

# Inlyta (axitinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Inlyta (axitinib)	May be subject to quantity limit

## **APPROVAL CRITERIA**

Requests for Inlyta (axitinib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of one of the following:
  - A. Kidney Cancer, advanced renal cell carcinoma (RCC); **AND**
    1. Individual has histological confirmation of RCC with clear cell component (NCCN 1, NCCN 2A); **AND**
    2. Individual is using in one of the following ways:
      - a. Individual is using as first-line therapy; **AND**
      - b. Using in one of the following combinations:
        - i. Individual is using in combination with avelumab; **OR**
        - ii. Individual is using in combination with pembrolizumab and has not received a prior PD-1 or PD-L1 agent;
  - OR**
  - c. Individual has relapsed or stage IV clear cell RCC; **AND**
  - d. Individual is using as subsequent therapy after first-line sunitinib therapy;  
**OR**
  - e. Individual is using as subsequent therapy in combination with pembrolizumab;
- OR**
- B. Kidney Cancer, advanced or metastatic renal cell carcinoma (Label, NCCN 2A);  
**AND**
  1. Individual is using after failure of one prior systemic therapy; **AND**
  2. Individual is using as a single-agent;
- OR**
- C. Thyroid Carcinoma, including papillary, follicular and Oncocytic (NCCN 2A);  
**AND**
  1. Other systemic therapies are not available or appropriate for treatment of progressive and/or symptomatic iodine-refractory disease;
- OR**
- D. Alveolar Soft Part Sarcoma (NCCN 2A); **AND**
  1. Individual is using in combination with pembrolizumab (Wilky 2019).

### **Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 29, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. Wilky BA, Trucco MM, Subhawong TK, et al. Axitinib plus pembrolizumab in patients with advanced sarcomas including alveolar soft-part sarcoma: a single-centre, single arm, phase 2 trial. *Lancet Oncol* 2019; 20:837-848.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on June 29, 2023.
  - a. Head and Neck Cancers. V2.2023. Revised May 15, 2023.
  - b. Kidney Cancer. V1.2024. Revised June 21, 2023.
  - c. Thyroid Carcinoma. V2.2023. Revised May 18, 2023.
  - d. Soft Tissue Sarcoma. V2.2023. Revised April 25, 2023

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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