

Understanding Breast Cancer

And Treatment Options

A GUIDEBOOK FOR PATIENTS AND CAREGIVERS

Provided as an educational service by

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Introduction

As you may know, being diagnosed with breast cancer is a life-changing experience. You and your loved ones may feel a range of emotions that include fear, anger, denial, and uncertainty. And the testing, treatments, and decisions you face can make you feel overwhelmed.

Hopefully, some of these feelings will lessen as you learn more about breast cancer, its diagnosis, and its treatment. You may gain a sense of control when you have the knowledge to make educated choices that are right for you. And, you may find hope in knowing that in the United States alone, there are over two million women living with breast cancer.

This booklet will help you understand and cope with female breast cancer.

Its purpose is to:

- Explain breast cancer, its risk factors, and prevention.
- Discuss the impact breast cancer may have on your life, and how it can be treated.
- Describe what doctors and other health care professionals know about treating breast cancer today.

This guidebook is divided into sections. To the left is the Table of Contents that can direct you to these various sections. If you have questions after reading this, you may want to write them down in the Notes section at the back. Then you can ask your doctor or health care professional these questions at your next visit.

We hope you find this booklet to be a useful resource, and we wish you all the best.

In the
United States alone,
there are over
two million women living
with breast cancer.

Words in *italics* are defined briefly in the text, and more completely in the Glossary at the back of the guide.

The Breast

A breast is made up of *lobules*, *ducts*, fatty tissue, blood vessels, *lymph vessels*, muscles, and nerves. The lobules are tiny sacs that make milk during breast feeding. There are about one million lobules in each breast. The ducts are tubes that carry the milk from the lobules to the nipple. The fatty tissue surrounds the lobules and ducts to provide support. Lymph vessels carry *lymph* to *lymph nodes* in the underarm, above the collarbone, and in the chest. There are also lymph nodes throughout the body. Figure 1 shows the parts of the breast.

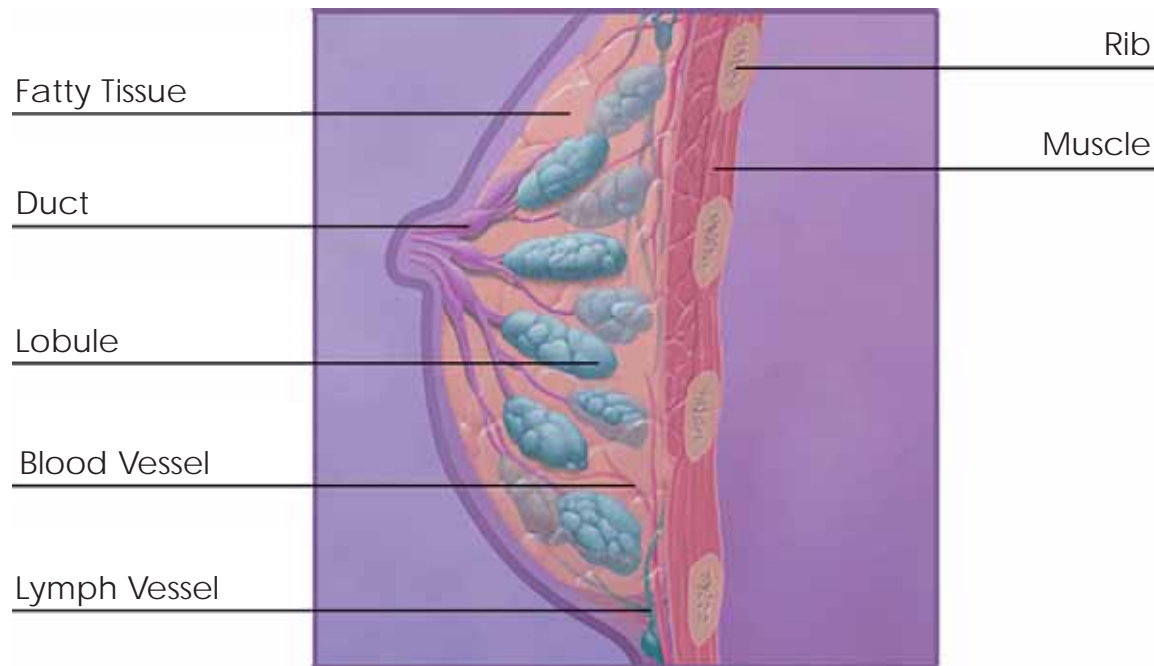


Figure 1: Illustration of the Breast

What Is Breast Cancer?

The body is made up of billions of cells that form our tissues and organs. In most organs, cells are replaced on a regular basis, allowing each organ to continue to function normally. During this process, cells that die are replaced by new cells.

Breast tumors

Occasionally, cells are replaced by abnormal cells, which grow in an uncontrolled way. As a result, there is an abnormal growth or lump of cells that form a *tumor*. As they increase in size, benign tumors can present as a lump in the breast.

There are two kinds of breast tumors: noncancerous tumors (*benign*) and cancerous tumors (*malignant*).

Benign breast tumors are not cancerous. They are made up of tumor cells that do not spread outside the breast in which they appear.

Malignant breast tumors are cancerous and are made up of cells that can spread from the breast to other parts of the body. Because of their ability to spread and grow in other organs, malignant breast tumors can interfere with normal body functions and be life-threatening.

How do breast cancer cells spread to other parts of the body?

Breast cancer cells can *metastasize* or break away from the main malignant tumor and travel to other parts of the body, commonly to the bones, liver, lungs, or brain. The blood and lymph are body fluids that can carry these cancer cells from the main tumor to other parts of the body.

If breast cancer spreads or metastasizes to other body parts, it is still considered breast cancer in that new site. For example, if breast cancer spreads to the lungs, the tumor in the lung is not lung cancer but breast cancer that has metastasized.



Figure 2: Normal Breast Cells versus Cancerous Cells

Breast Cancer Facts

Breast cancer is a malignant tumor that grows in one or both of the breasts. Breast cancer usually develops in the ducts or lobules of the breast. It is the most common cancer in women in the United States (US), and, after lung cancer, the second leading cause of cancer death in women. According to the American Cancer Society, over 200,000 women are diagnosed with breast cancer, and approximately 40,000 women die from the disease each year.*

African-American women have a slightly lower incidence of breast cancer after age 40 than Caucasian women, but they have a slightly higher incidence rate of breast cancer before age 40. However, African-American women are more likely to die from breast cancer at every age. Breast cancer is much less common in males. It's estimated that about 1,600 men are diagnosed with breast cancer in the US each year.*

Risk factors for breast cancer

There are various risk factors that may contribute to the development of breast cancer. Some have a stronger link to breast cancer than others. The following list describes some of the most significant risk factors for breast cancer.

Age. As a woman gets older, her risk for breast cancer increases.

Personal history of breast cancer. Having had breast cancer puts a woman at higher risk for developing it again.

Family history of cancer. The risk of breast cancer increases if a woman has a first-degree relative (mother, sister, or daughter) who had breast or ovarian cancer.

Genetics. There are inherited genetic mutations that increase the risk of breast cancer. Alterations in the *BRCA1* and *BRCA2* genes are found in about 5% to 10% of breast cancer cases. Women with alterations in these genes have up to an 85% chance of developing breast cancer in their lifetime.*

It's estimated
that more than 200,000
women will be diagnosed
with breast cancer
in the US each year.

High breast tissue density. The higher the breast tissue density the greater risk for breast cancer. Breast tissue density is generally higher when the breast has more ducts and lobules versus fat.

Breast hyperplasia. *Hyperplasia* is an increase in the growth of cells in a tissue, such as breast tissue. Breast hyperplasia can be detected only by taking a sample of the breast tissue and examining it under a microscope. Breast hyperplasia increases a woman's chance of developing breast cancer.

*Source: American Cancer Society Facts and Figures, 2005.

There are other risk factors that may contribute to the development of breast cancer.

These include:

A long lifetime exposure to estrogen. During puberty, estrogen levels dramatically increase. During menopause, estrogen levels decrease. The longer the time the breasts are exposed to estrogen, the higher the risk for developing breast cancer. Therefore, breast cancer risk may be higher in women who started menstruating before 12 years old or in women who went through menopause after 55 years old. Risk may also be higher in women who have taken oral contraceptives or hormone replacement therapy. Since estrogen strengthens bone, women with high bone mass may have a higher risk of breast cancer.

Not having children, or having a first child after 30. These factors may increase a woman's risk of developing breast cancer, since estrogen levels are lower during pregnancy. Also, not breast feeding may be a risk factor.

Radiation exposure. Prior radiation to the chest area increases the risk of breast cancer.

Having Ashkenazi Jewish heritage. These women may have an increased risk due to possible inherited gene mutations (such as in the BRCA1 or BRCA2 genes).

Other possible risk factors for breast cancer may include:

- Being overweight.
- Not exercising.
- Drinking alcohol. Drinking one or more alcoholic beverages per day can result in a slight increase in risk.



Risk-Reduction Strategies

Strategies to reduce the risk for breast cancer (sometimes called prevention) involve taking steps to try to lower the risk, or chance, of developing breast cancer. If you have multiple risk factors and are determined by your physician to be at high risk, there may be things you can do to lower your chance of developing breast cancer.

