XALKORI® 250 MG CAPSULES
CRIZOTINIB

EXPLORE
WHAT'S POSSIBLE.

If you have ALK+ or ROS1+ metastatic NSCLC, **we can help guide your journey.**

XALKORI® (crizotinib) is a prescription medicine used to treat people with non-small cell lung cancer (NSCLC) that has spread to other parts of the body and is caused by a defect in either a gene called ALK (anaplastic lymphoma kinase) or a gene called ROS1. It is not known if XALKORI is safe and effective in children.

Please see Important Safety Information on pages 4-5.
Click for the full Prescribing Information and Medication Guide or visit XALKORI.com.

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Having NSCLC can be a confusing experience. That's why, as pioneers in the treatment of ALK+ or ROS1+ metastatic NSCLC, we're here to be a dedicated and knowledgeable partner throughout your treatment with XALKORI® (crizotinib).

See the glossary on pages 16-17 for definitions of terms that may be unfamiliar to you.

- **In 2011, XALKORI became the first medication for people who test ALK-positive (ALK+) and have NSCLC that has spread to other parts of the body (metastatic). Since it was approved in 2011, XALKORI has been used to treat more than 15,000 patients.** This brochure tells you some things you should know about your treatment with XALKORI—from how XALKORI may be able to help to what you can expect when taking XALKORI. This includes possible side effects you may experience. As always, if you have any questions about your treatment, ask your doctor or nurse.

Remember, you can visit **XALKORI.com** anytime for more in-depth information or to register for additional resources.

Genetics is changing the way we look at and treat non-small cell lung cancer (NSCLC)

When it comes to the treatment of NSCLC, the options generally include surgery, radiation therapy, chemotherapy, and biomarker-driven therapy. Thanks to breakthroughs in genetics over the past decade, biomarker-driven therapy is giving doctors another important option for treating some people with NSCLC.

Biomarker testing may help guide treatment decisions

As scientists study cancer cells at the molecular level, they are finding genetic changes or defects that occur in certain types of cancer.

Biomarkers are signs of these genetic changes or defects. By testing a sample of your tumor for biomarkers, doctors can learn if your cancer has one of these defects—and then use that information to recommend specific treatment options.

That's why it's important for people with NSCLC that has spread to other parts of the body to ask their doctor if biomarker testing, also known as molecular profiling, is appropriate for them. Some NSCLCs are linked to known biomarkers, including ALK or ROS1.

Please see Important Safety Information on pages 4-5.
Click for the full Prescribing Information and Medication Guide or visit XALKORI.com.

The ALK and ROS1 genes

Advances in genetics have revealed a number of genetic changes or defects that are believed to cause some cancers to grow. Two of these defects result in genes called ALK and ROS1 fusion genes. Everyone has the ALK and ROS1 genes in their cells. But when a part of the ALK or the ROS1 gene breaks off and reattaches the wrong way, it becomes a fusion gene. This may cause the cell to multiply out of control, resulting in cancer growth.

It's important to know that if you test positive for ALK, you typically would not test positive for ROS1, and vice versa. Men and women of various races, ethnicities and ages have tested ALK+ or ROS1+. Some have smoked, but most have never smoked.

THESE NUMBERS MIGHT SEEM SMALL, BUT NOT IF YOU ARE ONE OF THEM

3% to 5% of people with NSCLC test positive for the ALK fusion gene.

1% to 2% of people with NSCLC test positive for the ROS1 fusion gene.

The only way to find out if your lung cancer is positive for ALK or ROS1 is to do a test.

Molecular testing can find rare biomarkers like ALK and ROS1.

If testing has shown that you do have ALK+ or ROS1+ NSCLC that has spread to other parts of your body, XALKORI® (crizotinib) may be an option for you.

Who can have ALK+ or ROS1+ NSCLC? The short answer is there is no one "type" of person who has it. Men and women with NSCLC who tested ALK+ or ROS1+ for clinical trials were of various ethnicities and a wide age range. Some had smoked, though most had never smoked. While some people may be more likely to carry either altered gene, there is no true way to know without getting tested.

What's involved in testing? Your doctor needs a tissue sample, or biopsy, of the tumor. If there's enough tissue from a previous biopsy, that sample could be used. If not, another biopsy would be needed. Once the tissue is sent to the lab, most results come back within 2 weeks. If you have any questions about biomarker testing or whether your tumor may be positive for ALK or ROS1, talk to your doctor.

Please see Important Safety Information on pages 4-5.
Click for the full Prescribing Information and Medication Guide or visit XALKORI.com.

Important Safety Information

XALKORI® (crizotinib) may cause serious side effects, some of which may include:

Liver problems — XALKORI may cause life-threatening liver injury that may lead to death. Your healthcare provider should do blood tests to check your liver every 2 weeks during the first 2 months of treatment with XALKORI, then once a month. Tell your healthcare provider right away if you get any of the following new or worsening symptoms:

- yellowing of your skin or the white part of your eyes
- severe tiredness
- dark or brown (tea color) urine
- nausea or vomiting
- decreased appetite
- pain on the right side of your stomach
- bleed or bruise more easily than normal
- itching

Lung problems (pneumonitis) — XALKORI may cause life-threatening lung problems that may lead to death. Symptoms may be similar to those symptoms from lung cancer. Tell your healthcare provider right away if you have any new or worsening symptoms, including:

- trouble breathing or shortness of breath
- cough with or without mucous
- fever

Heart problems — XALKORI may cause very slow, very fast, or abnormal heartbeats. Your healthcare provider may check your pulse rate and blood pressure during treatment with XALKORI. Tell your healthcare provider right away if you feel dizzy or faint or have abnormal heartbeats. Tell your healthcare provider if you take any heart or blood pressure medicines.

