

**Clinical Pharmacy Program Guidelines for Xalkori**

Program	Prior Authorization/Notification
Medication	Xalkori <sup>®</sup> (crizotinib)
Issue Date	9/2013
Pharmacy and Therapeutics Approval Date	11/2017
Effective Date	1/2018

**1. Background:**

Xalkori<sup>®</sup> (crizotinib) is a kinase inhibitor indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.<sup>1</sup> It is also approved for patients with metastatic NSCLC whose tumors are ROS1-positive.<sup>1</sup> The National Cancer Comprehensive Network (NCCN) also recommends the use of Xalkori as a single-agent for the treatment of inflammatory myofibroblastic tumor (IMT) with ALK translocation and in treatment of ROS1-positive NSCLC, MET-amplification positive NSCLC, or MET exon 14 skipping mutation NSCLC.<sup>2</sup>

**2. Coverage Criteria:**

<p><b>A. <u>Inflammatory Myofibroblastic Tumor (IMT) (off-label)</u></b></p> <p><b>1. <u>Initial Authorization</u></b></p> <p>a. Xalkori will be approved based on the following criterion:</p> <p>(1) Diagnosis of inflammatory myofibroblastic tumor (IMT) with ALK translocation</p> <p align="center"><b>Authorization will be issued for 12 months.</b></p> <p><b>2. <u>Reauthorization</u></b></p> <p>a. Xalkori will be approved based on the following criterion:</p> <p>(1) Patient does not show evidence of progressive disease while on Xalkori therapy</p> <p align="center"><b>Authorization will be issued for 12 months.</b></p> <p><b>B. <u>Non-Small Cell Lung Cancer (NSCLC)</u></b></p>
---

**1. Initial Authorization**

**a. Xalkori** will be approved based on **all** of the following criteria:

(1) Diagnosis non-small cell lung cancer (NSCLC)

**-AND-**

(2) Disease is **one** of the following:

(a) Metastatic

(b) Recurrent

**-AND-**

(3) **One** of the following:

(a) Tumor is anaplastic lymphoma kinase (ALK)-positive

(b) Tumor is ROS1-positive

(c) Tumor is positive for mesenchymal-epithelial transition (MET) amplification (off-label)

(d) Tumor is positive for MET exon 14 skipping mutation (off-label)

**Authorization will be issued for 12 months.**

**2. Reauthorization**

**a. Xalkori** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Xalkori therapy

**Authorization will be issued for 12 months.**

**3. References:**

1. Xalkori [package insert]. New York, NY: Pfizer Labs.; July 2017.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at [http://www.nccn.org/professionals/drug\\_compendium/content/contents.asp](http://www.nccn.org/professionals/drug_compendium/content/contents.asp). Accessed October 9, 2017.

Program	Prior Authorization - Xalkori (crizotinib)
<b>Change Control</b>	
9/2013	New guideline
12/2015	Annual review, no change
11/2016	Updated clinical criteria to align with Employer & Individual's

	policy
12/2016	Updated ROS-1 positive clinical criteria to reflect on-label indication (previously off-label). Updated background and references.
11/2017	Annual review with no changes to clinical coverage criteria. Updated references.