



POLICY NUMBER UM ONC_1223	SUBJECT Inlyta™(axitinib)	DEPT/PROGRAM UM Dept	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 10/03/12, 12/11/13, 03/16/15, 05/24/16, 03/06/17, 03/14/18, 03/13/19, 12/11/19, 03/11/20	APPROVAL DATE March 11, 2020	EFFECTIVE DATE March 27, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 10/03/12, 12/11/13, 03/16/15, 05/24/16, 03/06/17, 03/14/18, 03/13/19, 12/11/19, 03/11/20
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee	
URAC STANDARDS HUM 1	NCQA STANDARDS UM 2	ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS	APPLICABLE LINES OF BUSINESS All	

I. PURPOSE

To define and describe the accepted indications for Inlyta (axitinib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

1. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

- a. When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**
- b. When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**
- c. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies: <http://pathways.newcenturyhealth.com> **AND**
- d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
- e. When available, generic dug alternatives are preferred over Brand name drugs.

2. Renal Cell Carcinoma (RCC)

- a. **NOTE: The preferred oral tyrosine kinase inhibitor (TKI) agent, per NCH Policies, for first line, metastatic disease is:**
 - i. Pazopanib for good risk disease
 - ii. Cabozantinib for intermediate or poor risk disease.



- b. The member has relapsed or medically unresectable advanced renal cell carcinoma with clear cell histology **AND**
- c. Inlyta (axitinib) is being used as a single agent or in combination with pembrolizumab or avelumab as first-line or subsequent therapy.

III. EXCLUSION CRITERIA

1. Off-label indications for Inlyta (axitinib) in thyroid cancers shall be reviewed for appropriateness per National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or other compelling medical literature publications.
2. Member has disease progression while taking Inlyta (axitinib).
3. Inlyta (axitinib) is being used concurrently with other chemotherapy, tyrosine kinase inhibitors, or on concomitant MTOR inhibitor.
4. Dosing exceeds single dose limit of Inlyta (axitinib) 10 mg.
5. Treatment with Inlyta (axitinib) exceeds the maximum limit of 600 (1 mg) tablets or 120 (5mg) tablets a month.
6. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

1. Review – UM Department
2. Final Approval – UM Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Inlyta prescribing information. Pfizer Inc. New York, NY. 2020
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.