

## 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. Non-Small Cell Lung Cancer (NSCLC)  
Xalkori is indicated for the treatment of adult 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.
2. Anaplastic Large Cell Lymphoma (ALCL)  
Xalkori is indicated for the treatment of pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK-positive.
3. Inflammatory myofibroblastic tumor (IMT)  
Xalkori is indicated for the treatment of adult and pediatric patients 1 year of age and older with unresectable, recurrent, or refractory inflammatory myofibroblastic tumor (IMT) that is ALK-positive.

*Limitations of Use: The safety and efficacy of Xalkori have not been established in older adults with relapsed or refractory, systemic ALK-positive ALCL.*

##### B. Compendial Uses

1. Cutaneous Melanoma
2. NSCLC, recurrent, advanced or metastatic ALK rearrangement-positive or ROS1 rearrangement-positive tumors
3. NSCLC, recurrent, advanced or metastatic MET exon 14 skipping positive tumors
4. NSCLC with high-level MET amplification
5. Inflammatory myofibroblastic tumor (IMT) with ALK translocation
6. Anaplastic large cell lymphoma, relapsed or refractory ALK-positive
7. Histiocytic Neoplasms:
  - a. Erdheim-Chester Disease (ECD)
  - b. Langerhans Cell Histiocytosis (LCH)
  - c. Rosai-Dorfman Disease

All other indications are considered experimental/investigational and not medically necessary.

##### II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: ALK mutation or translocation status, ROS-1 mutation status, MET exon 14 skipping mutation status, or high-level MET amplification status (where applicable).

### III. 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, advanced or metastatic ALK-rearrangement positive NSCLC and will be used as a single agent.
2. Member has recurrent, advanced or metastatic ROS1-rearrangement positive NSCLC and will be used as a single agent.
3. Member has recurrent, advanced, or metastatic MET exon 14 skipping mutation-positive NSCLC and will be used as a single agent.
4. Member has NSCLC with high-level MET amplification.

#### B. Inflammatory Myofibroblastic Tumor (IMT)

Authorization of 12 months may be granted for treatment of ALK-translocation positive IMT as a single agent when either of the following criteria are met:

1. The member has uterine sarcoma and the disease is advanced, recurrent, metastatic, or inoperable
2. The member has a soft tissue sarcoma (not including uterine sarcoma)

#### C. Anaplastic Large Cell Lymphoma (ALCL)

Authorization of 12 months may be granted for initial palliative therapy or for treatment of relapsed or refractory ALK-positive ALCL as a single agent.

#### D. Histiocytic Neoplasms

Authorization of 12 months may be granted for treatment of any of the following histiocytic neoplasm subtypes as a single agent in members with an ALK gene fusion:

1. Symptomatic or relapsed/refractory Erdheim-Chester Disease (ECD)
2. Symptomatic or relapsed/refractory Rosai-Dorfman Disease
3. Langerhans Cell Histiocytosis (LCH)

#### E. Cutaneous Melanoma

Authorization of 12 months may be granted for subsequent treatment of unresectable or metastatic cutaneous melanoma when all of the following criteria are met:

1. The disease is ROS1 gene fusion-positive
2. The member had disease progression, had an intolerance or has a projected risk of progression with BRAF-targeted therapy (e.g., dabrafenib, encorafenib)
3. The requested medication will be used as a single agent

### IV. CONTINUATION OF THERAPY

#### A. ALK-rearrangement positive Non-Small Cell Lung Cancer (NSCLC) and ROS1-rearrangement positive Non-Small Cell Lung Cancer (NSCLC)

Authorization of 12 months may be granted for continued treatment of ALK-rearrangement positive non-small cell lung cancer (NSCLC) and ROS1-rearrangement positive non-small cell lung cancer (NSCLC) in members requesting reauthorization when there is no evidence of unacceptable toxicity while on the current regimen.

#### B. All Other Indications

Reference number(s)
1666-A

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

## V. REFERENCES

1. Xalkori [package insert]. New York, NY: Pfizer Inc.; September 2023.
2. The NCCN Drugs & Biologics Compendium ® © 2024 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed March 4, 2024.