Reference number(s)
1666-A

Specialty Guideline Management
Xalkori

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Xalkori	crizotinib

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.

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.

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.

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.

Compendial Uses[2]

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

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

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).

Coverage Criteria

Non-Small Cell Lung Cancer (NSCLC)[1,2]

Authorization of 12 months may be granted for treatment of NSCLC when the member meets any of the following criteria:

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

Inflammatory Myofibroblastic Tumor (IMT)[1,2]

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:

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

Anaplastic Large Cell Lymphoma (ALCL)[1,2]

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.

Histiocytic Neoplasms[2]

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:

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

Cutaneous Melanoma[2]

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

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

Continuation of Therapy

ALK-rearrangement positive Non-Small Cell Lung Cancer (NSCLC) and ROS1-rearrangement positive Non-Small Cell Lung Cancer (NSCLC) [1,2]

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.

All Other Indications[1,2]

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.

References

1. Xalkori [package insert]. New York, NY: Pfizer Inc.; September 2023.
2. The NCCN Drugs & Biologics Compendium ® © 2025 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 3, 2025.