Lifestyle changes: Being overweight and inactive are considered risk factors. You may possibly reduce your risk for developing breast cancer by keeping to an ideal weight and doing regular exercise.

Genetic testing: To determine if a woman is at extremely high risk for developing breast cancer, *genetic testing* may be done to look for inherited genetic mutations that increase the risk for breast cancer. Genetic testing may help to determine if the cancer risk in a particular family has been passed down through the genes. The family member with breast cancer would be the first to undergo genetic testing.

Blood is tested for alterations in genes that are known to increase the risk of breast cancer, such as BRCA1 and BRCA2. Alterations in the BRCA1 and BRCA2 genes are found in about 5% to 10% of breast cancer cases. Women with alterations in these genes have up to an 85% chance of developing breast cancer in their lifetime. BRCA1 and BRCA2 are the only currently identified gene mutations for breast cancer. Research is constantly being done to identify other possible, genetic alterations that may be linked to breast cancer.



Whether or not to have genetic testing is a difficult decision. You need to consider what you will do if you are found to be at high risk for developing breast cancer. If you were to test positive for either BRCA1 or BRCA2, you have options. Testing positive for these genes does not mean that you have breast cancer. Nor does it mean that you will definitely get breast cancer.

Knowing you are at risk for developing breast cancer may help you to make lifestyle changes such as diet and exercise, be more aware of changes in your body, and to be more dedicated to breast cancer screening.

Increased screening: You may choose to be monitored more often for signs of breast cancer (*mammograms* and/or other imaging tests such as *MRI* or ultrasound, or clinical breast exams).

Double mastectomy: You may choose to have a double mastectomy, which means both breasts are removed. This may not totally eliminate your chance of developing breast cancer, as not all breast tissue can be removed. Some women who have already developed breast cancer in one breast may choose to have a double mastectomy to reduce the risk of breast cancer coming back in the other breast.

Hormonal treatments: Breast cancer prevention clinical studies look for possible treatments to lower the chance of developing breast cancer. These studies usually involve women who have not had breast cancer but are at high risk for developing the disease. Researchers look for effective treatments to reduce the risk for breast cancer in women of different races and backgrounds. The majority of breast cancer prevention research is based on evidence linking the development of breast cancer to exposure to the hormone estrogen. Ongoing breast cancer prevention studies focus on the effectiveness of *hormonal treatments*. You can read more about hormonal treatments in the section entitled Types of Hormonal Treatments on page 30.



What Are the Different Types of Breast Cancer?

There are several different types of breast cancer that can be divided into two main categories – *noninvasive breast cancers* and *invasive breast cancers*. Noninvasive cancer may also be called *carcinoma in situ*. Noninvasive breast cancers are confined to the ducts or lobules and they do not spread to surrounding tissues. The two types of noninvasive breast cancers are ductal carcinoma in situ (referred to as DCIS) and lobular carcinoma in situ (referred to as LCIS).

Noninvasive Breast Cancer	Invasive Breast Cancer
<p>There are approximately 58,000 new cases of noninvasive breast cancer in the US each year. Of these, approximately 85% are DCIS. In DCIS, the cancer cells are found only in the milk <i>duct</i> of the breast. If DCIS is not treated, it may progress to invasive cancer.</p> <p>In LCIS, the abnormal cells are found only in the lobules of the breast. Unlike DCIS, LCIS is not considered to be a cancer. It is more like a warning sign of increased risk of developing an invasive breast cancer in the same or opposite breast. While LCIS is a risk factor for invasive cancer, it doesn't actually develop into invasive breast cancer in many women.</p>	<p>There are over 200,000 new cases of invasive breast cancer in women in the US each year. Invasive or infiltrating breast cancers penetrate through normal breast tissue (such as the ducts and lobules) and invade surrounding areas. They are more serious than noninvasive cancers because they can spread to other parts of the body, such as the bones, liver, lungs, and brain.</p> <p>There are several kinds of invasive breast cancers. The most common type is invasive ductal carcinoma, which appears in the ducts and accounts for about 80% of all breast cancer cases. There are differences in the various types of invasive breast cancer, but the treatment options are similar for all of them. For more information, please see the Treatment Options section.</p>

What Are the Signs and Symptoms of Breast Cancer?

In the early stages, breast cancer may not be painful and there may be no symptoms at all. As the cancer grows you may start to notice changes in the breast or underarm such as a lump.

Signs and Symptoms of Breast Cancer

- Lumps. Breast cancer lumps vary and may be hard or soft and have rounded or uneven edges.
- Swelling of part of the breast.
- Skin irritation or dimpling.
- Nipple pain or the nipple turning inward.
- Redness or scaliness of the nipple or breast skin.
- Nipple discharge other than breast milk.
- A lump in the underarm area.

These signs and symptoms do not necessarily mean that you have breast cancer. However, you should tell your doctor about any lump or any changes in the skin of the breast, nipple, or areola (the round area of dark-colored skin around the nipple).

The earlier you detect breast cancer, the sooner it can be treated and the better it responds to therapy. Because there may be no symptoms of breast cancer in its early stages, the American Cancer Society (ACS) suggests other techniques and tests for early detection.



How Is Breast Cancer Detected?

The American Cancer Society (ACS) has written guidelines for the early detection of breast cancer in women who don't have symptoms of breast cancer. The ACS recommends the following.

Mammogram. Women 40 years and older should have a screening mammogram every year. If you are younger than 40 years and have a family history of breast cancer or other concerns, discuss with your doctor when to begin screening.

A *mammogram* is an x-ray of the breast. During a mammogram, your breast is placed between two plates and compressed as the x-ray is taken. You may feel discomfort as the plates press on the breast, but it will last only a few seconds. A doctor will read the mammogram and look for abnormalities. If the doctor detects any abnormality or change in the mammogram, you may have to undergo additional testing.

A mammogram can detect many but not all cases of breast cancer. The routine use of screening mammograms has resulted in an increase in the number of breast cancers found before symptoms ever develop.

Other types of breast imaging include:

Breast Magnetic Resonance Imaging (MRI).

Magnetic resonance imaging, or MRI, uses magnetic fields instead of x-rays to create a picture. An MRI produces clearer images of your breast to help detect abnormalities.

Ultrasound. An *ultrasound* is used to determine if a lump is a solid mass or a fluid-filled cyst. It uses sound waves to create a picture of body tissues and fluids. Clinicians use ultrasound to help if a lump is normal or abnormal.

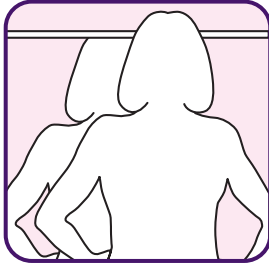
Clinical Breast Exam. Women between 20 and 39 years old should have a clinical breast exam by a health care professional at least every three years. Women 40 and older should have a clinical breast exam every year.

A *clinical breast exam* is a physical exam done by a health care professional such as a physician, nurse practitioner, or physician's assistant. The clinician will look at the breasts for any changes in size, shape, color, or smoothness. He or she will then closely feel each breast and underarm for any lumps or abnormalities. If there are any unusual findings, the clinician may recommend additional testing. This exam may reveal abnormalities that could be missed by a mammogram.

Monthly Breast Self-Exam. Women 20 years and older should do a monthly breast self-exam.

A *breast self-exam* (BSE) is similar to a clinical breast exam, except that you do the test on yourself. The ACS recommends a monthly BSE so that women can become familiar with how their breasts normally feel, so it's easier to detect any changes. It's best to do a BSE when the breasts aren't swollen or tender. You should tell your doctor right away if you find any changes in your breasts. You will most likely need a clinical breast exam and additional testing (such as a mammogram).

Breast Self-Exam: Do It Yourself



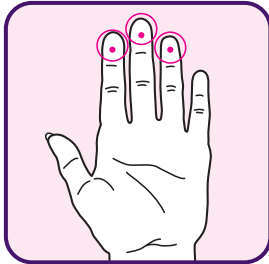
Before a mirror

1. Firmly press your hands down on your hips to tighten your chest muscles. Look carefully for any changes in the size, shape, or contour of your breasts. Check for anything unusual—discharge, puckering, dimpling, or changes in skin texture.

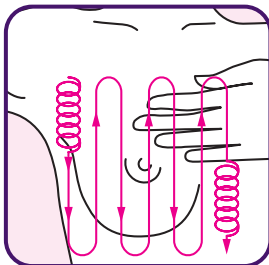


Lying down

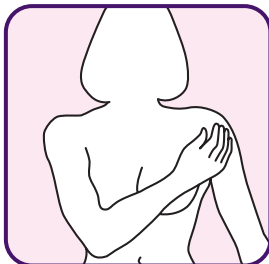
2. Lie flat on your back and place your left hand behind your head and a pillow under your left shoulder. Use the finger pads of the 3 middle fingers on your right hand to make overlapping dime-sized circular motions to feel your left breast.



Apply 3 different levels of pressure—light, medium, and firm—with your finger pads to check the breast tissue. Use each pressure level to feel for lumps before moving to the next spot. Start by your armpit, and move down to just below your breast.



Use the same circular motions using an up-and-down pattern to cover the entire breast area. Repeat on your right breast using your left hand.



