UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1364-1
Program	Prior Authorization/Non-Formulary
Medication	Xalkori® (crizotinib)*
P&T Approval Date	7/2021
Effective Date	1/1/2022; Oxford only: 1/1/2022

1. Background:

Xalkori® (crizotinib) is a kinase inhibitor indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test. It is also approved for patients with metastatic NSCLC whose tumors are ROS1-positive as detected by an FDA-approved test.[1] The National Cancer Comprehensive Network (NCCN) also recommends the use of Xalkori as a single-agent for the treatment of inflammatory myofibroblastic tumor (IMT) with ALK translocation, in treatment of MET-amplification positive NSCLC, MET exon 14 skipping mutation NSCLC, in treatment of ROS1-positive or ALK-positive brain metastases from NSCLC, and in the treatment of relapsed or refractory ALK-positive anaplastic large cell lympoma.[2]

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria:

A. <u>Patients less than 19 years of age</u>

1. **Xalkori*** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>Inflammatory Myofibroblastic Tumor (IMT)</u>

1. **<u>Initial Authorization</u>**

   a. **Xalkori** will be approved based on the following criterion:

(1) Diagnosis of inflammatory myofibroblastic tumor (IMT) with ALK translocation

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Xalkori** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Xalkori therapy

Authorization will be issued for 12 months.

C. Non-Small Cell Lung Cancer (NSCLC)

1. **Initial Authorization**

a. **Xalkori*** will be approved based on **all** of the following criteria:

(1) Diagnosis non-small cell lung cancer (NSCLC)

-AND-

(2) Disease is **one** of the following:

(a) Metastatic
(b) Recurrent
(c) Advanced

-AND-

(3) **One** of the following:

(a) Tumor is ROS1-positive
(b) Tumor is positive for mesenchymal-epithelial transition (MET) amplification
(c) Tumor is positive for MET exon 14 skipping mutation
(d) **Both** of the following:
i. Tumor is anaplastic lymphoma kinase (ALK)-positive

-AND-

ii. **One** of the following:
- Provider attests the patient has a contraindication, history of intolerance, or that the patient is not an appropriate candidate

(document reason) to **all** of the following therapies:
- Alecensa (alectinib)
- Alunbrig (brigatinib)
- Lorbrena (lorlatinib)

-OR-

- **Both** of the following:
  - Patient is currently on Xalkori therapy

-AND-

  - Patient has **not** received a manufacturer supplied sample at no cost from a prescriber's office, or any form of assistance from the Pfizer Oncology Together™ program (e.g. sample card which can be redeemed at a pharmacy for a free supply of medication) or a 30 day free trial from a pharmacy as a means to establish as a current user of Xalkori*

*Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Pfizer Oncology Together™ program shall be required to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Xalkori** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Xalkori therapy

Authorization will be issued for 12 months.

D. Central Nervous System (CNS) Cancers

1. **Initial Authorization**

a. **Xalkori** will be approved based on **both** of the following criteria:

(1) Diagnosis of metastatic brain cancer from NSCLC

-AND-

(2) **One** of the following:

(a) Tumor is anaplastic lymphoma kinase (ALK)-positive
(b) Tumor is ROS1-positive

Authorization will be issued for 12 months.

2. Reauthorization

a. **Xalkori** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Xalkori therapy

Authorization will be issued for 12 months.

E. Anaplastic Large Cell Lymphoma

1. Initial Authorization

a. **Xalkori** will be approved based on **all** of the following criteria:

(1) Diagnosis of anaplastic large cell lymphoma

-AND-

(2) Tumor is anaplastic lymphoma kinase (ALK)-positive

-AND-

(3) Disease is relapsed or refractory

Authorization will be issued for 12 months.

2. Reauthorization

a. **Xalkori** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Xalkori therapy

Authorization will be issued for 12 months.

F. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National

Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

*Xalkori is typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Xalkori [package insert]. New York, NY: Pfizer Labs.; June 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed December 14, 2020.

Program	Prior Authorization/Non-Formulary - Xalkori (crizotinib)
Change Control	
7/2021	New program.