IMPORTANT INFORMATION FOR THOSE AFFECTED BY HER2+ BREAST CANCER

HER hope

Understanding HER2+ Breast Cancer

Increase the Chance of Staying Cancer-Free Longer With Herceptin as Adjuvant Treatment, as Seen in 4 Clinical Trials*

Who is Herceptin for?

Herceptin is approved for the adjuvant treatment of HER2-overexpressing, node-positive or node-negative (ER/PR-negative or with one high-risk feature) breast cancer. Herceptin can be used several different ways:

- As part of a treatment regimen including doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
- With docetaxel and carboplatin
- As a single agent following multi-modality anthracycline-based therapy

THE WOMAN PICTURED HAS RECEIVED HERCEPTIN THERAPY.

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*See page 22.

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Introduction

Finding out you have breast cancer can be overwhelming. There can be a lot of information to absorb. This brochure can help you and your loved ones understand what HER2+ breast cancer is and how the adjuvant treatment of HER2+ breast cancer with Herceptin can increase the chance of staying cancer-free longer.[1] This brochure does not contain everything that is known about Herceptin. As a treatment, Herceptin does involve risks. Serious side effects have occurred in patients treated with Herceptin.

You should keep in mind that you have a team of knowledgeable healthcare professionals ready to help you with treatments and support. This brochure does not replace the advice of your healthcare team, but includes questions you may want to ask them about your diagnosis, your treatment plan, or Herceptin.

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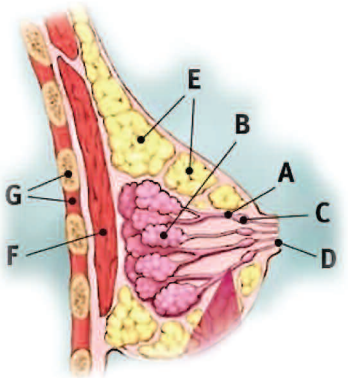
What is breast cancer?

Cancer is a general term that refers to cells that grow and multiply out of control and possibly spread to other parts of the body. There are many different types of breast cancer. Each may have different characteristics, and each one may require a different treatment.[2]

Cancer can cause harm in different ways. Cancer cells take nutrition and space away from normal cells. A lump of cancer cells, called a **tumor**, can invade or destroy normal tissue. Cancer cells can also spread to other parts of the body. This is called metastasis.[2]

Breast cancer is a common cancer among women in the United States and second only to skin cancer, affecting about 178,480 women in the United States in 2007.[3]

Most breast cancer begins in the milk ducts. These ducts connect the milk-producing glands (called **lobules**) to the nipple. Some breast cancer begins in the lobules themselves, and the rest begins in other tissues. The diagram shows where these parts are within the breast.[4]



A. Ducts

B. Lobules

C. Dilated section of duct to hold milk

D. Nipple

E. Fat

F. Muscle

G. Chest wall/rib cage

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Risk factors for breast cancer

A **risk factor** is something that may increase the chance of developing a disease.

The following are risk factors for developing breast cancer[5]:

- Female gender
- Increasing age
- Personal history of breast cancer or previous breast biopsies
- Family history
- Genetic factors – cancer causing mutations in BRCA1 (BReast CAncer gene 1) and BRCA2 (BReast CAncer gene 2) account for 5%-10% of all breast cancer cases
- Hormonal factors, such as earlier age at first period, later age at birth of first child, later age at menopause, and having no children

Stages of breast cancer

A cancer's stage refers to how much the cancer has grown and where it has spread. Tumors can be noninvasive or invasive.[5]

- Noninvasive breast cancer, or carcinoma in situ, is a tumor that has not spread beyond the ducts or the lobules, depending on where it started[5]
  - –Ductal carcinoma in situ (DCIS): Cancer that is confined to the ducts
  - –Lobular carcinoma in situ (LCIS): A condition that is confined to the lobules, or milk-making glands. Although not considered a true cancer, having LCIS increases the risk of getting cancer later
- An invasive tumor has spread beyond where it began. There are 3 different stages of invasiveness[5]:
  - –Localized stage: The tumor is still only within the breast
  - –Regional stage: The tumor has spread to the tissue surrounding the breast or there are cancer cells within nearby lymph nodes. Lymph nodes are small masses of tissues found throughout the body that are involved in fighting infection. The more lymph nodes with cancer, the more serious the cancer may be[2,5]
  - –Distant (advanced/metastatic) stage: The tumor has spread away from the breast to other tissues in the body (eg, lung, liver, bone, or brain)

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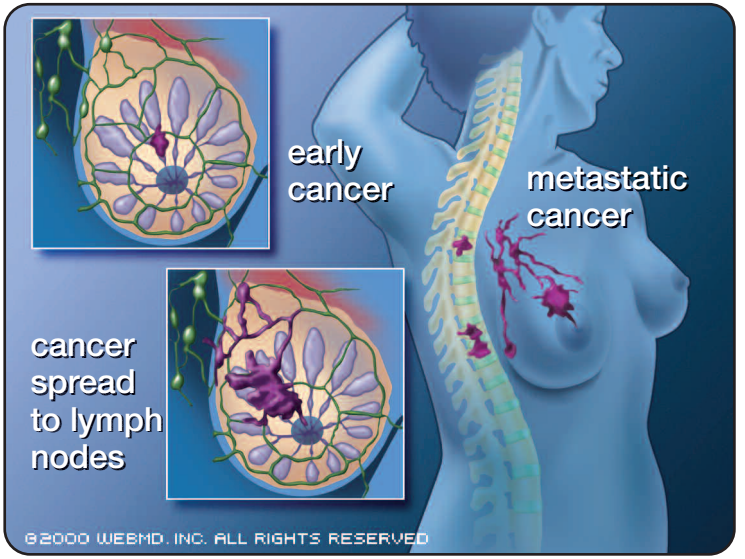

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TNM staging system

Staging systems help describe the cancer so that the doctor can decide what treatments are appropriate, such as whether the tumor is operable (meaning that surgery should be done to remove the tumor). The TNM (Tumor, Nodal, Metastasis) Staging System is the most common method of staging breast cancer. According to the TNM system, breast cancer is grouped into 5 stages from 0 to IV based on how large the tumor is, the tumor's **nodal status** (whether or not cancer cells have spread to the lymph nodes), and whether the tumor has spread (metastasis).[6]

The terms "early" and "advanced" are sometimes used to describe tumors, but these terms may be used differently by different doctors. Generally, "early" or "early-stage" breast cancer means that the cancer has not spread beyond the breast or lymph nodes under the arm (known as axillary lymph nodes). Stage 0, I, and II, as well as some stage III cancers, are usually considered early-stage. Ask your doctor or nurse for more information about the stage of your tumor. Here are brief descriptions of each stage of breast cancer, according to the TNM system.[7,8]

Stages 0-IV[6,7]

Stage 0 is very early breast cancer. The cancer cells are still only in the duct or lobule where they began.

