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
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, 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. Recurrent brain metastases from ALK rearrangement-positive NSCLC or ROS1 rearrangement-positive NSCLC

All other indications are considered experimental/investigational and are not a covered benefit.

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 (including brain metastases from NSCLC).
2. Member has recurrent, advanced 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 relapsed or refractory ALK-positive ALCL.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication in Section III who have not experienced disease progression or an unacceptable toxicity.

V. REFERENCES

1. Xalkori [package insert]. New York, NY: Pfizer Inc.; January 2019.
2. The NCCN Drugs & Biologics Compendium 2019 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 14, 2019.
3. The NCCN Clinical Practice Guidelines in Oncology Non-Small Cell Lung Cancer (Version 3.2019). 2019 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 14, 2019.
4. The NCCN Clinical Practice Guidelines in Oncology Soft Tissue Sarcoma (Version 2.2019). 2019 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 14, 2019.
5. The NCCN Clinical Practice Guidelines in Oncology T-Cell Lymphomas (Version 2.2019). 2019 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 14, 2019.
6. The NCCN Clinical Practice Guidelines in Oncology Central Nervous System Cancers (Version 1.2019). 2019 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 14, 2019.