

## Xalkori® (crizotinib) (Oral)

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### I. Length of Authorization

Coverage is provided for six months and may be renewed.

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [NDC Unit]:

- Xalkori 200 mg capsules: 60 capsules per 30 days (2 capsules per day)
- Xalkori 250mg capsules: 60 capsules per 30 days (2 capsules per day)

#### B. Max Units (per dose and over time) [HCPCS Unit]:

- 500 mg per day

### III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is at least 18 years old; **AND**

#### Universal Criteria

- Must be used as single agent; **AND**

#### Non-Small Cell Lung Cancer (NSCLC) †, Φ 1,2,5-7

- Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrent or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Patient's cancer is anaplastic lymphoma kinase (ALK) positive as detected by an FDA-approved or CLIA compliant test❖; **OR**
  - Patient's cancer is ROS-1 rearrangement positive as detected by an FDA-approved or CLIA compliant test❖; **OR**
- Patient has high level MET amplification or MET exon 14 skipping mutation

### Inflammatory Myofibroblastic Tumor (IMT) – Soft Tissue Sarcoma † 2,4,9

- Patient’s cancer is anaplastic lymphoma kinase (ALK) positive as detected by an FDA-approved or CLIA compliant test ❖

### Anaplastic Large Cell Lymphoma (ALCL) – T-cell Lymphomas † 2,3,8

- Patient’s cancer is anaplastic lymphoma kinase (ALK) positive as detected by an FDA-approved or CLIA compliant test ❖; **AND**
- Patient has relapsed or refractory disease; **AND**
  - Used as second-line therapy with no intention to transplant; **OR**
  - Used as initial palliative intent therapy with no intention to transplant; **OR**
  - Used as subsequent therapy

❖ *If confirmed using an immunotherapy assay-<http://www.fda.gov/companiondiagnostics>*

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); Ⓢ Orphan Drug

## IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hepatotoxicity (severe changes in liver function tests), interstitial lung disease/pneumonitis, QT prolongation, bradycardia, severe vision loss, etc.

## V. Dosage/Administration 1,8,9

Indication	Dose
All Indications	250 mg orally twice daily until disease progression or unacceptable toxicity.

## VI. Billing Code/Availability Information

HCPCS Code:

- J8999: Prescription drug, oral, chemotherapeutic, Not Otherwise Specified

NDC:

- Xalkori 200 mg capsule - 00069-8141-xx

- Xalkori 250 mg capsule - 00069-8140-xx

## VII. References

1. Xalkori [package insert]. New York, NY; Pfizer, Inc; June 2019. Accessed April 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Crizotinib. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2020.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) T-Cell Lymphomas. Version 1.2020. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2020.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Soft Tissue Sarcoma. Version 6.2019. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2020.
5. Solomon BJ, Mok T, Kim DW, et al. First-line crizotinib versus chemotherapy in ALK-positive lung cancer. *N Engl J Med*. 2014 Dec 4;371(23):2167-77. doi: 10.1056/NEJMoa1408440. Erratum in: *N Engl J Med*. 2015 Oct 15;373(16):1582.
6. Shaw AT, Kim DW, Nakagawa K, et al. Crizotinib versus chemotherapy in advanced ALK-positive lung cancer. *N Engl J Med*. 2013 Jun 20;368(25):2385-94. doi: 10.1056/NEJMoa1214886. Epub 2013 Jun 1. Erratum in: *N Engl J Med*. 2015 Oct 15;373(16):1582.
7. Shaw AT, Ou SH, Bang YJ, et al. Crizotinib in ROS1-rearranged non-small-cell lung cancer. *N Engl J Med*. 2014 Nov 20;371(21):1963-71. doi: 10.1056/NEJMoa1406766. Epub 2014 Sep 27.
8. Passerini CG, Farina F, Stasia A, et al. Crizotinib in Advanced, Chemoresistant Anaplastic Lymphoma Kinase-Positive Lymphoma Patients. *J Natl Cancer Inst*. 2014 Feb;106(2):djt378. PMID: 24491302. DOI: [10.1093/jnci/djt378](https://doi.org/10.1093/jnci/djt378)

9. Butrynski JE, D'Adamo DR, Hornick JL, et al. Crizotinib in ALK-rearranged Inflammatory Myofibroblastic Tumor. N Engl J Med. 2010 Oct 28;363(18):1727-33. PMID: 20979472. PMID: [PMCID: PMC3014292](https://pubmed.ncbi.nlm.nih.gov/20979472/). DOI: [10.1056/NEJMoa1007056](https://doi.org/10.1056/NEJMoa1007056)

## Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus or lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C49.4	Malignant neoplasm of connective and soft tissue of abdomen
C49.5	Malignant neoplasm of connective and soft tissue of pelvis
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
C84.60	Anaplastic large cell lymphoma, ALK-positive, unspecified site
C84.61	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of head, face, and neck
C84.62	Anaplastic large cell lymphoma, ALK-positive, intrathoracic lymph nodes
C84.63	Anaplastic large cell lymphoma, ALK-positive, intra-abdominal lymph nodes
C84.64	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of axilla and upper limb
C84.65	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of inguinal region and lower limb
C84.66	Anaplastic large cell lymphoma, ALK-positive, intrapelvic lymph nodes
C84.67	Anaplastic large cell lymphoma, ALK-positive, spleen

ICD-10	ICD-10 Description
C84.68	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of multiple sites
C84.69	Anaplastic large cell lymphoma, ALK-positive, extranodal and solid organ sites
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.831	Personal history of malignant neoplasm of soft tissue

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC