

Xalkori (crizotinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Xalkori (crizotinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Xalkori (crizotinib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of Non-small cell lung cancer (NSCLC), recurrent or metastatic; **AND**
- II. Test result is confirmed that the tumor is one of the following:
 - A. Anaplastic lymphoma kinase (ALK)-positive; **OR**
 - B. C-ros oncogene 1 (ROS1) positive; **OR**
 - C. Inflammatory Myofibroblastic Tumor (IMT) with ALK translocation (NCCN 2A); **AND**
- III. Individual has not received treatment with another ROS1 inhibitor (for example, entrectinib);

OR

- IV. Individual has a diagnosis of Soft Tissue Sarcoma or Uterine Sarcoma; **AND**
- V. Individual is using as monotherapy for Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation (Label, NCCN 2A);

OR

- VI. Individual has a diagnosis of Peripheral T-cell Lymphomas; **AND**
- VII. Individual is older than 1 year of age and younger than or equal to 21 years of age; **AND**
- VIII. Individual is using as monotherapy for relapsed/refractory ALK-positive anaplastic large cell lymphoma (Label, NCCN 2A);

OR

- IX. Individual has a diagnosis of cutaneous melanoma (NCCN 2A); **AND**
- X. Individual is using as monotherapy for metastatic or unresectable ROS1 positive disease; **AND**
- XI. Individual has disease progression when treated with BRAF-targeted therapy or is unable to use BRAF-targeted therapy; **OR**
- XII. Individual is using as second-line therapy;

OR

- XIII. Individual has a diagnosis of histiocytic neoplasm; **AND**
- XIV. Individual is using as monotherapy for ALK-positive disease.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. Durham BH, Lopez Rodrigo E, Picarsic J, et al. Activating mutations in CSF1R and additional receptor tyrosine kinases in histiocytic neoplasms. Nat Med 2019;25:1839-1842.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on September 21, 2023.
 - a. Central Nervous System Cancers. V1.2023. Revised March 24, 2023.
 - b. Histiocytic Neoplasms. V 1.2023. Revised August 11, 2023.
 - c. Melanoma: Cutaneous. V 2.2023. Revised March 10, 2023.
 - d. Non-Small Cell Lung Cancer. V3.2023. Revised April 13, 2023.
 - e. Soft Tissue Sarcoma. V2.2023. Revised April 25, 2023.
 - f. T-cell Lymphomas. V1.2023. Revised January 5, 2023.
 - g. Uterine Neoplasms. V2.2023. Revised April 28, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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