UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1046-12
Program	Prior Authorization/Notification
Medication	Inlyta® (axitinib)
P&T Approval Date	4/2012, 8/2012, 7/2013, 8/2014, 8/2015, 7/2016, 7/2017, 7/2018, 9/2019, 9/2020, 9/2021, 9/2022, 9/2023
Effective Date	12/1/2023

1. Background:

Inlyta (axitinib) is a kinase inhibitor indicated for the treatment of advanced renal cell carcinoma (RCC) after failure of one prior systemic therapy. It is also indicated in combination with either avelumab or pembrolizumab for the first-line treatment of patients with advanced RCC. The NCCN (National Comprehensive Cancer Network) recommends the use of Inlyta for treatment of unresectable, metastatic, or recurrent salivary gland tumors and follicular, oncocytic, and papillary carcinomas. The NCCN also recommends Inlyta as preferred therapy in combination with pembrolizumab for treatment of alveolar soft part sarcoma (ASPS) and as first-line treatment of stage IV renal cell carcinoma.

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. Patients less than 19 years of age

1. **Inlyta** will be approved based on the following criterion:

   (1) Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. Renal Cell Carcinoma

1. **Initial Authorization**

   a. **Inlyta** will be approved based on **one** of the following criteria:

      (1) **Both** of the following:

         (a) Diagnosis of advanced renal cell carcinoma

         -AND-

         (b) **One** of the following:

i. Patient has failed one prior systemic therapy

-OR-

ii. Inlyta will be used in combination with Bavencio (avelumab) or Keytruda (pembrolizumab)

-OR-

(2) Diagnosis of stage IV renal cell carcinoma

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Inlyta** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Inlyta therapy

Authorization will be issued for 12 months.

C. Thyroid Carcinoma

1. **Initial Authorization**

a. **Inlyta** will be approved based on **all** of the following criteria:

(1) **One** of the following diagnoses:

(a) Follicular Carcinoma
(b) Oncocytic Carcinoma
(c) Papillary Carcinoma

-AND-

(2) Disease is **one** of the following:

(a) Recurrent and unresectable
(b) Persistent
(c) Metastatic

-AND-

(3) Disease is not amenable to radioactive iodine treatment

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Inlyta** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Inlyta therapy

Authorization will be issued for 12 months.

D. Salivary Gland Tumor

1. **Initial Authorization**

a. **Inlyta** will be approved based on **all** of the following criteria:

(1) Diagnosis of salivary gland tumor

-AND-

(2) Disease is **one** of the following:

(a) Recurrent and unresectable
(b) Metastatic

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Inlyta** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Inlyta therapy

Authorization will be issued for 12 months.

E. Soft Tissue Sarcoma

1. **Initial Authorization**

a. **Inlyta** will be approved based on **all** of the following criteria:

(1) Diagnosis of alveolar soft part sarcoma (ASPS)

-AND-

(2) Inlyta will be used in combination with Keytruda (pembrolizumab)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Inlyta** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Inlyta therapy

Authorization will be issued for 12 months.

F. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Inlyta [package insert]. New York, NY: Pfizer, Inc.; September 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed July 31, 2023.

Program	Prior Authorization/Notification - Inlyta (axitinib)
Change Control	
8/2014	Annual review. Added coverage for non-clear cell kidney cancer, updated formatting, Background and References.
9/2014	Administrative change - Tried/Failed exemption for State of New Jersey removed.
8/2015	Annual review. Added new coverage criteria for follicular, Hürthle cell and papillary carcinomas per NCCN. Increased authorization and reauthorization from 7 months to 12 months. Updated background and references.
7/2016	Annual review. Revised criteria for advanced renal cell carcinoma. Updated references.
7/2017	Annual review with no change to criteria. Updated reference.
7/2018	Annual review with no change to criteria. Updated reference.
9/2019	Updated background and criteria aligning with NCCN recommended

	first-line use in stage IV renal cell cancer. Added general NCCN recommended review criteria.
9/2020	Updated background without change to clinical intent. Updated references.
9/2021	Annual review with no changes to coverage criteria. Updated references.
9/2022	Annual review. Added criteria for NCCN recommended use in salivary gland tumors and alveolar soft part sarcoma (ASPS). Revised criteria for renal cell carcinoma and thyroid carcinoma to align with label and NCCN recommendations. Added state mandate disclaimer and updated references.
9/2023	Annual review. Changed Hürthle cell naming convention to oncocytic carcinoma per NCCN standards. Updated references.