Applicable Drugs: Inlyta (axitinib)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 10/13/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

I. Documentation of one of the following diagnoses AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Documented diagnosis of advanced or stage IV renal cell carcinoma (RCC) and meets one of the following criteria:

i. Inlyta is used as a first-line agent in combination with Bavencio (avelumab) OR (Keytruda) pembrolizumab.

ii. Inlyta is used a single agent after treatment failure on at least one prior systemic therapy.

Other Uses With Supportive Evidence

A. Soft tissue sarcoma

B. Thymic carcinoma

C. Thyroid carcinoma

II. Minimum age requirement: 18 years old.

III. Treatment must be prescribed by or in consultation with an oncologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.

V. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- N/A

Quantity / Days Supply Restrictions

- Quantities of up to 120 tablets per 30 days.

Approval Length

- **Authorization:** 1 year
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

Appendix

N/A

References

1. Inlyta. Prescribing information. Pfizer Inc; 2024. Accessed October 13, 2025. https://labeling.pfizer.com/ShowLabeling.aspx?id=759
2. NCCN Clinical Practice Guidelines in Oncology. Kidney Cancer V.1.2026. Updated July 24, 2025. Accessed October 13, 2025. https://www.nccn.org/professionals/physician_gls/pdf/kidney_blocks.pdf.
3. NCCN Clinical Practice Guidelines in Oncology. Soft Tissue Sarcoma V.1.2025. Updated May 2, 2025. Accessed October 13, 2025. www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf.
4. NCCN Clinical Practice Guidelines in Oncology. Thyroid Carcinoma V.1.2025. Updated March 27, 2025. Accessed October 13, 2025. https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.