

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Inlyta Prior Authorization Policy

- Inlyta[®] (axitinib tablets – Pfizer)

REVIEW DATE: 06/19/2024

OVERVIEW

Inlyta, a kinase inhibitor, is indicated for **advanced renal cell carcinoma**, in combination with Bavencio[®] (avelumab intravenous infusion) as first-line treatment; in combination with Keytruda[®] (pembrolizumab intravenous infusion) as first-line treatment; and as a single agent after failure of one prior systemic therapy.¹

Guidelines

Inlyta is discussed in guidelines from the National Comprehensive Cancer Network (NCCN):

- **Kidney Cancer:** NCCN guidelines (version 4.2024 – May 30, 2024) for relapse or stage IV disease with clear cell histology recommend the following: Inlyta + Keytruda as a “preferred regimen” (category 1), Inlyta + Bavencio as one of the “other recommended regimens” (category 2A), and single agent Inlyta as “useful in certain circumstances” (category 2B). For subsequent therapy for clear cell histology, Inlyta monotherapy and Inlyta + Keytruda are category 2A options; Inlyta + Bavencio is a category 3 option. Single agent Inlyta is one of the systemic therapy options listed under “useful under certain circumstances” for relapse or Stage IV renal cell carcinoma with non-clear cell histology (category 2A).²
- **Soft Tissue Sarcoma:** NCCN guidelines (version 1.2024 – April 26, 2024) recommend Inlyta in combination with Keytruda as a “preferred” regimen for alveolar soft part sarcoma (category 2A).³
- **Thyroid Carcinoma:** For differentiated thyroid cancer subtypes, NCCN guidelines (version 2.2024 – March 12, 2024) have changed the naming of Hürthle cell neoplasm to oncocytic carcinoma.⁴ The guidelines recommend Inlyta as one of the kinase inhibitors to be considered if clinical trials or other systemic therapies are not available or appropriate for the treatment of progressive and/or symptomatic iodine refractory thyroid cancer. This recommendation is for all differentiated thyroid cancer subtypes (follicular, oncocytic, and papillary cancer) [all category 2A].

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Inlyta. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Inlyta is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. **Renal Cell Cancer.** Approve for 1 year if the patient meets BOTH of the following (A and B):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has relapsed or advanced disease.

Other Uses with Supportive Evidence

2. **Soft Tissue Sarcoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has alveolar soft part sarcoma; AND
 - C) The medication will be used in combination with Keytruda (pembrolizumab intravenous infusion).
3. **Thyroid Carcinoma, Differentiated.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has differentiated thyroid carcinoma; AND
Note: Examples of differentiated thyroid carcinoma include papillary, follicular, and oncocytic carcinoma (formerly Hürthle cell carcinoma).
 - C) The disease is refractory to radioactive iodine therapy.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Inlyta is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Inlyta® tablets [prescribing information]. New York, NY: Pfizer; September 2022.
2. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 4.2024 – May 30, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on June 17, 2024.
3. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 1.2024 – April 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on June 17, 2024.
4. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (version 2.2024 – March 12, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on June 17, 2024.