

NCCN Guidelines for Patients™



Version 2.2011

Table of contents

Part 1 About these guidelines 4

- 1.1 NCCN Guidelines for Patients™
- 1.2 NCCN Clinical Practice Guidelines in Oncology™
- 1.3 NCCN Guidelines Panel Members
- 1.4 How to use this booklet

Part 2 About my cancer 8

- 2.1 Breast growth
- 2.2 What is breast cancer?
- 2.3 Causes of breast cancer
- 2.4 Common types of breast cancer
- 2.5 Breast cancer screening

Part 3 Tests for breast cancer 16

- 3.1 Do I have breast cancer?
- 3.2 Tests after diagnosis
- 3.3 Risk assessment tool
- 3.4 The pathology report
- 3.5 Stages of breast cancer
- 3.6 Breast cancer grade

Part 4 Treating breast cancer 29

- 4.1 Choosing your treatment
- 4.2 Getting a 2nd opinion
- 4.3 Treatments for breast cancer
- 4.4 What are clinical trials?

Part 5 Treating signs and symptoms 43

- 5.1 Common side effects
- 5.2 Can I still have babies?
- 5.3 Symptom control
- 5.4 Breast reconstruction
- 5.5 Supportive care

Part 6 Beyond usual treatment 52

- 6.1 Aren't there other treatments?
- 6.2 What else can I do?
- 6.3 Caring for caregivers

Part 7 A step-by-step treatment guide..... 58

- 7.1 Carcinoma in situ
 - 7.1.1 Lobular carcinoma in situ
 - 7.1.2 Ductal carcinoma in situ
- 7.2 Local invasive breast cancer
 - 7.2.1 Initial tests and treatment
 - 7.2.2 Radiotherapy after lumpectomy
 - 7.2.3 Radiotherapy after mastectomy
 - 7.2.4 Adjuvant systemic treatment
- 7.3 Breast-saving treatment for large, local tumors
 - 7.3.1 Initial tests
 - 7.3.2 Neoadjuvant treatment
 - 7.3.3 Primary and adjuvant treatment
- 7.4 Locally advanced invasive breast cancer
 - 7.4.1 Initial tests
 - 7.4.2 Neoadjuvant treatment
 - 7.4.3 Primary and adjuvant treatment
- 7.5 Inflammatory breast cancer
 - 7.5.1 Initial tests
 - 7.5.2 Neoadjuvant treatment
 - 7.5.3 Primary and adjuvant treatment

- 7.6 Follow-up tests for first invasive cancer
- 7.7 Metastatic or recurrent breast cancer
 - 7.7.1 Tests for recurrence or metastases
 - 7.7.2 Treatment for local recurrence
 - 7.7.3 Treatment for lymph node recurrence
 - 7.7.4 Treatment for metastases
 - 7.7.5 Follow-up hormone therapy

Part 8 Dictionary..... 96

Part 9 Tools102

- 9.1 Questions to ask about testing for breast cancer
- 9.2 Questions to ask about treating breast cancer
- 9.3 Questions to ask about clinical trials
- 9.4 Suggestions for taking care of yourself
- 9.5 Suggestions for taking care of caregivers
- 9.6 Personal treatment record

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Part 1: About these guidelines

1.1 NCCN Guidelines for Patients™

NCCN aims to offer the most current and trustworthy cancer information to patients and their families in a manner that is easy to understand. To reach this goal, NCCN has developed the NCCN Patient Guidelines™. These guidelines are meant to help patients talk with doctors and make the best decisions possible. They are based on the NCCN Guidelines™ that are developed for doctors. For more information on NCCN or the most recent NCCN Patient Guidelines, visit NCCN.com

1.2 NCCN Clinical Practice Guidelines in Oncology™

The NCCN Guidelines are the most complete and most frequently updated clinical practice guidelines in medicine. They give a step-by-step course of action that many cancer doctors follow to make sure their decisions are well-informed. The NCCN Guidelines are developed by 44 group panels. These panels include near 900 well-known experts from the 21 NCCN Member Institutions (Figure 1). The panel members include experts from different fields of medicine, such as medical oncology, radiology, and social work.

