

Patient Resource: Understanding Treatment Options for Advanced ALK-Positive NSCLC

The goal of this resource is to increase your understanding of treatment options for advanced non-small-cell lung cancer (NSCLC) that is positive for a specific biomarker, an *ALK* gene rearrangement.

Knowledge can help make you better equipped to partner in decision-making with your oncology care team about your treatment. If you have not discussed this information with your oncology care team yet, take the time to ask them your questions since the more you know about your the cancer, the more involved you can be in your care.

What Is ALK-Positive NSCLC?

Prior to treatment, your oncology care team will test the cancer cells to determine the presence of specific biomarkers or genetic alterations that can help the team understand the driving forces that may be behind the cancer. If a biomarker is found, that can affect prognosis and treatment choices.

Tests for biomarkers are usually done using a tissue biopsy from the tumor. If there is not enough tumor tissue obtained from a biopsy procedure for testing, another biopsy may be done. In addition, a blood sample (or liquid biopsy) may be used. The recommended testing procedure evaluates the tumor tissue/blood sample for several different biomarkers that can be treated with different medicines based on the specific biomarker identified.

ALK is a gene that normally assists in early development; a rearrangement or fusion of the *ALK* gene with another gene can result in the production an abnormal protein that can drive cancer development. *ALK* rearrangements occur in ~5% of advanced NSCLC cases; NSCLC with an *ALK* rearrangement can also be called ALK-positive NSCLC.



What if I Have ALK-Positive NSCLC?

If you have advanced ALK-positive NSCLC that has spread to other sites in your body, current national guidelines recommend treatment with a medicine that can specifically inhibit ALK protein activity; these drugs are known as ALK inhibitors.

Guideline-Recommended ALK Inhibitors as Initial Therapy for Advanced ALK-Positive NSCLC

Preferred	Useful in Certain Circumstances
Alectinib	Ceritinib
Brigatinib	Crizotinib
Ensartinib	
Lorlatinib	

- If you have started treatment with another regimen, such as chemotherapy with or without immunotherapy, and then you are found to have ALK-positive NSCLC, guidelines recommend that this regimen be discontinued and an ALK inhibitor be started.

Your oncology care team should discuss therapy choice with you prior to starting treatment.

What Can I Expect During Treatment With an ALK Inhibitor?

- ALK inhibitors are tablets taken by mouth once or twice a day with or without food depending on which one you are prescribed.
- ALK inhibitors have distinct side effect profiles. The most common or concerning side effects noted with the various ALK inhibitors are listed below, with the overall frequency reported from clinical trials in parentheses. In general, more severe side effects are uncommon.

Drug	Dosing (All Are Oral Tablets)	Frequent Side Effects (Incidence in Clinical Trials)		Key Lab Abnormalities (Grade 3/4 Incidence in Clinical Trials)
Alectinib	600 mg twice daily with food	☐ Liver injury (41%) ☐ Constipation (39%) ☐ Fatigue (36%) ☐ Muscle ache or pain (31%)	☐ Swelling in limbs or body (29%) ☐ Rash (23%) ☐ Cough (21%)	☐ Increase in muscle enzyme (CPK) (6%)
Brigatinib	90 mg once daily for 7 days, then 180 mg once daily	☐ Diarrhea (53%) ☐ Rash (40%) ☐ Cough (35%) ☐ Fatigue (32%) ☐ Nausea (30%) ☐ Muscle ache or pain (28%)	☐ Shortness of breath (25%) ☐ Headache (22%) ☐ Vomiting (21%) ☐ Interstitial lung disease (5%) ☐ Hypertension (NA)	☐ Increase in muscle enzyme (CPK) (24%)
Ensartinib	225 mg once daily	☐ Rash (66%) ☐ Musculoskeletal pain (36%) ☐ Constipation (31%) ☐ Cough (31%) ☐ Itching (30%)	☐ Nausea (28%) ☐ Swelling in limbs or body (27%) ☐ Fever (22%) ☐ Fatigue (21%)	☐ Increased urate (39%)
Lorlatinib	100 mg once daily	☐ Swelling in limbs or body (56%) ☐ Peripheral neuropathy (44%) ☐ Weight gain (31%) ☐ Cognitive effects (28%) ☐ Fatigue (27%)	☐ Shortness of breath (27%) ☐ Arthralgia (24%) ☐ Diarrhea (23%) ☐ Mood effects (21%) ☐ Cough (21%)	☐ Increase in cholesterol (21%) ☐ Increase in triglyceride levels (21%)
Ceritinib	450 mg once daily with food	☐ Diarrhea (85%) ☐ Nausea (69%) ☐ Vomiting (67%) ☐ Abdominal pain (40%)	☐ Fatigue (45%) ☐ Decreased appetite (34%) ☐ Cough (25%)	☐ Increased GGT (49%) ☐ Increased ALT (34%)
Crizotinib	250 mg twice daily	☐ Vision disorders (71%) ☐ Diarrhea (61%) ☐ Swelling in limbs or body (49%) ☐ Vomiting (46%)	☐ Constipation (43%) ☐ URI (32%) ☐ Abdominal pain (26%) ☐ Dysgeusia (26%)	☐ Increased ALT (15%) ☐ Decrease in neutrophils (a white blood cell) (11%) ☐ Hypophosphatemia (10%)

