PRIOR AUTHORIZATION POLICY

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

TAC APPROVAL DATE: 05/08/2019

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 3.2019 – February 6, 2019) recommend Inlyta in patients with relapsed or Stage IV clear cell histology.² It is listed among the first-line options under “useful under certain circumstances” for favorable and poor/intermediate risk patients (category 2B). Inlyta is a category 1 recommended therapy under “other recommended regimens” for subsequent therapy. 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 1.2019 – March 28, 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; August 2018.

HISTORY

<table>
<thead>
<tr>
<th>Type of Revision</th>
<th>Summary of Changes*</th>
<th>TAC Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual revision</td>
<td>The Renal Cell Carcinoma criterion was revised to add predominant clear cell histology and non-clear cell histology is included. Differentiated Thyroid Carcinoma criteria were revised to only require that the patient’s disease is refractory to radioactive iodine therapy. Head and Neck Cancer and Hepatocellular Carcinoma were added to the list of conditions not recommended for approval.</td>
<td>02/10/2016</td>
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<tr>
<td>Annual revision</td>
<td>Approval was removed for patient has been started on Inlyta for an indication or condition addressed as an approval in the Recommended Authorization Criteria section.</td>
<td>03/08/2017</td>
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<tr>
<td>Annual revision</td>
<td>Conditions Not Recommended for Approval: Acute Myeloid Leukemia, Breast Cancer, and Myelodysplastic Syndrome were removed.</td>
<td>04/11/2018</td>
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<tr>
<td>Annual revision</td>
<td>No criteria changes</td>
<td>04/24/2019</td>
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<tr>
<td>Early Annual revision</td>
<td>For Renal Cell Carcinoma, deleted “advanced” and “predominant” with reference to clear cell histology. Added criteria that patient has relapsed or Stage IV disease. Deleted all conditions listed under Conditions Not Recommended for Approval.</td>
<td>05/08/2019</td>
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*TAC – Therapeutic Assessment Committee; * For a further summary of criteria changes, refer to respective TAC minutes available at: http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx.