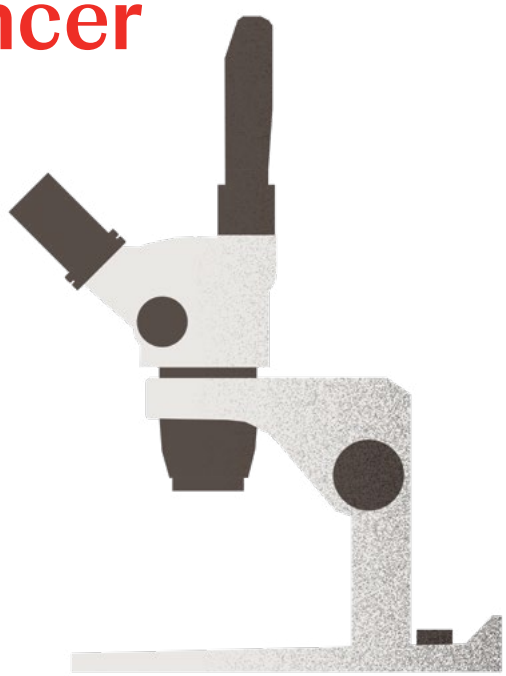
Precision Medicine and You:

Biomarkers in Bladder Cancer

Johnson&Johnson

Your guide to precision medicine in bladder cancer



What is precision medicine?

Not all bladder 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 found within the 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.

Understanding gene and protein changes, or biomarkers, can help you and your doctor create a treatment plan that is personalized to you

With precision medicine, you and your doctor can:

- Understand the likelihood of your cancer responding to certain treatments
- Determine your eligibility for clinical trials
- Understand you or your family's risk of developing bladder cancer or similar conditions

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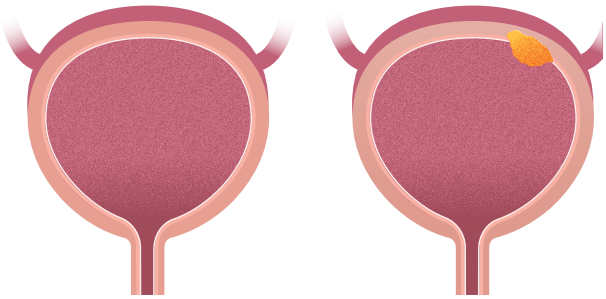
In this resource, you will explore how precision medicine may be involved in your care, with topics including:

Basics of bladder cancer

Bladder cancer is a result of uncontrolled cell growth

Bladder cancer occurs when **abnormal bladder cells grow rapidly** in parts of the bladder or elsewhere in the body where they are not supposed to be.



Healthy bladder *Bladder cancer*

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

Certain characteristics may increase the chances that bladder cancer will develop

Risk factors for bladder cancer include:

Age	Most often diagnosed in men who are **65 years or older**
Race	More likely to develop in **white patients** than in patients from other racial and ethnic backgrounds
Sex	More likely to develop in **men** than in women
Family history	About 4% of patients with bladder cancer **have an immediate relative with bladder cancer**
Changes in certain genes	Changes in certain **genes** increase the risk of developing bladder cancer

There are different types of bladder cancer

Bladder cancer can be classified based on **how far** it has spread.

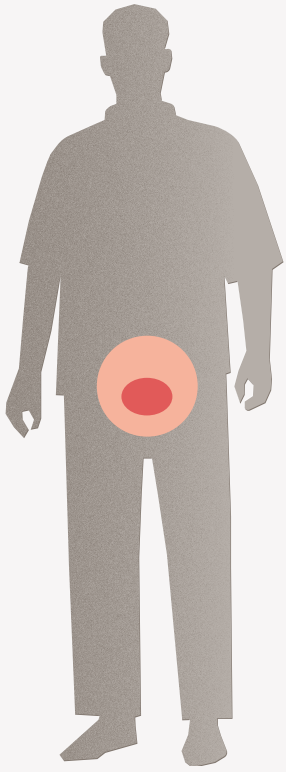
Within your bladder

- Non-muscle invasive
- Muscle invasive
- Non-muscle invasive may progress to muscle invasive

Within your body (inside and outside the bladder)

- Localized, regional, or metastatic (distant)
  - Localized may progress to regional, which may also progress to metastatic

It is possible for bladder cancer types to change over time



May progress to

May progress to

Localized bladder cancer has not spread beyond the bladder

- May be non-muscle invasive or muscle invasive

Regional bladder cancer means that the cancer has spread to **organs** or **lymph nodes** near the bladder

- Muscle invasive

Metastatic bladder cancer means that cancer has spread to more distant parts of the body

Bladder cancer disease progression

Non-muscle invasive bladder cancer (NMIBC) is a form of bladder cancer that has not reached the muscle layers of the bladder wall

Muscle invasive bladder cancer (MIBC) is a form of bladder cancer that has reached the muscle layers of the bladder wall

mUC

N M I B C

Non-muscle invasive
Limited to the inner layers of the bladder wall
(Tumor stages: T_0 – T_1)

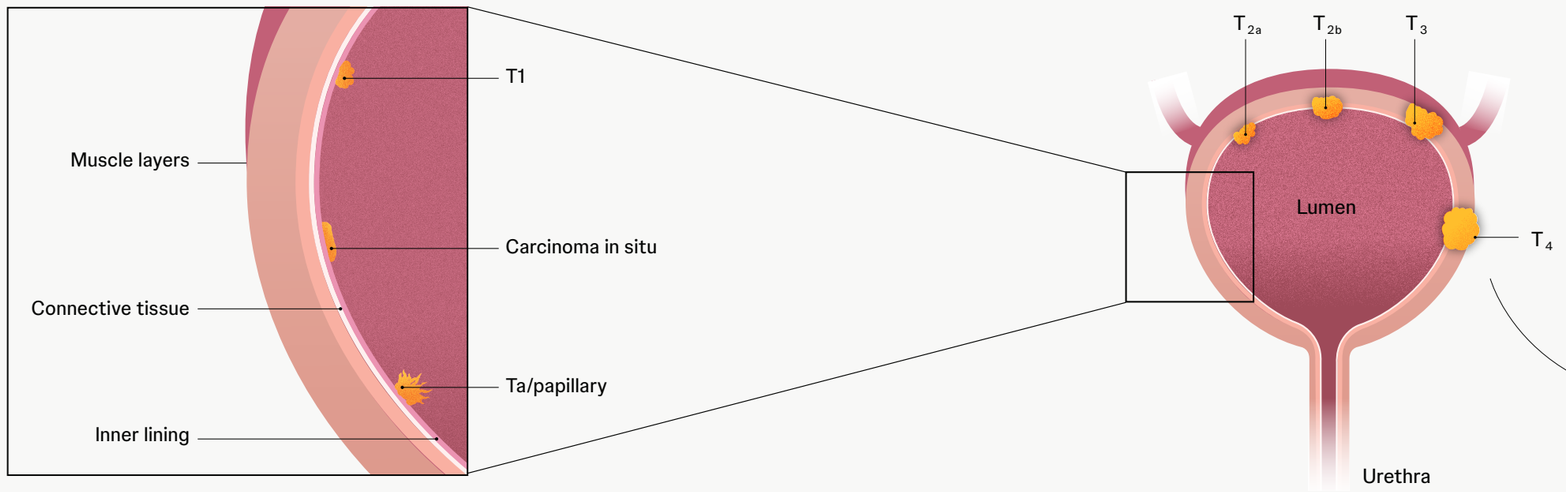
Bladder cancer

- Most cases of bladder cancer are NMIBC
- NMIBC can progress to MIBC (see next page) over time
- NMIBC is considered **localized,** as it has not spread beyond the bladder

M I B C

Muscle invasive
Has invaded the muscle layer and potentially beyond the bladder
(Tumor stages: T_2 – T_4)

Bladder cancer



Did you know?

When bladder cancer is metastatic, it may be referred to as mUC or metastatic urothelial cancer.

Biomarkers are recommended to determine therapy in advanced regional and metastatic bladder cancer.

