. Prescribed by or in consultation with an oncologist;
3. As preferred therapy in combination with Keytruda®;

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):

1. Member is currently receiving medication, excluding manufacturer samples;

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 December 08, 2023.
2. National Comprehensive Cancer Network Guidelines. Thyroid Carcinoma Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed December 08, 2023.
3. National Comprehensive Cancer Network Guidelines. Soft Tissue sarcoma Version 2.2022. available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed December 08, 2023.
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 December 08, 2023.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	02/2020	03/06/2020
Policy was reviewed: 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.	06/14/2020	09/14/2020
Policy was reviewed: 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
Policy was reviewed: 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
Policy was reviewed: 1. Initial Approval Criteria, I.A.2: Updated prescriber	01/18/2023	04/13/2023

criteria from For clear cell histology, prescribed as (must meet one of the following): 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): 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 Carcinoma. 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.		
Policy was reviewed: 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