Severe vision problems — Vision problems are common with XALKORI. These problems usually happen within 1 week of starting treatment with XALKORI. Vision problems with XALKORI can be severe and may cause partial or complete loss of vision in one or both eyes. Your healthcare provider may hold or stop XALKORI and refer you to an eye specialist if you develop any vision problems during treatment with XALKORI. Tell your healthcare provider right away if you have any new vision problems, loss of vision or any change in vision, including:

- double vision
- seeing flashes of light
- blurry vision
- light hurting your eyes
- new or increased floaters

Before you take XALKORI, tell your healthcare provider about all of your medical conditions including if you:

- have liver or kidney problems
- have lung problems
- have heart problems, including a condition called long QT syndrome
- have vision or eye problems

Important Safety Information (continued)

Before you take XALKORI® (crizotinib), tell your healthcare provider if you:

- are pregnant, or plan to become pregnant. XALKORI can harm the unborn baby
  - **Females** who are able to become pregnant should use effective birth control during treatment with XALKORI and for at least 45 days after the final dose of XALKORI.
  - Your healthcare provider will check to see if you are pregnant before starting treatment with XALKORI
  - **Males** who have female partners who can become pregnant should use condoms during treatment with XALKORI and for at least 90 days after the final dose of XALKORI.
  - Talk to your healthcare provider about birth control methods that may be right for you.
  - If you or your partner becomes pregnant, tell your healthcare provider right away.
- are breastfeeding or plan to breastfeed. It is not known if XALKORI passes into the breast milk. Do not breastfeed during treatment with XALKORI and for 45 days after the final dose. Talk to your healthcare provider about the best way to feed the baby during this time

Tell your healthcare provider about the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements.

Do not drink grapefruit juice, eat grapefruit or take supplements containing grapefruit extract during treatment with XALKORI. It may increase the amount of XALKORI in your blood to a harmful level.

The most common side effects of XALKORI include:

- vision problems
- nausea, diarrhea, or vomiting
- swelling of your hands, feet, face, and eyes
- constipation
- increased liver function blood test results
- tiredness
- decreased appetite
- upper respiratory infection
- dizziness
- feeling of numbness or tingling in your arms or legs

XALKORI can cause changes in vision, dizziness, and tiredness. Do not drive or operate machinery if you have any of these symptoms.

Avoid spending prolonged time in sunlight. XALKORI can make your skin sensitive to the sun (photosensitivity), and you may burn more easily. You should use sunscreen and wear protective clothing that covers your skin to help protect against sunburn if you have to be in the sunlight during treatment with XALKORI.

XALKORI may cause fertility problems in females and males, which may affect the ability to have children.

These are not all of the possible side effects of XALKORI.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

ABOUT XALKORI® (CRIZOTINIB)

XALKORI 250 MG CAPSULES
CRIZOTINIB

EXPLORE
WHAT'S POSSIBLE.

XALKORI is a prescription medicine used to treat people with non-small cell lung cancer (NSCLC) that has spread to other parts of the body and is caused by a defect in either a gene called ALK (anaplastic lymphoma kinase) or a gene called ROS1. It is not known if XALKORI is safe and effective in children.

How XALKORI works

XALKORI is only used for certain types of lung cancer. These types are called ALK-positive (ALK+) or ROS1-positive (ROS1+), depending on which gene is abnormal. XALKORI treats ALK+ or ROS1+ NSCLC that has spread to other parts of the body (metastatic). By blocking the action of the abnormal ALK or ROS1 fusion genes, XALKORI may shrink or slow the growth of either type of tumor. In clinical studies, XALKORI did not make the cancer go away. But in the majority of people with ALK+ or ROS1+ metastatic NSCLC, XALKORI was able to shrink or slow the growth of patients' tumors for a period of time.

How XALKORI may be able to help

ALK+ study results

XALKORI was tested in clinical studies of people with ALK+ NSCLC that had spread to other parts of their bodies. A total of 1,669 people received XALKORI in these studies.

For many patients in these studies, XALKORI shrank or slowed tumor growth for a certain length of time. For some of these patients, that meant their cancer did not get worse during this time.

Please see Important Safety Information on pages 4-5.
Click for the full Prescribing Information and Medication Guide or visit XALKORI.com.

How XALKORI may be able to help (continued)

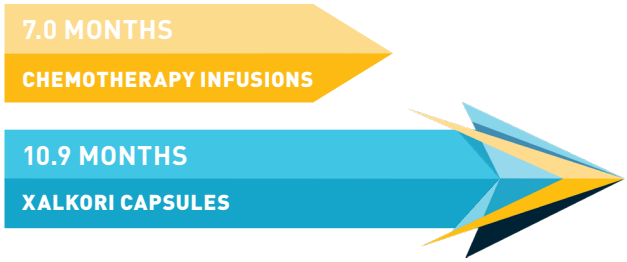
Length of time during which ALK+ cancer did not get worse

In one study, 172 people took XALKORI and 171 people were given chemotherapy. In the group of people taking XALKORI, the length of time during which their cancer did not get worse was longer than for those in the group receiving chemotherapy.

