

A Patient's Guide to Cancer Immunotherapy

for Breast Cancer

From a Patient's Perspective



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I was diagnosed with stage 1 triple-negative breast cancer in 2015. Two years later, the cancer returned as stage 4 metastatic disease, and I was told I might have only 18 to 24 months to live.

I realized very quickly that I had to get up to speed. I wanted to understand my diagnosis, what testing could tell me, who was doing the research, and what treatment options might be available. I needed enough information to make an informed decision rather than react out of fear.

Seeking a second opinion made a tremendous difference. My oncologist took the time to explain my diagnosis, my options, and the steps ahead. That was when I first learned that immunotherapy and clinical trials might be options for me.

I enrolled in a phase 1 immunotherapy clinical trial, and eight weeks later, my tumors had shrunk by 72%. A couple years later I was in remission.

Today, I often tell other patients not to try to do this alone. Find your tribe. That might be a friend who comes to appointments and takes notes, a social worker, a patient navigator, or a medical expert who can help you understand the science. Ask questions and be clear about what you need, whether that is a second opinion, more information, or help understanding your choices.

Immunotherapy worked for me, but that does not mean it is right for everyone. The important questions are: Is this an option for me? Why or why not? Patients deserve the information and support they need to take an active role in decisions about their care.



Starting with What You Need to Know

Hearing the words “*You have breast cancer*” can feel overwhelming. You may feel scared, confused, or uncertain about what comes next. These feelings are not unexpected — and you are not alone. You don’t have to become an expert overnight.

Breast cancer is not one disease, and treatment can vary widely depending on the stage and features of the cancer. This guide from the Cancer Research Institute (CRI) is designed to help you understand a treatment option called immunotherapy, when it may be used for breast cancer, and what questions you may want to ask your health care team along the way.



Getting a Diagnosis: What is Breast Cancer?

What is breast cancer?

Breast cancer begins when cells in the breast grow out of control. Most breast cancers begin in the ducts, which carry milk toward the nipple, or the lobules, which are glands that can make milk.

Some breast cancers stay within the ducts or lobules; these are called ductal or lobular carcinoma *in situ* (DCIS/LCIS) and are noninvasive. Invasive breast cancer has grown into nearby breast tissue and may spread to lymph nodes or other parts of the body.

Breast cancer is much more common in women, but anyone with breast tissue can develop it.

Are there different types of breast cancer?

Yes. Breast cancers are often grouped according to proteins found on or inside the cancer cells. These features are important because they help guide treatment decisions.

- **Hormone receptor-positive breast cancer** has estrogen receptors (ER), progesterone receptors (PR), or both.
- **HER2-positive breast cancer** has high levels of a protein called HER2.
- **Triple-negative breast cancer (TNBC)** does not have estrogen or progesterone receptors and does not have high levels of HER2.

Most of the immunotherapy information in this guide applies to people with TNBC. Hormone receptor-positive and HER2-positive breast cancer may be treated differently.

What does my breast cancer stage mean?

Staging describes how much cancer is present and whether it has spread. Breast cancer is staged from stage 0 to stage 4. Early-stage breast cancer is limited to the breast or nearby lymph nodes. Metastatic breast cancer, or stage 4 breast cancer, means the cancer has spread to another part of the body.

Your stage, breast cancer subtype, and biomarkers all help your health care team decide which treatments may be appropriate.

Getting a Diagnosis: What is Breast Cancer? (Cont.)

What genetic and biomarker testing might I need?

Genetic and biomarker testing can help guide treatment and identify hereditary DNA mutations that may also be important for your family. Your health care team may recommend hereditary genetic testing, usually using blood or saliva, as well as tumor testing, which looks at features of the cancer itself.

All invasive breast cancers are tested for hormone receptors and HER2. Depending on your diagnosis, additional testing may include:

- **PD-L1**, a protein that can help cancer cells avoid an immune attack
- **BRCA1 and BRCA2 and other hereditary cancer-risk genes**, which may affect treatment and can provide important information for you and your family
- **Other tumor biomarkers**, which may help identify targeted treatments or, in some cases, immunotherapy options

Ask your health care team which tests are appropriate for you and what the results mean.

Should I ask about fertility, menopause, or sexual health before treatment?

Some breast cancer treatments can affect fertility, menstrual cycles, menopause, or sexual health.

If these issues are important to you, bring them up before treatment begins whenever possible. Your health care team can discuss what effects are possible and whether referral to a fertility or other specialist may be appropriate.



Making a Decision:

Understanding Immunotherapy

What is immunotherapy?

Immunotherapy is a type of cancer treatment that helps your immune system recognize and attack cancer cells.

