Clinical Policy: Crizotinib (Xalkori)

Reference Number: ERX.SPA.84
Effective Date: 03.01.14
Last Review Date: 05.20
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Crizotinib (Xalkori®) is a kinase inhibitor.

FDA Approved Indication(s)
Xalkori is indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK) or ROS1-positive as detected by an FDA-approved test.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Xalkori is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Non-Small Cell Lung Cancer (must meet all):
1. Diagnosis of recurrent, advanced, or metastatic NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is ALK, ROS1, or MET positive;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 500 mg (2 capsules) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid – 6 months
Commercial – Length of Benefit

B. Inflammatory Myofibroblastic Tumor (off-label) (must meet all)**:**
1. Diagnosis of inflammatory myofibroblastic tumor (a soft tissue sarcoma);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is ALK positive;
5. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.*

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid – 6 months
Commercial – Length of Benefit

C. Anaplastic Large Cell Lymphoma (off-label) (must meet all)**:**
1. Diagnosis of anaplastic large cell lymphoma (a peripheral T-cell lymphoma);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is ALK positive;
5. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.*

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – Length of Benefit

D. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Xalkori for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 500 mg (2 capsules) per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid – 12 months
Commercial – Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALK: anaplastic lymphoma kinase
FDA: Food and Drug Administration
MET: mesenchymal-epithelial transition
NCCN: National Comprehensive Cancer Network
NSCLC: non-small cell lung cancer
ROS1: ROS proto-oncogene 1

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NSCLC	250 mg PO BID	500 mg/day

VI. Product Availability

Capsules: 200 mg, 250 mg

VII. References

1. Xalkori Prescribing Information. New York, NY: Pfizer, Inc.; June 2019. Available at http://labeling.pfizer.com/showlabeling.aspx?id=676. Accessed February 11, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed February 11, 2020.
3. National Comprehensive Cancer Network Guidelines. Non-Small Cell Lung Cancer Version 2.2020. Available at www.nccn.org. Accessed February 11, 2020.
4. National Comprehensive Cancer Network Guidelines. Central Nervous System Cancers Version 3.2019. Available at www.nccn.org. Accessed February 11, 2020.
5. National Comprehensive Cancer Network Guidelines. Soft Tissue Sarcoma Version 6.2019. Available at www.nccn.org. Accessed February 11, 2020.
6. National Comprehensive Cancer Network Guidelines. T-Cell Lymphomas Version 1.2020. Available at www.nccn.org. Accessed February 11, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy converted to new template. Added new indication for ROS1-positive NSCLC per package insert. Added NCCN recommendations for use per NCCN guidelines and compendium.	07.16	09.16
Converted to new template. Age added. Maximum and minimum doses added. Off-label dosing guidance added. All off-label uses are referred to the off-label use policy. Approval periods increased from 3/6 to 6/12 months. References updated.	07.17	08.17
2Q 2018 annual review: minimum dose removed; off-label NSCLC recurrent disease added; off-label IMT, ALCL added; NCCN and FDA approved uses summarized for improved clarity; specialist involvement in care added; continuity of care statement added; approval durations increased to length of benefit; references reviewed and updated.	02.13.18	05.18
2Q 2019 annual review: no significant changes; NCCN designation of advanced added to NSCLC; references reviewed and updated.	02.19.19	05.19
2Q 2020 annual review: no significant changes; added Medicaid line of business with 6/12 month initial/continued authorization duration; references reviewed and updated.	02.11.20	05.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional

medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.