

## Clinical Policy: Crizotinib (Xalkori)

Reference Number: CP.PHAR.90

Effective Date: 11.01.11

Last Review Date: 05.20

Line of Business: Commercial, HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

Crizotinib (Xalkori<sup>®</sup>) is a kinase inhibitor.

### FDA Approved Indication(s)

Xalkori is indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK) or ROS1-positive as detected by an FDA-approved test.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Xalkori is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Non-Small Cell Lung Cancer (must meet all):

1. Diagnosis of recurrent, advanced or metastatic NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  18 years;
4. Disease is ALK, ROS1 or MET positive;
5. Request meets one of the following (a or b):\*
  - a. Dose does not exceed 500 mg (2 capsules) per day.
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

*\*Prescribed regimen must be FDA-approved or recommended by NCCN*

##### Approval duration:

**Medicaid/HIM** – 6 months

**Commercial** – Length of Benefit

##### B. Inflammatory Myofibroblastic Tumor (off-label) (must meet all):

1. Diagnosis of inflammatory myofibroblastic tumor (a soft tissue sarcoma);
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  18 years;
4. Disease is ALK positive;

5. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).\*

*\*Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration:**

**Medicaid/HIM** – 6 months

**Commercial** – Length of Benefit

**C. Anaplastic Large Cell Lymphoma (off-label) (must meet all):**

1. Diagnosis of anaplastic large cell lymphoma (a peripheral T-cell lymphoma);
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  18 years;
4. Disease is ALK positive;
5. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).\*

*\*Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration:**

**Medicaid/HIM** – 6 months

**Commercial** – Length of Benefit

**D. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. All Indications in Section I (must meet all):**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Xalkori for all approved indications and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):\*
  - a. New dose does not exceed 500 mg (2 capsules) per day;
  - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

*\*Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration:**

**Medicaid/HIM** – 12 months

**Commercial** – Length of Benefit

**B. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

**Approval duration: Duration of request or 6 months (whichever is less); or**

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

ALK: anaplastic lymphoma kinase	NCCN: National Comprehensive Cancer Network
FDA: Food and Drug Administration	NSCLC: non-small cell lung cancer
MET: mesenchymal-epithelial transition	ROS1: ROS proto-oncogene 1

*Appendix B: Therapeutic Alternatives*

Not applicable

*Appendix C: Contraindications/Boxed Warnings*

None reported

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
NSCLC	250 mg PO BID	500 mg/day

**VI. Product Availability**

Capsule: 200 mg, 250 mg

**VII. References**

1. Xalkori Prescribing Information. New York, NY: Pfizer, Inc.; June 2019. Available at <http://labeling.pfizer.com/showlabeling.aspx?id=676>. Accessed February 11, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at [www.nccn.org](http://www.nccn.org). Accessed February 11, 2020.
3. National Comprehensive Cancer Network Guidelines. Non-Small Cell Lung Cancer Version 2.2020. Available at [www.nccn.org](http://www.nccn.org). Accessed February 11, 2020.
4. National Comprehensive Cancer Network Guidelines. Central Nervous System Cancers Version 3.2019. Available at [www.nccn.org](http://www.nccn.org). Accessed February 11, 2020.
5. National Comprehensive Cancer Network Guidelines. Soft Tissue Sarcoma Version 6.2019. Available at [www.nccn.org](http://www.nccn.org). Accessed February 11, 2020.
6. National Comprehensive Cancer Network Guidelines. T-Cell Lymphomas Version 1.2020. Available at [www.nccn.org](http://www.nccn.org). Accessed February 11, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
<p>Added pregnancy category and treatment duration                      Added recommendation for severe renal impairment in body of Safety section Updated statistical information for 2015                      Added NCCN guideline recommendation to background                      Removed “Is patient responding to Xalkori therapy?” from Figure 1                      Added “More than one systemic lesion found?” to Figure 1 for all patients currently receiving therapy                      Removed “Will the dose be adjusted according to Table 1 or 2?” from Figure 1                      Changed “Experiencing any adverse events listed in Table 1?” to “Has the patient experienced an adverse event requiring permanent discontinuation?” in Figure 1</p>	01.15	02.15
<p>Policy converted to new template.                      Criteria: added age.                      Background: limited to description/MOA and FDA approved indication.                      Appendices: removed safety appendix requiring discontinuation – inserted safety information directly into re-auth criteria set.                      References: limited to PI and NCCN NSCLC;                      NCCN data used in re-auth criteria for evidence of multiple systemic symptomatic lesions in presence of progression.</p>	01.16	02.16
<p>Criteria: Added new indication for ROS1-positive NSCLC per PI.                      Added NCCN recommendations for use. Removed age and prescriber restriction.                      Removed the criteria regarding presence of lesion. Background: added formulations.</p>	06.16	08.16
<p>Maximum and minimum doses added. Reasons to discontinue removed.                      Approval periods increase from 3/6 to 6/12 months.</p>	07.17	08.17
<p>2Q 2018 annual review: policies combined for Commercial and Medicaid; added HIM line of business; age added; minimum dose removed; off-label NSCLC recurrent disease added; off-label ALCL added; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; added continuity of care statement; references reviewed and updated.</p>	02.13.18	05.18
<p>2Q 2019 annual review: NCCN designation of advanced added to NSCLC; references reviewed and updated.</p>	02.19.19	05.19
<p>2Q 2020 annual review: revised continued approval duration from 6 to 12 months; references reviewed and updated.</p>	02.11.20	05.20

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted

standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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