

## Xalkori<sup>®</sup> (crizotinib) (Oral)

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Date of Origin: 11/01/2012

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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) [Pharmacy Benefit]:

- 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) [Medical Benefit]:

- 500 mg per day

### III. Initial Approval Criteria

Coverage is provided in the following conditions:

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

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

#### Non-Small Cell Lung Cancer (NSCLC) †

- Patient's disease is metastatic or recurrent; **AND**
  - Patient's cancer is anaplastic lymphoma kinase (ALK) positive as detected by an FDA approved test; **OR**
  - Patient's cancer is ROS-1 positive as detected by an FDA approved test; **OR**
  - Patient has high level MET amplification or MET exon 14 skipping mutation

#### Inflammatory Myofibroblastic Tumor (IMT) – Soft Tissue Sarcoma‡

- Patient's disease has an ALK translocation as detected upon standard laboratory diagnostic tests (e.g., FISH)

### **Anaplastic large cell lymphoma – T-cell Lymphomas†**

- Patient has relapsed or refractory disease; **AND**
- Patient’s cancer is anaplastic lymphoma kinase (ALK) positive as detected by an FDA approved test; **AND**
- Must be used as a subsequent therapy

### **Central Nervous System Cancer (Brain Metastases) ‡**

- Used for recurrent or recurrent-stable disease for the treatment of brain metastases; **AND**
- Xalkori is active against the primary tumor (ALK-positive or ROS1 positive Non-Small Cell Lung Cancer)

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

## **IV. Renewal Criteria**

Coverage can be renewed based upon the following criteria:

- Tumor response with 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**

<b>Indication</b>	<b>Dose</b>
All Indications	250 mg PO twice daily

## **VI. Billing Code/Availability Information**

HCPCS:

J8999 Prescription drug, oral, chemotherapeutic, Not Otherwise Specified  
C9399 Unclassified drugs or biologicals (Hospital Outpatient Use ONLY)

NDC:

- Xalkori 200 mg capsule - 00069-8141-20 (Pfizer US Pharmaceuticals)
- Xalkori 250 mg capsule - 00069-8140-20 (Pfizer US Pharmaceuticals)

## **VII. References**

1. Xalkori [package insert]. New York, NY; Pfizer, Inc; February 2018. Accessed February 2018.

2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Crizotinib. National Comprehensive Cancer Network, 2018. 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 February 2018.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) T-Cell Lymphomas. Version 2.2018. National Comprehensive Cancer Network, 2018. 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 February 2018.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Central Nervous System Cancers. Version 1.2017. National Comprehensive Cancer Network, 2017. 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 February 2018.

## 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

ICD-10	ICD-10 Description
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
C79.31	Secondary malignant neoplasm of brain
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
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) and Local Coverage Determinations (LCDs) 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):

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

### Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
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