Recommendations in the NCCN Guidelines are based on clinical trials and the experience of the panel members. Most of the panel members have jobs that include clinical research and treating people with cancer. Members work on the guidelines that match their area of expertise. Some guidelines panels also include patient

NCCN abbreviations and acronyms

NCCN®

National Comprehensive Cancer Network®

NCCN Patient Guidelines™

NCCN Guidelines for Patients™

NCCN Guidelines™

NCCN Clinical Practice Guidelines in Oncology™

advocates to include the point of view of patients in the panel meetings. Panel members volunteer more than 15,000 hours each year to revise the NCCN Guidelines so that new information can be quickly included.

Doctors use the NCCN Guidelines to inform their decisions when diagnosing and treating people with cancer. There are guidelines for 97% of the tumors seen among patients treated at cancer clinics. Each is continually updated as new information becomes available. The NCCN Guidelines allow doctors and patients to have access to the same information that is used by NCCN Panel Members to treat their patients. Doctors in your community may or may not perform research, but by using the NCCN Guidelines they have access to the newest information from clinical trials.

By identifying what is the standard of care, the NCCN Guidelines can help patients in two ways. First, they can reduce the number of differences in how patients are treated. Second, patients can get the best care for their situation.

It is important to note that a certain treatment may not be right for everyone. Research shows that some treatments are better for a specific disease than others. Likewise, studies have shown that among patients with the same type of cancer, some patients may need different treatments.

The treatment included in the NCCN Guidelines is what the NCCN doctors feel is most useful based on science and their experience. Therefore, even if a treatment is part of the NCCN Guidelines, it may not be the right treatment for everyone. This is because each patient has his or her own medical history and circumstances.

On the other hand, if a treatment is not included in the NCCN Guidelines, it only means that there is not enough proof at this time to support using it as a standard of care. Because of differences between patients and other factors, the NCCN Guidelines do not replace the expertise and clinical judgment of your doctors.

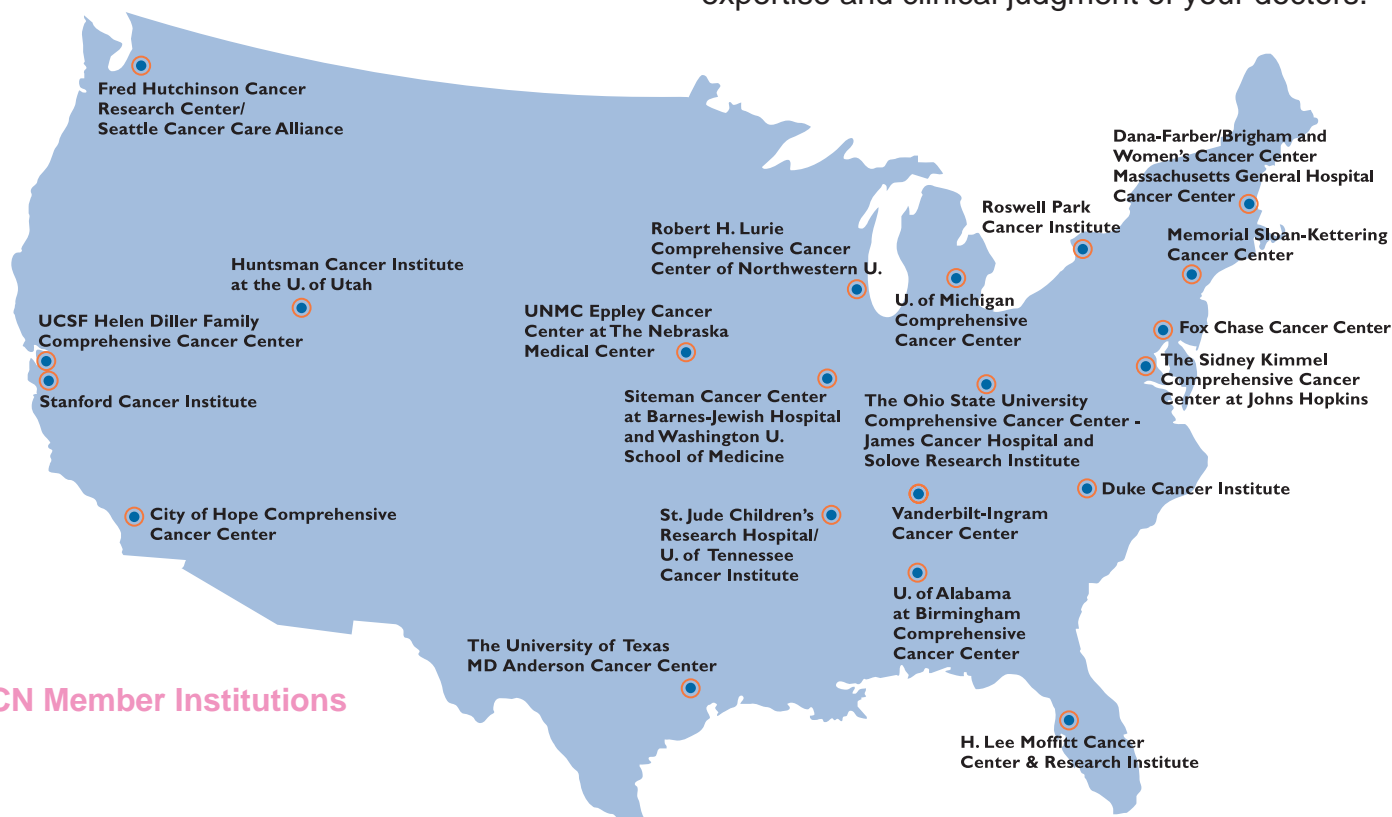


Figure 1. NCCN Member Institutions

1.3 NCCN Guidelines Panel Members

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1.4 How to use this booklet

The NCCN Guidelines for Patients™: Breast Cancer are designed to help you better understand cancer treatment. These guidelines address all the stages of breast cancer, so not all of the information will apply to you. In addition, although the guidelines recommendations apply to most patients, they depend on the general health and situation of each patient.

The guidelines include several important parts:

- You will find information to help you understand what breast cancer is and what tests and treatments are available in Parts 2 through Part 6.
- Tables and figures are included throughout the guidelines to either simplify information or to provide you with more information.
- A treatment guide is included in Part 7. It shows the step-by-step course of action from diagnosis through all the phases of treatment. This information is presented in charts and is explained further in the text.
- Definitions of words or phrases that you may not know are provided throughout the text and in Part 8.
- There are pages in Part 9 to help you talk with your doctor and track your medical care.

This booklet can help you and your doctors decide which choices best meet your medical and personal needs. Making decisions about treatment is important for your long-term health and the quality of your life since there are risks and benefits to every choice. Getting enough information to make an informed decision is an important first task.

To give you the information you need, these guidelines cover most aspects of cancer care. Many medical terms are included that describe cancer, tests, and treatment. These are terms that you will likely hear your treatment team use in the months and years ahead. Most of the information may be new to you, and it may be a lot to learn. Don't be discouraged as you read. Keep reading and review the information. There is a Dictionary in Part 8 that may help. With time, you'll become more familiar with the medical information in these guidelines.

Reading the guidelines in order from the beginning to the end may be the most helpful if you do not know much about breast cancer. The first half of the guidelines provides more basic information that will make it easier to understand the more detailed treatment guide. As you read through these guidelines, you may find it helpful to learn about general issues in order to create a list of questions to ask your doctor. A suggested list of questions is in Part 9, but you may think of more questions to ask.

Main Points

- In girls, breasts grow during puberty to be able to make milk for babies.
- Most breast cancer occurs in women. It is the most common type of cancer in women.
- It is not known what causes breast cancer.
- Breast cancer often starts in the milk ducts or lobules and then spreads into the fatty tissue of the breast.
- Starting at age 20, you should be given screening exams to find breast cancer early.

