Drug Policy:

Xalkori™ (crizotinib)

POLICY NUMBER UM ONC_1206	**SUBJECT** Xalkori™ (crizotinib)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 02/08/12, 12/11/13, 03/11/15, 04/12/16, 02/06/17, 02/14/18, 02/06/19, 12/11/19, 02/12/20, 11/11/20, 03/10/21	**APPROVAL DATE** March 10, 2021	**EFFECTIVE DATE** March 26, 2021	**COMMITTEE APPROVAL DATES** (latest version listed last) 02/08/12, 12/11/13, 03/11/15, 04/12/16, 02/06/17, 02/14/18, 02/06/19, 12/11/19, 02/12/20, 11/11/20, 03/10/21	
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 Xalkori (crizotinib) 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. Non-Small Cell Lung Cancer (NSCLC)

1. NOTE: The preferred agent, per NCH Policies, for first line therapy of metastatic , ALK+ NSCLC is Alecensa (alectinib). Please refer to *UMC ONC_1277 Alecensa (alectinib)* policy.
2. NOTE: For ROS1 + metastatic Non-Small Cell Lung Cancer, Xalkori (crizotinib) is the preferred agent for members without brain metastases. Rozlytrek (entrectinib) is the preferred agent for members with brain metastases because of improved brain penetration. Please refer to *UMC ONC_1367 Rozlytrek (entrectinib)* policy.
3. The member has locally advanced, recurrent, or metastatic NSCLC and Xalkori (crizotinib) is being used as a single agent for any of the following:
   a. ROS1 rearrangement-positive tumors without brain metastases as first line or subsequent therapy OR
   b. ALK-positive tumors for members who are intolerant to/have a contraindication to/have failed therapy with Alecensa (alectinib).

C. Soft Tissue Sarcoma – Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation

1. Xalkori (crizotinib) is being used as a single agent for inflammatory myofibroblastic tumor (IMT) with ALK translocation.

D. ALK+ Anaplastic Lymphoma

1. Xalkori (crizotinib) may be used as a single agent for members 21 years old or younger with Anaplatic Lymphoma that is:
   a. Positive for ALK- Anaplastic Lymphoma Kinase (confirmed by testing), AND
   b. The member has experienced disease progression on at least one prior therapy.

III. EXCLUSION CRITERIA

A. Xalkori (crizotinib) is being used concurrently with chemotherapy.

B. Dosing exceeds single dose limit of Xalkori (crizotinib) 250 mg.

C. Treatment exceeds the maximum limit of 60 (250mg) capsules a month.

D. 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

A. Xalkori prescribing information. Pfizer Labs, New York, NY 2020.

B. Clinical Pharmacology Elsevier Gold Standard 2021.

C. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2021.

D. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2021.

E. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2021.

New Century Health