

Xalkori® (crizotinib) – New indication

- On January 14, 2021, [Pfizer announced](#) the FDA approval of [Xalkori \(crizotinib\)](#), for the treatment of pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is anaplastic lymphoma kinase (ALK)-positive.
 - The safety and efficacy of Xalkori have not been established in older adults with relapsed or refractory, systemic ALK-positive ALCL.
- Xalkori is also approved for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ALK or ROS1-positive as detected by an FDA-approved test.
- The approval of Xalkori for the new indication was based on a single arm, open-label study in 26 patients 1 to ≤ 21 years of age with relapsed or refractory, systemic ALK-positive ALCL. Patients received Xalkori until disease progression or unacceptable toxicity. Efficacy was based on objective response rate (ORR) and duration of response (DOR).
 - The ORR was 88% (95% CI: 71, 96). Among the 23 patients who achieved a response, 22% maintained a response at 12 months.
- The most common adverse reactions (≥ 35%) with Xalkori use in patients with ALCL were diarrhea, vomiting, nausea, vision disorder, headache, musculoskeletal pain, stomatitis, fatigue, decreased appetite, pyrexia, abdominal pain, cough, and pruritus. Grade 3 to 4 laboratory abnormalities (≥ 15%) were neutropenia, lymphopenia, and thrombocytopenia.
- The recommended dose of Xalkori for the treatment of ALCL is 280 mg/m² orally twice daily until disease progression or unacceptable toxicity. The recommended dosage is based on body surface area (BSA) and provided in the table below.

| BSA | Recommended Xalkori dosage |
|--------------------------------|----------------------------|
| 0.60 – 0.80 m ² | 200 mg orally twice daily |
| 0.81 – 1.16 m ² | 250 mg orally twice daily |
| 1.17 – 1.51 m ² | 400 mg orally twice daily |
| 1.52 – 1.69 m ² | 450 mg orally twice daily |
| 1.70 m ² or greater | 500 mg orally twice daily |

- The recommended dosage for patients with a BSA less than 0.60 m² has not been established.
- Refer to the Xalkori drug label for dosing in NSCLC.