UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Xalkori

Program	Prior Authorization/Notification
Medication	Xalkori® (crizotinib)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York CHIP, New York EPP, Pennsylvania- CHIP, South Carolina, Rhode Island
Issue Date	9/2013
Pharmacy and Therapeutics Approval Date	2/2021
Effective Date	4/2021

1. Background:

Xalkori® (crizotinib) is a kinase inhibitor indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.[1] 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]

2. Coverage Criteria:

A. <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. <u>Reauthorization</u>

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.

B. 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 anaplastic lymphoma kinase (ALK)-positive
(b) Tumor is ROS1-positive
(c) Tumor is positive for mesenchymal-epithelial transition (MET) amplification
(d) Tumor is positive for MET exon 14 skipping mutation

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. 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.

D. 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 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.

E. NCCN Recommended Regimens

1. Initial Authorization

a. **Xalkori** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Xalkori therapy

Authorization will be issued for 12 months.

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 - Xalkori (crizotinib)
Change Control	
9/2013	New guideline
12/2015	Annual review, no change
11/2016	Updated clinical criteria to align with Employer & Individual's policy
12/2016	Updated ROS-1 positive clinical criteria to reflect on-label indication (previously off-label). Updated background and references.
11/2017	Annual review with no changes to clinical coverage criteria. Updated references.
11/2018	Updated background and criteria to align with NCCN

	recommendations for metastatic brain cancer and ALK-positive anaplastic large cell lymphoma. Added NCCN recommended regimen review criteria. Updated references.
1/2019	Updated NSCLC and anaplastic large cell lymphoma based on NCCN guidance.
1/2020	Annual review. Updated background and references.
1/2021	Annual review. No changes to clinical criteria. Added Additional Clinical Rules section.
2/2021	Updated reference.