In 2011, FDA granted accelerated approval to crizotinib, a targeted oral cancer therapy known as a tyrosine kinase inhibitor. The medicine was approved to treat patients with locally advanced or metastatic non-small cell lung cancer (NSCLC)* whose tumors have a particular abnormality caused by a rearrangement in the anaplastic lymphoma kinase (ALK) gene, which leads to cancer cell growth.1 Ongoing research and clinical studies in certain types of lung cancer have revealed survival benefits that were not known at the time of initial approval of crizotinib based on available data.2

As changes in the ALK gene have been found in tumors across several cancer types, crizotinib has since been studied and approved across several indications, including FDA approvals granted a decade after initial approval.3,4 These approvals provide important new treatment options for both adult and pediatric patients in certain rare cancer types.

**Crizotinib (XALKORI®)**

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**Additional Value Demonstrated in Approved Indication**

**(November 2013):** Granted traditional approval for the treatment of metastatic ALK-positive metastatic NSCLC, based on clinical data in previously treated patients demonstrating over 50% improvement in progression-free survival compared to standard-of-care chemotherapy at the time.5,6 Patients with ALK-positive cancer tend to be younger than the average lung cancer patient and have little to no smoking history.7

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**Additional Value Demonstrated in Approved Indication**

**(December 2014):** New clinical data showed that crizotinib, for the treatment of patients with previously untreated ALK-positive metastatic NSCLC, significantly improved progression-free survival vs. chemotherapy. This data underscores the importance of biomarker-driven treatment in patients newly diagnosed with lung cancer, the leading cause of cancer death worldwide.8

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**Additional Indication**

**(March 2016):** Approved for the treatment of patients with metastatic NSCLC whose tumors are ROS1-positive. Occurring in approximately 1–2% of NSCLC cases, rearrangements in the ROS1 gene can contribute to cancer cell growth.9,10 Patients with ROS1-positive cancer tend to be younger than the average lung cancer patient and have little to no smoking history.10 As the first treatment to specifically target the ROS1 biomarker, FDA granted breakthrough therapy designation to crizotinib.9,11

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**Additional Value Demonstrated in Approved Indication**

**(July 2019):** Updated clinical study data for crizotinib in ROS1-positive NSCLC showed mature median overall survival data of 51.4 months, continuing to demonstrate the clinically meaningful benefit of this targeted therapy. This data served as a new benchmark for overall survival in patients with ROS1-positive NSCLC.5

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**Additional Indication**

**(January 2021):** Approved for the treatment of pediatric and young adult patients with ALK+ anaplastic large cell lymphoma (ALCL) that has returned or not responded to prior treatment. The FDA granted priority review, orphan drug designation, and breakthrough designation for this indication.12 ALCL is a rare form of non-Hodgkin lymphoma with approximately 100 new cases in the US every year.1,12,14,15,16,17 This marks the first FDA-approved, biomarker-driven therapy available to children and young adults with this specific type of ALCL and was based on an 88% response rate. Approximately 90% of ALCL cases in children and young adults are ALK-positive and this approval marked a particularly valuable treatment advance for these patients.3

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**Additional Indication**

**(July 2022):** Approved for the treatment of adult and pediatric patients with ALK-positive inflammatory myofibroblastic tumors (IMT) that have returned, not responded to prior treatment, or cannot be removed by surgery.4 IMT is very rare with only 150–200 people diagnosed in the US annually—most commonly children and young adults.4 Up to 50% of cases have this particular ALK gene abnormality.19

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*Indication was later modified to metastatic ALK-positive NSCLC15

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*Indication was later modified to metastatic ALK-positive NSCLC17


19 Xalkori. [prescribing information]. Pfizer Labs: New York, NY, USA; 2022.