Localized | **Regional** | **Metastatic**

Key terms

Localized bladder cancer—has not spread beyond the bladder

Regional bladder cancer—cancer has spread to the **tissue** or **lymph nodes** near the bladder

Metastatic bladder cancer—cancer has spread to more distant parts of the body

Carcinoma in situ—abnormal cells that are found in tissue of the bladder

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

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

Your doctors will consider your type of bladder cancer to help them decide on appropriate testing and treatment.

The ins and outs of biomarker testing

Testing helps determine whether your tumor has a biomarker that affects your treatment options and is typically done for certain patients

You may receive biomarker testing that includes genetic testing if you have:

Metastatic MIBC	**Advanced regional MIBC**	**Certain events in your or your family's medical history**

Biomarker testing involves several steps

Step 1 Biopsy

To perform biomarker testing, your doctor will collect a sample of your **tumor**, or your blood, or urine.

Key term

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

Step 2 **Testing**

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

Biomarker testing may assess a single biomarker at a time or multiple biomarkers at once

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

Comprehensive biomarker testing

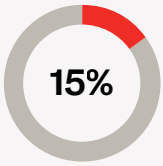
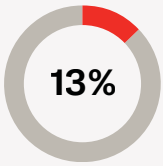
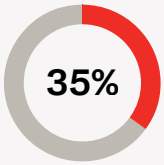
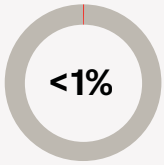
This is an efficient way to test for multiple biomarkers at once to provide a more holistic view of your collective biomarkers

Key terms

Comprehensive biomarker testing may also be referred to as:

- Comprehensive genomic profiling (CGP)
- Next-generation sequencing (NGS)

Bladder cancer has many different biomarkers that can affect your treatment options

Biomarkers	Percent of patients with distant MIBC or advanced regional MIBC who test positive
FGFR	
HER2	
PD-L1	
High MSI	
High TMB	

Did you know?
Rare genetic changes that contribute to bladder cancer development can be inherited. Ask your doctor whether you and/or your family members should be tested.

Step 3 Treatment decision

Depending on the type of testing performed, after 1–3 weeks, your doctor will get a report of what biomarkers your tumor has.

You and your doctor can use the information to choose the right treatment for your cancer.

Note: While testing can sometimes take longer, it is important to wait for all the results to help choose the right treatment.

Key terms

FGFR—a gene that may be altered in bladder cancer in ways that drive the growth and spread of the cancer

HER2—a protein that, when present in high amounts, may cause cancer cells to grow and spread

PD-L1—a protein that may be present in higher-than-normal amounts on some types of cancer cells

MSI—a condition in some cancers in which cells have more than the normal amount of DNA changes

TMB—a measure of the total number of changes in the DNA of cancer cells

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."

Example biomarkers for targeted therapy:

HER2
FGFR

Key terms

Targeted therapy—treatment that uses substances that target specific molecules based on changes to certain genes in cancer cells

Immunotherapy—treatment designed to modify the body's immune system in ways that fight cancer

Your biomarker results can help determine a treatment choice that's tailored to your 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."

