

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), advanced, recurrent or metastatic (Label, NCCN 1, 2A); **AND**
- II. Test result shows that the tumor is one of the following:
 - A. Anaplastic lymphoma kinase (ALK)-positive; **OR**
 - B. C-ros oncogene 1 (ROS1) positive; **OR**
 - C. Mesenchymal-Epidermal Transition (MET) amplifications are present (NCCN 2A);

OR

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

OR

- V. Individual has a diagnosis of relapsed/refractory anaplastic large cell lymphoma (ALCL); **AND**
- VI. Individual has ALK-positive disease; **AND**
- VII. Individual is using as monotherapy; **AND**
- VIII. Individual is older than 1 year of age and younger than or equal to 21 years of age; **OR**
- IX. Individual is using as second-line, subsequent therapy, or palliative intent therapy (NCCN 2A);

OR

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

OR

- XV. Individual has a diagnosis of histiocytic neoplasm (NCCN 2A); **AND**

XVI. Individual is using as monotherapy for ALK-positive disease.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. 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.; 2024; 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™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on September 9, 2024.
 - a. Central Nervous System Cancers. V2.2024. Revised July 25, 2024.
 - b. Histiocytic Neoplasms. V2.2024. Revised July 19, 2024.
 - c. Melanoma: Cutaneous. V 2.2024. Revised April 3, 2024.
 - d. Non-Small Cell Lung Cancer. V9.2024. Revised August 9, 2024.
 - e. Soft Tissue Sarcoma. V2.2024. Revised July 31, 2024.
 - f. T-cell Lymphomas. V4.2024. Revised May 28, 2024.
 - g. Uterine Neoplasms. V2.2024. Revised March 6, 2024.

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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