UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1046-10
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
Effective Date	12/1/2021; Oxford only: 12/1/2021

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) also recommends the use of Inlyta for treatment of follicular, Hürthle cell and papillary carcinomas and for the 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. 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. Advanced Renal Cell Carcinoma

1. **Initial Authorization**

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

      (1) Diagnosis of renal cell cancer

-AND-

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

(a) Disease has relapsed

-OR-

(b) Diagnosis of stage IV disease

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 diagnosis:

(a) Follicular Carcinoma
(b) Hürthle Cell Carcinoma
(c) Papillary Carcinoma

-AND-

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

(a) Unresectable recurrent
(b) Persistent locoregional disease
(c) Metastatic disease

-AND-

(3) Disease is refractory to radioactive iodine treatment

Authorization will be issued for 12 months.

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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. 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.

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.; June 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed July 21 2021.

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.

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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.

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