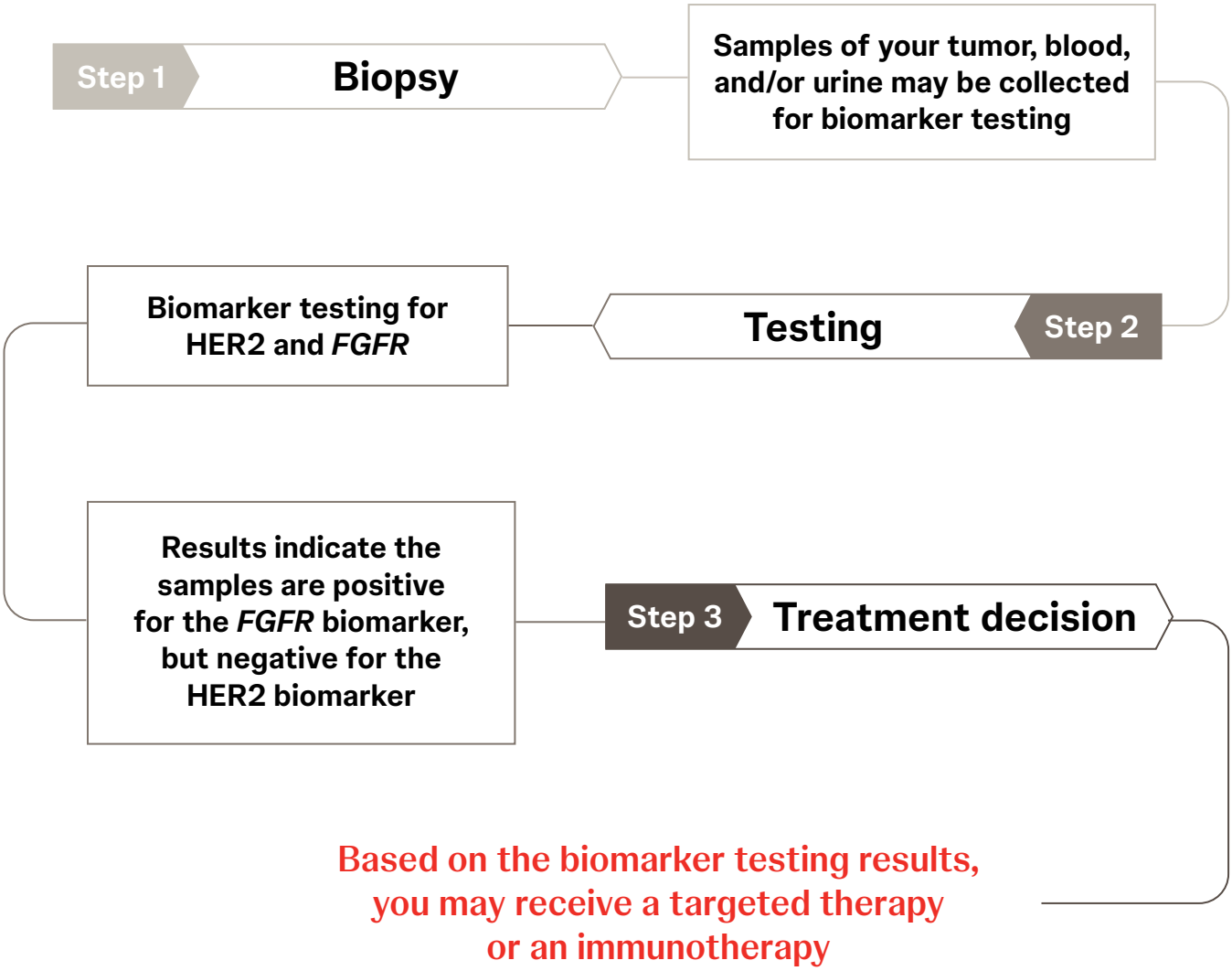
Example biomarkers for immunotherapy:

TMB
PD-L1
MSI

Other treatments, such as chemotherapy, are available if your tumor does not test positive for biomarkers that would suggest a specific treatment.

Bringing it all together

Review key concepts you've learned by exploring this bladder cancer biomarker testing roadmap



Precision medicine provides a way for your doctors to decide on your personalized treatment plan based on your tumor's specific features. Wait for all results, so that you and your doctor can determine the appropriate treatment for your specific cancer.

Questions for your doctor

What kind of bladder cancer do I have? What does this mean for my treatment?

What biomarkers should my tumor be tested for?

Can I get a comprehensive biomarker test for all the biomarkers we need to know about?

When can we expect to get my biomarker results back?

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

Based on my tumor biomarker results, should my family be tested? Who in my family should be tested?

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

More information to explore

As you get treated for bladder cancer, remember that you're not alone. Access helpful information from organizations whose purpose it is to help people like you.

Biomarker Collaborative https://biomarkercollaborative.org/

A global network dedicated to introducing patients and care partners to biomarker support groups and other resources.

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

Bladder Cancer Advocacy Network https://bcan.org/

A network that gives patients useful information and community support to inspire hope for tomorrow

Urology Care Foundation https://www.urologyhealth.org/

A foundation that supports, through philanthropic efforts, the improvement of urological care globally by funding research, clinical education, patient education, and humanitarian programs

Solutions start with a conversation

Take action and speak with your doctor about cancer biomarker testing

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