Stage I means that the tumor is small, 0 to 2 cm (about 1 inch) wide, with negative lymph nodes (no cancer cells in the lymph nodes). The tumor has not spread outside of the breast.

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Stage II means one of the following:

- The tumor is 2 to 5 cm (about 1 to 2 inches) wide, and lymph nodes under the arm on the same side of the body as the tumor may be positive (meaning that the lymph nodes have cancer cells in them)

or

- The tumor is more than 5 cm (about 2 inches) wide, but the lymph nodes are still negative

Stage III, sometimes known as locally advanced cancer, means one of the following:

- The tumor has grown larger than 5 cm wide, and cancer has spread to lymph nodes under the arm

or

- The tumor is any size, but more lymph nodes are now positive. These nodes may be under the arm and attached to one another or in the surrounding tissue and enlarged

or

- The tumor is any size and has spread to the chest wall or the skin

or

- The tumor is any size and there are positive lymph nodes in the chest above or just below the collarbone

Stage IV means that the breast cancer is metastatic: the cancer has spread to somewhere else in the body.

Understanding your pathology report[6,9]

To classify exactly what kind of breast cancer you have, your doctor may take a **biopsy** of your tumor, which is a sample taken from the tumor either during surgery or using a needle. That sample tissue is then studied in a lab to determine exactly what kind of tumor it is. Tests are done to look for different substances in the tumor, and each test result is assigned a status, such as positive or negative. The results are called your **pathology report**.

Knowing the details about the tumor helps the doctor understand how quickly the cancer might grow and what treatments may be best.

For breast cancer, a doctor wants to know a cancer's **hormone-receptor status** and **HER2 status**. Hormones such as estrogen and progesterone play a role in the growth of many breast cancers, and it is important to know whether a tumor is positive or negative for either of these hormone receptors. An estrogen–receptor-positive tumor is called "ER+," and a progesterone–receptor-positive tumor is called "PR+." Tumors that are positive for either of these hormone receptors may benefit from **hormonal therapy**.

Similarly, HER2 status can tell a lot about how aggressive the breast cancer is, as well as what treatments may provide the most benefit. HER2 status and hormone-receptor status are not the same thing, and being positive for one does not mean the cancer is positive for the other. Again, knowing what kind of cancer you have is critical to deciding what the best course of treatment may be.

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Potential treatment options for early breast cancer[6]

Depending on your risk factors and the stage of the tumor, your doctor will select an appropriate treatment plan for you. Most women with early breast cancer will have surgery to get rid of as much of the cancer as possible. The surgery will be 1 of 2 types:

Mastectomy – Surgery to remove the entire breast.

Lumpectomy, or breast-conserving surgery – Surgery to remove only the tumor plus some normal tissue around it.

Treatment may also include the following:

Radiation therapy – Treatment with high-energy rays aimed at the area around the tumor.

Chemotherapy – A drug that kills cancer cells.

Hormonal therapy – A drug that reduces the amount of estrogen in the body or blocks the effect of estrogen (estrogen causes some tumors to grow).

Therapy with **monoclonal antibodies** (sometimes called **targeted biologic therapy**) – Antibodies, produced by specialized immune cells, are part of the body's normal defense against bacteria, viruses, and abnormal cells, such as cancer cells. Monoclonal antibodies are produced in a laboratory by making multiple copies of a single cell. Monoclonal antibodies are designed to recognize a specific protein on certain cells and signal the body's immune system to destroy the cell. Monoclonal antibodies are generally a more targeted therapy than chemotherapy.[10,11]

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Adjuvant therapy

When you are first diagnosed with breast cancer, the surgery you receive is meant to remove as many of the cancer cells in your breast as possible. Cancer cells are very small and can be hard to detect, and it is possible that some of these cells are still in your breast, lymph nodes, or elsewhere in your body even after surgery. These cells may begin to multiply again and another tumor can appear. This is called recurrence.[2,6]

To help prevent cancer from coming back, patients may be given adjuvant therapy. Adjuvant means "in addition to." In this case, it means treatment given after your initial surgery. Different adjuvant treatments, such as chemotherapy, radiation, hormonal therapy, and targeted biologic therapy, have different ways of keeping whatever cancer cells may still be in your body from growing and multiplying into a tumor.[6]

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Risk of cancer returning (recurrence)[12]

Depending on your type of cancer, one or more of these treatments can reduce your risk of recurrence. Your chance of recurrence depends on many factors, known as risk factors, such as:

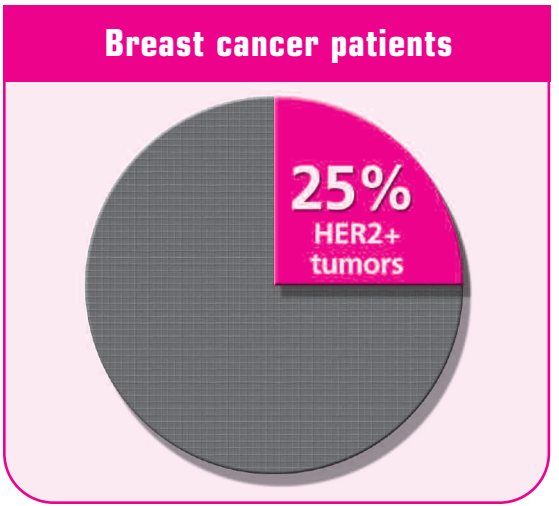
- How large the tumor is
- How quickly the cancer cells grow and multiply
- Whether there are cancer cells in the lymph nodes
- Your cancer's hormone receptor status
- Your cancer's HER2 status

Knowing what kind of tumor you have helps your doctor decide how much you are at risk for cancer coming back and which adjuvant treatments you should receive.

What is HER2 testing?

HER2 status and why it is important[13-15]

Studies show that approximately **25%** of breast cancer patients have tumors that are HER2+. HER2 stands for **H**uman **E**pidermal growth factor **R**eceptor **2**. It is very important to find out your cancer's **HER2 status**. This is because HER2+ tumors tend to grow and spread more quickly than tumors that are not HER2+. In addition, the treatment of HER2+ breast cancer may be different from the treatment of breast cancer that is not HER2+. See the next section "How is HER2+ breast cancer different?" for more information. Women who are uncertain of their cancer's HER2 status should talk to their doctor.



HER2+ breast cancer is aggressive, so it is important to find out your cancer's HER2 status.[13-15] This can help your doctor choose which treatments may be right for you.

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Testing of HER2 tumor status[6,16,17]

HER2 testing is performed with the tumor sample removed during surgery or using a needle.

There are 2 types of tests available to determine HER2 status: **F**luorescence **I**n **S**itu **H**ybridization (FISH) and **I**mmuno**H**isto**C**hemistry (IHC).