In people taking XALKORI, the tumors did not grow or spread for a median time period of 10.9 months. Median time period means that half the people went longer than 10.9 months with no tumor growth or spread, and the other half went less than 10.9 months with no tumor growth or spread.

For people treated with chemotherapy, the median time period was 7 months with no tumor growth or spread.

Length of time during which cancer did not get worse



How did ALK+ tumors respond to XALKORI?

- The objective response rate (ORR) measures tumor response to treatment, including tumor shrinkage
- The results showed that the ORR of patients taking XALKORI was 74%—meaning 74% of patients saw their tumors respond to XALKORI—compared to 45% of patients taking chemotherapy
  - Three patients in the XALKORI group had all signs of cancer disappear (known as a complete response, but this does not mean that the cancer is cured). Two of the patients in the chemotherapy group had a complete response
  - 125 of the 172 patients in the XALKORI group had the spread of cancer lessened, or had tumors that shrank (known as a partial response). In the chemotherapy group, 75 of the 171 patients had a partial response
- The length of time these partial and complete responses lasted before the tumors resumed growing or spreading was a median time period of 11.3 months for people who took XALKORI and a median of 5.3 months for people who had chemotherapy
- This study also measured the total time patients lived after starting each treatment (overall survival). While no significant difference was found in overall survival between patients taking XALKORI and chemotherapy, it's important to note that most patients (84%) who were in the chemotherapy group went on to receive XALKORI

Study description: The 343 people in this study with ALK+ NSCLC that had spread to other parts of their bodies were split into 2 groups and given different treatments. One group took XALKORI capsules twice a day, and the other group received chemotherapy infusions every 21 days. None of these people had received previous systemic treatment for their non-small cell lung cancer that had spread to other parts of the body.

Please see Important Safety Information on pages 4-5.
Click for the full Prescribing Information and Medication Guide or visit XALKORI.com.

How XALKORI may be able to help (continued)

ROS1+ study results

The ability of XALKORI to treat ROS1+ tumors was tested in a clinical study that included 50 people with ROS1+ NSCLC that had spread to other parts of their bodies. This study did not compare XALKORI to another medication such as chemotherapy.

How ROS1+ tumors responded to XALKORI

- The objective response rate (ORR) measures tumor response to treatment, including tumor shrinkage
- The results showed that the ORR of patients taking XALKORI was 66%, meaning 66% of patients saw their tumors respond to XALKORI
  - One patient had all signs of cancer disappear (known as a complete response, but this does not mean that the cancer is cured)
  - 32 of 50 patients had the spread of cancer lessened or had tumors that shrank (known as a partial response)
- The length of time these partial and complete responses lasted before the tumors resumed growing or spreading was a median time period of 18.3 months
  - This means that after the tumors responded, half of the patients went longer than 18.3 months before their tumor grew or spread, and half went less than 18.3 months before their tumor grew or spread

Study description: The 50 people in this study with ROS1+ NSCLC that had spread to other parts of their bodies were treated with XALKORI capsules twice a day. All of the people in the study took XALKORI; the results were not compared to results with another medication. Most of the people in the study had received previous systemic treatment for their NSCLC that had spread to other parts of the body.

50 PATIENTS TOOK XALKORI TO TREAT THEIR ROS1-POSITIVE METASTATIC NSCLC

Objective Response Rate

66% **of patients taking XALKORI had their tumor respond**

- 1 patient's tumor was not detectable after XALKORI treatment. (This does not mean that the cancer is cured.)
- 32 patients' tumors shrank more than 30%.

Time Without Tumor Growth or Spread

18.3

months was the median time period that patients went before their tumors grew or spread, after the tumors initially shrank or their spread lessened.

- The side effects experienced by the 50 patients with ROS1+ NSCLC were similar to those experienced by ALK+ patients treated with XALKORI
- 92% of ROS1+ patients experienced vision problems while on XALKORI
- The median amount of time that ROS1+ patients were on XALKORI in this study was 34.4 months, meaning that half the patients were on XALKORI for more than 34.4 months, and half for less than 34.4 months

Please see Important Safety Information on pages 4-5.
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XALKORI 250 MG CAPSULES
CRIZOTINIB

EXPLORE
WHAT'S POSSIBLE.

XALKORI® (crizotinib) side effects

XALKORI has side effects you should know about before you start taking it. Tell your healthcare provider right away if you have any side effect that bothers you or that does not go away.

XALKORI has been known to cause serious side effects, including:

Liver problems

XALKORI may cause life-threatening liver injury that may lead to death. Your healthcare provider should do blood tests to check your liver every 2 weeks during the first 2 months of treatment with XALKORI, then once a month. Tell your healthcare provider right away if you get any of the following new or worsening symptoms:

- yellowing of your skin or the white part of your eyes
- severe tiredness
- dark or brown (tea color) urine
- nausea or vomiting
- decreased appetite
- pain on the right side of your stomach
- bleed or bruise more easily than normal
- itching

Please see Important Safety Information on pages 4-5.
Click for the full Prescribing Information and Medication Guide or visit XALKORI.com.

XALKORI® (crizotinib) side effects (continued)

Lung problems (pneumonitis)

XALKORI may cause life-threatening lung problems that may lead to death. Symptoms may be similar to those symptoms from lung cancer. Tell your healthcare provider right away if you have any new or worsening symptoms, including:

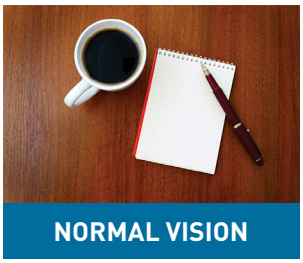
- trouble breathing or shortness of breath
- cough with or without mucous
- fever

Heart problems

XALKORI may cause very slow, very fast, or abnormal heartbeats. Your healthcare provider may check your pulse rate and blood pressure during treatment with XALKORI. Tell your healthcare provider right away if you feel dizzy or faint or have abnormal heartbeats. Tell your healthcare provider if you take any heart or blood pressure medicines.

Severe vision problems

Vision problems are common with XALKORI. These problems usually happen within 1 week of starting treatment with XALKORI. Vision problems with XALKORI can be severe and may cause partial or complete loss of vision in one or both eyes. Your healthcare provider may hold or stop XALKORI and refer you to an eye specialist if you develop any vision problems during treatment with XALKORI. Tell your healthcare provider right away if you have any new vision problems, loss of vision or any change in vision, including double vision, seeing flashes of light, blurry vision, light hurting your eyes, or new or increased floaters.



YOU CAN ALSO USE THESE IMAGES TO PROVIDE YOUR DOCTOR WITH A MORE SPECIFIC DESCRIPTION OF YOUR VISION CHANGES.

Risks related to pregnancy

If you are pregnant, or plan to become pregnant, XALKORI can harm the unborn baby. **Females** who are able to become pregnant should use effective birth control during treatment with XALKORI and for at least 45 days after the final dose of XALKORI. Your healthcare provider will check to see if you are pregnant before starting treatment with XALKORI. **Males** who have female partners who can become pregnant should use condoms during treatment with XALKORI and for at least 90 days after the final dose of XALKORI. Talk to your healthcare provider about birth control methods that may be right for you. If you or your partner becomes pregnant, tell your healthcare provider right away.

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XALKORI® (crizotinib) side effects (continued)

Common side effects

The most common side effect of XALKORI is vision problems.

A majority of people in two XALKORI studies reported visual changes that happened about 4 to 7 times per week. These visual changes usually lasted up to 1 minute and had mild or no impact on their daily activities, according to a questionnaire that patients had responded to.

If you have any new vision problems, loss of vision or any change in vision—such as double vision, seeing flashes of light, blurry vision, light hurting your eyes, or new or increased floaters—tell your healthcare provider right away. Use the images on the previous page to describe visual changes to your healthcare provider.

Other common side effects of XALKORI include:

- nausea
- diarrhea
- vomiting
- swelling of your hands, feet, face, and eyes
- constipation
- increased liver function blood test results
- tiredness
- decreased appetite
- upper respiratory infection
- dizziness
- feeling of numbness or tingling in your arms or legs

XALKORI can cause changes in vision, dizziness, and tiredness. Do not drive or operate machinery if you have any of these symptoms.

XALKORI may cause fertility problems in females and males, which may affect the ability to have children.

These are not all of the possible side effects of XALKORI. For more information, ask your healthcare provider or pharmacist.

As always, it's important to keep your cancer care team aware of how you're feeling. But it's even more important when you're starting a treatment such as XALKORI. Always tell your doctor or nurse right away about any side effects. Your doctor may change the dose of XALKORI or some of your other medications, choose different medicines while you are taking XALKORI, or stop your treatment.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Please see Important Safety Information on pages 4-5.
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XALKORI 250 MG CAPSULES CRIZOTINIB

EXPLORE
WHAT'S POSSIBLE.

If your doctor prescribes XALKORI, there are some things you should know about how to take it and what to expect.

Before you start XALKORI

Before you start XALKORI, it's important to talk with your healthcare provider about all your health issues and the other medications you are taking.

Be sure to tell your healthcare provider if you:

- have liver or kidney problems
- have lung problems
- have heart problems, including a condition called long QT syndrome
- have vision or eye problems
- are pregnant, or plan to become pregnant. XALKORI can harm the unborn baby
  - **Females** who are able to become pregnant should use effective birth control during treatment with XALKORI and for at least 45 days after the final dose of XALKORI
  - Your healthcare provider will check to see if you are pregnant before starting treatment with XALKORI
  - **Males** who have female partners who can become pregnant should use condoms during treatment with XALKORI and for at least 90 days after the final dose of XALKORI
  - Talk to your healthcare provider about birth control methods that may be right for you
  - If you or your partner becomes pregnant, tell your healthcare provider right away

Please see Important Safety Information on pages 4-5.
Click for the full Prescribing Information and Medication Guide or visit XALKORI.com.

Before you start XALKORI (continued)

Be sure to tell your healthcare provider if you:

- are breastfeeding or plan to breastfeed. It is not known if XALKORI passes into the breast milk. Do not breastfeed during treatment with XALKORI and for 45 days after the final dose. Talk to your healthcare provider about the best way to feed the baby during this time

Tell your healthcare provider about the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements. Keep a list of them to show to your doctor or pharmacist, and tell them when you get a new medicine.