Sitting or standing

3. Raise arm slightly. Use the same circular motions with your finger pads to examine each underarm.

This self-exam is not a substitute for periodic exams by a qualified doctor. Report any lumps or changes to your doctor.

How Is Breast Cancer Diagnosed?

Breast self-exams, clinical breast exams, and imaging techniques (such as mammogram, MRI, or ultrasound) can detect abnormalities or changes in the breast that may suggest cancer. They do not provide exact information to tell what those abnormalities or changes are. To diagnose or confirm the presence of cancer, a sample of cells must be taken from the tumor. A *biopsy* is the removal and examination of a tissue sample from the tumor to determine if it is cancerous. Biopsies can be done in several ways depending on the size and location of the tumor. There are surgical biopsies or needle biopsies.

A surgical biopsy is a short procedure that lasts about an hour using a local or general anesthetic. You may also be given a medication that will make you feel relaxed and drowsy. The physician then makes an incision into the breast and removes all of the tumor or irregular tissue (*excisional biopsy*) or just a part of the lump or tissue (*incisional biopsy*).

A needle biopsy is less involved than a surgical biopsy and may be done in the doctor's or radiologist's office. A local anesthetic may be used to numb the breast tissue. A needle is inserted into the tumor in the breast. A *fine needle aspiration* uses a smaller needle to remove a sample of cells, and a *core biopsy* uses a larger needle to remove a piece of tissue.

The biopsy tissue is sent to a *pathologist* who examines it under a microscope to determine if

there are cancer cells present. If the tissue contains cancer cells, the pathologist will also determine what type of breast cancer it is and the grade, or how much the cancer cells differ from normal cells. A report will be sent to your doctor, who will discuss the results with you. It may take several days until the results are made available to your doctor.

Once cancer cells are detected, tests are performed to determine the clinical stage of your cancer.

A biopsy is the removal and examination of a tissue sample from the tumor to determine if it is cancerous.

Common tests to determine tumor characteristics

Tumor Marker Testing

The tissue that was taken for the biopsy (which was used to diagnose breast cancer) will be examined for the presence of certain “tumor markers.” Tumor markers are special proteins that may be on the surface or inside cancer cells. In breast cancer, tumors are tested for *hormone receptors* and *HER2/neu*. The status of tumor markers can help predict how the cancer will respond to certain treatments.

Hormone receptor (HR) testing checks for the presence or absence of estrogen and/or progesterone receptors on the cancer cells. Some breast cancers have *estrogen receptors* and are called estrogen receptor positive (ER+). Cancers that are ER+ use estrogen to grow and may respond to hormonal treatment that blocks or decreases estrogen. Some breast cancers have *progesterone receptors* and are referred to as progesterone receptor positive (PR+ or PgR+). PgR+ cancers use progesterone to grow and these too may respond to hormonal treatment. The majority of breast cancers are ER+ and PgR+, but some are ER and/or PgR negative. HR+ tumors appear to grow less aggressively than those that are HR-.

HER2/neu is a protein (receptor) on breast cancer cells. Some breast cancer cells overproduce the HER2/neu protein and are called HER2/neu positive. HER2/neu-positive cancers may respond to therapy that targets the HER2/neu protein and may respond better to certain types of *chemotherapy*.

If breast cancer is diagnosed, you may be referred to a *medical oncologist* who specializes in the medical treatment of cancer. Additional tests will be needed to determine specific tumor characteristics, tumor size, and location, and if it has spread to other parts of the body. You may have one or more of these additional tests during the course of diagnosis and treatment, but you may not undergo all of them. Talk to your doctor about which tests are needed.

How Is Breast Cancer Diagnosed? (continued)

Common tests to help determine the clinical stage of cancer

Physical Exam

Your doctor will perform a complete physical exam to determine your general health and to look for signs that cancer has not spread to other parts of your body. This includes examination of lymph nodes, lungs, liver, and skin.

Blood Tests

Blood tests are commonly performed to check the liver and bones for any potential signs of cancer spread (*metastases*). Blood tests may also be performed to assess your overall health.



Chest X-Ray

A chest x-ray uses small amounts of radiation to take a picture of the inside of your chest. It may be used to see if the breast cancer has spread to your ribs or lungs.

Bone Scan

A bone scan is used to check the bones for metastases. If breast cancer has spread to the bones, it would likely be detected on a bone scan.

Computed Tomography (CT) Scan

Computed tomography scan, also known as a CAT or CT Scan, is similar to an x-ray, but it gives a more detailed picture. It can detect extremely small tumors that may not be seen on an x-ray. Also, it may help your doctor determine whether or not the breast cancer has spread into the surrounding lymph nodes, liver, lung, or bones.

Positron Emission Tomography (PET) Scan

Positron emission tomography, or PET scan, determines the way the body's cells act in the presence of sugar. Normal cells take in sugar and use it to make energy. Cancer cells usually take in more sugar than normal cells. You will be given a special type of sugar before the test. The PET scan will detect the presence of tumors by detecting hot spots, which are bright-colored areas on the picture where the sugar has been taken in by cells. The more sugar the tumor takes in, the more likely it is a cancer. A PET scan is useful in detecting cancer that has spread outside of the breast.

The Stages of Breast Cancer

Early breast cancer

The term “early breast cancer” refers to stages of breast cancer labeled 0, I, II, and IIIA.



Stage 0

Cancer cells are present in either the lining of a breast lobule or a duct, but they have not spread to the surrounding fatty tissue. This stage is also called ductal carcinoma in situ, or DCIS.



Stage I

Cancer has spread from the lobules or ducts to nearby tissue in the breast. At this stage and beyond, breast cancer is considered to be invasive. The tumor is 2 cm or less in diameter (approximately 1 inch or less); the cancer has not spread to the lymph nodes.



Stage II

In this stage, the tumor can range from 2 cm to less than 5 cm in diameter (approximately 1 to 2 inches); sometimes cancer may have spread to the lymph nodes.

Stage IIIA

In this stage, the tumor is 5 cm or greater in diameter (approximately 2 inches or greater); or the tumor may be of any size where cancer cells have grown extensively into axillary (underarm) lymph nodes.

Advanced stages of breast cancer.

The term “advanced breast cancer” refers to stages of breast cancer labeled IIIB and IV.



Stage IIIB

Known as locally advanced cancer; tumor may be of any size, but has spread into the skin of the breast or tissues of the chest wall.



Stage IV

Known as metastatic; cancer has spread from the breast to other parts of the body, such as bone, liver, lung, or brain.

Understanding the Risk for Recurrence for Early Breast Cancer

Risk for Recurrence

Even after initial treatment for early breast cancer, it's possible that breast cancer can come back (recur). *Recurrence* is the term used to describe the return of cancer following primary (initial) treatment, either at the same site as the original tumor or somewhere else in the body. Just like tumor markers and clinical stage, an individual's risk of recurrence may affect the treatments they receive. (See What are the Different Treatment Options for Breast Cancer section starting on page 20 for additional information.)

Local recurrence occurs in the breast where the cancer first started, or in the skin and underlying tissues where the breast used to be. This type of recurrence can happen even if you've had a mastectomy.

Regional recurrence occurs in the lymph nodes near the affected breast. These regional lymph nodes include nodes found under the arm (axillary nodes), in the neck, and those in the chest wall.

Distant recurrence occurs in other parts of the body, such as the bones, liver, lungs, or brain.

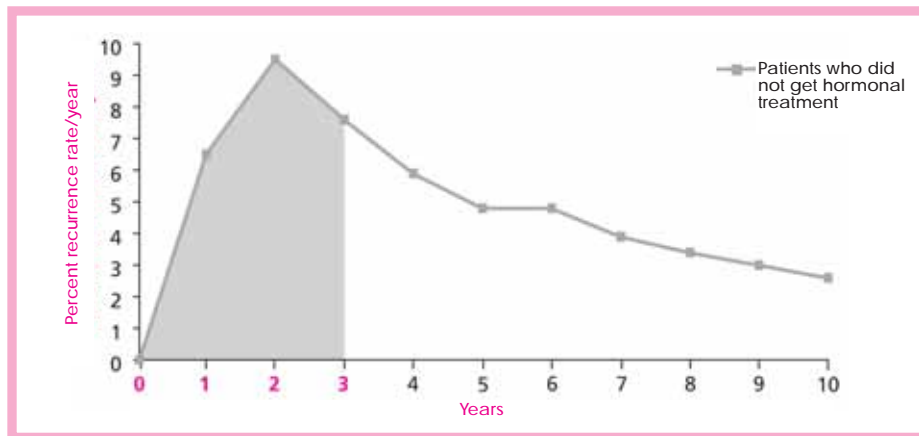
The risk for recurrence can be between 20% and 50% by five years after diagnosis. Doctors assess your risk for recurrence by looking at several factors.

Factors that help determine the risk for breast cancer recurrence

- **Cancer cells in the lymph nodes:** Surgeons often remove some of these nodes in the underarm area to see if cancer cells are present. Women with cancer cells in their lymph nodes (node positive) are more likely to have a recurrence than women who do not have cancer cells in their nodes (node negative). The number of lymph nodes in which cancer is found is also an important factor.
- **Size of the tumor:** In most cases, the smaller the tumor, the lower the risk for recurrence.
- **Cancer grade:** Doctors use a microscope to determine how cancer cells look. The more cancer cells resemble normal cells, the lower the grade and the lower the risk for recurrence.
- **Cell growth rate:** Cancer cells that grow more slowly are linked to a lower risk for recurrence.
- **Hormone receptor status:** About two-thirds of all breast cancer tumors are hormone receptor positive. Women whose tumors are hormone receptor positive have a lower risk for recurrence than women whose tumors are hormone receptor negative.

