

POLICY NUMBER UM_ONC_1206	SUBJECT Xalkori™ (crizotinib)		DEPT/PROGRAM UM Dept	PAGE 1 OF 2
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	APPROVAL DATE February 12, 2020	EFFECTIVE DATE March 01, 2020	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	
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 Xalkori (crizotinib) 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 alternatives are preferred over brand-name drugs.

2. Non-Small Cell Lung Cancer (NSCLC)

- a. **NOTE: The preferred agent, per NCH Policies, for first line therapy of metastatic , ALK+ NSCLC is ALECTINIB.**
- b. The member has locally advanced, recurrent, or metastatic NSCLC and Xalkori (crizotinib) is being used as a single agent for any of the following:
 - i. ROS1 rearrangement-positive tumors as first line therapy **OR**



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- ii. Anaplastic lymphoma kinase (ALK)-positive tumors as first line or subsequent therapy for relapsed or refractory disease.
3. **Soft Tissue Sarcoma – Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation**
 - a. Xalkori (crizotinib) is being used as a single agent for inflammatory myofibroblastic tumor (IMT) with ALK translocation.

III. EXCLUSION CRITERIA

1. Xalkori (Crizotinib) is being used concurrently with chemotherapy.
2. Dosing exceeds single dose limit of Xalkori (Crizotinib) 250 mg.
3. Treatment exceeds the maximum limit of 60 (250mg) capsules a month.
4. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

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. Xalkori prescribing information. Pfizer Labs, New York, NY. 2018.
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.