UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Xalkori

Program	Prior Authorization/Notification
Medication	Xalkori® (crizotinib)
Issue Date	9/2013
Pharmacy and Therapeutics Approval Date	11/2017
Effective Date	1/2018

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.[1] It is also approved for patients with metastatic NSCLC whose tumors are ROS1-positive.[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 and in treatment of ROS1-positive NSCLC, MET-amplification positive NSCLC, or MET exon 14 skipping mutation NSCLC.[2]

2. Coverage Criteria:

A. Inflammatory Myofibroblastic Tumor (IMT) (off-label)

1. Initial Authorization

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.

B. Non-Small Cell Lung Cancer (NSCLC)

UnitedHealthcare Community Plan

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

-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 (off-label)
(d) Tumor is positive for MET exon 14 skipping mutation (off-label)

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.

3. References:

1. Xalkori [package insert]. New York, NY: Pfizer Labs.; July 2017.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed October 9, 2017.

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.