

| Market Applicability | | | | | | | |
|----------------------|----|----|----|----|----|----|----|
| Market | DC | GA | KY | MD | NJ | NY | WA |
| Applicable | X | X | X | X | X | X | X |

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. Mesenchymal-Epidermal Transition (MET) amplifications are present (NCCN 2A); **OR**
 - D. 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 Central Nervous System Cancers; **AND**
 - V. Individual has a primary diagnosis of ALK or ROS1 mutation positive NSCLC; **AND**
 - VI. Disease has metastasized to the brain;
- OR**
- VII. Individual has a diagnosis of Soft Tissue Sarcoma; **AND**
 - VIII. Individual is using as monotherapy for Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation (NCCN 2A);
- OR**
- IX. Individual has a diagnosis of Peripheral T-cell Lymphomas; **AND**
 - X. Individual is using as monotherapy for relapsed/refractory ALK-positive anaplastic large cell lymphoma (NCCN 2A).

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| Applicable | X | X | X | X | X | X | X |

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. 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>. Accessed: October 8, 2019
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on October 8, 2019.
 - a. Central Nervous System Cancers. V2.2019. Revised September 16, 2019.
 - b. Non-Small Cell Lung Cancer. V7.2019. Revised August 30, 2019.
 - c. Soft Tissue Sarcoma. V4.2019. Revised September 12, 2019.
 - d. T-cell Lymphomas. V2.2019. Revised December 17, 2018.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.