VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 12/22/2021; selected revision 06/22/2022 and 8/10/2022

OVERVIEW

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

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

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines address the use of Xalkori:

- **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).[2,3]
- **Non-Small Cell Lung Cancer:** Guidelines (version 3.2022 – March 16, 2022) recommend Xalkori for the treatment of *ALK* rearrangement-positive non-small cell lung cancer and *ROS1*-rearrangement-positive non-small cell lung cancer.[4] Xalkori is also recommended for the treatment of non-small cell lung cancer with mesenchymal-epithelial transition (*MET*) exon 14 skipping mutation or high-level *MET* amplification.
- **Soft Tissue Sarcoma:** Guidelines (version 2.2022 – May 17, 2022) recommend Xalkori for the treatment of inflammatory myofibroblastic tumor with *ALK* translocation.[3,5]
- **T-Cell Lymphoma:** Guidelines (version 2.2022 – March 7, 2022) recommend Xalkori as a treatment option for patients with relapsed or refractory *ALK*-positive anaplastic large cell lymphoma (ALCL). 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.[6]

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 ≥ 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 with Anaplastic Lymphoma Kinase (ALK) Translocation.** Approve for 1 year.

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 ≥ 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 ≥ 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

4. **Histiocytic Neoplasm.** Approve for 1 year if patient meets one of the following criteria (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 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.

5. **Non-Small Cell Lung Cancer with Mesenchymal Epithelial Transition (*MET) M*utation.** Approve for 1 year if the patient meets the following criteria (A and B):
   A) Patient is ≥ 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 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 August 5, 2022.
3. The NCCN Drugs & Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 5, 2022. Search term: crizotinib.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 3.2022 – March 16, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 5, 2022.
5. 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 August 5, 2022.
6. The NCCN T-Cell lymphomas Clinical Practice Guidelines in Oncology (version 2.2022 – March 7, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 5, 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	12/16/2020
Selected Revision	**Anaplastic Large Cell Lymphoma:** Added new approval condition and criteria based on FDA-approval and guidelines. **Peripheral T-Cell Lymphoma – Anaplastic Large Cell Lymphoma (ALCL), ALK-Positive:** Deleted this approval condition and criteria from Other Uses with Supportive Evidence, now that is addressed as an FDA-approved indication.	01/27/2021
Annual Revision	**Non-Small Cell Lung Cancer – Anaplastic Lymphoma Kinase (ALK)-Positive:** Added requirement that the patient is ≥ 18 years of age. Added "Anaplastic lymphoma kinase (ALK)-positive" to the condition name. **Non-Small Cell Lung Cancer with ROS1 Rearrangement:** Added requirement that the patient is ≥ 18 years of age; Revised the criterion "Patient has recurrent or metastatic non-small cell lung cancer to "Patient has metastatic non-small cell lung cancer". **Histiocytic Neoplasms:** Added new approval condition and criteria. **Non-Small Cell Lung Cancer with *MET* mutation:** Condition was reworded to as listed; previously, this was titled "Non-Small Cell Lung Cancer with High Level *MET* Amplification or *MET* Exon 14 Skipping Mutation". The requirements for high level *MET* amplification or *MET* exon 14 skipping mutation were moved from the approval condition into criteria. Added requirement that patient is ≥ 18 years of age.	12/22/2021
Selected Revision	For all approval conditions, the approval duration was changed from 3 years to 1 year.	06/22/2022
Update	08/05/2022: **Other Uses with Supportive Evidence, Soft Tissue Sarcoma – Inflammatory Myofibroblastic Tumor with Anaplastic Lymphoma Kinase (*ALK*) translocation** – Deleted this approval condition and criteria from Other Uses with Supportive Evidence, now that it is addressed as an FDA-approved indication.	--
Selected Revision	**Anaplastic Large Cell Lymphoma:** Revised the patient age requirement, between ≥ 1 year of age and < 21 years of age to ≥ 1 year of age (without an upper limit) since NCCN supports use of Xalkori for this condition in adults. Replaced the criterion that "Patient has received at least one prior systemic treatment regimen" with criteria that patient has either relapsed or refractory disease. **Non-Small Cell Lung Cancer – Anaplastic Lymphoma Kinase (ALK)-Positive.** Added criterion that disease is advanced or metastatic; previously, the criterion read: Patient has metastatic non-small cell lung cancer. **Non-Small Cell Lung Cancer – ROS1-Rearrangement Positive.** Added criterion that disease is advanced or metastatic; previously, the criterion read: Patient has metastatic non-small cell lung cancer. **Soft Tissue Sarcoma – Inflammatory Myofibroblastic Tumor with Anaplastic Lymphoma Kinase (ALK) Translocation:** Removed the "Soft Tissue Sarcoma" from condition name.	08/10/2022