Always tell your healthcare provider right away about any side effects. They may change the dose of XALKORI or some of your other medicines, choose different medicines while you are taking XALKORI, or stop your treatment.

For more information on XALKORI and its possible side effects, visit **XALKORI.com**.

How to take XALKORI

AM **PM** Pills not shown in actual size.

XALKORI is a pill you take twice a day, with or without food—without interruption. In other words, there are no "cycles" or scheduled times when you should stop taking XALKORI and then begin taking it again.

If your doctor prescribes XALKORI, make sure you:

- take XALKORI exactly as your healthcare provider tells you
- swallow XALKORI capsules whole
- know that your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with XALKORI if you have certain side effects. Do not change your dose or stop taking XALKORI unless your healthcare provider tells you
- do not take more than 1 dose of XALKORI at a time
- do not drink grapefruit juice, eat grapefruit or take supplements containing grapefruit extract during treatment with XALKORI. These may increase the amount of XALKORI in the blood

Easy ways to remember each dose

There are some simple ways to remember to take XALKORI twice each day. Here are a few ideas you can try:

Use a calendar.
Record your dosage times on a calendar or planner. You can then check off each dose as you take it.

Use a weekly pill caddy.
It can help you to organize your capsules in separate compartments. Refer back to the pill caddy to make sure you've taken XALKORI twice each day.

Use a diary or journal.
It can help you keep track of how much medicine to take and when. You can also use it to track symptoms and side effects for doctor visits.

Ask for a reminder.
A caregiver, friend, or family member can be helpful in reminding you to take each dose of your medicine.

Place your pill bottle in plain sight.
Keep your medicine where you will see it, such as on your nightstand. Just make sure it is out of the reach of children and pets.

What to do if you miss a dose:
If you miss a dose of XALKORI, take it as soon as you remember EXCEPT if your next scheduled dose is in less than 6 hours. In that case, just take the next pill at your regular time.

If you vomit after taking a dose of XALKORI, do not take an extra dose; just take your next dose at your regular time.

How will you know if XALKORI is working?
It's important to keep taking XALKORI exactly as directed until your healthcare provider tells you to stop. Regular scans by your cancer care team will reveal whether your tumor is responding to treatment with XALKORI. Your healthcare provider will determine when those scans should be scheduled.

XALKORI® CRIZOTINIB

EXPLORE
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Helping you get the medicine you need

You can get XALKORI® (crizotinib) through certain specialty pharmacies. These are pharmacies that handle medicines, including XALKORI, that are often not stocked at regular neighborhood pharmacies.

The specialty pharmacy can help you verify your insurance and set up the delivery of your prescription.

Go to the next page to see a glossary of common terms you may come across in your treatment journey

GLOSSARY

ALK gene:
ALK stands for anaplastic lymphoma kinase. Everyone has the ALK gene in their cells. When a part of the ALK gene breaks off and reattaches in the wrong way, it becomes an abnormal ALK gene, also known as an ALK fusion gene. This can lead to cancer cell growth and tumor survival.

ALK+ NSCLC:
A type of non-small cell lung cancer (NSCLC) where an ALK fusion gene is present. Also written as ALK-positive NSCLC.

Biomarker:
A tumor biomarker is a molecule that indicates there is a change in a tumor cell's genes that may be related to the development or spread of cancer. A biomarker may help a doctor choose a specific treatment plan for a patient based on the characteristics of his or her cancer. Also called a molecular marker.

Biomarker-driven therapy:
A type of treatment that is designed to block the action of abnormal genes or proteins that may be contributing to cancer growth. For people whose tumors test positive for a certain biomarker, it may be possible to base their treatment plan on this biomarker.

Biomarker testing or molecular profiling:
A process that allows doctors to analyze tumors to look for changes that may be contributing to cancer growth. This type of test helps a doctor develop a treatment plan for a patient. Also called a tumor marker test, molecular testing, or mutation profiling.

Biopsy:
The removal of cells or tissue for biomarker testing or study under a microscope to look for signs of disease.

Carcinoma:
A cancer that begins in a specific area of the skin's tissue or in the lining of the internal organs.

Chemotherapy:
A cancer treatment that may work by stopping or slowing the growth of fast-dividing cancer cells.

Chromosome:
A strand of DNA that contains genes and is found in the center of cells.

Clinical trial:
A research study meant to test new medical approaches. In cancer, a clinical trial may test new ways to find, diagnose, and treat cancer.

GLOSSARY

DNA:
The genetic information passed on from parent to child. DNA is found within cells.

Gene:
A short piece of DNA that "tells" cells what to do.

Median time period:
In a cancer treatment study, it often means that half of the patients responded to a treatment for at least a specific amount of time, and half responded for less than that specific amount of time.

Metastatic:
Having to do with metastasis, which is the spread of cancer from where it started to other places in the body.

Non-small cell lung cancer (NSCLC):
A group of lung cancers that are named for the kinds of cells found in the cancer and how the cells look under a microscope. Non-small cell lung cancer is the most common kind of lung cancer.

Patient Prescribing Information:
A version of a medicine's label or package insert that is written in language meant to be understood by patients.

ROS1 gene:
Everyone has the ROS1 gene in their cells. When a part of the ROS1 gene breaks off and reattaches in the wrong way, it becomes an abnormal ROS1 gene, also known as a ROS1 fusion gene. This can lead to cancer cell growth and tumor survival.