A woman's risk for breast cancer recurrence is highest in the first 5 years following diagnosis, peaking within the first 3 years. The chart* below shows the risk for breast cancer recurrence in each year during the 10-year period after diagnosis of early breast cancer in patients who received no adjuvant treatment (treatment following surgery with or without radiation).

Greatest risk for recurrence is in the first 5 years after diagnosis.



For women with early breast cancer who do not take hormonal treatment following surgery, the risk for recurrence peaks in the first three years after diagnosis of early breast cancer.

The data in the chart above were derived by evaluating results from 55 clinical trials involving 37,000 patients. All trials began before 1990. When results from different studies are combined and evaluated in this way, it is called a “meta-analysis.”

The Early Breast Cancer Trialists’ Collaborative Group (EBCTCG) conducted the meta-analysis of these 55 trials.

The more you know, the more you’ll be able to make informed decisions about your care. You can learn more about factors that affect risk for recurrence at the Web site for the National Cancer Institute at http://cis.nci.nih.gov/fact/7_20.htm.

*Source: Early Breast Cancer Trialists’ Collaborative Group. Tamoxifen for early breast cancer: an overview of the randomized trials. *Lancet*. 1998;351:1451-1466.

What Are the Different Treatment Options for Breast Cancer?

There are many factors that need to be considered when selecting a treatment plan, including stage of disease, tumor *histology*, new diagnosis versus recurrence, tumor marker status, menopausal status, patient's age, prior treatment(s), and patient's overall health and lifestyle. Patient preference for treatment may play an important role in the decision-making process, especially in certain situations in which the survival rates are similar for different treatment options.

There are several different options for treating breast cancer and for reducing the risk for recurrence. The following table lists the most common initial treatment options for patients with newly diagnosed or recurrent breast cancer.

Initial Disease Stage at Diagnosis	Most Common Initial Treatment Options
Stage 0 or DCIS	Surgery ± radiation ± hormonal treatment
Stage I, II, and IIIA	Surgery + lymph node dissection if node-positive ± radiation ± chemotherapy ± hormonal treatment
Stage IIIB	Chemotherapy to shrink the tumor before surgery + surgery + radiation ± postsurgical chemotherapy ± hormonal treatment or Chemotherapy ± radiation ± hormonal treatment
Stage IV	Hormonal treatment ± chemotherapy or <i>Palliative care</i> to reduce breast cancer symptoms
Recurrence (local, regional, or distant)	Hormonal treatment ± chemotherapy ± novel targeted therapy

While there are several different ways to treat breast cancer, all options can be divided into two categories: *local therapy* or *systemic therapy*.

Local therapy is directed only at the cancer cells in the breast area. Surgery and radiation are the two local therapies for treating breast cancer. Local therapies only treat a specific area of the body and they are often used in combination with systemic therapy. Systemic therapy may be used to help reduce the risk for recurrence after local therapy is completed.

Systemic therapy is the use of medications that travel in the bloodstream to affect or treat cancer cells. Systemic therapies are often used in combination with local therapy in early breast cancer. It may also be used alone in more advanced stages when cancer has spread to other parts of the body. Hormonal treatment, chemotherapy, and novel targeted therapy are the different types of systemic therapies used to treat breast cancer.



Local Therapy

Surgery

Surgery is the most common local treatment for early breast cancer. Depending on the stage of cancer, tumor markers, and your overall health, radiation, chemotherapy, and/or hormonal treatment may be used in combination with surgery. If the cancer has spread to other parts of the body, surgery is generally not an option. The following are brief descriptions of the various types of surgeries to treat breast cancer.

Lumpectomy. The removal of only the tumor and some surrounding tissue. It is usually done for DCIS and smaller invasive tumors. Depending on the amount of tissue removed, the breast may look virtually unchanged. A lumpectomy is also called *breast-conserving surgery* or a partial mastectomy. A lumpectomy is almost always followed by radiation therapy.

Total or simple mastectomy. The removal of the entire breast but not lymph nodes or muscle.

Modified radical mastectomy. The removal of the breast and some lymph nodes under the arm. The surgery is used to remove cancer that may have spread to nearby lymph nodes.

Radical mastectomy. The removal of the breast, lymph nodes, and the muscle underneath the breast. This surgery is less common but may be used for tumors that extend to the chest wall.

Sentinel lymph node biopsy. The removal of a few lymph nodes through a small incision. This procedure is less extensive than axillary lymph node surgery. In this procedure, a radioactive dye is injected into the breast near the tumor. The dye travels from the tumor to the underarm. The first lymph node it comes to is the sentinel lymph node. The sentinel lymph node and a few other nearby lymph nodes are removed through a small incision and sent for testing. If cancer cells are found in the sentinel node, then an *axillary lymph node dissection* is usually done. If cancer cells are not found, it is likely that the cancer has not spread and an axillary lymph node dissection is not needed.

Axillary lymph node dissection. The surgical removal of most of the lymph nodes under the arm. The lymph nodes in the armpit area can be removed through the same incision as the mastectomy. With a lumpectomy, a separate incision is needed to remove the lymph nodes under the arm.

Breast reconstruction. Surgery that is done to recreate the appearance of a breast in women who have had a mastectomy. Depending on preference, body type, and overall physical condition, the surgeon may use breast implants (such as silicone or saline) and/or tissue from other parts of your body (such as your abdomen) to reshape the breast. Breast reconstruction may be done during the mastectomy or it may be done at a later time. If you're thinking about reconstructive breast surgery, you should talk to your doctor about your options and concerns.

What should I expect with surgery?

Lumpectomy

Possible effects from lumpectomy may include:

- Pain or tenderness at the site of surgery
- Reaction to anesthesia (such as nausea or vomiting)
- Some bleeding, bruising, or swelling at the site of surgery

Mastectomy

Possible effects from mastectomy may include:

- Numbness and tenderness around the incision
- Fluid collection under the scar, which your doctor may remove with a needle
- Infection in the surgical area, which is usually discovered early and responds well to treatment

Lymph Node Surgery

The removal of lymph nodes from the underarm may prevent proper drainage of the lymph fluid from the arm to the rest of the body. As a result, lymph fluid may build up in the arm, which is called *lymphedema*. The accumulation of lymph fluid in the hand and arm can result in swelling, which could lead to numbness and pain. It can occur immediately after surgery or years later. Most women do not develop lymphedema following lymph node dissection, and it is not possible to predict who will develop it. Lymphedema is a permanent condition that may be manageable through specific exercises, massage, and compression sleeves.

Aside from the physical effect of the surgery, there are emotional and psychological effects of having a breast removed or visually altered. You should discuss these concerns with your doctor both before and after surgery.

Breast reconstruction may be done during the mastectomy or it may be done at a later time.



Local Therapy (continued)

Radiation Therapy

Radiation therapy or *radiotherapy* uses x-rays to kill breast cancer cells. Radiation therapy is often used in combination with surgery for early breast cancer. It may be used to shrink the tumor before surgery, or eliminate any tumor cells that may remain after surgery. Depending on the stage of cancer, radiation may be used alone or with hormonal treatment and/or chemotherapy.

Here are some other important facts about radiation therapy:

- After lumpectomy, radiation is directed at the breast and an additional boost is given to the incisional site.
- After mastectomy, radiation may be used depending on lymph node status.
- For metastatic disease, some patients may also receive radiation therapy to treat an area where the cancer has spread. For example, if the breast cancer has spread to the bones and is causing pain, radiation to the bone may lessen the bone pain.
- If surgery cannot be performed, radiation may still be used.

Most side effects from radiation can be improved with medications and will usually lessen after treatment is completed.





How is radiation given?

There are two ways in which radiation can be given: external beam radiation and a type of internal radiation called *brachytherapy*.

External beam radiation is the most common type of radiation used for the treatment of breast cancer. With external beam radiation, you're positioned under a machine that sends x-rays toward the tumor. The radiation only lasts for a few minutes at each session, and is usually given once daily for five days a week for up to six to eight weeks.

Brachytherapy is a form of internal radiation therapy. During this treatment, your doctor will temporarily place the source of radiation inside of your breast where the tumor was removed. This source is a small implant that gives off radiation to a localized area of tissue.

What are the side effects of radiation?

Side effects will be different for every patient and they may continue for several months after radiation treatment is over. Most side effects can be improved with medications and will usually lessen after treatment is completed. Make sure you tell your doctor if you experience any of these side effects:

- **Skin redness.** Your skin's reaction to radiation will be localized to the area of the x-ray beam and will be similar to a sunburn – with pinkness or redness, itching, burning, soreness, and possible peeling – although it will probably develop more slowly than a sunburn. If you develop blisters and if they become infected, your radiation oncologist may recommend taking a short break in treatment to allow for skin recovery. Radiation-induced skin irritation may worsen for about a week after treatment has ended but will then begin to improve.
- **Fatigue.** A feeling of overall exhaustion affects many patients who undergo radiation treatment. To counter or limit the effects of this treatment-induced fatigue, try to do some moderate daily exercise to energize the body. Rest when you need to during the day, and ask for help with chores that make you feel tired.
- **Swelling and soreness.** During radiation treatment, your breast may feel swollen, sore, tender, or numb. These unpleasant sensations will gradually disappear over time, although in some cases they may not go away completely. You may also feel pain in the chest wall area, which will get better once treatment is over.

Systemic Therapy

Surgery and radiation are the two local therapy treatment options for breast cancer. These are almost always used in combination with a systemic therapy such as:

- chemotherapy
- hormonal treatment
- novel targeted therapy

Systemic therapies may be given before and/or after a local therapy depending on the stage of disease. When a systemic therapy is used before surgery or radiation it is called *neoadjuvant therapy*. Neoadjuvant therapy may reduce the size of the tumor so it is easier to remove during surgery or easier to treat with radiation. In some cases, neoadjuvant therapy may reduce the tumor size so it's small enough to allow for breast-conserving surgery (lumpectomy) versus a mastectomy.

When systemic therapy is used immediately after surgery or radiation it is called *adjuvant therapy*, meaning “in addition to.” Adjuvant therapy may kill any cancer cells that remain in the body after surgery or keep them from growing and spreading to other parts of the body. The purpose of adjuvant systemic therapy is to reduce the risk for recurrence (see Risk for Recurrence on page 18).

Adjuvant therapy may kill any cancer cells that remain in the body after surgery.



Chemotherapy

Chemotherapy is the use of drugs to destroy cancer cells, particularly those that have spread to areas other than the breast. If given after surgery to kill any remaining cancer cells in the body, it is called adjuvant chemotherapy. If given before surgery to shrink the tumor before removal, it is called neoadjuvant chemotherapy. For tumors that have spread and cannot be removed by surgery, chemotherapy may be the main type of treatment.

The drugs used in chemotherapy are called *cytotoxic* drugs because they kill cells. The drugs circulate throughout the body in the bloodstream and may kill any rapidly growing cells, including cancer cells and some healthy cells. Chemotherapy drugs are carefully controlled in both dosage and frequency so that cancer cells are destroyed while minimizing the risk to healthy cells. Several different types of cytotoxic agents are used to treat breast cancer. The best results are usually obtained when several drugs are used together, which is known as combination chemotherapy.

How is chemotherapy given?

The drugs used for chemotherapy come in many different forms. While some are given directly into a vein (*intravenous*) or a muscle (*intramuscular*), others may be taken by mouth. Some of the drugs must be given in the doctor's office or clinic while others can be taken at home. Certain types of chemotherapy need to be given in the hospital because they require special monitoring of both the treatment and its possible side effects. There are many different chemotherapy drugs. Individual drugs work in

different ways, and they are often combined for increased effect.

Chemotherapy can be used for different stages of breast cancer. Depending on your disease, it may be used alone or in combination with surgery, radiation, and other systemic therapies.

What should I expect with chemotherapy?

Chemotherapy is administered in "cycles," with breaks between cycles that may help to reduce side effects. A cycle varies for different chemotherapy agents and different chemotherapy regimens. Chemotherapy regimens for breast cancer usually consist of four to eight cycles with each cycle ranging in length from 14 to 28 days. You may not receive chemotherapy on every day of a cycle, and you may not always receive the same drug or drugs on treatment days.

For example, you may receive one chemotherapy drug on day one of a cycle, while you may get a second chemotherapy drug in combination with the first drug on day 1 and by itself on day 8. Your doctor will determine what drug or combination of drugs is the most appropriate for you by considering your type and stage of breast cancer, previous treatments that you have received, other illnesses you may have, and the possible side effects of the therapy. You should talk to your doctor about how your chemotherapy will be given and what possible side effects you may experience with chemotherapy.

Systemic Therapy (continued)

Sometimes chemotherapy is given at a clinic or hospital over a period of several hours, so you will need to make arrangements to get to your scheduled appointments. Depending on the type of chemotherapy that you receive, you may be given “premedications” (medications given before the chemotherapy) to prevent certain side effects. You may also have to receive intravenous fluids before or after the chemotherapy.

What are the side effects of chemotherapy?

Chemotherapy drugs circulate throughout the whole body and they can affect both healthy and cancer cells. When healthy cells are affected you may experience side effects. The specific side effects depend upon which drugs and regimens are used. Common side effects may include hair loss, nausea, vomiting, diarrhea, a tingling or numbing sensation of the hands and feet, temporary or permanent loss of menstruation, blisters or sores in the mouth and throat, and a feeling of tiredness. More serious side effects include lowered blood counts, reduced ability of the blood to clot, an increased risk of infection, and heart or lung disorders. You may need to receive other medications to treat or prevent these serious side effects.

Some side effects occur temporarily or are more noticeable at the start of treatment. Many of the side effects disappear when the drugs are stopped. For instance, hair will grow back once chemotherapy is stopped. You should talk to your doctor about what side effects you may expect for your therapy and how to manage them if they occur.

Hormonal Treatment

Hormonal treatment is a way of treating breast cancer through the use of drugs to block the effect of estrogen or to reduce estrogen levels. Hormones, such as *estrogen* and *progesterone*, are naturally produced by organs in your body, and they affect bodily processes. Some breast cancer tumors need estrogen and/or progesterone to grow. These tumors are said to have receptors for the hormones estrogen and/or progesterone (see page 15). Breast cancer tumors that have these receptors are called estrogen receptor positive and/or progesterone receptor positive, also called hormone receptor positive. About two-thirds of women with breast cancer have tumors that contain estrogen receptors.

Lab tests of your cancer biopsy can give your medical team information about the hormone receptor status of your cancer. Hormonal treatment works best when the tumor cells are hormone receptor positive. For those cancers that are not hormone receptor positive, hormonal treatment usually has little effect and thus is generally not used.

The goal of hormonal treatment in early breast cancer is to reduce the risk for recurrence. In advanced breast cancer, the goal of hormonal treatment is to slow or delay disease progression.

Hormonal treatment is not the same as *hormone replacement therapy*. Hormonal treatment for breast cancer is used to block the effect of estrogen or to reduce estrogen levels. The goal is to keep estrogen from reaching cancer cells.

Hormone replacement therapy (also called HRT) is different in that it supplies estrogen to women to help to ease the symptoms of *menopause*. HRT should not be used if you have been diagnosed with breast cancer.

Hormonal treatment is not meant to take the place of surgery and/or radiation for early breast cancer. Rather, it is used before or after these initial treatments.

The goal of hormonal treatment in early breast cancer is to reduce the risk for recurrence.

Menopausal Status

A patient's menopausal status plays an important role in determining the appropriate type of hormonal treatment. *Menopause* is the stage in a woman's life when she permanently stops having periods. This usually happens naturally at about the age of 50. At menopause, the ovaries gradually become less active and eventually stop making estrogen. Menopause can also be brought on by the following:

- By removing the ovaries through surgery (oophorectomy)
- Following cancer chemotherapy
- Following radiation to the ovaries
- By using *luteinizing hormone-releasing hormone* (LHRH) agonists, a type of hormonal treatment that makes the ovaries stop working

Estrogen production is different between *premenopausal* women and *postmenopausal* women. In the body, estrogen production is controlled by a number of hormones made by the *hypothalamus*, *pituitary gland*, *ovaries*, and *adrenal glands*. In premenopausal women, estrogen production occurs mainly in the ovaries. In postmenopausal women, most of the estrogen production occurs in other body tissues. (This type of estrogen production also happens in premenopausal women but the amount of estrogen made by other body tissues is small compared to the amount of estrogen made by the ovaries.)

Because the ovaries produce more estrogen than other tissues in the body, premenopausal women have higher levels of estrogen in their bodies than postmenopausal women. One goal of treatment in premenopausal women is to make their ovaries stop producing estrogen by one of the methods previously described.

There are various types of hormonal treatments available, depending on your menopausal status. Some hormonal treatments may be used for premenopausal or postmenopausal women, while some are only for postmenopausal women. Hormonal treatments may be used in early breast cancer or advanced breast cancer. Your doctor will determine which type of hormonal treatment is right for you.

Systemic Therapy (continued)

Types of Hormonal Treatments

The main goal of hormonal treatment is to prevent your body's natural estrogen from reaching the cancer cells that depend on hormones to grow. This can occur by either blocking the effect of estrogen or reducing estrogen levels. There are several types of hormonal treatments used. These treatments differ in the way that they affect estrogen in your body. There are a number of side effects that may be associated with hormonal treatments based on their actions in the body. Knowing about these side effects and what may be done to help manage them can help you cope with treatment. Side effects of these medications may vary depending on the particular hormonal treatment used.

Antiestrogens

One type of hormonal treatment blocks the hormone's ability to reach the cancer cells and cause them to grow. These drugs are called *antiestrogens*, also referred to as *selective estrogen receptor modulators* (SERMs) or *estrogen receptor antagonists*.

These drugs work by blocking the ability of the estrogen to reach tumor cells that need estrogen to grow. These tumors are said to have receptors for the hormone estrogen. These receptors and

the estrogen fit together like the pieces of a puzzle would fit together. Once the estrogen fits into the receptor, the tumor cells are stimulated to grow. Antiestrogens work by binding to the receptor and preventing the estrogen from fitting into the receptor. This stops estrogen's ability to stimulate growth of the tumor cell. So even though estrogen is present, its activity is blocked.

