PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Inlyta Prior Authorization Policy
- Inlyta® (axitinib tablets – Pfizer)

REVIEW DATE: 06/22/2022

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 4.2022 – December 21, 2021) 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 is a category 1 recommendation, Inlyta + Keytruda is a category 2A option, and Inlyta + Bavencio is a category 3 option; all are listed under other recommended regimens. Single agent Inlyta is one of the systemic therapy options listed under "useful under certain circumstances" for relapse or Stage IV RCC with non-clear cell histology (category 2A).[2]
- **Thyroid Carcinoma:** NCCN guidelines (version 2.2022 – May 5, 2022) 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.[3] This recommendation is for follicular, Hürthle cell, and papillary cancer subtypes (all category 2A).
- **Soft Tissue Sarcoma:** NCCN guidelines (version 2.2022 – May 17, 2022) recommend Inlyta in combination with Keytruda as a preferred regimen for alveolar soft part sarcoma (category 2A).[4]

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 the following criteria (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has relapsed or advanced disease.

Other Uses with Supportive Evidence

2. **Thyroid Carcinoma, Differentiated.** Approve for 1 year if the patient meets the following criteria (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 Hürthle cell thyroid carcinoma.
   C) The disease is refractory to radioactive iodine therapy.

3. **Soft Tissue Sarcoma.** Approve for 1 year if the patient meets the following criteria (A and B):
   A) Patient has alveolar soft part sarcoma; AND
   B) The medication will be used in combination with Keytruda (pembrolizumab intravenous infusion).

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; June 2020.
2. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 4.2022 – December 21, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 14, 2022.
3. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (version 1.2021 – April 9, 2021). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 14, 2022.
4. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 2.2022 – May 17, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 14, 2022.