Generic Name: Axitinib

Therapeutic Class or Brand Name: Inlyta®

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 11/5/2024

PRIOR AUTHORIZATION CRITERIA

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

I. Documentation of one of the following diagnoses A through C 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

B. Advanced differentiated thyroid cancer

i. Documented diagnosis of papillary, follicular, or oncocytic (Hurthle) carcinoma.

ii. The disease is refractory to radioactive iodine therapy.

iii. Disease is locally recurrent and unresectable, advanced, and/or metastatic.

C. Soft tissue sarcoma

i. Documented diagnosis of alveolar soft part sarcoma

ii. Inlyta will be used in combination with Keytruda (pembrolizumab).

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 clinical practice guidelines.

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 60 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 November 5, 2024. http://labeling.pfizer.com/ShowLabeling.aspxd=759
2. NCCN Clinical Practice Guidelines in Oncology. Kidney Cancer V.2.2024. Updated September 6, 2024. Accessed November 5, 2024. https://www.nccn.org/professionals/physician_gls/pdf/kidney_blocks.pdf.
3. NCCN Clinical Practice Guidelines in Oncology. Soft Tissue Sarcoma V.3.2024. Updated September 27, 2024. Accessed November 5, 2024. https://www.nccn.org/professionals/physician_gls/pdf/kidney_blocks.pdf.
4. NCCN Clinical Practice Guidelines in Oncology. Thyroid Carcinoma V.4.2024. Updated August 19, 2024. Accessed November 5, 2024. https://www.nccn.org/professionals/physician_gls/pdf/kidney_blocks.pdf.