

Clinical Policy: Crizotinib (Xalkori)

Reference Number: PA.CP.PHAR.90

Effective Date: 01/18

Last Review Date: 04/18

[Revision Log](#)

Description

The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for crizotinib (Xalkori®).

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

It is the policy of Pennsylvania Health and Wellness that Xalkori is **medically necessary** when one of the following criteria is met:

I. Initial Approval Criteria

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

1. Diagnosis of ALK-, ROS1- or MET-positive recurrent or metastatic NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 18 years;
4. Prescribed dose does not exceed 500 mg/day.

Approval duration: 6 months

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

1. Diagnosis of ALK-positive inflammatory myofibroblastic tumor (a soft tissue sarcoma);
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 18 years;
4. Request meets one of the following (a or b):
 - a. Dose does not exceed 500 mg/day;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval duration: 6 months

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

1. Diagnosis of ALK-positive anaplastic large cell lymphoma (a peripheral T-cell lymphoma);
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 18 years;
4. Request meets one of the following (a or b):
 - a. Dose does not exceed 500 mg/day;

- b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval duration:

Medicaid/HIM - 6 months

D. Other diagnoses/indications: Refer to PA.CP.PHAR.57-Global Biopharm Policy

II. Continued Approval

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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/day;
 - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval duration: 6 months

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

Background

Description/Mechanism of Action:

Crizotinib is an inhibitor of receptor tyrosine kinases including ALK, Hepatocyte Growth Factor Receptor (HGFR, c-Met), ROS1 (c-ros), and Recepteur d'Origine Nantais (RON). Translocations can affect the ALK gene resulting in the expression of oncogenic fusion proteins. The formation of ALK fusion proteins results in activation and dysregulation of the gene's expression and signaling which can contribute to increased cell proliferation and survival in tumors expressing these proteins. Crizotinib demonstrated concentration-dependent inhibition of ALK, ROS1, and c-Met phosphorylation in cell-based assays using tumor cell lines and demonstrated antitumor activity in mice bearing tumor xenografts that expressed EML4- or NPM-ALK fusion proteins or c-Met.

Formulations:

Xalkori oral capsules: 200 mg, 250 mg

Appendices

Appendix A: Abbreviation Key

ALK: anaplastic lymphoma kinase
 ALT: alanine aminotransferase
 AST: aspartate aminotransferase
 IMT: inflammatory myofibroblastic tumor
 NSCLC: non-small cell lung cancer

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: 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.		

References

1. Xalkori Prescribing Information. New York, NY: Pfizer, Inc.; July 2017. Available at <http://labeling.pfizer.com/showlabeling.aspx?id=676>. Accessed February 2018.
2. Crizotinib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed February 2018.
3. Non-small cell lung cancer (Version 2.2018). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed February 2018.
4. Central nervous system cancers (Version 1.2017). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed February 2018.
5. Soft tissue sarcoma (Version 1.2018). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed February 2018.
6. T-cell lymphomas (Version 2.2018). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed February 2018.