UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Inlyta

Program	Prior Authorization
Medication	Inlyta® (axitinib)
Markets in Scope	Arizona, California, Colorado, Hawaii, Nevada, Maryland, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	9/2014
Pharmacy and Therapeutics Approval Date	9/2020
Effective Date	11/2020

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. [1] The NCCN (National Comprehensive Cancer Network) recommends use of Inlyta for treatment of follicular, Hürthle cell and papillary carcinomas and for the first-line treatment of stage IV renal cell carcinoma.[2]

2. Coverage Criteria:

A. <u>Advanced Renal Cell Carcinoma</u>

1. <u>Initial Authorization</u>

a. **Inlyta** will be approved based on **<u>all</u>** of the following criteria:

(1) Diagnosis of renal cell cancer

-AND-

(2) **<u>One</u>** 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.

B. 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.

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. NCCN Recommended Regimens

1. Initial Authorization

a. **Inlyta** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Inlyta therapy

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. AccessedAugust 6, 2020.

Program	Prior Authorization –Inlyta (axitinib)
Change Control	
Date	Change
9/2014	New guideline
7/2016	Updated clinical criteria to align with Employer and Individual notification policy and updated policy to new template
7/2017	Annual review with no change to criteria. Updated references.
7/2018	Added NCCN recommended regimen criteria. Updated references.

9/2019	Updated background and criteria to align with NCCN guidance for first-line use in stage IV renal cell cancer. Updated references.
9.2020	Annual review. Updated background without change to clinical intent. Updated references. Added Additional Clinical Rules section.