ROS1+ NSCLC:
A type of non-small cell lung cancer (NSCLC) where a ROS1 fusion gene is present. Also written as ROS1-positive NSCLC.

Specialty pharmacy provider:
A pharmacy that focuses on providing medicines for patients with complex diseases, like cancer. Specialty pharmacies handle medicines that are often not stocked at regular neighborhood pharmacies.

Tumor:
A mass of tissue that is caused by abnormal growth of cells or by cells that live longer than normal.

XALKORI financial assistance

Finding financial support options. Together.

Commercially Insured

Resources for eligible commercial, private, employer, or state health insurance marketplace coverage:

- Co-pay assistance: Eligible, commercially insured patients may pay as little as $0 per month for XALKORI. Limits, terms, and conditions apply.* There are no income requirements, forms, or faxing to enroll

*Patients are not eligible to use this card if they are enrolled in a state or federally funded insurance program, including but not limited to Medicare, Medicaid, TRICARE, Veterans Affairs health care, a state prescription drug assistance program, or the Government Health Insurance Plan available in Puerto Rico. Patients may receive up to $25,000 in savings per product annually. **The offer will be accepted only at participating pharmacies. This offer is not health insurance.** No membership fees apply. Pfizer reserves the right to rescind, revoke, or amend this offer without notice. For full Terms and Conditions, please see PfizerOncologyTogether.com/terms. For any questions, please call 1-877-744-5675, visit PfizerOncologyTogether.com/terms or write: Pfizer Oncology Together Co-Pay Savings Program, 2250 Perimeter Park Drive, Suite 300, Morrisville, NC 27560.

For patients starting XALKORI® (crizotinib)

PfizerPledge™

WARRANTY PROGRAM FOR XALKORI® (crizotinib)

Pfizer stands by its commitment to patients

As part of its commitment, Pfizer is proud to offer the Pfizer Pledge Warranty Program for XALKORI (the "Program").* With the Program, eligible patients can get their out-of-pocket costs for XALKORI refunded. See below and the following pages for requirements. The Pfizer Pledge Warranty Program is available to cash, commercial (those with employer-sponsored or private insurance), and Medicare Part D patients who discontinue XALKORI before the fourth 30-day supply is dispensed.

Who is eligible for the Pfizer Pledge Warranty Program for XALKORI?

You are eligible if:

- XALKORI was prescribed for you to treat a condition for which it is FDA approved
- You have commercial or Medicare Part D insurance, or paid cash for XALKORI
- You used XALKORI according to the instructions provided by your physician
- Due to a physician's decision to discontinue, you stopped taking XALKORI before the 4th prescription was dispensed
- Your doctor has provided a signed Physician Attestation Form noting the clinical rationale for discontinuation

*Terms and Conditions apply. See pages 22-23.

How does the Pfizer Pledge Warranty Program for XALKORI® (crizotinib) work?

The Pfizer Pledge Warranty Program for XALKORI will refund eligible patients' out-of-pocket costs as follows:

1. If you are a cash, commercial, or Medicare Part D patient, you are eligible for the warranty if you receive your first dispense of XALKORI during the period of June 1, 2021, through December 31, 2021.

2. If you discontinue XALKORI for clinical reasons defined at the discretion of your healthcare provider before your pharmacy dispenses the fourth bottle (30-day supply) of XALKORI, you become eligible for a warranty claim payment.

3. You can start the reimbursement process by downloading the **Patient Warranty Claim Form** and **Patient Declarations and Authorizations Form** from **XALKORI.com/Pledge** or by calling **1-866-330-7902**. The call center is open Monday-Friday, 7 AM-7 PM CT. The call center representative can walk you through the forms and provide instructions on how to complete them. If needed, someone who speaks your language may be able to help. The completed forms, together with your receipts for your out-of-pocket costs for XALKORI, can be mailed, emailed, or sent by fax.

4. Your healthcare provider completes the **Physician Attestation Form** and submits it with your consent. Your healthcare provider may also give the signed form to you to submit.

5. When the information provided is validated, the Program will reimburse you for what you paid out of pocket for XALKORI up to the first three 30-day supply bottles.

Personal information will be kept confidential and will not be shared with anyone outside of the Program.

What can I do in advance to prepare?

If your first 30-day supply of XALKORI® (crizotinib) is dispensed on or after June 1, 2021, and you discontinue therapy before your fourth refill is dispensed, you may be eligible to receive a warranty payment.

Following these 2 simple steps when you are purchasing XALKORI will make the process easier should you need to file a warranty claim:

1. 

Keep or use a smartphone to take photos of the first 3 pharmacy receipts to document what you paid for XALKORI.

2. 

Use a smartphone to take photos of the first 3 pill bottle labels for XALKORI to document the prescribing details.

Although you can obtain this documentation after starting XALKORI, we suggest gathering it at the start of treatment.

Be sure to carefully review the Terms and Conditions (on pages 22-23; also available at **XALKORI.com/Pledge**) before initiating the reimbursement process.

