VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Inlyta® (axitinib tablets – Pfizer)

DATE REVIEWED: 05/20/2020

OVERVIEW

Inlyta, a kinase inhibitor, is indicated for the treatment of advanced renal cell carcinoma (RCC) after failure of one prior systemic therapy.[1]

Guidelines

The NCCN clinical practice guidelines on kidney cancer (version 2.2020 – August 5, 2019) recommend Inlyta + Keytruda (pembrolizumab for intravenous use) as a "preferred regimen" (category 2A) for favorable risk and poor/intermediate risk patients as first-line therapy for clear cell histology.[2] Inlyta + Imfinzi (avelumab for intravenous use) is recommended as one of the "Other recommended regimens" (category 2A) in the same populations. Inlyta as a monotherapy is a category 2B recommended regimen for first-line therapy. Inlyta is a category 1 recommended therapy under "other recommended regimens" for subsequent therapy. Inlyta + Keytruda is another category 2A option in this setting; Inlyta + Imfinzi is a category 3 option. It 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).

The NCCN thyroid carcinoma guidelines (version 2.2019 – September 16, 2019) 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).

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Inlyta. All approvals are provided for 3 years.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Renal Cell Carcinoma – Clear Cell or Non-Clear Cell Histology.** Approve for 3 years for relapsed or Stage IV disease.

Other Uses with Supportive Evidence

2. **Differentiated (i.e., papillary, follicular, and Hürthle cell) Thyroid Carcinoma.** Approve for 3 years if refractory to radioactive iodine therapy.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Inlyta has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below.

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 Inc; January 2020.
2. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (Version 2.2020 – August 5, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 17, 2020.
3. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (Version 2.2019 – September 16, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 17, 2020.