- A **FISH** test checks to see whether or not the cancer cells have a normal number of HER2 genes. Using a special microscope, the pathologist looks at cancer cells to see whether there are too many HER2 genes there, compared with some other normal genes
- An **IHC** test measures how much HER2 protein there is on the surface of the cancer cells. The test is scored on a scale of 0 to 3+
  - A patient who has a tumor with a score of 3+ is considered to have HER2+ breast cancer

Accurate testing is important; your pathology report may contain inconclusive results. Sometimes one test may not be enough to determine with certainty whether your tumor is HER2+. Ask your doctor to discuss the results of your pathology report, explain how your tumor's HER2 status was determined, and to let you know whether another test may be necessary.

How is HER2+ breast cancer different?

HER2 stands for **H**uman **E**pidermal growth factor **R**eceptor **2**. Each normal breast cell contains copies of the HER2 gene, which helps normal cells grow. The HER2 gene is found in the DNA of a cell, and this gene contains the information for making the HER2 protein.[18]

The HER2 protein, also called the HER2 receptor, is found on the surface of some normal cells in the body. In normal cells, HER2 proteins help send growth signals from outside the cell to the inside of the cell. These signals tell the cell to grow and divide.[18]

In HER2+ breast cancer, the cancer cells have an abnormally high number of HER2 genes per cell. When this happens, too much HER2 protein appears on the surface of these cancer cells. This is called HER2 protein **overexpression**. Too much HER2 protein is thought to cause cancer cells to grow and divide more quickly. This is why HER2+ breast cancer is aggressive.[13-15]

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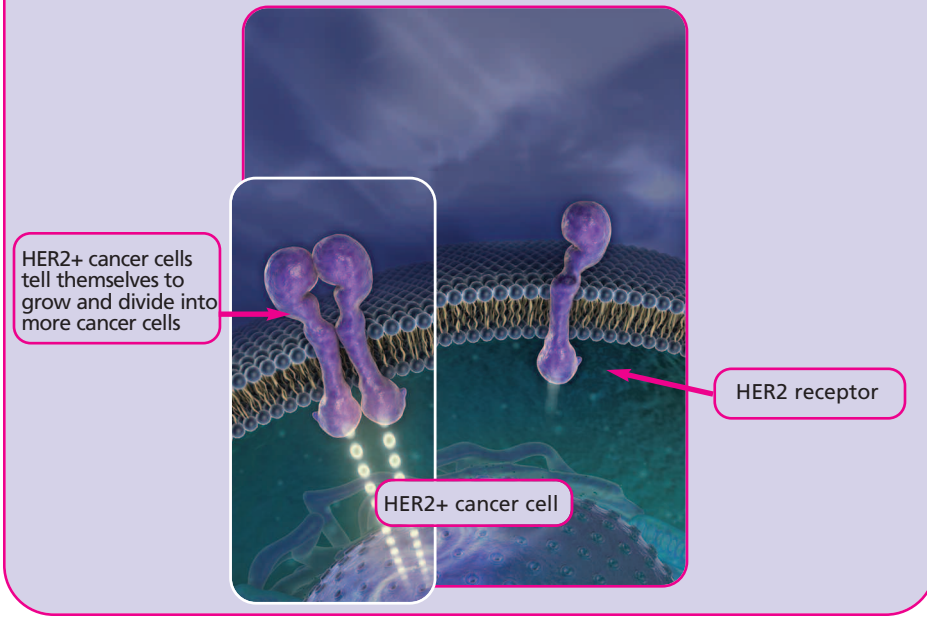
HER2+ breast cancer cell



HER2+ breast cancer is aggressive, so it is important to find out your cancer's HER2 status.[13-15] This can help your doctor choose which treatments may be right for you.

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Higher risk of cancer returning (recurrence)[13,14]

Women with HER2+ breast cancer:

- May be less likely to respond to certain treatments
- May be more likely to have a recurrence (return) of their cancer

Inheriting the HER2 gene

Your tumor's HER2 status is not hereditary. This means that HER2 status is not passed down from your parents, and you can't pass it on to your children. However, there is a relationship between the genes in a person's DNA and breast cancer in general. Ask your doctor for more information about the relationship between genes and breast cancer.[18]

HER2/*neu*-positive, HER2-overexpressing, and HER2+ breast cancer

HER2/*neu* is another name for HER2, which stands for **H**uman **E**pidermal growth factor **R**eceptor **2**. HER2-overexpressing means there is too much HER2 protein/receptor on the surface of the cancer cells. HER2/*neu*-positive breast cancer and HER2-overexpressing breast cancer are exactly the same as HER2+ breast cancer.[18]

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What is Herceptin?

Herceptin is a treatment for women with breast cancer whose tumors have too much HER2 protein. This type of cancer is known as "HER2-positive," "HER2+," or "HER2-overexpressing." HER2+ tumors tend to grow and spread more quickly than tumors that are not HER2+. This is why it is so important to find out your cancer's HER2 status.[1,13]

Clinical experience with Herceptin for the adjuvant treatment of HER2+ breast cancer began in 2000.[19] In 2006, Herceptin was approved for the adjuvant treatment of HER2+ breast cancer.[1]

Who is Herceptin for?

Herceptin is approved for the adjuvant treatment of HER2-overexpressing, node-positive or node-negative (ER/PR-negative or with one high-risk feature) breast cancer. Herceptin can be used several different ways:

- As part of a treatment regimen including doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
- With docetaxel and carboplatin
- As a single agent following multi-modality anthracycline-based therapy

High-risk features

High-risk features are defined as ER/PR+ with 1 of the following characteristics:

- Age less than 35 years
- Tumor size larger than 2 cm wide
- Tumor grade 2/3

What important safety information should I know about Herceptin?

Herceptin treatment can result in heart problems, including those without symptoms (reduced heart function) and those with symptoms (congestive heart failure). The risk and seriousness of these heart problems were highest in people who received both Herceptin and a certain type of chemotherapy (anthracycline). Your doctor will stop or strongly consider stopping Herceptin if you have a significant drop in your heart function.

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Herceptin is not chemotherapy or hormonal therapy. Herceptin is a type of targeted cancer therapy known as a monoclonal antibody (sometimes called targeted biologic therapy). Antibodies are part of the body's normal defense against bacteria, viruses, and abnormal cells, such as cancer cells.[1,20]

- Monoclonal antibodies are produced in a laboratory by making multiple copies of a single cell. Monoclonal antibodies are designed to recognize a specific protein on certain cells and signal the body's immune system to destroy the cell[10]
- Monoclonal antibodies are generally a more targeted therapy than chemotherapy[10,11]

To receive Herceptin, your tumor must be tested and be HER2+. Talk to your doctor to find out if Herceptin is right for you.

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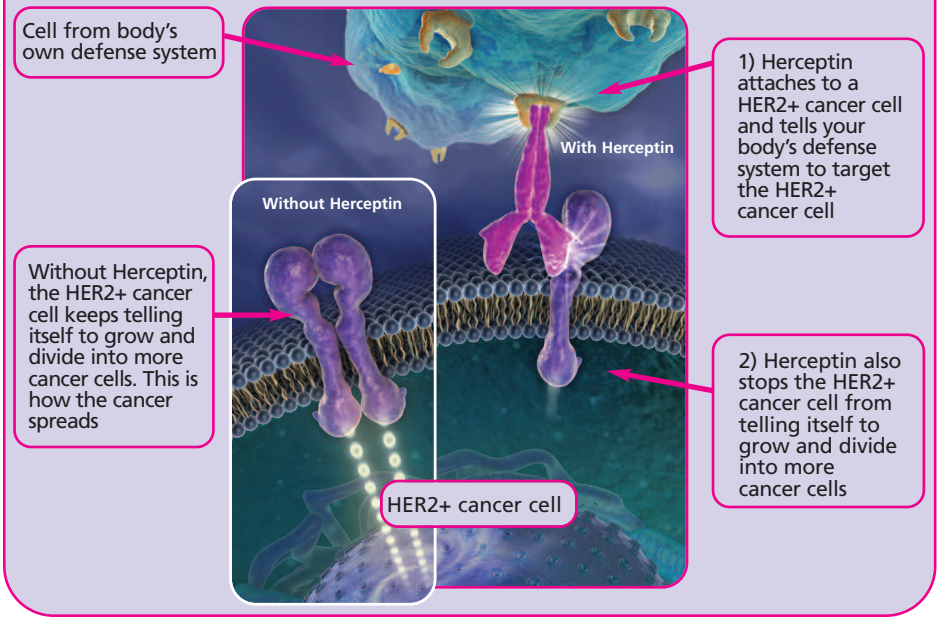
How Herceptin works

Herceptin is designed to target HER2+ cancer cells. Based on laboratory studies, Herceptin works 2 ways to stop the HER2+ cancer cell from growing.[1]

How Herceptin Works



What important safety information should I know about Herceptin?

You should be monitored for decreased heart function before your first dose of Herceptin, and frequently during the time you are receiving Herceptin and after your last dose of Herceptin. If you must permanently or temporarily stop Herceptin due to heart problems, you should be monitored more frequently. In one study with Herceptin and certain types of chemotherapy, an inadequate blood supply to the heart occurred.

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Herceptin has been studied for the adjuvant treatment of HER2+ breast cancer[1]

Herceptin has been studied as an adjuvant treatment for HER2+ breast cancer in 4 large clinical trials including a total of more than 10,000 women. All of the women in these studies received chemotherapy. They also received hormonal therapy and/or radiation therapy if it was thought to be helpful for their treatment. About half the women received Herceptin, while the other half did not.

Four adjuvant trials of over 10,000 women showed Herceptin benefit[1]

1 year of Herceptin
lowered the risk
of HER2+ breast cancer returning

Women who received 1 year of Herceptin had a lower risk of cancer returning than women who did not receive Herceptin.

In 2 of the trials, Herceptin was started with chemotherapy (paclitaxel) after patients finished another chemotherapy regimen (doxorubicin and cyclophosphamide). When looking at the entire population of women in both of these trials:

- Women who received Herceptin with chemotherapy had a **52% lower risk** of breast cancer returning compared with those who received chemotherapy alone

In the third trial, Herceptin was given on its own after surgery and chemotherapy.

- Women who received Herceptin had a **46% lower risk** of breast cancer returning than those who did not receive Herceptin

In the fourth trial, Herceptin was started with different kinds of chemotherapies. Some women received Herceptin with chemotherapies called docetaxel and carboplatin.

- Women who received this treatment had a **33% lower risk** of breast cancer returning compared with those who received chemotherapy alone

For some women in the fourth trial, Herceptin was started with chemotherapy (docetaxel) following completion of another chemotherapy regimen (doxorubicin and cyclophosphamide).

- Women who received this treatment had a **40% lower risk** of breast cancer returning compared with those who received chemotherapy alone

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The potential benefits received from Herceptin were in addition to those received from surgery, chemotherapy, radiation, and hormonal therapy.

Every person who has HER2+ breast cancer is unique, and no cancer treatment works for every person. Your experience may be different from those of the women who participated in the clinical trials. Further, because of the aggressive nature of HER2+ breast cancer, the status of these women may change over time.

What important safety information should I know about Herceptin?

Some patients have had serious infusion reactions and lung problems; fatal infusion reactions have been reported. In most cases, these reactions occurred during or within 24 hours of receiving Herceptin. Your Herceptin infusion should be temporarily stopped if you have shortness of breath or very low blood pressure. Your doctor will monitor you until these symptoms go away. If you have a severe allergic reaction, swelling, lung problems, inflammation of the lung, or severe shortness of breath, your doctor may need to completely stop your Herceptin treatment.

Taking Herceptin: how long, how often, and with which other therapies[1]

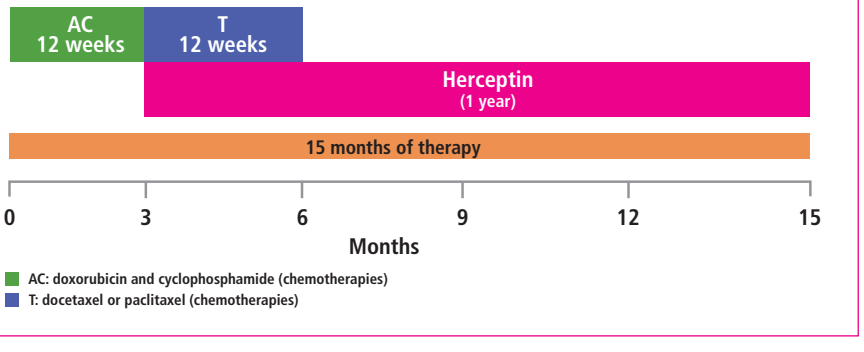
It is recommended that Herceptin be taken for 1 year. You may receive it in combination with different therapies, or on different schedules. The combination of drugs you receive, and the order in which you receive them, are known as your treatment "regimen." There are several options available for different regimens that include Herceptin, as shown below and on the next page.

The choice of which regimen you receive will affect the total amount of time you will be going for infusions. You should also be aware that different chemotherapies have different side effects, so it's important to talk to your healthcare team about any health issues you have. This information may help them decide whether it's better for you to take one kind of chemotherapy over another.

