

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Xalkori Prior Authorization Policy

- Xalkori® (crizotinib capsules – Pfizer)

**REVIEW DATE:** 01/11/2023

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### OVERVIEW

Xalkori, an oral kinase inhibitor, is indicated for the following uses:<sup>1</sup>

- **Anaplastic large cell lymphoma (ALCL)**, treatment of pediatric patients  $\geq$  1 year of age and young adults with relapsed or refractory, systemic ALCL that is anaplastic lymphoma kinase (*ALK*)-positive.
- **Inflammatory Myofibroblastic tumor (IMT)**, treatment of patients  $\geq$  1 year of age with unresectable, recurrent, or refractory inflammatory myofibroblastic tumor that is *ALK*-positive.
- **Non-small cell lung cancer (NSCLC)**, metastatic, whose tumors are *ALK*-positive or *ROS* proto-oncogene 1 (*ROS1*)-positive as detected by an FDA-approved test.

### Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines address the use of Xalkori:<sup>5-8</sup>

- **Histiocytic Neoplasms:** Guidelines (version 1.2022 – May 20, 2022) recommend Xalkori as a “useful in certain circumstances” treatment option for the following types of histiocytic neoplasm with *ALK* rearrangement/fusion: Langerhans cell histiocytosis, Erdheim-Chester disease, and Rosai-Dorfman disease (category 2A).<sup>3</sup>
- **Inflammatory Myofibroblastic Tumor (IMT):** NCCN Soft Tissue Sarcoma guidelines (version 2.2022 – May 17, 2022) and NCCN Uterine Neoplasms guidelines (version 1.2023 – December 22, 2022) recommend Xalkori as a treatment option for IMT with *ALK* translocation.<sup>4,5</sup>
- **Melanoma: Cutaneous:** Guidelines (version 1.2023 – December 22, 2022) recommend Xalkori as a treatment option for cutaneous melanoma with *ALK* or *ROS1* fusions.<sup>6</sup>
- **NSCLC:** Guidelines (version 1.2023 – December 23, 2022) recommend Xalkori as a treatment option for *ALK* rearrangement-positive NSCLC and as a treatment option for NSCLC with mesenchymal-epithelial transition (*MET*) exon 14 skipping mutation or high-level *MET* amplification.<sup>7</sup>
- **T-Cell Lymphoma:** Guidelines (version 1.2023 – January 5, 2023) recommend Xalkori as a treatment option for relapsed or refractory *ALK*-positive ALCL.<sup>7</sup> NCCN notes that Xalkori also demonstrated activity in adults with relapsed or refractory *ALK*-positive ALCL, after at least one line of prior cytotoxic therapy.<sup>8</sup>

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Xalkori. All approvals are provided for the duration noted below.

**Automation:** None.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Xalkori is recommended in those who meet one of the following criteria:

### FDA-Approved Indications

1. **Anaplastic Large Cell Lymphoma.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
  - A) Patient is  $\geq$  1 year of age; AND
  - B) Patient has anaplastic lymphoma kinase (*ALK*)-positive disease; AND
  - C) Patient meets one of the following criteria (i or ii):
    - i. Patient has relapsed disease; OR
    - ii. Patient has refractory disease.
  
2. **Inflammatory Myofibroblastic Tumor.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
  - A) Patient is  $\geq$  1 year of age; AND
  - B) Patient has anaplastic lymphoma kinase (*ALK*)-positive disease; AND
  - C) Patient meets one of the following criteria (i or ii):
    - i. Patient has advanced, recurrent, or metastatic disease; OR
    - ii. The tumor is inoperable.
  
3. **Non-Small Cell Lung Cancer – Anaplastic Lymphoma Kinase (*ALK*)-Positive.** Approve for 1 year if the patient meets the following criteria (A, B, C, and D):
  - A) Patient is  $\geq$  18 years of age; AND
  - B) Patient has advanced or metastatic disease; AND
  - C) Patient has anaplastic lymphoma kinase (*ALK*)-positive disease; AND
  - D) The mutation was detected by an approved test.
  
4. **Non-Small Cell Lung Cancer – *ROS1* Rearrangement-Positive.** Approve for 1 year if the patient meets the following criteria (A, B, C, and D):
  - A) Patient is  $\geq$  18 years of age; AND
  - B) Patient has advanced or metastatic disease; AND
  - C) Patient has *ROS1* rearrangement-positive disease; AND
  - D) The mutation was detected by an approved test.

### Other Uses with Supportive Evidence

5. **Histiocytic Neoplasm.** Approve for 1 year if patient meets one of the following criteria (A, B, and C).
  - A) Patient is  $\geq$  18 years of age; AND
  - B) Patient has anaplastic lymphoma kinase (*ALK*) rearrangement/fusion-positive disease; AND
  - C) Patient meets one of the following criteria (i, ii, or iii):
    - i. Patient has Langerhans cell histiocytosis; OR
    - ii. Patient had Erdheim-Chester disease; OR
    - iii. Patient has Rosai-Dorfman disease.
  
6. **Melanoma, Cutaneous.** Approve for 1 year if patient meets the following criteria (A and B):
  - A) Patient is  $\geq$  18 years of age; AND
  - B) Patient meets one of the following criteria (i or ii):
    - i. Patient has anaplastic lymphoma kinase (*ALK*) fusion disease; OR
    - ii. Patient has *ROS1* fusion disease.

- 7. Non-Small Cell Lung Cancer with Mesenchymal Epithelial Transition (*MET*) Mutation.** Approve for 1 year if the patient meets the following criteria (A and B):
- A)** Patient is  $\geq 18$  years of age; AND
  - B)** Patient meets one of the following criteria (i or ii):
    - i.** Patient has non-small cell lung cancer with high level *MET* amplification; OR
    - ii.** Patient has non-small cell lung cancer with *MET* exon 14 skipping mutation.

#### **CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Coverage of Xalkori is not recommended in the following situations:

- 1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

#### **REFERENCES**

1. Xalkori® capsules [prescribing information]. New York, NY: Pfizer; July 2022.
2. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 5, 2023. Search term: crizotinib.
3. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (version 1.2022 – May 20, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 5, 2023.
4. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 2.2022 – May 17, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 5, 2023.
5. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 1.2023 – December 22, 2022) © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 6, 2023.
6. The NCCN Melanoma: Cutaneous Clinical Practice Guidelines in Oncology (version 1.2023 – December 22, 2022 – May 17, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 6, 2023.
7. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 1.2023 – December 22, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 5, 2023.
8. The NCCN T-Cell lymphomas Clinical Practice Guidelines in Oncology (version 1.2023 – January 5, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 5, 2023.

