

## 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

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.

###### B. Compendial Uses

1. NSCLC, recurrent or metastatic disease with ALK or ROS1-positive tumors
2. NSCLC with high-level MET amplification or MET exon 14 skipping mutation
3. Inflammatory myofibroblastic tumor (IMT) with ALK translocation
4. ALK-positive anaplastic large cell lymphoma
5. Brain metastases from ALK-positive or ROS1-positive NSCLC

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. Member has recurrent or metastatic ALK-positive NSCLC (including brain metastases from NSCLC)
2. Member has recurrent or metastatic ROS1-positive NSCLC (including brain metastases from NSCLC)
3. 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.

###### C. **Anaplastic large cell lymphoma (ALCL)**

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

##### III. CONTINUATION OF THERAPY

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

##### IV. REFERENCES

Reference number(s)
1666-A

1. Xalkori [package insert]. New York, NY: Pfizer Inc.; February 2018.
2. The NCCN Drugs & Biologics Compendium® © 2017 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed March 22, 2018.
3. The NCCN Clinical Practice Guidelines in Oncology® Non-Small Cell Lung Cancer (Version 3.2018).© 2018 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed March 20, 2018.
4. The NCCN Clinical Practice Guidelines in Oncology® Soft Tissue Sarcoma (Version 1.2018).© 2018 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed March 27, 2018.
5. The NCCN Clinical Practice Guidelines in Oncology® T-Cell Lymphomas (Version 3.2018).© 2018 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed March 27, 2018.
6. The NCCN Clinical Practice Guidelines in Oncology® Central Nervous System Cancers (Version 1.2018).© 2018 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed March 22, 2018.