Some antiestrogens may be used in both premenopausal women and postmenopausal women to prevent the tumor cells from getting the estrogen they need to keep growing. Some may be used for the treatment of early breast cancer or advanced breast cancer. Antiestrogens may be given in the form of a pill or injection.

Some of the most common side effects associated with the use of certain antiestrogens include, but are not limited to, hot flashes, vaginal discharge, vaginal bleeding, change in your periods, cancer of the uterus, blood clots in your veins or lungs, stroke, *cataracts* or increased chance of needing cataract surgery, and liver problems, including *jaundice*. Other possible side effects include gastrointestinal symptoms (including nausea, vomiting, constipation, diarrhea, and abdominal pain), headache, back pain, weakness, and sore throat. Not all of these side effects are seen with each different treatment. Talk to your doctor about what side effects you may expect and how you may be able to manage them if they occur. Make sure you tell your doctor if you experience any side effects.

When used as an adjuvant treatment for early breast cancer, antiestrogens should be used for a period of five years, or until your disease returns. When used as treatment for advanced breast cancer, antiestrogens should be used until your disease progresses.

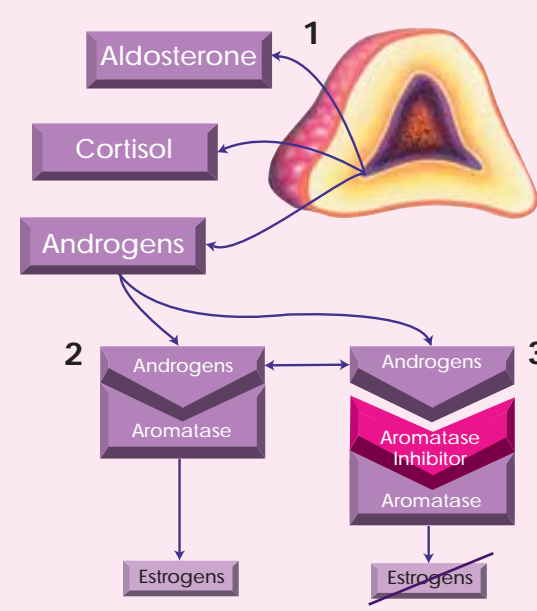
Aromatase Inhibitors

Another type of hormonal treatment works by reducing estrogen levels in your body. By reducing the amount of estrogen in your body, there is less estrogen available to stimulate tumor growth. One type of these drugs is called *aromatase inhibitors* (AIs). Hormones in your

body called androgens are changed into estrogen by an enzyme called *aromatase*. An aromatase inhibitor is a drug that blocks aromatase. Before menopause (premenopausal), your ovaries make most of your estrogen. After menopause (postmenopausal), you can still have estrogen in your body. AIs work by lowering the amount of estrogen in your body after menopause.

AIs should only be used in postmenopausal women. Since they do not stop the ovaries from making estrogen, they are not able to lower estrogen levels enough in premenopausal women to stop tumor growth. AIs are given as a pill. Some AIs may be used for the treatment of

How Aromatase Inhibitors Work



The diagram illustrates the biochemical pathway of androgen conversion to estrogen. At the top, a cross-section of an adrenal gland is shown with three arrows pointing to boxes labeled 'Aldosterone', 'Cortisol', and 'Androgens', labeled with a '1'. Below this, two boxes labeled 'Androgens' are shown. The left box is labeled '2' and contains an 'Aromatase' enzyme, with an arrow pointing down to a box labeled 'Estrogens'. The right box is labeled '3' and contains an 'Aromatase Inhibitor' (a red shape) bound to an 'Aromatase' enzyme, with a red 'X' over the arrow pointing down to a box labeled 'Estrogens', indicating that the conversion is blocked.

- 1** After menopause, estrogen is no longer produced by the ovaries. However, estrogen can still be produced by the adrenal glands, which are located above your kidneys.
- 2** The adrenal glands produce hormones, including aldosterone, cortisol, and androgens. A hormone is a substance produced by organs or cells in your body that affects bodily processes. The enzyme called aromatase converts androgens to estrogens in various parts of the body. Aromatase is found in muscle, fat, the liver, and also in breast tumors.
- 3** When an aromatase inhibitor (AI) is taken, it attaches to the aromatase enzyme. With an AI attached, aromatase cannot convert androgens to estrogens. That is why it is known as an aromatase inhibitor. An aromatase inhibitor actually lowers the amount of estrogen in your body. That means there is less estrogen to fuel the growth of cancer cells.

Systemic Therapy (continued)

early breast cancer or advanced breast cancer.

Some of the most common side effects associated with the use of AIs include, but are not limited to, hot flashes, joint problems, fatigue, weakness, mood changes, pain, nausea and vomiting, sore throat, depression, effects on bone (including fractures and decreased bone density), vaginal discharge, and vaginal bleeding. Not all of these side effects are seen with each different AI. Talk to your doctor about what side effects you may expect and how you may be able to manage them if they occur. Make sure you tell your doctor if you experience any side effects.

When used as adjuvant treatment for early breast cancer, the optimal treatment period for AIs is unknown. AIs should be stopped if your disease returns. When used as treatment for advanced breast cancer, aromatase inhibitors should be used until your disease progresses.

Luteinizing Hormone-Releasing Hormone Agonists

Luteinizing Hormone-Releasing Hormone Agonists (LHRH agonists) are a type of hormonal treatment that work by reducing estrogen levels in your body. LHRH agonists lower the amount of estrogen in your body by making your ovaries stop working. When your ovaries are not working, there is less estrogen available to cause tumor cells to grow. These agents are used to treat advanced breast cancer in premenopausal women (who still have functioning ovaries) and *perimenopausal* women (who have not yet reached menopause, but have changes in estrogen and other hormone levels). LHRH agonists may be used

for the treatment of advanced breast cancer. Some of the most common side effects associated with the use of

LHRH agonists include, but are not limited to, hot flashes, decreased sex drive, vaginitis, headache, tumor flare, mood changes, depression, and nausea. Talk to your doctor about what additional side effects you may expect and how to manage them if they occur. Make sure you tell your doctor if you experience any side effects.

When used as treatment for advanced breast cancer, LHRH agonists should be used as treatment until your disease progresses, or spreads.

Hormonal Treatment: Primary Adjuvant Therapy versus Extended Adjuvant Therapy

Hormonal treatment is commonly used as adjuvant therapy. This means that it is used immediately after surgery to remove the tumor and/or radiation to kill any remaining tumor cells.

Primary adjuvant therapy refers to the period of hormonal treatment immediately after surgery and/or radiation up to a length of five years.

Extended adjuvant therapy refers to the period of hormonal treatment after the initial five years of hormonal treatment (given as primary adjuvant therapy). There is published and ongoing research on the use of aromatase inhibitors as extended adjuvant therapy in women who have previously completed primary adjuvant therapy with an antiestrogen.

Use of Different Hormonal Treatments after Disease Progression

If the cancer does spread or progress during hormonal treatment, the use of another hormonal treatment that works in a different way may be an option. However, women who have not previously had an initial response to hormonal treatment would not be expected to have a response to further hormonal treatment.

Staying on Hormonal Treatment

For early breast cancer that is hormone receptor positive, hormonal treatment may help reduce your risk of breast cancer coming back. For advanced breast cancer that is hormone receptor positive, hormonal treatment may help slow the growth and spread of the cancer. The effectiveness of any medication has been tested and proven at a specific dose and dosing schedule. That's why it's important to take your hormonal treatment as prescribed by your doctor, unless your doctor tells you to stop. That means taking the correct amount of your medicine as often as prescribed, for as long as prescribed.

If you experience side effects while taking your hormonal treatment, be sure to tell your doctor about them as soon as you can. He or she may be able to help you manage some of the side effects.

Here are some ways to help you remember to take your hormonal treatment:

- Take it at the same time every day.
- Take it along with meals or other daily events, like brushing your teeth.
- Use special pillboxes that help you keep track, like the ones divided into days of the week. You can find these at any pharmacy.
- Ask people who are close to you to help by reminding you.
- Keep a “medicine calendar” near your medicine and make a note every time you take your dose.

Systemic Therapy (continued)

Novel Targeted Therapies

Researchers are constantly trying to find new ways to treat cancer. In recent years, scientists have been working to develop novel targeted therapies for the treatment of various cancers including breast, colorectal, and lung. Novel targeted therapies work differently from traditional chemotherapy and are designed to look for certain markers on cancer cells or work on specific pathways important for cell growth.

One type of targeted therapy is specifically used for the treatment of advanced breast cancer. This type of targeted therapy only works against breast cancer cells that make too much of a protein called HER2/neu. These cancer cells tend to grow more rapidly. This therapy works by binding to HER2/neu proteins (receptors) on tumor cells. This causes the HER2/neu proteins to stop working and the tumor cells are no longer able to grow. This type of therapy can also be given together with chemotherapy.

Some of the side effects associated with the use of targeted therapy include, but are not limited to, allergic reactions, heart-related problems, fever, diarrhea, infections, chills, increased cough, and headaches. Talk to your doctor about what side effects you may expect and how you may be able to manage them if they occur. Make sure you tell your doctor if you experience any side effects.