Pfizer Pledge™
WARRANTY PROGRAM FOR XALKORI® (crizotinib)

PFIZER STANDS BY ITS COMMITMENT TO PATIENTS

- Call **1-866-330-7902 Monday-Friday, 7 AM-7 PM CT** to learn more about the Pfizer Pledge Warranty Program for XALKORI
- Program forms can be downloaded from **XALKORI.com/Pledge** or requested at the number above

Terms and Conditions

Pfizer, Inc. (referred to as "us", "we" and similar terms) is proud to offer the Pfizer Pledge Warranty Program for XALKORI (the "Program") to each Patient (referred to as "you", "your" and similar terms) who meets the Eligibility Requirements and follows the Program Procedures described below, subject to all of the terms and conditions in this document (the "Terms"). You should carefully review these Terms.

Overview of Program

For Patients who meet the Eligibility Requirements, Pfizer will refund the out-of-pocket amount that you paid for up to the **first three (3)** bottles (30-day supply) of XALKORI, up to a maximum of $19,144 for each bottle (30-day supply) or an aggregate maximum of up to $57,432 (the "Maximum"). If your commercial insurance or Medicare and/or other payers ("Your Plan(s)") paid for all or a portion of the cost of XALKORI, Pfizer will, on your behalf, refund to Your Plan(s) up to the Maximum that Your Plan(s) paid, less documented copayments provided by you. Payments to all parties must be equal to or less than the cost paid by each party and may reset Your Plan(s)'s out-of-pocket deductible and/or true out-of-pocket ("TrOOP") cost in accordance with Your Plan(s)'s benefit design and Medicare requirements. The order of priority of warranty payments is first to you and then to Your Plan that is primary and then to Your Plan(s) that are secondary as determined by information provided by you and documented proof of payment that you provide to us. You are responsible for submitting proof of payment for you and for Your Plan(s). All claims payments will be reported to Your Plan(s) and to Medicare as required by law.

Medication Eligible for the Program

1. XALKORI® (crizotinib) 200mg and 250mg

Eligibility Requirements

In order for you to be eligible to use the Program, you must satisfy all of the criteria listed below:

1. You are a resident of the fifty (50) United States of America or the District of Columbia (the Program is void for any request made by anyone living outside the fifty (50) United States or the District of Columbia).
2. You were prescribed XALKORI by your physician for an FDA-approved indication.
3. You used XALKORI according to the instructions provided by your physician.
4. You discontinued XALKORI for clinical reasons defined at the discretion of the physician. Discontinuation solely due to patient choice or affordability does not qualify for the Program.
5. You, or you and Your Plan(s), paid, in whole or in part, for XALKORI. Patients whose XALKORI was covered, in whole or in part, by Medicaid or other federal healthcare programs (other than Medicare) are not eligible to use the Program.
6. Your first bottle (30-day supply) of XALKORI must be dispensed on or after June 1, 2021 and on or before December 31, 2021 (the "Coverage Period").
7. You must discontinue using XALKORI prior to a pharmacy dispensing your fourth bottle (30-day supply) of XALKORI.
8. You must submit all receipts for the amount of money you paid for XALKORI and documentation showing what Your Plan(s) paid for XALKORI, including your primary insurance, secondary insurance, and any other third-party payers (including patient assistance programs) to ensure accurate payment of claims. It is your responsibility to submit proof of payment towards the cost of XALKORI from Your Plan(s) before any warranty payments are dispersed.
9. You must submit all Claims Information (as described below) within **one hundred and twenty (120) days** following the dispense date of your last bottle (30-day supply) of XALKORI.

Benefit Request Process

In order to be eligible for a refund under this Program, you must satisfy the requirements and submit the information below (the "Claims Information"), within one hundred and twenty (120) days following the dispense date of your last bottle (30-day supply) of XALKORI.

1. Call 1-866-330-7902 and a representative will provide you with a Patient Warranty Claim Form, a Patient Declarations and Authorizations Form, and a Physician Attestation Form, or these forms may be downloaded from www.xalkori.com.
2. You will then need to return a fully completed and signed (i) Patient Warranty Claim Form, (ii) Patient Declarations and Authorizations Form, and (iii) Physician's Attestation Form in accordance with their instructions, which will include the following information:
    1. Patient Warranty Claim Form:
        - Your name, date of birth, phone number, address, gender, and email address.
        - Prescribing physician name, phone number and address.
        - For each bottle (30-day supply), the dispensing pharmacy name, phone number and address.
        - For each bottle (30-day supply), Your Plan(s)'s information and amounts paid by Your Plan(s), including the following:
            1. For each primary insurer, secondary insurer and prescription Insurer, the insurance type, primary insurer name, phone number, address, policy/Medicare beneficiary ID#, group ID#, policyholder name, policyholder relationship, policyholder date of birth.
            2. A photocopy of each respective insurance card.
        - Prescription information that includes: prescription #, Date of Dispense, Dose Dispensed (250mg or 200mg), number of pills dispensed, and days of supply.
        - Proof of your out-of-pocket expense (e.g. receipts from your pharmacy)
        - Documents showing payments made by Your Plan(s) (e.g. Commercial or Medicare Part D) including any secondary and/or other third-party payers (e.g. patient assistance programs), if applicable.
    2. Patient Declarations and Authorizations Form which includes your:
        - Attestation that you have discontinued XALKORI before the 4th dispense date of your last bottle (30-day supply) of XALKORI.
        - Consent for the Pfizer Pledge.
        - Consent to Receive Communication from our representative to process your claim.
        - Authorization to share Health Information in order to process your claims.
        - Acknowledgment of laws.
    3. Physician's Attestation Form completed and signed by your prescribing physician which includes the following information:
        - Your name and date of birth.
        - Prescribing physician name, phone number and address.
        - Prescribing physician attestation that XALKORI was prescribed for on-label use, and the clinical rationale for discontinuance of XALKORI (no confirmatory documentation required).
3. If your Claims Information passes the verification process, we will notify you via telephone or email that you have been approved for coverage.

