PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Xalkori Prior Authorization Policy
- Xalkori® (crizotinib capsules and oral pellets – Pfizer)

REVIEW DATE: 01/17/2024

OVERVIEW

Xalkori, an oral kinase inhibitor, is indicated for the following uses:[1]

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

Guidelines

Xalkori has been addressed in National Comprehensive Cancer Network (NCCN) guidelines:[5-8]

- **Histiocytic Neoplasms:** Guidelines (version 1.2023 – August 11, 2023) 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).[3]
- **Inflammatory Myofibroblastic Tumor (IMT):** NCCN Soft Tissue Sarcoma guidelines (version 3.2023 – December 12, 2023) and NCCN Uterine Neoplasms guidelines (version 1.2024 – September 20, 2023) recommend Xalkori as a treatment option for IMT with *ALK* translocation.[4,5]
- **Melanoma: Cutaneous:** Guidelines (version 3.2023 – October 27, 2023) recommend Xalkori as a treatment option for cutaneous melanoma with *ALK* or *ROS1* fusions.[6] Case reports or limited clinical trial data have suggested activity for various gene fusions; Xalkori is noted for *ROS1* and *ALK* fusions.
- **NSCLC:** Guidelines (version 1.2024 – December 21, 2023) recommend Xalkori as a treatment option for *ROS1* rearrangement, *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.[7]
- **T-Cell Lymphoma:** Guidelines (version 1.2024 – December 21, 2023) recommend Xalkori as a treatment option for *ALK*-positive ALCL either as initial palliative-intent therapy or for relapsed or refractory disease.[7] 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.[8]

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 (A, B, and C):
   - **A)** Patient is ≥ 1 year of age; AND
   - **B)** Patient has anaplastic lymphoma kinase (*ALK*)-positive disease; AND
   - **C)** Patient meets one of the following (i or ii):
     - **i.** The medication is used for palliative-intent therapy; OR
     - **ii.** Patient has relapsed or refractory disease.

2. **Inflammatory Myofibroblastic Tumor.** Approve for 1 year if the patient meets the following (A, B, and C):
   - **A)** Patient is ≥ 1 year of age; AND
   - **B)** Patient has anaplastic lymphoma kinase (*ALK*)-positive disease; AND
   - **C)** Patient meets one of the following (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 (A, B, C, and D):
   - **A)** Patient is ≥ 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 (A, B, C, and D):
   - **A)** Patient is ≥ 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 the following (A, B, and C).
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has anaplastic lymphoma kinase (*ALK*) rearrangement/fusion-positive disease; AND
   - **C)** Patient meets one of the following (i, ii, or iii):
     - **i.** Patient has Langerhans cell histiocytosis; OR
     - **ii.** Patient had Erdheim-Chester disease; OR
     - **iii.** Patient has Rosai-Dorfman disease.

Melanoma, Cutaneous. Approve for 1 year if patient meets the following (A and B):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient meets one of the following (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) M*utation. Approve for 1 year if the patient meets the following (A and B):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient meets one of the following (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 and oral pellets [prescribing information]. New York, NY: Pfizer; September 2023.
2. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 12, 2024. Search term: crizotinib.
3. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (version 1.2023 – August 11, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 14, 2024.
4. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 3.2023 – December 12, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 14, 2023.
5. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 1.2024 – September 20, 2023) © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 14, 2023.
6. The NCCN Melanoma: Cutaneous Clinical Practice Guidelines in Oncology (version 3.2023 – October 27, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 14, 2024.
7. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 1.2024 – December 21, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 14, 2024.
8. The NCCN T-Cell lymphomas Clinical Practice Guidelines in Oncology (version 1.2024 – December 21, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 14, 2024.