Reference number(s)
1666-A

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 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-positive NSCLC and will be used as a single agent.
2. Member has recurrent, advanced or metastatic ROS1-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-positive IMT as a single agent.

C. Anaplastic Large Cell Lymphoma (ALCL)

Authorization of 12 months may be granted 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-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-positive Non-Small Cell Lung Cancer (NSCLC) and ROS1-positive Non-Small Cell Lung Cancer (NSCLC)

Authorization of 12 months may be granted for continued treatment of ALK-positive non-small cell lung cancer (NSCLC) and ROS1-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

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

Reference number(s)
1666-A

1. Xalkori [package insert]. New York, NY: Pfizer Inc.; July 2022.
2. The NCCN Drugs & Biologics Compendium 2023 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed January 13, 2023.