



CHARITY WELCOMES NICE APPROVAL OF FIRST-LINE TREATMENT FOR ALK-POSITIVE LUNG CANCER

Latest targeted therapy offers new hope for people with non-smoking lung cancer

ALK Positive UK has today (7 October 2025) welcomed the announcement from the National Institute for Health and Care Excellence (NICE), which recommends lorlatinib (tradename Lorbrena) as a first treatment for people newly diagnosed with advanced ALK-positive non-small cell lung cancer (NSCLC) in England and Wales.¹

ALK-positive is a rare form of lung cancer, which typically affects younger people, often women, and those who have never smoked (or smoked a little). It is caused by a genetic mutation involving the anaplastic lymphoma kinase (ALK) gene and is usually diagnosed at an advanced stage.²

The NICE recommendation is based on the CROWN study,³ which found:

- 60% of patients on lorlatinib remained progression-free after five years
- Strong protection against brain metastases
- The longest progression-free survival reported for any targeted therapy in metastatic solid tumours

Commenting on the NICE approval, Dr Shobhit Baijal, consultant medical oncologist at University Hospitals Birmingham, said: *“NICE’s approval of lorlatinib as a first treatment for ALK-positive lung cancer is a big step forward for patients in England. Not only does it give those who have been newly diagnosed an additional targeted treatment option, but pivotal research shows it can help prevent the disease from progressing, for longer—and it can help prevent it from spreading to the brain.”*

Lorlatinib has been available first line in Scotland since 2022 and is also available in most countries across Europe. In England and Wales, it will be accessible to NHS patients living with ALK-positive lung cancer within 90 days. The decision applies only to those starting treatment and does not affect those already receiving other ALK inhibitors.

Debra Montague, Chair of ALK Positive UK, said: *“This is welcome progress and brings hope to those newly diagnosed with ALK-positive lung cancer. Early access to the most effective treatment is vital, and today’s decision reflects our call for equitable testing and optimal care without delay. It now means that more people with ALK-positive lung cancer across the UK can live better, for longer.”*

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About ALK-positive lung cancer

ALK-positive occurs in about 4-5 percent of NSCLC cases.² It disproportionately affects younger adults (half under 50), women (64%) never-smokers (70%), and people of East Asian descent. Diagnosis requires specialised genomic testing, and most patients begin treatment with targeted oral therapies.² An X-ray, CT scan or PET scan may identify lung cancer, but an ALK rearrangement has to be diagnosed through genomic testing (also known as molecular profiling). About 85% of ALK-positive patients are diagnosed at Stage 4 and are likely to be treated with oral drugs that work to shrink the tumours.^{2,4}

About Lorlatinib

Lorlatinib, taken as a once-daily tablet, is part of a new generation of targeted therapies known as tyrosine kinase inhibitors (TKIs). It works by blocking the abnormal ALK protein that drives cancer growth and spread. The treatment reduces the need for hospital visits and has shown exceptional results in clinical trials.³

About ALK Positive UK

ALK Positive UK is the leading charity for people affected with ALK-positive lung cancer in the UK. Its vision is to ensure that people with ALK-positive lung cancer thrive and live a long and fulfilling life unhindered by their disease. The charity provides a wealth of information to help support, advocate, and campaign for those living with ALK-positive lung cancer and their families. www.alkpositive.org.uk

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References:

1. From 00.01hrs on 7th October 2025 the NICE Final Appraisal Document for 'Lorlatinib for ALK-positive advanced non-small-cell lung cancer that has not been treated with an ALK inhibitor' will be published here: <https://www.nice.org.uk/guidance/indevelopment/gid-ta11570>
2. Prevalence and natural history of ALK-positive non-small-cell lung cancer and the clinical impact of targeted therapy with ALK inhibitors. Accessed October 2025 at: <https://pubmed.ncbi.nlm.nih.gov/25429239/>
3. Lorlatinib Versus Crizotinib in Patients with Advanced ALK-positive Non-Small Cell Lung Cancer: 5-Year Outcomes From the Phase III CROWN Study. Accessed October 2025 at: <https://ascopubs.org/doi/10.1200/JCO.24.00581>
4. ALK Positive UK: <https://www.alkpositive.org.uk/about-alk-positive-lung-cancer>

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