Springer Healthcare IME

A guide to biomarker testing and targeted therapies in NSCLC

The discovery of biomarkers has changed the way that non-small cell lung cancer (NSCLC) can be treated. This leaflet will help you understand what a biomarker is, how the biomarker testing process works, and how biomarkers can be used to determine the right treatment for you. By understanding these key points, you will be better prepared to discuss your treatment options with your healthcare provider.

What is a biomarker?

Biomarkers are special markers found in your tissues or blood that provide information about how your cancer behaves, how quickly it might grow and how well certain treatments might work. They give doctors important information to make the best decisions about your care.

What is biomarker testing?

What?

Biomarker testing, also called **genetic (genomic)** or **molecular testing**, looks at your cancer cells to find out which biomarkers you have. People with NSCLC may have different biomarkers, and you can have one or a combination of a few.

Why?

By understanding exactly what causes your cancer to grow, doctors can determine the most effective treatment for you. Biomarker testing helps to find out if any approved **targeted therapies** could be offered to you or if you qualify for any **ongoing clinical trials** based on any specific biomarker(s) present.

Who?

It is recommended that all patients with NSCLC have biomarker testing to personalize their treatment plan based on their cancer's specific features. Ideally, biomarker testing should be done as soon as you are diagnosed with NSCLC to ensure that you receive the most appropriate therapy based on its results.

What types of biomarkers are used to determine the best treatment for me?

In NSCLC, several different types of biomarkers may cause your cancer to grow or spread.

A biomarker can be a **gene** or a **protein** that has gone wrong. Here are some terms that you may hear when talking about biomarkers in NSCLC:

Driver mutation

A change in DNA that causes the cancer to grow.

Activating mutation

A change in DNA that keeps a gene constantly active, making the cancer grow.

Fusion

When two genes join together, resulting in a unique protein that causes cancer growth.

Amplification

An increase in the number of copies of a gene, leading to increased protein activity and cancer growth.

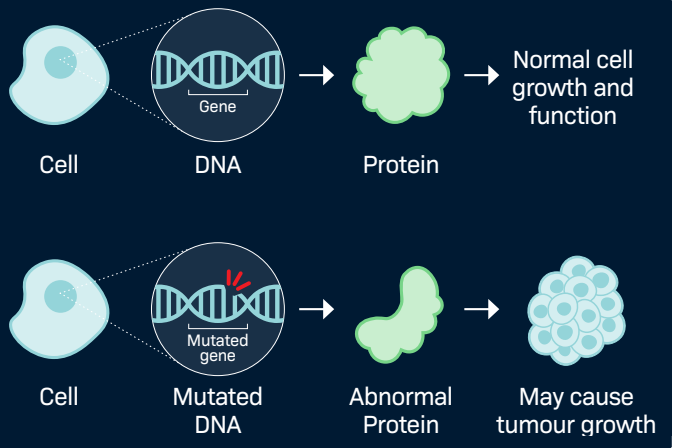
Deletion

A piece of the gene is missing, leading to reduced levels of protein.

What are mutations?

Our bodies are made of **cells**, each containing **DNA** which is a unique code that has all of the information needed for your body to work. Our DNA is organized into segments called **genes**. Each gene contains instructions that tell the cell how to make **proteins**. Proteins carry out important functions that keep our cells **working correctly**.

For cells to work correctly, the DNA in each gene needs to be correct. **Mutations** are mistakes in our DNA that can stop the protein from working correctly. This can cause cancer cells to grow and spread.



Biomarkers found in NSCLC patients include:

EGFR, *ALK*, *ROS1*, *BRAF V600E*, *MET*, *KRAS G12C*, *RET*, *NTRK*, *HER2*, and *PD-L1*

This is a changing list as new biomarkers are still being discovered.

Mutations can be **acquired** (only in your cancer cells and not passed on to children) or **inherited** from one or both of your parents (present in all cells of your body and could be passed on to children). This leaflet covers **acquired mutations**.

How is biomarker testing carried out?

Testing

Biomarker testing requires a sample of your cancer. Your healthcare team will remove part of your tumor (biopsy) or draw blood and send this to be tested at the laboratory.