Grade 3 side effects are severe but not immediately life-threatening; grade 4 side effects are life-threatening and require urgent intervention.

What Do I Need to Tell My Oncology Care Team Before Treatment With an ALK Inhibitor ?

Think carefully about your personal expectations, desires, and hopes for treatment and how treatment will affect your life.

What is your most important goal for treatment?

Cost issues? Fears?

Do you need help talking with loved ones?

Is it which drug may help you live the longest, even if that drug may cause more toxicity than another one?



Particular life milestones or events that your medical team should be aware of?

Do you have a social/familial support system?

What other concerns do you have?

Make notes about the things you want to discuss with your doctor and oncology care team.

Your satisfaction with treatment requires weighing all the factors for medical success (controlling the cancer) and a happy life (doing the things you want to do, when you want to do them, not limited by side effects of the medicine). You may need to give more weight to one or the other from time to time, and it's ok that those goals shift. Knowing what you value overall will help you do this. It is also very important that you share these values and goals with your treatment team so they can choose and adjust treatment to help you reach them.

What Does My Oncology Care Team Need to Tell Me Before Treatment With an ALK Inhibitor?

Answers to the following questions can help guide treatment decisions. If your answer to any question is **“I don't know,”** consult with your specialist or a member of your healthcare team to help you reach a treatment decision that is right for you.

As you learn more about advanced NSCLC, you will become more confident in decision-making for your disease. Working together, you and your doctor can make sure your health and treatment are balanced with all the other parts of your life. Note that biomarker testing before treatment is one of the most important things you can do for your advanced NSCLC. Obtaining the appropriate biomarker tests will guide treatment decisions and help predict how aggressively the disease might behave in the future.

The following questions are appropriate assuming you have advanced or metastatic ALK-positive NSCLC.

What is your treatment setting?

- ☐ Newly diagnosed, considering my first treatment option
- ☐ Previously received 1 treatment regimen, considering my next treatment option
- ☐ Previously received 2 treatment regimens, considering my next treatment option
- ☐ I don't know



Do you have a history of any of the following?



☐ Anemia



☐ Bradycardia (slow heart rate)



☐ Elevated cholesterol and elevated triglycerides



☐ Hypertension (elevation in blood pressure)



☐ Liver disease



☐ Mental health issues



☐ Pneumonitis (inflammation in the lungs which can cause shortness of breath or cough)



☐ Vision disorders



☐ I don't know

If you have had previous treatment for your advanced ALK-positive NSCLC, what medicine(s) did you received?

- | | |
|----------------------------------|---|
| ☐ Alectinib | ☐ Crizotinib |
| ☐ Brigatinib | ☐ Chemotherapy plus immunotherapy |
| ☐ Ensartinib | ☐ Chemotherapy alone |
| ☐ Lorlatinib | ☐ Something else |
| ☐ Ceritinib | ☐ I don't know |

Why did you stop your most recent therapy?

- ☐ My disease progressed/worsened
- ☐ I could not tolerate the side effects of the medicine anymore
- ☐ I don't know

Additional Resources to Understand Your Cancer

- NCCN Guidelines for Patients
- Specific drug manufacturer websites



If you are a healthcare professional, you can find our healthcare professional–focused resources at clinicaloptions.com/ALKLung2025Program

Patients may also find these useful educational resources.



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