

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.
2. Xalkori is indicated for the treatment of patients with metastatic NSCLC whose tumors are ROS1-positive.

B. Compendial Uses

1. NSCLC
2. 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.