New Century Health

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, 11/15/21, 12/08/21, 05/11/22, 11/09/22, 03/08/23, 05/10/23	APPROVAL DATE May 10, 2023	EFFECTIVE DATE May 26, 2023	COMMITTEE APPROVAL DATES 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, 11/15/21,12/08/21, 05/11/22, 11/09/22, 03/08/23, 05/10/23	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM v8: UM 1-2; UM 2-1	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. Continuation requests for a not-approvable medication shall be exempt from this NCH policy provided:

1. The requested medication was used within the last year, AND
2. The member has not experienced disease progression and/or no intolerance to the requested medication, AND
3. Additional medication(s) are not being added to the continuation request.

B. Renal Cell Carcinoma (RCC)

1. Inlyta (axitinib) may be used in combination with Keytruda (pembrolizumab) as first line treatment for recurrent or metastatic, IMDC favorable risk renal cell carcinoma.

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

2. NOTE: The use of Inlyta (axitinib) in RCC is not supported by NCH Policy when used as follows:
   a. First line, favorable/intermediate/poor risk clear cell RCC: single agent Inlyta (axitinib)
   b. Subsequent line clear cell RCC: Inlyta (axitinib) + Bavencio (avelumab).

   The above policy position is based on the lack of Level 1 Evidence (randomized clinical trials and/or meta-analyses) to show superior outcomes compared to NCH recommended alternatives agents/regimens, including but not limited to regimens at http://pathways.newcenturyhealth.com.

III. EXCLUSION CRITERIA

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

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

C. Treatment with Inlyta (axitinib) exceeds the maximum limit of 180 (1mg) tablets or 120 (5mg) tablets a month.

D. Investigational use of Inlyta (axitinib) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
   1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
   2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
   3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
   4. Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
   5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
   6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

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

A. Sternberg CN, et al. A randomised, double-blind phase III study of pazopanib in patients with advanced and/or metastatic renal cell carcinoma: final overall survival results and safety update. Eur J Cancer. 2013 Apr;49(6):1287-96.

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.

C. Buti, Sebastiano, et al. First-line pazopanib in non-clear cell renal carcinoma: The Italian retrospective multicenter PANORAMA study. J Clin Oncol 34, 2016 (suppl; abstr e16081).

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.

F. Inlyta prescribing information. Pfizer Inc. New York, NY 2021.

G. Clinical Pharmacology Elsevier Gold Standard 2023.

H. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan2023.

I. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2023.

J. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2023.

K. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

L. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

M. NCQA UM 2023 Standards and Elements.