The main type of immunotherapy currently used for breast cancer is an immune checkpoint inhibitor. Immune checkpoint inhibitors block signals cancer can use to suppress immune cells, helping “release the brakes” so your immune system can respond more effectively.

When is immunotherapy used for breast cancer?

Immunotherapy may be an option for certain people with TNBC or other factors such as tumor biomarkers. The immunotherapy that is approved by the U.S. Food and Drug Administration (FDA) for use in certain breast cancer situations is an immune checkpoint inhibitor called pembrolizumab (Keytruda®).

Making a Decision: Understanding Immunotherapy (Cont.)

Your Situation	What Immunotherapy May Be Used
High-risk, early-stage TNBC	Can be given along with chemotherapy before surgery and continued after surgery
Unresectable locally advanced or metastatic TNBC	May be an option if the tumor has enough PD-L1
Microsatellite instability high (MSI-H) / Deficient DNA mismatch repair (dMMR) / Tumor mutational burden high (TMB-H)	May also qualify for immunotherapy based on these tumor features

What is a clinical trial, and when should I consider participating?

Clinical trials are carefully monitored research studies that test new treatments or new ways of using existing treatments. They may provide access to promising therapies that are not yet approved by the FDA.

Clinical trials can be worth considering at different points in your care, including when you are first diagnosed, if the cancer comes back, or if standard treatments are no longer working. Ask your doctor about trials at your treatment center or use CRI’s Clinical Trial Finder to explore trials that you may be eligible for.



Starting Treatment:
What to Expect

How is immunotherapy for breast cancer given?

Pembrolizumab is usually given at a cancer center or outpatient clinic. Depending on the formulation and treatment plan, it may be administered through an IV (intravenous) or an injection under the skin (subcutaneous).

For early-stage TNBC, pembrolizumab is given with chemotherapy before surgery and may then continue after surgery. Treatment may last up to about one year.

For advanced TNBC, pembrolizumab is given together with another cancer treatment. Your health care team will explain which medicines you will receive, how they are given, and how often you will need treatment.

What side effects should I expect?

Many people tolerate immunotherapy well, but side effects can occur because the immune system becomes more active and may affect healthy tissues. Common side effects may include fatigue, skin changes (such as rash or itching), and diarrhea. Less commonly, immune-related side effects can affect the colon, liver, lungs, hormone-producing glands, or other organs.

Tell your health care team about new or worsening symptoms as soon as possible, even if they seem minor.

Starting Treatment: What to Expect (Cont.)

How will I know if treatment is working?

Your health care team will monitor how you are responding to treatment based on your stage and treatment plan. If you are receiving immunotherapy before surgery, your doctor may use breast exams and imaging to assess how the cancer is responding. After surgery, the removed tissue is examined to determine how much cancer remains.

For metastatic breast cancer, your health care team may use imaging scans, blood tests, physical exams, and your symptoms to determine whether the cancer is shrinking, stable, or growing.



Looking and Living Forward: Post-Treatment Support

What ongoing care will I need?

After treatment for early-stage breast cancer, you will continue to have regular follow-up visits. Your care may include physical exams, mammograms or other breast imaging when appropriate, and monitoring for treatment side effects and signs that the cancer has returned.

If you are living with metastatic breast cancer, treatment and monitoring usually continue over time. Your health care team may change treatment if the cancer begins growing or side effects become difficult to manage.

What if immunotherapy doesn't work, or my breast cancer comes back?

Not everyone responds to immunotherapy, and it can be difficult if treatment does not work as hoped. If immunotherapy isn't effective, your doctor may recommend another standard treatment, additional testing to look for new treatment options, or a clinical trial.

If breast cancer returns in another part of the body, testing the recurrent cancer can be important because hormone receptor and HER2 status can sometimes be different from the original tumor.

Where can I find support from others affected by breast cancer?

Connecting with other people affected by breast cancer can provide practical and emotional support. You can explore personal stories and resources for people navigating cancer and immunotherapy. Organizations such as Susan G. Komen and Living Beyond Breast Cancer also provide breast-cancer-specific education, support programs, helplines, and opportunities to connect with others.

What comes next?

No matter where you are in your journey — newly diagnosed, in treatment, or considering next steps — your questions matter. Keep asking. Bring support when you can. And let your health care team know how you're feeling, both physically and emotionally.

Appendix

10 Questions to Ask Your Doctor About Breast Cancer and Immunotherapy

Being diagnosed with breast cancer can bring a lot of new information at once. Understanding your diagnosis and the reasons behind your treatment plan can help you take an active role in your care.