AC→TH

If you and your doctor decide that you will receive Herceptin as part of the "AC→TH" regimen:

- After surgery, you will receive 2 kinds of chemotherapy, known as doxorubicin (A) and cyclophosphamide (C), for 12 weeks
- You will then begin to receive Herceptin weekly, along with another kind of chemotherapy known as a taxane (T)
- After 12 weeks, the taxane will stop, and you will receive Herceptin alone, once every 3 weeks, for another 9 months



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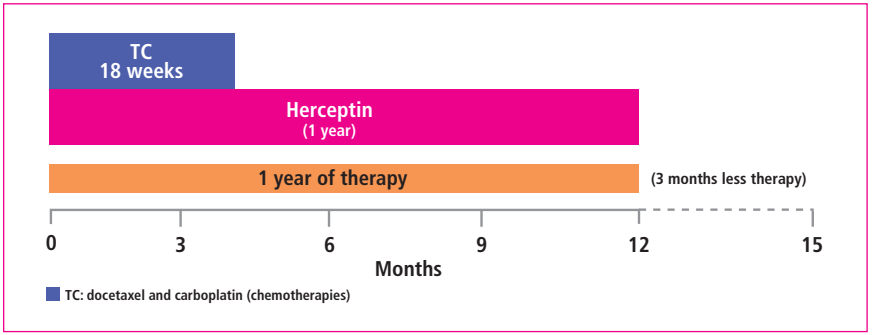
TCH

If you and your doctor decide that you will receive Herceptin as part of the "TCH" regimen:

- You will begin to receive Herceptin after surgery, on a once-weekly schedule. At the same time, you will be getting 2 kinds of chemotherapy: a taxane (T) and a carboplatin (C). Note that the "C" in TCH is different from the "C" in the AC→TH option described on the previous page
- After 18 weeks, the taxane and the carboplatin will stop, and you will receive Herceptin alone, once every 3 weeks. This will continue until you have received 1 year of therapy



Herceptin given alone after all chemotherapy

You and your doctor may decide to first complete any surgery, chemotherapy, and radiation therapy that are planned, and then begin taking Herceptin. If this is the case, you will receive Herceptin once every 3 weeks for 1 year.

Your healthcare team may also choose to give you other drugs, such as hormonal therapies, during the time you are receiving Herceptin.

Talk to your healthcare team to decide which therapies and schedule are right for you.

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Taking Herceptin with other cancer treatments[1]

Herceptin can be given with other cancer treatments. Remember, Herceptin is not chemotherapy or hormonal therapy. The potential benefits of Herceptin are **in addition** to the potential benefits you may receive from surgery, chemotherapy, hormonal therapy, or radiation therapy. Herceptin is not a substitute for any of these therapies. Talk to your doctor about what therapies are right for you.

Getting Herceptin therapy

Herceptin is usually given at your doctor's office or clinic. You take Herceptin through an intravenous (IV) infusion, which means that the drug comes through a needle that your nurse inserts into a vein. Herceptin can also be given through a central line or a port, which are 2 different devices placed under the skin to make it easier to receive medications that are given through an infusion. Talk to your doctor about which option is best for you.

Infusions will usually last between 30 and 90 minutes, depending on the dosage you are receiving, how frequently you are getting infusions, and how well you are tolerating the infusions. Infusions may be slowed or stopped if you experience discomfort from side effects.

Know your healthcare team

In clinical trials, some people receiving Herceptin experienced serious side effects. You have a team of knowledgeable healthcare professionals ready to help you with your care, and this brochure does not replace the advice of your healthcare team. If you have questions or concerns about your treatment, or any signs or symptoms you are experiencing, please talk to your doctor.

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What important safety information should I know about Herceptin?

What are the possible side effects of Herceptin?

Herceptin treatment can result in heart problems, including those without symptoms (reduced heart function) and those with symptoms (congestive heart failure). The risk and seriousness of these heart problems were highest in people who received both Herceptin and a certain type of chemotherapy (anthracycline). Your doctor will stop or strongly consider stopping Herceptin if you have a significant drop in your heart function.

You should be monitored for decreased heart function before your first dose of Herceptin, and frequently during the time you are receiving Herceptin and after your last dose of Herceptin. If you must permanently or temporarily stop Herceptin due to heart problems, you should be monitored more frequently. In one study with Herceptin and certain types of chemotherapy, an inadequate blood supply to the heart occurred.

Some patients have had serious infusion reactions and lung problems; fatal infusion reactions have been reported. In most cases, these reactions occurred during or within 24 hours of receiving Herceptin. Your Herceptin infusion should be temporarily stopped if you have shortness of breath or very low blood pressure. Your doctor will monitor you until these symptoms go away. If you have a severe allergic reaction, swelling, lung problems, inflammation of the lung, or severe shortness of breath, your doctor may need to completely stop your Herceptin treatment.

Worsening of low white blood cell counts associated with chemotherapy has also occurred.

Herceptin can cause low amniotic fluid levels and harm to the fetus when taken by a pregnant woman.

The most common side effects associated with Herceptin were fever, nausea, vomiting, infusion reactions, diarrhea, infections, increased cough, headache, fatigue, shortness of breath, rash, low white and red blood cells, and muscle pain.

Because everyone is different, it is not possible to predict what side effects any one person will have. If you have questions or concerns about side effects, talk to your doctor.

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Why is my heart being monitored while I'm on Herceptin?

Herceptin can cause heart problems including an inability to pump blood effectively, irregular heartbeats, high blood pressure, disabling heart failure, weakening of the heart muscle, and sudden loss of heart function leading to death. Herceptin may cause reduced heart function even if there are no symptoms.

Before taking your first dose of Herceptin, your doctor should check to see if you have any health conditions that may increase your chance of having serious heart problems. This includes a review of your health history and tests to see how well your heart muscle is working. These tests may include an echocardiogram, which is an ultrasound image of the heart, or a MUGA scan, which takes a moving picture of your heart pumping blood following an injection of a radioactive substance.

In addition, you should be frequently monitored for decreasing heart function during the time you are receiving Herceptin and after your last dose of Herceptin. If you must permanently or temporarily stop Herceptin due to heart problems, you should be monitored more frequently.

How many women had to stop Herceptin due to heart problems in the Herceptin adjuvant trials?

- 16% of patients in 1 study who received Herceptin with doxorubicin, cyclophosphamide, and paclitaxel
- 2.6% of patients in a second study, who received Herceptin alone after all chemotherapy was completed
- 2.9% of patients in a third study who received Herceptin with docetaxel and carboplatin, and 5.7% of patients in the same study who received Herceptin with doxorubicin, cyclophosphamide, and docetaxel

What happened to these women after their Herceptin was stopped?

In 2 of the clinical trials, among 32 patients with significant heart problems:

- One died of significantly weakened heart muscle
- All others were on heart medication at their last checkup
- Approximately half of the surviving patients had heart function that returned to normal while on ongoing heart medications
- For patients with Herceptin-related decrease in heart function, the safety of continuing or restarting Herceptin therapy has not been studied

Please see accompanying full Prescribing Information for **Boxed WARNINGS** and additional important safety information.

What side effects may I experience with my first dose of Herceptin?

When you receive the first dose of Herceptin, you may have chills and fever as well as nausea, vomiting, pain, headache, dizziness, shortness of breath, low blood pressure, rash, and weakness.

