Generic Name: Crizotinib

Applicable Drugs: Xalkori®

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 1/25/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through III are met)

I. Documented diagnosis of one of the following conditions A through E AND must meet ALL criteria listed under applicable diagnosis:

A. Non-small lung cell cancer (NSCLC)

i. Age ≥ 18 years old with advanced, recurrent, or metastatic disease.

ii. Documentation of tumor biomarker testing results indicating ONE of the following:

1. Anaplastic lymphoma kinase (ALK) rearrangement positive.
2. C-ros oncogene (ROS1) rearrangement positive.
3. MET exon 14 skipping mutation positive.

B. Anaplastic large cell lymphoma (ALCL)

i. Age:

1. ≥ 1 to < 22 years old with recurrent or refractory systemic disease.
2. > 18 years old recurrent or refractory systemic disease.

ii. Documentation of tumor biomarker testing results indicating ALK positive disease.

C. Inflammatory myofibroblastic tumor (IMT)

i. Age ≥ 1 year old with unresectable, recurrent, or refractory disease.

ii. Documentation of tumor biomarker testing results indicating ALK rearrangement positive disease.

D. Histiocytic neoplasms of ONE of the following subtypes (Langerhans's Cell histiocytosis, Erdheim-Chester Disease, or Rosai-Dorfman Disease)

i. Langerhans's Cell histiocytosis

1. Initial or recurrent treatment with CNS lesions, or multisystem or single system lung disease.

2. Documentation of tumor biomarker testing results indicating ALK positive disease.

ii. Erdheim-Chester Disease

1. Initial or recurrent treatment.
2. Documentation of tumor biomarker testing results indicating ALK positive disease.

iii. Rosai-Dorfman Disease

1. Initial or recurrent treatment.
2. Documentation of tumor biomarker testing results indicating ALK positive disease.

II. Prescriber is an oncologist or a hematologist.

III. Medication is prescribed in accordance with FDA labeling or current clinical practice guidelines.

IV. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Pregnancy
- Lactation

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Up to 120 capsules per 30 days

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** Updated progress notes showing current medical necessity criteria are met and that the medication is effective with acceptable toxicity.

APPENDIX

Table 1. Xalkori dosage by indication.[1-12]

Indication	Dosage[a]

NSCLC[b]	Age: ≥ 18 years old: 250 mg orally twice daily
ALCL[b]	Age: ≥ 1 to < 22 years old: 280 mg/m^2 twice daily up to 500 mg twice daily
IMT[b]	Age: • ≥ 1 to < 22 years old: 280 mg/m2 twice daily up to 500 mg twice daily • > 18 years old: 250 mg orally twice daily
Histiocytic neoplasms[c]	Off-label doses not published in literature case studies.

[a] See prescribing information for detailed information about recommendations for dosage modifications to manage adverse reactions and for patients with moderate or severe hepatic impairment or severe renal impairment for FDA-labeled indications.
[b]FDA-labeled indication.
[c]Off-label NCCN recommended indication.
Abbreviations: non-small lung cell cancer, NSCLC; anaplastic large cell lymphoma, ALCL; inflammatory myofibroblastic tumor, IMT.

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