PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 06/07/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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 4.2023 – January 18, 2023) 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 2.2023 – April 25, 2023) 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, the NCCN guidelines (version 2.2023 – May 18, 2023) 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.

- **Inlyta® (axitinib tablets (Pfizer)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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. **Soft Tissue Sarcoma.** 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 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 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 oncocytic carcinoma (formerly Hürthle cell carcinoma).
   C) The disease is refractory to radioactive iodine therapy.

CONDITIONS NOT COVERED

- **Inlyta® (axitinib tablets (Pfizer)**

is(are) considered experimental, investigational or unproven for ANY other use(s).

REFERENCES

1. Inlyta® tablets [prescribing information]. New York, NY: Pfizer; September 2022.
2. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 4.2023 – January 18, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 2, 2023.
3. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 2.2023 – April 25, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 2, 2023.
4. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (version 2.2023 – May 18, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 2, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Renal Cell Cancer:** The approval duration was changed from 3 years to 1 year. **Thyroid Carcinoma, Differentiated:** The approval duration was changed from 3 years to 1 year. **Soft Tissue Sarcoma:** Condition of approval and criteria were added based on NCCN guideline recommendations.	06/22/2022
Annual Revision	**Thyroid Carcinoma, Differentiated:** For examples of thyroid carcinoma, changed Hürthle cell carcinoma name to "oncocytic carcinoma (formerly Hürthle cell carcinoma)" based on guideline changes. **Soft Tissue Sarcoma:** A requirement was added that the patient is ≥ 18 years of age.	06/07/2023