In most cases, these reactions occurred during or within 24 hours of receiving Herceptin.

If you have shortness of breath or very low blood pressure during an infusion, Herceptin treatment should be temporarily stopped. Your doctor will monitor you until these symptoms go away.

Serious and fatal reactions have been reported. If you have severe or life-threatening side effects while receiving treatment, your doctor should stop Herceptin completely.

Are the potential side effects with Herceptin the same as with chemotherapy?

Herceptin is not chemotherapy. Once you finish your chemotherapy and are receiving Herceptin alone, many of the chemotherapy-related side effects will likely go away or be less severe. For instance, Herceptin does not usually cause hair loss. See "What are the possible side effects of Herceptin?" section for more information.

What should I look out for when I'm on Herceptin therapy, and what symptoms should I immediately report to my doctor?

Be sure to tell your doctor about any health conditions you have had, as well as any new symptoms that arise. Call your doctor immediately if you have any of the following: new or worsening shortness of breath; cough; swelling of the ankles or legs; swelling of the face; heartbeats that are unusually strong, fast, slow, or irregular in rhythm; weight gain of more than 5 pounds in 24 hours; dizziness; or loss of consciousness.

Can I take Herceptin if I am pregnant?

Herceptin can cause harm to the fetus when taken by a pregnant woman. This may be related to a lowering of amniotic fluid levels in the second and third trimesters.

You should use effective contraceptive methods while receiving Herceptin and for at least 6 months after you finish taking Herceptin.

Talk to your doctor if you are pregnant or become pregnant while taking Herceptin.

If you are pregnant and receiving Herceptin, consider joining the Cancer and Childbirth Registry by calling 1-800-690-6720. By joining this registry, you can help others understand the effects of taking Herceptin while pregnant.

Can I drive after my Herceptin treatment?

During the period you are taking both chemotherapy and Herceptin, you will have to discuss with your doctor or nurse whether you will be able to drive home after your infusion. After chemotherapy has been completed, and you are taking Herceptin alone, you will likely be able to drive home from your treatment. Everyone is different, however. It is not possible to predict whether you will feel well enough to drive after each infusion. Talk to your doctor or nurse.

Is Herceptin right for me?

Because everyone is different, it is not possible to predict what side effects any one person will have, or whether Herceptin treatment will be effective for you. It's important to discuss potential treatment benefits and risks with your doctor and to have realistic expectations of Herceptin therapy.

Please see accompanying full Prescribing Information for **Boxed WARNINGS** and additional important safety information.

How do I access patient support services?

Financial resources

We're here to help

Handling insurance matters can be confusing. That's where Access Solutions can help. Although you are not required to use this free information resource, you may find it reassuring to know that Access Solutions is here for you if you need help with certain insurance matters.

What is Access Solutions?

Access Solutions, sponsored by Genentech, Inc., is a free resource that can provide patients and their healthcare providers with helpful insurance reimbursement information, patient assistance and informational resources regarding Herceptin. You can access more information about Access Solutions on the Internet at www.HerceptinAccessSolutions.com, or speak to an Access Solutions reimbursement specialist at 1-888-249-4918 (6 AM to 5 PM Pacific time, Monday-Friday).

Here are a few questions that Access Solutions may help you answer:

- What happens if my health insurance plan won't pay for Herceptin?
- What if I don't have insurance or if I'm underinsured?
- What is co-pay assistance?

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What if I don't have insurance?

Not all Herceptin patients have complete medical coverage, so we've provided some alternative resources.

Please note: This section contains the Web addresses for a number of other organizations that may offer useful information. We suggest visiting those sites directly to obtain information on specific details of coverage, and educational and financial support services for Herceptin. Unless otherwise indicated, Genentech, Inc. is not a partner or affiliated with any company listed. The availability of insurance coverage and financial assistance varies from company to company, plan to plan, and state to state. Genentech, Inc. does not imply or guarantee that your insurance company nor any other company will provide coverage or assistance for Herceptin. Genentech, Inc. is not responsible for any decisions of partial or noncoverage of Herceptin.

Genentech Access to Care Foundation

Although Genentech's products are covered by most government and private insurance, Genentech has established the Genentech Access to Care Foundation for its marketed products. We are committed to eligible patients having access to all of our drugs for approved indications. For eligible patients who are treated in the United States, Genentech will provide products to those who cannot afford to pay because we believe it is the right thing to do.

For other alternative resources, you may want to visit the following sites:

Cancer*Care*

Cancer*Care* is a national nonprofit organization whose mission is to provide free professional help to people with all cancers through counseling, education, information, referral, and direct financial assistance. www.cancercare.org

Please see front cover for information about who Herceptin is for and pages 27-30 for important safety information.
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NeedyMeds

NeedyMeds is a place to learn about patient assistance programs and other programs designed to help those who can't afford their medicines. NeedyMeds is not a program but an information source. www.needymeds.com

Patient Advocate Foundation

Patient Advocate Foundation is a national nonprofit organization that serves as an active liaison between the patient and their insurer, employer and/or creditors to resolve insurance, job retention, and/or debt crisis matters relative to their diagnosis through case managers, doctors, and attorneys. Patient Advocate Foundation seeks to safeguard patients through effective mediation assuring access to care, maintenance of employmen, and preservation of their financial stability. www.patientadvocate.org

The Wellness Community

This is a patient advocacy group that provides support and education to cancer patients and their families. www.thewellnesscommunity.org

Educational and helpful resources

You should feel free to ask your doctor or nurse any questions about your cancer or your treatment plan. In addition, there are also support groups and national organizations that may be helpful to you and your family.

For more information on HER2+ breast cancer and available treatments, talk with your doctor or nurse.

For more information on Herceptin, visit **www.herceptin.com**

Unless otherwise indicated, Genentech, Inc. is neither affiliated with nor endorses any of the following organizations. The information provided by Genentech or these organizations is meant for informational purposes only and is not meant to replace your physician's medical advice. Most of the contact phone numbers are toll-free. Many of these organizations can refer you to a local chapter for more information.

Breastcancer.org

www.breastcancer.org: This Web site is dedicated to providing reliable and current medical information about treatment options, symptoms, diagnosis, and prevention. The site also includes up-to-date research news, online "ask the expert" conferences, and discussion boards.

Breast Cancer Network of Strength™

YourShoes™ offers peer support, including a 24/7 hotline with real-time interpretation in more than 150 languages. Call 1.800.221.2141 (English) or 1.800.986.9505 (Spanish). Additional programs, services, multilingual publications, and a list of affiliates across the country are available at www.networkofstrength.org. All YourShoes services are conducted by breast cancer survivors.

Please see front cover for information about who Herceptin is for and pages 27-30 for important safety information.
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HER2 Support Group

www.HER2support.org: HER2support.org offers information on news and current research for HER2-positive breast cancer, along with online message boards, which serve as forums for discussion among patients, family members, caregivers, and medical professionals.

