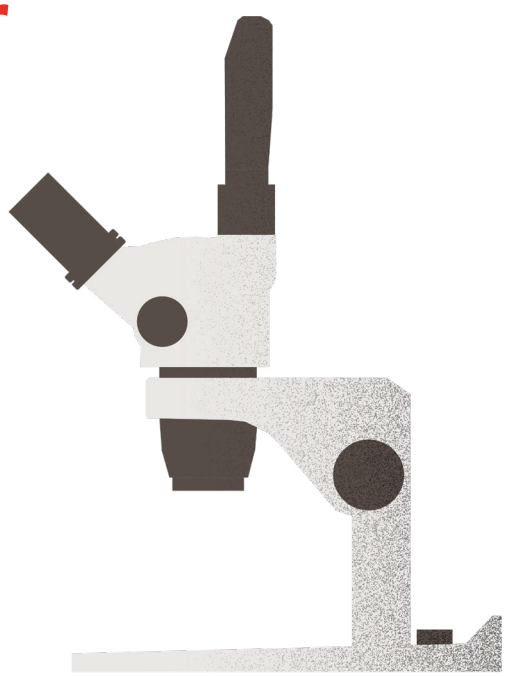
Precision Medicine and You:

Biomarkers in Lung Cancer

Johnson&Johnson

Your guide to precision medicine in lung cancer



What is precision medicine?

Not all cancers are the same. **Precision medicine** considers the individual features of your specific tumor to select a treatment. These features are called **biomarkers**.

What is a biomarker?

A biomarker is any molecule produced by your body that can be measured as the sign of a normal or abnormal process. Some biomarkers are molecules that drive the tumor's growth and spread.

Precision medicine provides a way for you and your doctors to decide on **your personalized treatment plan** based on your cancer's specific features.

With precision medicine, you and your doctor can:

- Determine what's making your cancer grow and spread
- Select the appropriate treatment for you
- Understand the likelihood of your cancer responding to certain treatments

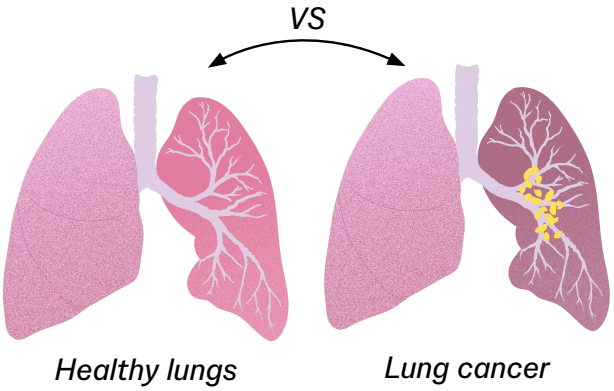
Table of contents

In this resource, you will explore how precision medicine may be involved in your care, with topics including:

Basics of lung cancer

Lung cancer is a result of uncontrolled cell growth

Lung cancer occurs when **new lung cells** grow rapidly in parts of the lungs or other parts of the body where they are not supposed to be.



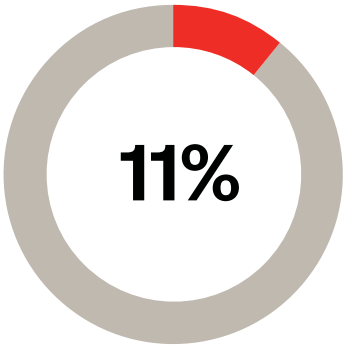
Key terms

Cells—the units that make up the tissues of the body and contain DNA

DNA—the genetic information needed for a person to develop and grow, which is passed from one generation to the next

If you have lung cancer, you're not alone—it's the third most common cancer in the US

Lung cancer accounts for over



of all new cancer cases

- About **600,000** people lived with lung and **bronchus** cancer in 2021
- Nearly **200,000** people will develop lung cancer in 2025

Key term

Bronchus—a large airway that leads from the windpipe to one of your lungs

The way your lung cancer is classified depends on how your cancer cells look under a microscope

