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.

B. Compendial Uses
1. NSCLC, recurrent, advanced or metastatic ALK rearrangement-positive or ROS1 rearrangement-positive tumors
2. NSCLC with high-level MET amplification or MET exon 14 skipping mutation
3. Inflammatory myofibroblastic tumor (IMT) with ALK translocation
4. Anaplastic large cell lymphoma, relapsed or refractory ALK-positive
5. 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 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 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 the 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)

IV. CONTINUATION OF THERAPY

A. ALK-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) 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

1. Xalkori [package insert]. New York, NY: Pfizer Inc.; January 2021.
2. The NCCN Drugs & Biologics Compendium 2020 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 10, 2021.