Please see Important Safety Information on pages 4-5.
Click for the full Prescribing Information and Medication Guide or visit XALKORI.com.

Terms and Conditions (continued)

4. If your Claims Information does not pass the verification process, we will notify you via email that your Request has been denied and the email will include the reason for the denial (such as, incomplete information, mismatched information, etc.). You will be given the opportunity to resubmit your Claims Information within thirty (30) days of the email notification.

Additional Terms and Conditions

By submitting your Claims Information under the Program, you are representing and warranting that you took the medication in accordance with the Instructions that were provided by your prescribing physician.

1. We reserve the right to modify the processes, procedures, parameters, or other terms of the Program, or terminate the Program entirely, at any time, without prior notice to you. If we terminate the Program, we will: (i) continue to honor valid warranty claims related to initial doses of XALKORI, prescribed by your physician, dispensed during the Coverage Period. The current status of the Program and applicable terms are available at www.xalkori.com.
2. We are refunding payments under this Program to you and Your Plan(s) based on the information provided by you. You are responsible for resolving any disagreements related to reimbursements made by us, on Your behalf, to Your Plan(s).
3. **LIMITATION OF LIABILITY**

   IN NO EVENT, UNDER ANY CAUSE OF ACTION OF THEORY OF LIABILITY, SHALL PFIZER, ITS DISTRIBUTORS OR SUPPLIERS BE LIABLE TO YOU OR ANY THIRD PARTY FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY OR PUNITIVE DAMAGES, OF ANY NATURE WHATSOEVER, ARISING OUT OF OR IN CONNECTION WITH THE PROGRAM, EVEN IF PFIZER HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

   NOTWITHSTANDING ANY DAMAGES THAT YOU MIGHT INCUR FOR ANY REASON WHATSOEVER INCLUDING, WITHOUT LIMITATION, ALL DAMAGES REFERENCED HEREIN AND ALL DIRECT OR GENERAL DAMAGES IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, THE ENTIRE AGGREGATE LIABILITY OF PFIZER AND ANY OF ITS DISTRIBUTORS AND/OR SUPPLIERS SHALL BE LIMITED TO THE MAXIMUM AMOUNT SET FORTH ABOVE FOR THE PRODUCT THAT IS SUBJECT TO THE PROGRAM. SOME STATES AND/OR JURISDICTIONS DO NOT ALLOW THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATIONS OR EXCLUSIONS MAY NOT APPLY TO YOU. THE LIMITATIONS OF LIABILITY SET FORTH ABOVE SHALL APPLY TO THE MAXIMUM EXTENT PERMITTED UNDER APPLICABLE LAW.

   ARBITRATION: Read the following arbitration provision ("Provision") carefully. It limits certain of your rights, including your right to obtain relief or damages through court action.

   To begin Arbitration, either you or we must make a written demand to the other party for arbitration for the applicable claim ("Claim"). The Arbitration will take place before a single arbitrator. It will be administered in keeping with the Expedited Procedures of the Commercial Arbitration Rules ("Rules") of the American Arbitration Association ("AAA") in effect when the Claim is filed. You may get a copy of these AAA's Rules by visiting www.adr.org. The filing fees to begin and carry out arbitration will be shared equally between you and us. This does not prohibit the arbitrator from giving the winning party their fees and expenses of the arbitration. Unless you and we agree, the arbitration will take place in the county and state where you live. The Federal Arbitration Act, 9 U.S.C. Ch. 1, et seq., will govern and not any state law on arbitration. YOU AGREE AND UNDERSTAND THAT this arbitration provision means that you give up your right to go to court on any Claim covered by this provision. You also agree that any arbitration proceeding will only consider your Claim. Claims by, or on behalf of, other individuals will not be arbitrated in any proceeding that is considering your Claims. THE DEGREE TO WHICH ARBITRATION CAN BE USED AS A DISPUTE RESOLUTION PROCESS FOR CONSUMER CLAIMS VARIES FROM STATE TO STATE, SO THIS ARBITRATION PROVISION MAY NOT APPLY TO YOU, DEPENDING ON YOUR STATE OF RESIDENCE. In the event this Arbitration provision is not approved by the appropriate state regulatory agency, and/or is stricken, severed, or otherwise deemed unenforceable by a court of competent jurisdiction, you and us specifically agree to waive and forever give up the right to a trial by jury. Instead, in the event any litigation arises between you and us, any such lawsuit will be tried before a judge, and a jury will not be impaneled or struck.

XALKORI® 250MG CAPSULES
CRIZOTINIB

EXPLORE
WHAT'S POSSIBLE.

Getting the most out of your XALKORI® (crizotinib) treatment

Remember: always follow your doctor's instructions exactly, and be sure to report any side effects you may experience right away.

Register for the XALKORI Support Program at **XALKORI.com/register**.

Visit **XALKORI.com** for more in-depth information or to register for additional resources.

Pfizer Oncology

Please see Important Safety Information on pages 4-5.
Click for the full Prescribing Information and Medication Guide or visit XALKORI.com.