

Clinical Pharmacy Program Guidelines for Inlyta

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| Program | Prior Authorization |
| Medication | Inlyta [®] (axitinib) |
| Issue Date | 9/2014 |
| Pharmacy and Therapeutics Approval Date | 7/2017 |
| Effective Date | 9/2017 |

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.¹ The NCCN (National Comprehensive Cancer Network) recommends use of Inlyta for treatment of follicular, Hürthle cell and papillary carcinomas.²

2. Coverage Criteria:

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| <p>A. <u>Advanced Renal Cell Carcinoma</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Inlyta will be approved based on <u>all</u> of the following criteria:</p> <p>(1) Diagnosis of renal cell cancer</p> <p style="text-align: center;">-AND-</p> <p>(2) <u>One</u> of the following:</p> <p>(a) Disease has relapsed</p> <p style="text-align: center;">-OR-</p> <p>(b) <u>Both</u> of the following:</p> <p style="margin-left: 40px;">i. Medically or surgically unresectable tumor</p> <p style="margin-left: 40px;">ii. Diagnosis of Stage IV disease</p> <p style="text-align: center;">Authorization will be issued for 12 months.</p> |
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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.

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.

3. References:

1. Inlyta [package insert]. New York, NY: Pfizer, Inc.; August 2014.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed June 6, 2017.

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| 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. |