Here are 10 questions you may want to ask your health care team:

- 1 What is my exact diagnosis and stage?
- 2 What are my ER, PR, and HER2 results, and what do they mean for my treatment?
- 3 Do I need additional biomarker testing, such as PD-L1 or tumor genetic testing?
- 4 Should I have hereditary genetic testing, including testing for *BRCA1* and *BRCA2*?
- 5 Is immunotherapy an option for me now? If not, could it become an option later?
- 6 What treatments do you recommend, and will I need treatment before or after surgery?
- 7 What side effects should I watch for, and when should I contact you?
- 8 How will we know whether my treatment is working?
- 9 Are there clinical trials I should consider now or later?
- 10 Could treatment affect my fertility, long-term health, or quality of life?

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Glossary

Adjuvant therapies

Adjuvant therapies are additional cancer treatments given after primary treatment, such as surgery, to lower your risk of recurrence. Immunotherapies are often used as adjuvant therapies.

Biomarkers

Biomarkers are proteins, genes, or other features that provide more information about cancer, including how it may behave and how it might respond to treatment.

Chemotherapy

Chemotherapy, often called “chemo”, is a cancer treatment that uses drugs to kill fast-dividing cells. It can be used alone or in combination with other types of treatments.

Clinical trials

Clinical trials are research studies that evaluate new treatments to determine whether they are safe and effective.

Genetic mutations

Genetic mutations are changes in your DNA. Some are linked to cancer and may help predict how well certain treatments, including immunotherapy, will work.

Immune checkpoint inhibitors (ICIs)

Immune checkpoint inhibitors are a type of immunotherapy that help “release the brakes” on your immune system so it can better recognize and attack cancer cells.

Immune system

The immune system is a network of organs, cells, and molecules that protects your body from infections and diseases, including cancer.

Immune-related side effects (irAEs)

Immune-related side effects occur when your immune system becomes overactive and begins to affect healthy parts of your body. These side effects can involve organs such as your skin, colon, liver, lungs, or hormone-producing glands and may require prompt treatment.

Immuno-oncology

Immuno-oncology is the study and development of cancer treatments that use your body’s immune system.

Immunotherapy

Immunotherapy is a type of cancer treatment that uses your immune system to prevent, control, or eliminate cancer. It can be used alone or in combination with other treatment types.

Lymph nodes

Lymph nodes are small, bean-shaped structures located throughout your body that are part of your immune system. They help filter harmful substances and can trap cancer cells, which is why they are often checked to see if cancer has spread.

Metastatic disease

Metastatic disease refers to cancer that has spread through your blood or lymph system to form new tumors in other parts of your body distinct from the original site.

Neoadjuvant therapies

Neoadjuvant therapies are treatments given before primary treatment, such as surgery, to improve its effectiveness. Immunotherapies are often used as neoadjuvant therapies.

Proteins

Proteins are molecules that perform many essential functions in your body, including building tissues and supporting immune responses.

Recurrence

Recurrence is when cancer returns after treatment.

Remission

Remission is a decrease or disappearance of signs and symptoms of cancer. It is a time in which the disease is considered under control.

Staging

Staging describes how advanced a cancer is, including whether it has spread and how much of your body is affected.

Targeted therapy

Targeted therapy is a type of cancer treatment that blocks specific genes, proteins, or signals that help cancer cells grow and survive. It acts directly on cancer cells and is often used when tumors have certain genetic mutations, such as *BRCA1* or *BRCA2*.

Tumor

A tumor is an abnormal lump or mass of tissue. Tumors can be benign (non-cancerous) or malignant (cancerous).

Disclaimer

This information is intended for educational purposes only and is not a substitute for professional medical advice, diagnosis, or treatment. Always talk with your health care team about questions or decisions related to your care.

About CRI

The Cancer Research Institute (CRI) is a nonprofit organization dedicated to advancing the field of cancer immunotherapy through rigorous scientific research and global collaboration. Since 1953, CRI has been instrumental in uncovering the fundamental biology of the immune system and its application to cancer treatment, laying the groundwork for breakthroughs such as checkpoint blockade, cancer vaccines, and engineered cell therapies.

CRI's mission is to create a world immune to cancer by driving scientific discovery, accelerating collaboration, and turning breakthroughs into life-saving treatments. Our work bridges the gap between discovery and patient impact, ensuring that scientific innovation translates into real-world treatments.

To date, CRI has committed over \$600 million to research impacting more than 35 cancer types. Our funding strategy is built on the framework of People × Biology × Data: supporting world-class scientists, deepening understanding of tumor-immune system interactions, and harnessing data to guide discovery and translation. By uniting these elements, CRI catalyzes innovation through our global research ecosystem to drive the next generation of discoveries forward.



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