Living Beyond Breast Cancer

1.888.753.5222. www.lbbc.org: A nonprofit organization dedicated to empowering all women affected by breast cancer to live as long as possible with the best quality of life.

American Cancer Society

1.800.227.2345. www.cancer.org: Comprehensive Web site with information for cancer patients, families, friends, survivors, professionals, and volunteers.

National Cancer Institute

1.800.4.CANCER (1.800.422.6237). www.cancer.gov: Web site provides easy access to comprehensive research-based information and resources for cancer researchers, health professionals, patients and their families, advocates, news media, and the public.

Genentech Patient Support Program: HER connection

This program will provide you with resources you need to help you understand more about your disease. Enroll today and receive important information about your condition, your treatment options, and how to partner with your healthcare team.

There are 3 ways to enroll in the program:

1) Web site: www.HERconnection.com

2) Phone: 1-866-449-HER2

3) Mail: An enrollment form may be available at your doctor's office

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Glossary[6,8,21,22]

ADJUVANT THERAPY – Treatment that is given as an add-on to primary treatment, such as surgery or radiation therapy, in an effort to decrease the risk of recurrence or death.

ANEMIA – A decreased number of red blood cells and a reduced volume of hemoglobin (the protein within red blood cells that carries oxygen).

ANTIBODIES – Produced by specialized immune cells when substances such as toxins, bacteria, and cells of foreign bodies are introduced into the body.

ANTI-ESTROGEN – Used to treat breast cancers that depend on estrogen for growth.

ARCHIVED TISSUE – Tissue biopsy samples that have been preserved in wax for future study; ask your doctor about the location of your stored tissue.

BIOLOGIC THERAPY – Treatment that uses substances derived from living cells; it is not chemotherapy.

BIOPSY – The removal and examination of a sample of tissue for study purposes; this is the only method that can determine if the tissue contains cancer cells.

BIOTECHNOLOGY – The application of the principles of engineering and technology to the life sciences, for example, using biological substances to create new drugs.

CARDIAC DYSFUNCTION – A disease or disorder of the heart muscle which results in reduced heart function.

CARDIAC EJECTION FRACTION – The amount of blood pumped from the heart with each heartbeat; this may be used to measure the loss of heart muscle function.

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CELL – The fundamental, structural, and functional unit of living organisms.

CELL NUCLEUS – The control center of the cell where genetic material is located.

CHEMOTHERAPY – The treatment of cancer using chemicals or drugs that are destructive to cells and tissues.

CLINICAL TRIAL – A research study designed to answer specific questions about new therapies or new drugs.

CORE BIOPSY – A type of biopsy where a needle is used to remove a small core of tissue for study.

CYCLOPHOSPHAMIDE – Included in a class of chemotherapy drugs (alkylating agents) that promotes cancer cell death.

DNA (DEOXYRIBONUCLEIC ACID) – The building blocks of the genetic code, located in the cell nucleus.

DOXORUBICIN – Included in a class of chemotherapy drugs (anthracyclines) used to inhibit or prevent the development and growth of cancer cells.

ESTROGEN RECEPTORS (ER) – A special type of protein found in some cancer cells. Estrogen attaches to the receptor, and this can cause the cancer cells to grow.

FINE-NEEDLE ASPIRATION – A type of biopsy where a needle is used to remove a few cells to be examined under a microscope.

FIRST-LINE – First treatment initiated for the condition being treated.

FLUORESCENCE IN-SITU HYBRIDIZATION (FISH) – A method of testing tissue samples to determine if there is a gene abnormality in the cells, including the overexpression of HER2.

GENE – Portion of DNA that directs the production of a specific protein.

GENE ALTERATION – Any change or difference in the usual makeup or function of a gene, including changes that result in too much or not enough of a protein being produced or alterations in the property of the protein produced.

GENE AMPLIFICATION – The presence of a greater than normal number of copies of a gene in a cell.

HER2 GENE – A gene that directs the cell to produce HER2 growth factor receptors on the cell's surface, which can control the growth and division of the cell.

HER2-NEGATIVE – Indicates that a biopsy revealed a normal level of the HER2 gene or protein.

HER2-POSITIVE – Indicates that a biopsy revealed abnormally high levels of the HER2 gene or protein.

HER2 PROTEIN (RECEPTOR) – Also called the HER2 receptor; a cell-surface protein that helps control normal cell growth, cell division, and cell survival.

HER2 PROTEIN OVEREXPRESSION – The excess production of HER2 receptors that results from a change in the HER2 gene in cancer cells; thought to cause cancer cells to grow and divide more quickly.

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HER2 RECEPTOR – Human Epidermal Growth Factor Receptor 2, one of the many proteins on a cell's surface that signals the cell to divide and helps control normal cell growth, cell division, and cell survival.

HORMONE THERAPY – Administering hormones, such as anti-estrogen, to help block hormone uptake in tumors.

IMMUNOHISTOCHEMISTRY (IHC) – A method that uses antibodies to identify, locate, and stain specific protein molecules in tissue sections (using a microscope), such as overexpression of HER2.

INTRAVENOUS INFUSION – Introduction of a solution, such as various cancer therapies, into the body through a vein using a small catheter or a central line.

LEUKOPENIA – An abnormally low number of white blood cells in the blood; white blood cells help to fight infection.

LYMPH NODES – Small bean-shaped collections of immune system tissue such as lymphocytes; located along lymphatic vessels.

MALIGNANT – Cancerous.

MARGIN – The normal tissues around a tumor.

MECHANISM OF ACTION – The method by which a drug or therapy affects the body in order to produce a specific result.

METASTATIC BREAST CANCER – Breast cancer that has spread to other sites in the body; also referred to as invasive or infiltrating.

MONOCLONAL ANTIBODY – An antibody produced in a laboratory by making multiple copies of a single cell; designed to recognize a specific protein on certain cells and signal the body's immune system to destroy the cell.

MYELOSUPPRESSIVE CHEMOTHERAPY – Chemotherapy that can suppress the production of blood cells by your bone marrow.

NATURAL KILLER CELLS – Immune system cells that destroy foreign bodies or abnormal cells that are marked with antibodies.

NEUTROPENIA – A decreased number of a specific kind of white blood cell, known as neutrophils, that help fight infection.

NODAL STATUS – Indicates whether a breast cancer has spread (node-positive) or has not spread (node-negative) to lymph nodes in the armpit (axillary nodes).

NODE DISSECTION – Lymph nodes in the armpit are removed and examined to find out if cancer has spread.

ONCOLOGIST – A doctor who treats patients with cancer.

OVEREXPRESSION – The excess production of growth factor receptors (cell-surface receptors) that results from alteration of a gene in cancer cells.

PACLITAXEL – Included in a class of chemotherapy drugs (taxanes) that prevents cancer cell division and growth, and promotes cancer cell death.