Analysis

Your sample will be tested for biomarkers at the laboratory and matched with treatment options. A report of the findings will be sent to your healthcare team. You may wish to ask your healthcare team when to expect the results.

Reporting

Your doctor will discuss your biomarker test results and treatment options with you. They will explain the implications of your results and help you decide on a treatment.

How will my healthcare team obtain a sample for biomarker testing?

There are several different ways doctors can obtain a sample of your cancer. The best method will depend on the size and location of your tumor – your doctor should discuss the risks and benefits of each method with you:

Needle biopsy

A thin needle is used to take a small sample of tissue from the lung, lymph nodes or other areas where cancer may have spread (metastases). Be sure to confirm with your doctor that enough tissue will be taken to run all the biomarker tests.

Bronchoscopy

A thin tube with a camera is inserted into the lungs via your nose or mouth. Tools are passed down the tube to take tissue samples.

Thoracentesis

A needle is used to remove fluid from around the lungs, which is tested for cancer cells.

Surgical biopsy

A larger tissue sample is taken during surgery. This can involve small cuts in the chest wall to access the lung (thoracoscopy) or a cut above the breastbone to access the lymph nodes in the chest (mediastinoscopy).

Liquid biopsy

A blood test that looks for cancer cells or DNA from cancer cells circulating in your blood.

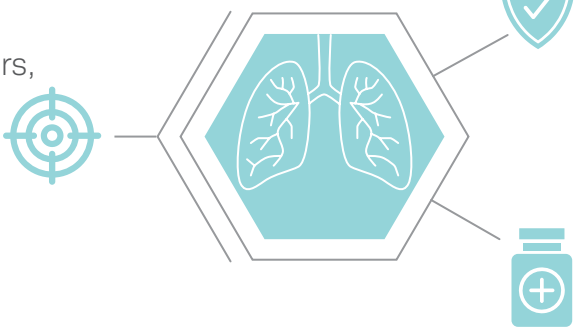
You may need multiple biopsies before starting your treatment and further biomarker testing at several points during your treatment journey. Your doctor should explain why additional tests are required and the potential risks and benefits of each procedure.

How will my biomarker test results impact treatment decisions?

The results of biomarker tests help doctors decide if **targeted therapies** are right for you. Biomarker test results can also be used to see if you would benefit from **immunotherapy** or enrolment in a **clinical trial**.

Targeted therapies

If you have certain biomarkers, you may benefit from a targeted therapy. Targeted therapies specifically target the changes in your cells causing your cancer.



Immunotherapies

Biomarker test results can also indicate if immunotherapy is a good option for you. It can help your immune system recognize and fight cancer cells more effectively.

Clinical trials

Your biomarker test results might also make you eligible for clinical trials that are testing new therapies.

Biomarkers with approved treatment options include *EGFR* (including exon 20 insertion mutations), *ALK*, *ROS1*, *BRAF V600E*, *MET*, *KRAS G12C*, *RET*, *NTRK*, *HER2*, and PD-L1.

Not everyone with NSCLC will have a biomarker that can be matched to an available targeted treatment or clinical trial. However, your biomarker test results can still help you and your healthcare team decide on the right treatment – ask your doctor about which options are available to you.

What happens once I've started treatment?

Coping with side effects

Your healthcare team will advise you on potential side effects and will help you manage any side effects from your treatment. Side effects can often be managed through dose adjustments, additional medications, and supportive care. It's important that you don't miss your infusion appointment or stop your oral medication without speaking to your doctor first.

Monitoring effectiveness

Regular scans (e.g., CT, PET, MRI, etc.) will help check how well the targeted therapy is working. During regular follow-up appointments, your doctor will explain your scan results and what changes in symptoms to look out for. It's important to tell them about any new or worsening symptoms. Your targeted therapy may stop working after a while – your healthcare team will explain to you what other options, including potential new targeted therapies and clinical trials, are available to you.

What should I do if I want to get tested for biomarkers?

The decision to undergo biomarker testing will be a joint decision between you and your doctor - speak to your healthcare team about any questions that you have and to arrange for your tumor to be tested. You can use our **consultation companion** as a guide to help you ask the right questions in consultations with your healthcare team.

My questions

My notes

This independent medical education program is supported by an educational grant from Bayer HealthCare Pharmaceuticals Inc.