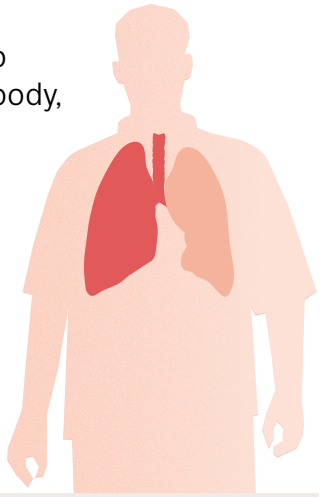
- **Small cell lung cancer (SCLC)** affects the small cells of the lung and is less common (15% of all lung cancers)
- **Non-small cell lung cancer (NSCLC)** affects larger cells of the lung and is more common (85% of all lung cancers)

SCLC

If you have **SCLC,** how far it has spread is described as limited or extensive.

Limited stage:
Cancer is in only one of your lungs, and may have spread to nearby **lymph nodes**.

Extensive stage:
Cancer has spread to distant parts of the body, such as the opposite lung from where it started or other organs in your body.



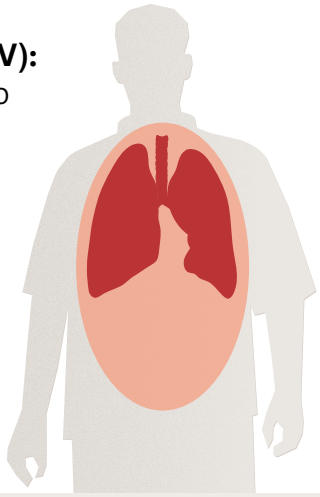
NSCLC

If you have **NSCLC**, how far it has spread is described with a numerical stage.

Early-stage (stage 0/I):
Cancer is confined to the lung.

Locally advanced (stage II/III):
Cancer has spread to **tissue** or **lymph nodes** near the lungs.

Metastatic (stage IV):
Cancer has spread to more distant parts of the body, such as the liver or bones.



Key terms

Lymph nodes—small structures throughout the body that function as part of the immune system

Tissue—a group of cells that work together to perform a specific function

Precision medicine for your lung cancer

Why are biomarkers important in lung cancer?

If you have **SCLC**, it is less likely that your tumor has biomarkers that affect what treatment is appropriate for your specific type of cancer. While biomarker testing is less common in SCLC, you can ask about it, especially if you have no smoking history.

But if you have **NSCLC**, there's a good chance your tumor has a biomarker that affects your treatment options. In fact, there are **more than 10 known** biomarkers in NSCLC. If your tumor has one of them, it will help you and your doctor determine what treatment is most appropriate for you.

Biomarkers in lung cancer	
ALK	*MET*
BRAF	*NRG1*
c-Met	*NTRK*
EGFR	PD-L1
HER2	*RET*
KRAS	*ROS1*

The ins and outs of biomarker testing

Biomarker testing is more commonly done for patients with NSCLC than those with SCLC

NSCLC

Samples are tested for different biomarkers that have specific treatment options.

ALK	*EGFR*	*MET*	PD-L1
BRAF	HER2	*NRG1*	*RET*
c-Met	*KRAS*	*NTRK*	*ROS1*

SCLC

Samples may undergo biomarker testing depending on a patient's risk factors.

Biomarker testing involves several steps

Step 1

Biopsy

In most cases, the best way to determine whether your cancer has biomarkers is to test a sample of the tumor. Taking this sample is called a biopsy, which can be done using one of the methods below.

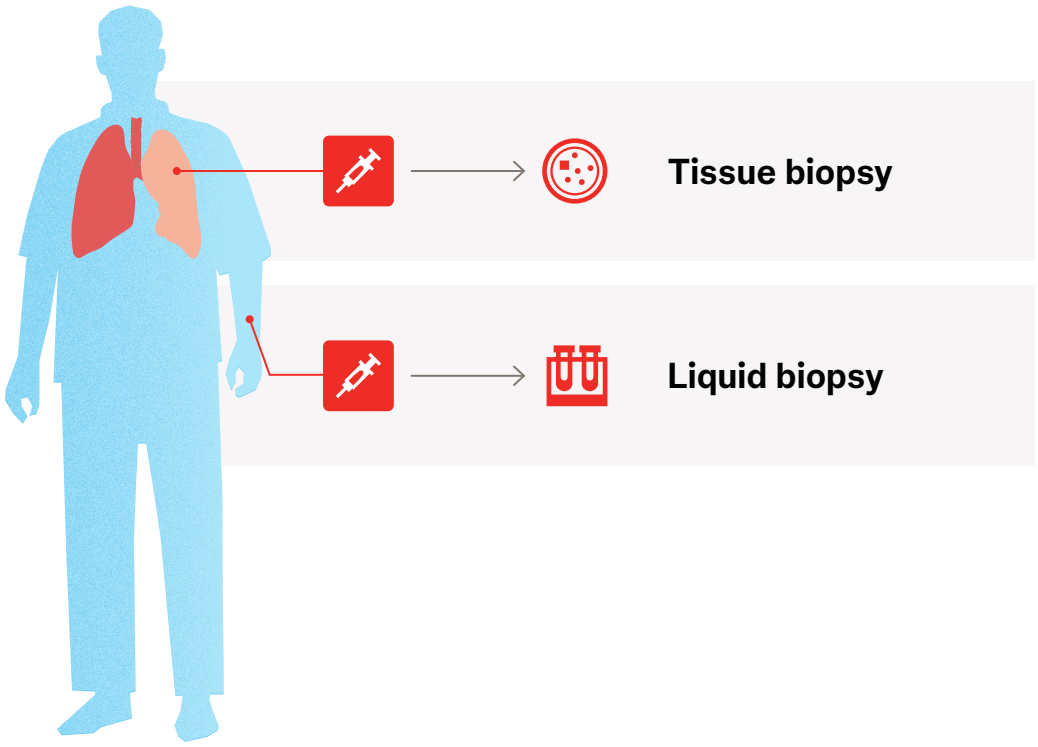
Surgical biopsy is a type of biopsy where a piece of your body with suspicious cells is removed.

Needle biopsy is a type of biopsy where a special needle is inserted through the skin to collect cells from a suspicious area.

Endoscopic biopsy is a type of biopsy where your healthcare provider uses a thin, flexible tube called an endoscope, with a light on its end to see structures inside your body. Your healthcare provider uses special tools to take small samples for testing.

Skin biopsy is a type of biopsy where cells from your skin are removed.

Liquid biopsy is a type of biopsy where your blood sample is collected instead of, or in addition to, a tumor biopsy.



Key terms

Tumor—an abnormal growth or lump in the body. Tumors may or may not be cancerous

Tumor biopsy—a procedure where a sample of cancer cells is collected to be tested in a laboratory

Step 2 **Testing**

Your tumor biopsy samples will be sent to a laboratory where a doctor called a pathologist conducts biomarker testing.

NSCLC has many important biomarkers—comprehensive testing helps you and your doctor get the full picture of your cancer

	Individual biomarker testing			**Comprehensive biomarker testing**
	Test 1	Test 2	Test 3	Test 1
Biomarker 1	✓			✓
Biomarker 2		✓		✓
Biomarker 3			✓	✓

Comprehensive biomarker testing

This is an efficient way to test for multiple biomarkers at once to provide a more holistic view of your collective biomarkers

- ✓ Can screen up to hundreds of genes at once
- ✓ Gets more information from smaller amounts of DNA
- ✓ Gives you and your doctor information about which biomarkers can be targeted with treatment

Getting comprehensive testing helps you get the results you and your doctor need to choose your treatment.

Step 3 Treatment decision

After 1 to 3 weeks, your doctor will get a report of what biomarkers your tumor has.

Results of biomarker tests can **help doctors choose the treatment** that will be most appropriate for your type of cancer and avoid treatment that won't be helpful. Waiting for all your results will guide this decision.

Sometimes, your tumor may be positive for a certain biomarker, but there isn't an approved treatment for it yet. If that's the case for your cancer, there may still be options. Ask your doctor what that could mean for your cancer treatment.

Some tests can be performed more quickly than others, but it is important to wait for all results, so that you and your doctor can determine the appropriate treatment for your specific cancer.

What can you do while you wait for your biomarker test results?

Educate yourself

Ask your care team about where to find reputable information.

Learn about your cancer type and understand the basics of your diagnosis from reputable and trusted sources like:

- **CancerCare: Biomarkers** https://www.cancercare.org/biomarkers

A page with educational resources, like worksheets, videos, and patient stories, to help you talk about biomarkers with your doctor

Stay in touch with your care team

Proactively communicate with and prepare for conversations with your healthcare providers by:

- Scheduling appointments
- Preparing questions for your doctor like those on the next page
- Discuss the potential timeline of therapy initiation
- Requesting support from a nurse navigator or social worker to help you through the next steps
- Schedule a follow-up with your Genetic Counselor
- Consulting with a nutritionist to guide you with healthy food choices

Focus on mental and emotional health

A cancer diagnosis can be mentally and emotionally stressful, but you do not have to go through this alone:

- Join a Patient Advocacy Group like:
  - **Biomarker Collaborative** https://biomarkercollaborative.org/
    - A global network dedicated to introducing patients and care partners to biomarker support groups and other resources
  - **LUNGevity** https://gateway.lungevity.org/
    - Find biomarker specific resources and connect with others with the same type of lung cancer
- Seek support—family, friends, advocacy groups, and community resources

Certain biomarkers indicate whether a particular treatment may work for you

Targeted therapy

Some biomarkers show that changes in genes are driving the growth and spread of your cancer. It may be possible to target those genes with medicine.

This is called “targeted therapy”.

In NSCLC, important biomarkers that can be targeted include:

EGFR
ROS1
MET
ALK

Systemic treatment

If you do not test positive for a specific biomarker, a systemic treatment such as **chemotherapy** may be considered.

Key term

Chemotherapy—treatment that stops cancer cells from growing by killing them or stopping them from dividing

Your biomarker results can help determine a treatment choice that's tailored to your lung cancer's specific features

Immunotherapy

Some biomarkers show that your cancer may be vulnerable to your immune system, if your immune system is boosted to recognize and attack the cancer.

This is called "immunotherapy".

An example biomarker for immunotherapy is:

PD-L1

If you have both types of biomarkers (for targeted therapy and for immunotherapy), ask your doctor about the appropriate way to proceed.

Bringing it all together

Review key concepts you've learned by exploring this lung cancer biomarker testing example

Step 1: Biopsy

Samples of your tumor or your blood may be collected for biomarker testing

Biopsies for biomarker testing

Step 2: Testing

Sample(s) sent for testing

Gene
biomarker testing

Immune
biomarker testing

Step 3: Treatment decision

My lung cancer is...

- **POSITIVE** for **GENE** biomarkers **AND** **POSITIVE** for **IMMUNE** biomarkers → **TARGETED THERAPY** may be the first treatment you receive
- **POSITIVE** for **GENE** biomarkers **AND** **NEGATIVE** for **IMMUNE** biomarkers → **TARGETED THERAPY** may be the first treatment you receive
- **NEGATIVE** for **GENE** biomarkers **AND** **POSITIVE** for **IMMUNE** biomarkers → **IMMUNOTHERAPY** may be the first treatment you receive
- **NEGATIVE** for **GENE** biomarkers **AND** **NEGATIVE** for **IMMUNE** biomarkers → **IMMUNOTHERAPY + CHEMOTHERAPY or CHEMOTHERAPY ALONE** may be the first treatment you receive

Ensure all biomarker results are in before you and your doctor determine the best treatment for your cancer.

Questions for your doctor

What type of lung cancer do I have? What does this mean for my treatment?

Will my tumor biopsy be tested for biomarkers? Will I also have a blood test?

What biomarkers is my tumor being tested for?

When can we expect to get my biomarker test results back?

Is there any concern waiting for test results to start treatment? What can I do while I wait?

What gene or protein changes did my tumor show, and how will that change my treatment plan?

How have people with the same race or ethnicity as mine tolerated the different treatments available?

Solutions start with a conversation

Take action and speak with your doctor about cancer biomarker testing

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