Please see front cover for information about who Herceptin is for and pages 27-30 for important safety information.
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PATHOLOGIST – A doctor who studies and examines tissue samples for signs of cancer or other abnormalities.

PATHOLOGY LAB – The location, or laboratory, where pathologists work.

POTENTIAL – A potential product is one that is experimental and is not yet approved by the FDA for that specific use.

PROGESTERONE RECEPTORS (PR) – A protein found inside some cancer cells. The hormone progesterone will bind to the receptors inside the cells and may cause the cells to grow.

RADIATION THERAPY – The use of high-energy rays or substance particles to kill or shrink cancer cells.

STAGE – A method of describing the size and location of a cancer based upon characteristics of the tumor, the lymph nodes, and whether it has spread to other organs.

STEREOTACTIC CORE NEEDLE BIOPSY – A method of needle biopsy that is useful when calcifications or a mass can be seen on mammogram but cannot be located by touch.

SYSTEMIC THERAPY – Treatment that reaches and affects cells throughout the body (ie, chemotherapy or biologic therapy).

TARGETED THERAPY – A type of cancer treatment that targets only certain types of cell activities.

THE WOMAN PICTURED HAS RECEIVED HERCEPTIN THERAPY.

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THROMBOCYTOPENIA – A decrease in the number of platelets in the blood, resulting in the potential for increased bleeding and decreased ability for clotting.

TUMOR – An abnormal growth of tissue that does not have normal body function.

TUMOR BLOCK – Section of tissue biopsy preserved in wax for future study.

Please see front cover for information about who Herceptin is for and pages 27-30 for important safety information.
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Special Tear-Out Section

Questions to ask your doctor and/or nurse

About your diagnosis:

WHAT KIND OF BREAST CANCER DO I HAVE?

WHAT STAGE IS MY CANCER AND HOW DOES IT AFFECT MY TREATMENT PLAN?

HOW IS EARLY STAGE BREAST CANCER DIFFERENT FROM METASTATIC BREAST CANCER?

HAS MY TUMOR BEEN TESTED FOR HER2?

IF SO, IS MY CANCER HER2 POSITIVE?

IS MY CANCER HORMONE-RECEPTOR POSITIVE?

About treatment:

WHAT ARE MY TREATMENT OPTIONS?

SHOULD I BE ON MULTIPLE THERAPIES?

HOW LONG WILL I NEED TO STAY ON THESE TREATMENTS?

HOW WILL I KNOW THIS TREATMENT IS WORKING?

WHAT ARE THE CHANCES MY CANCER WILL COME BACK AFTER TREATMENT?

Who is Herceptin for?

Herceptin is approved for the adjuvant treatment of HER2-overexpressing, node-positive or node-negative (ER/PR-negative or with one high-risk feature) breast cancer. Herceptin can be used several different ways:

- As part of a treatment regimen including doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
- With docetaxel and carboplatin
- As a single agent following multi-modality anthracycline-based therapy

Please see next page for important safety information. Please see accompanying full Prescribing Information for **Boxed WARNINGS** and additional important safety information.

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About Herceptin:

WHAT SHOULD I DO TO BE READY FOR MY INFUSION?

HOW DOES MY HERCEPTIN TREATMENT DIFFER FROM CHEMOTHERAPY?

HOW LONG WILL I NEED TO BE ON HERCEPTIN?

HOW OFTEN WILL I NEED TO GET INFUSIONS?

HOW WILL I KNOW IF THE TREATMENT IS WORKING?

WHAT SIDE EFFECTS CAN I EXPECT TO HAVE?

WHAT TYPES OF THINGS CAN I DO TO HELP COPE WITH ANY SIDE EFFECTS THAT I MAY HAVE DURING MY TREATMENT?

ARE THERE ANY SYMPTOMS OR PROBLEMS I MIGHT HAVE DURING MY HERCEPTIN TREATMENT THAT I SHOULD IMMEDIATELY TELL YOU ABOUT?

HOW OFTEN WILL MY ONCOLOGY NURSE FOLLOW UP WITH MY ONCOLOGIST ABOUT MY HERCEPTIN TREATMENT AND MY PROGRESS?

HOW OFTEN WILL MY HEART BE TESTED?

What important safety information should I know about Herceptin?

Herceptin treatment can result in heart problems, including those without symptoms (reduced heart function) and those with symptoms (congestive heart failure). Some patients have had serious infusion reactions and lung problems; fatal infusion reactions have been reported. Worsening of low white blood cell counts associated with chemotherapy has also occurred. Herceptin can cause low amniotic fluid levels and harm to the fetus when taken by a pregnant woman. The most common side effects associated with Herceptin were fever, nausea, vomiting, infusion reactions, diarrhea, infections, increased cough, headache, fatigue, shortness of breath, rash, low white and red blood cells, and muscle pain.

Because everyone is different, it is not possible to predict what side effects any one person will have. If you have questions or concerns about side effects, talk to your doctor.

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Summary

HER2+ breast cancer is aggressive, so it is important to find out your cancer's HER2 status.[13-15]

Herceptin was studied in large adjuvant clinical trials for HER2+ breast cancer. While individual results vary [1]:

- In the 2 trials in which Herceptin was started with chemotherapy (paclitaxel) after patients finished another chemotherapy regimen (doxorubicin and cyclophosphamide), 1 year of Herceptin reduced the risk of cancer returning by **52%** compared with chemotherapy alone
- In the third trial in which Herceptin was given on its own after surgery and chemotherapy (with or without radiation), 1 year of Herceptin reduced the risk of cancer returning by **46%**
- In the fourth trial in which Herceptin was started with different kinds of chemotherapies:
  - 1 year of Herceptin, with docetaxel and carboplatin, lowered the risk of cancer returning by **33%**
  - 1 year of Herceptin, with docetaxel following completion of doxorubicin and cyclophosphamide, reduced the risk of cancer returning by **40%**
- The potential benefits received from Herceptin were **in addition** to those received from surgery, chemotherapy, radiation therapy and hormonal therapy

Ask your doctor if 1 year of Herceptin therapy can increase the chance of staying CANCER-FREE longer.

What important safety information should I know about Herceptin?

Herceptin treatment can result in heart problems, including those without symptoms (reduced heart function) and those with symptoms (congestive heart failure). Some patients have had serious infusion reactions and lung problems; fatal infusion reactions have been reported. Worsening of low white blood cell counts associated with chemotherapy has also occurred. The most common side effects associated with Herceptin were fever, nausea, vomiting, infusion reactions, diarrhea, infections, increased cough, headache, fatigue, shortness of breath, rash, low white and red blood cells, and muscle pain.

Because everyone is different, it is not possible to predict what side effects any one person will have. If you have questions or concerns about side effects, talk to your doctor.

Please see accompanying full Prescribing Information for **Boxed WARNINGS** and additional important safety information.

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