

Inlyta (axitinib)

(Oral)

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I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Inlyta 1 mg tablets: 210 tablets per 30 days (7 tablets per day)
- Inlyta 5 mg tablets: 120 tablets per 30 days (4 tablets per day)

B. Max Units (per dose and over time) [Medical Benefit]:

- 20mg daily

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is 18 years or older; **AND**

Renal Cell Carcinoma †

- Must be used as a single agent; **AND**
 - Patient must have advanced disease after failure of one prior systemic therapy †; **OR**
 - Patient's disease must be relapsed or surgically unresectable stage IV; **AND**
 - Must be used as first-line or subsequent therapy for clear cell histology; **OR**
 - Patient has non-clear cell histology

Thyroid Carcinoma – (Follicular carcinoma/Hurthle cell carcinoma/Papillary carcinoma) ‡

- Patient's has unresectable recurrent, persistent, or metastatic disease; **AND**
- Patient has progressive and/or symptomatic iodine-refractory disease; **AND**
- Other therapies are not available or appropriate

†FDA Approved Indication(s); ‡Compendia Recommended Indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria as defined by section III; **AND**
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples include the following: uncontrolled elevated blood pressure; signs or symptoms of Reversible Posterior Leukoencephalopathy syndrome (RPLS) (which include headache, encephalopathy, visual symptoms, and seizures); severe kidney/ hepatic impairment.

V. Dosage/Administration

Indication	Dose
All indications	5mg twice daily initially, may increase to 10mg twice daily

VI. Billing Code/Availability Information

Jcode:

- J8999 Prescription drug, oral, chemotherapeutic, Not Otherwise Specified

NDC:

- Inlyta 1mg tablets – 00069-0145-xx
- Inlyta 5mg tablets – 00069-0151-xx

VII. References

1. Inlyta [package insert]. New York, NY; Pfizer Inc; August 2014. Accessed June 2017.
2. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) axitinib. National Comprehensive Cancer Network, 2017. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2017.

Appendix 1 – Covered Diagnosis Codes

ICD-10 Codes	Diagnosis
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis

C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C73	Malignant neoplasm of thyroid gland
Z85.528	Personal history of other malignant neoplasm of kidney

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Cahaba Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC