

XALKORI (crizotinib)

Diagnosis Considered for Coverage:

- Non-Small Cell Lung Cancer (NSCLC) – advanced, recurrent, metastatic
- ALK-positive anaplastic large cell lymphoma (ALCL) – relapsed or refractory
- Inflammatory myofibroblastic tumor, ALK-positive, unresectable, recurrent, or refractory disease

Coverage Criteria:

For ALK-positive anaplastic large cell lymphoma (ALCL):

- Being used for one of the following:
 - Relapsed or refractory disease, or
 - As initial palliative intent therapy (e.g., patient is not eligible for treatment with NCCN-supported first-line chemotherapy combination regimens)
- Presence of anaplastic lymphoma kinase (ALK) gene mutation, and
- Being used as single agent therapy, **and**
- Dose does not exceed 500 mg per day.

For Non-Small Cell Lung Cancer (NSCLC):

- Diagnosis of recurrent, advanced, or metastatic disease, **and**
- Being used as monotherapy for NSCLC, **and**
- Dose does not exceed 500 mg per day, **and**
- Presence of one of the following:
 - Anaplastic lymphoma kinase (ALK) gene mutation,
 - C-ros oncogene 1 (ROS1 gene) mutation,
 - High level mesenchymal-epidermal transition (MET) gene amplification,
 - MET gene exon 14 skipping mutation.

For histiocytic neoplasms: Langerhans cell histiocytosis, Erdheim-Chester disease, and Rosai-Dorfman disease:

- Presence of anaplastic lymphoma kinase (ALK)-fusion, **and**
- Being used as single agent therapy, **and**
- Dose does not exceed 500 mg per day.

For melanoma:

- Disease is metastatic or unresectable, and
- Presence of ROS1 gene fusion, and

- Being used as a single agent, and
- Patient has disease progression on or is not a candidate for BRAF-targeted therapy, **and**
- Dose does not exceed 500 mg per day.

For soft tissue sarcoma:

- Presence of ALK translocation, **and**
- Being used for inflammatory myofibroblastic tumor (IMT), **and**
- Being used as a single agent, **and**
- Dose does not exceed 500 mg per day.

For uterine sarcoma:

- Disease is advanced, recurrent/metastatic, or inoperable, and
- Being used for inflammatory myofibroblastic tumor (IMT) with ALK translocation, and
- Being used as single agent therapy, **and**
- Dose does not exceed 500 mg per day.

Coverage Duration: one year

Effective Date: 8/30/2023