



# SPECIALTY GUIDELINE MANAGEMENT

# XALKORI (crizotinib)

#### **POLICY**

#### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

## A. FDA-Approved Indications

- 1. Xalkori is indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.
- Xalkori is indicated for the treatment of patients with metastatic NSCLC whose tumors are ROS1positive.

## B. Compendial Uses

- A. NSCLC
- B. Inflammatory myofibroblastic tumor (IMT) with ALK translocation

All other indications are considered experimental/investigational and are not a covered benefit.

#### **II. CRITERIA FOR INITIAL APPROVAL**

### A. Non-small cell lung cancer (NSCLC)

Authorization of 12 months may be granted for treatment of NSCLC when the member meets any of the following criteria:

- 1. The member has ALK-positive NSCLC
- 2. The member has ROS-1 positive NSCLC
- 3. The member has NSCLC with high-level MET amplification or MET exon 14 skipping mutation

### B. Inflammatory myofibroblastic tumor (IMT)

Authorization of 12 months may be granted for treatment of ALK-positive IMT.

### **III. CONTINUATION OF THERAPY**

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

#### IV. REFERENCES

- 1. Xalkori [package insert]. New York, NY: Pfizer Inc.; January 2017.
- 2. The NCCN Drugs & Biologics Compendium® © 2017 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed February 27, 2017.
- 3. The NCCN Clinical Practice Guidelines in Oncology® Non-Small Cell Lung Cancer (Version 4.2017).© 2017 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed February 27, 2017.

Xalkori SGM P2017 CareSource.docx

© 2017 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.





Xalkori SGM P2017 CareSource.docx

© 2017 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.