UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 1115-15
Program	Prior Authorization/Notification
Medication	Xalkori® (crizotinib)
P&T Approval Date	9/2011, 8/2012, 07/2013, 2/2014, 2/2015, 2/2016, 12/2016, 11/2017, 11/2018, 1/2019, 2/2020, 2/2021, 2/2022, 2/2023, 2/2024, 2/2025, 2/2026
Effective Date	5/1/2026

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 or ROS1-positive as detected by an FDA-approved test. It is also approved for pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK-positive and adult and pediatric patients 1 year of age and older with unresectable, recurrent, or refractory inflammatory myofibroblastic tumor (IMT) that is ALK-positive. 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 uterine neoplasms, 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, in histiocytic neoplasms that are positive for ALK rearrangement, and in metastatic or unresectable cutaneous melanoma that is ROS1 gene fusion-positive as second-line or subsequent therapy for disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy.

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]:

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. Soft Tissue Sarcoma

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

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

(1) Diagnosis of Soft Tissue Sarcoma

-AND-

(2) Tumor is an 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 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.

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. Histiocytic Neoplasms

1. **Initial Authorization**

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

(1) Diagnosis of **one** of the following:

(a) Langerhans Cell Histiocytosis
(b) Erdheim-Chester Disease
(c) Rosai-Dorfman Disease

-AND-

(2) Disease is positive for ALK rearrangement

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.

G. Melanoma

1. **Initial Authorization**

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

(1) Diagnosis of metastatic or unresectable cutaneous melanoma

-AND-

(2) Disease is ROS1 gene fusion-positive

-AND-

(3) Used as second-line or subsequent therapy for disease progression, intolerance, and/or projected risk of progression with BRAF-targeted 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.

H. Uterine Neoplasms

1. **Initial Authorization**

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

(1) Diagnosis of uterine sarcoma

-AND-

(2) Tumor is an inflammatory myofibroblastic tumor (IMT) with ALK translocation

-AND-

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

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

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.

I. 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.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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.; September 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed January 9, 2026.

Program	Prior Authorization/Notification - Xalkori (crizotinib)
Change Control	
2/2014	Updated references.
2/2015	Annual review. Added coverage for MET-amplification positive NSCLC. Updated background and references.
2/2016	Annual review. Updated clinical criteria for metastatic non-small cell lung cancer. Updated background and references.
12/2016	Annual review. 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	Annual review. Updated background and criteria to align with NCCN recommendations for metastatic brain cancer and for ALK-positive anaplastic large cell lymphoma. Updated references.
1/2019	Updated criteria for anaplastic large cell lymphoma and NSCLC.
2/2020	Annual review. Added general NCCN recommendations for use criteria. Updated references.
2/2021	Annual review with no changes to clinical coverage criteria. Updated references.
2/2022	Annual review. Updated background and references. Added clinical criteria for histiocytic neoplasms that are positive for ALK rearrangement.
2/2023	Annual review with no change to clinical criteria. Updated background and references. Added state mandate footnote.
2/2024	Annual review. Updated background and coverage criteria for cutaneous melanoma per NCCN. Updated references.
2/2025	Annual review with no change to clinical criteria. Updated references.

2/2026	Annual review. Updated background and coverage criteria for uterine neoplasms per NCCN. Updated reference.