Palliative Care

Palliative care is meant to relieve common symptoms that patients may experience in more advanced stages of the disease. Some of these symptoms may include pain, shortness of breath, lack of appetite, weakness, anxiety, and depression. Some of these symptoms may be managed with appropriate medications. Hormonal treatments are an option as palliative care in some patients with advanced breast cancer. For example, LHRH agonists may be used for the palliative treatment of advanced breast cancer in premenopausal and

Discuss all treatment options with your doctors to decide which choices are best for you.

perimenopausal patients.

Palliative care is also an integral part of *hospice*. Hospice is a special type of care meant to provide comfort and support to patients and their families when a life-threatening illness such as cancer no longer responds to active treatment. Hospice care doesn't prolong life; nor does it hasten death.

Clinical Trials

You may be able to get additional options for treatment by participating in a clinical trial. A clinical trial, also known as a research study, is used to answer specific questions about a potential new type of treatment, or to study new ways of using an existing treatment.

The purpose of a clinical trial is to determine whether a treatment is safe in humans and effective in treating a particular disease or condition. This includes looking at the benefits, as well as the potential risks, of the treatment. Generally, clinical trials for cancer compare the standard treatment with a potential new treatment option. However, there may be some trials that compare the potential new treatment option with a placebo. A placebo is an inactive drug that contains no medicine and is sometimes called a sugar pill. Depending on the clinical trial, you could receive the potential new treatment, a standard treatment, or a placebo.

If you decide to participate in a breast cancer clinical trial, your health will be closely monitored, and you will be evaluated for any side effects you may experience from therapy. Participation in a trial may require more of your time because it could include several trips to the doctor's office or hospital, more tests, procedures, or hospital stays. You may be one of the first to receive a new treatment and you will gain the personal satisfaction of knowing that you are contributing to the advancement of cancer research.

You may want to discuss participation in a clinical trial with your physician so that you know all available options. Your doctor can help you determine if a clinical trial is right for you.

The purpose of a clinical trial is to determine whether a therapy is safe in humans and effective in treating a particular disease or condition.

The Health Care Professional's Role in Your Care

Many different health care professionals are involved in the diagnosis and treatment of breast cancer. These professionals are often experts in a specific area of care or treatment. The table below has a brief description of various health care professionals that you may see if you've been diagnosed with breast cancer. You may or may not see all of these people during your treatment. It's important to remember that you are at the center of this team of experts, and the more you learn about what they do, the more you can become an active participant in your treatment. Be sure to share your concerns and decisions with all of the professionals who are involved in your care.

Health Care Professional	Who are they?
Medical Oncologist	A physician who specializes in the medical treatment of cancer.
Surgical Oncologist	A physician who specializes in the surgical removal of cancerous tumors.
Radiation Oncologist	A physician specializing in the use of radiation therapy for the treatment of cancer.
Plastic Surgeon (breast reconstruction)	A physician who performs surgical restoration, reconstruction, correction, or improvement of the shape and appearance of the breast.
Lymphedema Specialist	A health care specialist with expertise in the management of <i>lymphedema</i> that may result from lymph node dissection.

Health Care Professional	Who are they?
Oncology Nurse	A registered nurse with training and experience in the delivery of cancer treatment.
Oncology Pharmacist	A pharmacist who is trained to prepare drugs that treat cancer and provide medicines that may decrease the side effects of treatment.
Social Worker	A trained professional who provides information on support services such as home care, support groups, and transportation, to help you cope with cancer.
Nutritionist	A trained professional who can help you manage your diet during and after cancer treatment.

Questions to Ask Your Doctor

It is important to ask questions. The more you know about your condition, the better equipped you and your family will be to make informed decisions about your treatment options.

Diagnosis

What stage is my breast cancer?

Has the cancer spread to my lymph nodes or to other parts of my body (metastasis)?

Am I node negative or node positive?

How does my nodal status affect my risk for recurrence?

Is this a new cancer or a recurrence?

If this is a recurrence of my previous breast cancer, is the recurrence local, regional, or distant?

What does this mean for my treatment and outlook?

What treatment choices are appropriate for my stage of cancer?

Are there any other medical issues I should know about that could affect my breast cancer treatment?

Tumor Testing

What kind of tests will be done on my tumor?

How will the test results affect my treatment options?

Is my breast cancer hormone receptor positive (estrogen and/or progesterone receptor positive)? Will this affect my treatment options?

Is my breast cancer HER2/neu positive? Will this affect my treatment options?

Surgery

What type of surgery do you recommend and why?

Are there other surgical options for me?

Can breast reconstruction be performed at the time of surgery or later?

What can I expect with surgery?

What are the side effects I can expect with surgery?

What do you recommend for managing the side effects of surgery?

Where will my surgery be done?

If done in the hospital, how long will I be there?

How long will it take to recover?

What type of help or care will I need at home?

After my surgery, what kind of follow-up care will I receive?

Radiation

Do you recommend radiation therapy and why?

How many radiation treatments will I receive?

How long will treatment take?

How will the radiation be given?

What are the side effects I can expect with radiation therapy?

What do you recommend for managing the side effects of radiation therapy?

After I finish radiation, what kind of follow-up care will I receive?

Chemotherapy

Do you recommend chemotherapy and why?

What type of chemotherapy do you recommend and why? Are there any other chemotherapy options that may be right for me?

How will the chemotherapy be given?

How many chemotherapy treatments will I receive?

How long will treatment take?

What are the side effects of chemotherapy? Will these side effects last a long time?

What do you recommend for managing the side effects of chemotherapy?

After I finish chemotherapy, what kind of follow-up care will I receive?

Hormonal Treatment

Do you recommend hormonal treatment and why?

What kind of hormonal treatment is best for me and why?

Are there other hormonal treatment options that may be right for me?

When will I start the hormonal treatment and how long will I need to take the hormonal treatment?

How will the hormonal treatment be given?

What are the side effects of hormonal treatment? Will these side effects last a long time?

What do you recommend for managing the side effects of hormonal therapy?

Will I need follow-up care after hormonal treatment? For how long?

Recurrence

What is my risk for recurrence?

What steps can I take to help reduce my risk of cancer from coming back?

What symptoms might indicate a breast cancer recurrence?

What is my risk for other types of cancer? Is there anything I can do to reduce that risk?

Will I need tests to screen for cancer? If yes, how often?

Do I need to change my diet? Can a nutritionist help me with this?

Can I start exercising? How often and at what level should I workout?

Resources

Below are some of the breast cancer organizations and Web sites that offer more information, as well as support and assistance for you, your family, and friends.

This list of resources is provided merely as a convenience. AstraZeneca takes no responsibility for the content of, or services provided by, these resources and makes no representation as to the accuracy or completeness of any information provided. AstraZeneca shall have no liability for any damages or injuries of any kind arising from the information provided.

Support

Breastcancer.org

www.breastcancer.org

Click on “Support and Community”

American Society of Clinical Oncology

1-703-299-0150

www.plwc.org

Click on “Community Center”

The National Coalition for Cancer Survivorship

1-877-NCCS-YES

www.canceradvocacy.org

Click on “Listen” to access “Cancer Survival Toolbox”

Y Me National Breast Cancer Organization

1-800-221-2141

www.y-me.org

Click on “I’m looking for support and services”

Treatment Options

American Cancer Society

1-800-ACS-2345

www.cancer.org

Click on treatment options or search for hormonal treatment

www.breastcancer-answers.com

Read the latest information about early-stage breast cancer and treatment options

Staying Committed to Your Treatment

www.canceradvocacy.org/resources/essential/heartmind

Tips for coping with side effects, health insurance, and communicating with your doctor

www.breastcancer.org/blth.html

Tips to help you remember to take your medication

These Web sites and many more can be accessed through www.bcknowledge.com.

Glossary

Adjuvant therapy (ad'ju-vant): therapy that is given immediately after radiation or surgery in order to destroy any cancer cells that may remain.

Adrenal glands (ah-dre'nal): small glands located on the top part of each kidney. They receive chemical signals from the pituitary gland and they produce estrogen.

Anti-estrogen: any medication that blocks estrogen from reaching and stimulating breast cancer cells.

Aromatase (ah-ro'mah-tas): an enzyme in the body that is needed to make estrogen.

Aromatase inhibitors: a type of hormonal treatment for breast cancer. These drugs block the action of aromatase resulting in a decrease in estrogen in postmenopausal women.

Axillary lymph node dissection (ak'sil-ar-e-limf node di-sek'shun): surgical removal of lymph nodes under the arm.

Benign (be-nine'): a tumor that is not cancerous and does not spread to other parts of the body, and does not normally threaten a person's life.

Biopsy (bi'op-see): a small sample of tissue that is taken and examined for the presence of cancer.

Brachytherapy (brak-e-ther'a-pee): radiation therapy where the radiation is placed inside the body.

BRCA1: an inherited gene. Alterations in this gene may increase the risk of breast cancer.

BRCA2: an inherited gene. Alterations in this gene may increase the risk of breast cancer.

Breast-conserving surgery: removal of a malignant lesion from the breast with preservation of the essential anatomy of the breast.

Breast reconstruction (brest re-con-struk'shun): surgery used to restore the appearance of a breast after a mastectomy.

