Drug Policy:

Inlyta™(axitinib)

POLICY NUMBER UM ONC_1223	**SUBJECT** Inlyta™(axitinib)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
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, 01/13/21	**APPROVAL DATE** January 13, 2021	**EFFECTIVE DATE** January 29, 2021	**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, 01/13/21	
PRIMARY BUSINESS OWNER: UM		**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** Commercial, Exchange, Medicaid	

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 Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH 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

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. 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
2. 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

3. 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 AND
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When available, generic alternatives are preferred over brand-name drugs.

B. Renal Cell Carcinoma (RCC)

1. NOTE #1: The preferred agents, per NCH Policies, for first line metastatic disease are: Votrient (pazopanib) for IMDC Good Risk Disease and Cabometyx (cabozantinib) or [Yervoy (ipilimumab) + Opdivo (nivolumab)] for IMDC Intermediate & Poor Risk Disease.
2. NOTE #2: Inlyta (axitinib) + Keytruda (pembrolizumab) is a non-preferred regimen for the first line setting for metastatic renal cell carcinoma due to the lack of Level 1 evidence showing superiority of Inlyta (axitinib) + Keytruda (pembrolizumab)/Bavencio (avelumab) over [Yervoy (ipilimumab) + Opdivo (nivolumab)] in IMDC Intermediate & Poor Risk disease.

IMDC criteria: please see table below:

CRITERIA = Assign 1 point of each	RISK CATEGORIES = RISK SCORE
Time to systemic treatment less than 1 year from diagnosis	Favorable Risk = 0
Performance Status <80% Karnofsy Scale	Intermediate Risk = 1-2
Hemoglobin < LLN; 12 g/dL	Poor Risk = 3-6
Calcium > ULN; >12 mg/dL	
Neutrophils > ULN	
Platelets > ULN	

3. Inlyta (axitinib) may be used as a single agent in members with relapsed, medically unresectable, advanced, or metastatic renal cell carcinoma and Inlyta (axitinib) is being used in the second or later line of therapy.

III. EXCLUSION CRITERIA

A. Member has disease progression while taking Inlyta (axitinib).

B. Inlyta (axitinib) is being used concurrently with anti-cancer therapy.

C. Dosing exceeds single dose limit of Inlyta (axitinib) 10 mg.

D. Treatment with Inlyta (axitinib) exceeds the maximum limit of 60 (1mg) tablets or 120 (5mg) tablets a month.

E. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

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

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

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B. Motzer RJ, et al. Overall survival in renal-cell carcinoma with pazopanib versus sunitinib. N Engl J Med. 2014 May 1;370(18):1769-70.

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D. Choueiri TK, et al. Cabozantinib versus Everolimus in Advanced Renal-Cell Carcinoma. N Engl J Med. 2015 Nov 5;373(19):1814-23.

E. Motzer RJ, et al. Nivolumab plus Ipilimumab versus Sunitinib in Advanced Renal-Cell Carcinoma. N Engl J Med. 2018 Apr 5;378(14):1277-1290.

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I. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.

J. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.