Breast self-exam: a self-exam of the breast by feeling the breast tissue and checking for abnormalities.

Carcinoma in situ: see under *Noninvasive breast cancer*.

Cataracts (kat'ah-rakt): a whitening or opacity of the lens of the eye.

Chemotherapy (kee-mo-ther'a-pee): treatment with powerful drugs that attack cancer cells but may also temporarily harm certain types of healthy cells.

Clinical breast exam: a physical exam performed by a health care professional to feel the breast tissue and check for abnormalities of the breast.

Glossary (continued)

Computed tomography scan (to-mog'ra-fee); also known as CT or CAT scan: an x-ray machine test that uses safe amounts of radiation to take a picture of organs and tissues, and uses a computer to create a detailed image. It is similar to an x-ray.

Core biopsy (bi'op-see): a biopsy procedure using a large needle to remove a small bit of tissue and examining it for cancer.

Cytotoxic (si-to-tok'-sik): drugs that kill cancer cells and some rapidly growing normal cells.

Distant recurrence (re-kur'ens): the recurrence of breast cancer in parts of the body other than the breast. It may develop in lymph nodes, lung, liver, bone, or brain.

Ducts (dukts): small tubes in the breast that carry milk from the lobules to the nipple during breastfeeding.

Estrogen (es'tro-jen): a hormone produced by the ovaries, adrenal glands, and other tissues. It is responsible for the development of female sex characteristics and it is important in menstruation and fertility. Estrogen may also cause the growth of some breast cancers (those that are determined to be estrogen-receptor-positive).

Estrogen receptor (es'tro-jen re-sep'tor): a hormone receptor that uses estrogen to help feed/grow the cancer cells.

Estrogen receptor antagonists: also known as **antiestrogens:** drugs that are used to treat breast cancer. These drugs block estrogen from reaching and stimulating the breast cancer cells.

Excisional biopsy (ek-sizh'un-al bi'op-see): a surgical biopsy procedure used to remove all of a tumor or irregular tissue and examine it for cancer.

Extended adjuvant therapy: the continuation of hormonal treatment after an initial five years of primary adjuvant hormonal treatment.

Fine needle aspiration (ne'dl as-pi-ra'shun): a biopsy procedure using a small needle to remove a small bit of tissue and examine it for cancer.

Genetic testing (je-net'ik): testing that identifies any mutations or alterations in genes.

HER2/neu: protein receptor on the surface of breast cancer cells.

Histology (his-tol'o-je): refers to the smallest parts and characteristics of cells and tissues.

Hormonal treatment: a way of treating breast cancer through the use of drugs that block the effect of estrogen or decrease estrogen levels in the body. It is different from hormone replacement therapy.

Hormone receptor (hor-mon re-sep'tor): proteins on the inside or surface of cancer cells.

Hormone receptor positive: In breast cancer, this means the tumor cells have hormone receptors (see Hormone receptor, above) and therefore depend on hormones to grow.

Hormone replacement therapy: treatment that provides estrogen to women to help ease the symptoms of menopause.

Hospice: medical or social supportive care that provides support to patients and their families when a life-threatening illness no longer responds to active treatment and a cure is not possible.

Hyperplasia (hi-per-pla'zhe-a): an increase in the number of normal cells in a tissue or organ.

Hypothalamus (hi'po-thal'ah-mus): an area of the brain that sends chemical signals to the pituitary gland and helps control the amount of estrogen in the body.

Incisional biopsy (in-sizh'un-al bi'op-see): a surgical procedure used to remove a part of a lump or tissue to examine for cancer.

Intramuscular (in-tra-mus'kyu-lar): within the muscle.

Intravenous (in-tra-vee'nus): within the vein.

Invasive breast cancer (in-va'siv brest kan'ser): cancer that penetrates ducts and lobules and other surrounding tissues.

Jaundice (jawn'dis): a syndrome related to liver abnormalities in which there is excess bile in the blood, resulting in a yellow coloration of the skin and whites of the eyes.

Lobule (lob'ul): a small sac in the breast that makes breast milk during breastfeeding.

Local recurrence (re-kur'ens): the return of breast cancer in the breast where the original tumor developed or in the skin or underlying tissue where the breast was removed.

Local therapy: a treatment that is directed only at the area where the cancer is, such as surgery or radiation to the breast in breast cancer.

Lumpectomy (lum-pek'to-mee): the surgical removal of a tumor and some surrounding tissue.

Luteinizing hormone-releasing hormone (LHRH) agonist (loo'te-in'i-zing): a type of hormonal treatment for breast cancer. LHRH agonists cause a decrease in estrogen.

Lymph (limf): a clear fluid collected from tissues around the body and returned to the blood by the lymphatic system.

Lymphedema (lim'fe-de'mah): accumulation of lymph fluid in the arm and hand as a result of the removal of lymph nodes in the underarm area. This may be associated with swelling, tingling sensation, and pain.

Lymph nodes (limf nodes): small bean-shaped structures scattered along the vessels of the lymphatic system. The lymph nodes may trap cancer cells that travel through the lymphatic system.

Lymph or lymphatic vessels (lim-fah'tik ves'els): a series of tubes in the body that carry lymph.

Glossary (continued)

Magnetic resonance imaging: a test that uses magnetic fields to create clear images of your internal body parts including tissues, muscles, nerves, and bones; often referred to as an MRI.

Malignant (mah-lig'nant): a tumor that is cancerous and may spread to other parts of the body and may be life-threatening.

Mammogram (mam'o-gram): an x-ray examination of the breast that can detect breast cancer.

Medical oncologist (med'i-kal ong-kol'o-jist): a physician specializing in the medical treatment of cancer.

Menopause (men'o-paws): a stage in a woman's life when menstruation stops and the ovaries stop producing eggs and estrogen.

Metastasis (me-tas'tah-sis): a tumor or growth of cells in a part of the body that is different from where the original or primary tumor was located. Metastases is the plural for metastasis.

Metastasize (me-tas'ta-siz): cancer cells breaking off from their primary site and spreading to nearby or distant areas through the blood and/or lymph.

Modified radical mastectomy (mas-tek'to-mee): excision of the entire breast, and lymph nodes under the arm.

Neoadjuvant therapy (ne'o-ad-ju-vant): therapy that is used before surgery or radiation in an attempt to reduce the size of the tumor.

Noninvasive breast cancer (non-in'-va-siv brest kan'ser)/Carcinoma in situ: cancer within the ducts and lobules that does not spread to any other surrounding tissues.

Ovary (o'vah-ree): a female sex organ that is responsible for the production and maturation of eggs. It is the main source of estrogen production in premenopausal women. Ovaries is the plural for ovary.

Palliative care (pa'lee-a-tiv): therapy that is intended to provide relief of symptoms but is unlikely to cure a disease.

Pathologist (pa-thol'o-jist): a physician who evaluates tissue samples for diagnosis.

Perimenopause (peri'men-o-pawz'):: the period just before menopause where women experience changes in estrogen and other hormone levels.

Pituitary gland (pi-tu'i-tar'ee): a small gland located at the base of the brain. It receives chemical signals from the hypothalamus and produces chemicals (such as luteinizing hormones) that control the amount of estrogen the body produces.

Positron emission tomography (to-mog'-ra-fee): a test for cancer that produces an image of the body based on the uptake of glucose by cells; often referred to as a PET scan.

Postmenopausal (post'men-o-paw'zal): occurring after menopause.

Premenopausal (pre'men-o-paw'zal): occurring before menopause.

Primary adjuvant therapy: the use of hormonal treatment immediately following surgery and/or radiation. Primary adjuvant therapy may be continued for up to five years.

Progesterone (pro-jes'ter-own): a hormone that is important in menstruation and fertility. It may affect the growth of some breast cancers (those that are determined to be progesterone receptor positive).

Progesterone receptor (pro-jes'ter-own re-sep'tor): a type of hormone receptor that uses progesterone to help feed/grow the cancer cells.

Radiation and radiotherapy (ra-de-a'shun) (ra-de-o-ther'a-pee): the use of x-rays to treat cancer.

Radical mastectomy (rad-i-kal mas-tek'to-me): excision of the entire breast, lymph nodes, and the muscles underlining the breast.

Recurrence (re-kur'ens): the return of signs or symptoms of a disease after having had an original cancer removed completely.

Regional recurrence: the recurrence of breast cancer in the lymph nodes near the affected breast after having had the original cancer removed completely.

Selective estrogen receptor modulators (SERMs) (re-sep'tor mod'u-la-tor): also called antiestrogens; a type of hormonal treatment for breast cancer. These drugs block estrogen from reaching and stimulating breast cancer cells.

Sentinel lymph node biopsy (limf node bi'op-see): a procedure using radioactive dye that is injected into the breast near the tumor to locate the sentinel lymph node. The sentinel lymph node is then removed through a small incision and examined by a pathologist for the presence of cancer cells.

Systemic therapy: treatments that travel through the bloodstream to affect or treat cells throughout the body. In breast cancer, systemic therapies may include chemotherapy and hormone treatment.

Total mastectomy (mas-tek'to-mee): excision of the entire breast.

Tumor (too'mor): abnormal tissue that grows more quickly than normal, due to cellular proliferation. The growth continues after the initial cause of the new growth has ended.

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