Breast cancer is the most common type of cancer in women. In contrast, it is rare among men. In women, it is second to lung cancer as the cause of cancer-related death. Although more women have been diagnosed with breast cancer in recent decades, fewer women have died because of early diagnosis and better treatments. The information in these guidelines is about breast cancer in women.

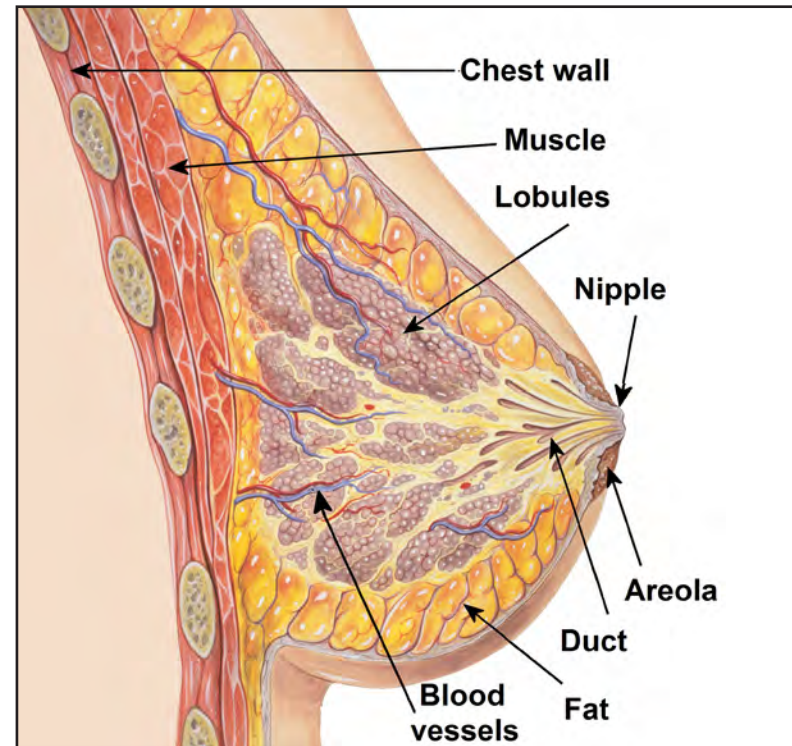


Figure 2. Parts of the female breast

Derivative work of Breast Anatomy by Patrick J. Lynch and C. Carl Jaffe, MD available at http://commons.wikimedia.org/wiki/File:Breast_anatomy_normal_scheme.png under a Creative Commons Attribution 3.0 Unported license



2.1 Breast growth

Before puberty, breasts of boys and girls are similar. Both have nipples, areoles, and little fat. During puberty, girls have increases in female hormones that boys do not. These female hormones cause the growth of lobules, milk ducts, and fat in the breasts of girls (Figure 2). Fat and connective tissue give shape to the breast.

The breast also contains small tubes that carry blood and lymph. Blood brings food to and removes cell waste from breast tissue. Lymph is a clear fluid that returns protein to the blood and gathers germs. Lymph travels between tissues, blood, and lymph nodes, where the germs it collects are destroyed. Lymph vessels and nodes are found everywhere in the body.

2.2 What is breast cancer?

Cells are the building blocks that form tissues, which in turn make up the organs of the body. Normal cells grow and then divide to form new cells as the body needs them, but stop when they have developed fully. When normal cells grow old or get damaged, they die. Cancer cells do not. Cancer cells form new cells when the body does not need them, and old or damaged cells do not die as they should (Figure 3).

Unlike normal cells, cancer cells do not stay in one part of the body but spread to other sites. This process is called metastasis. The uncontrolled growth and spread of cancer cells makes cancer dangerous. Cancer cells can replace or deform normal tissue in the breast and in other parts of the body, like the brain or bone.

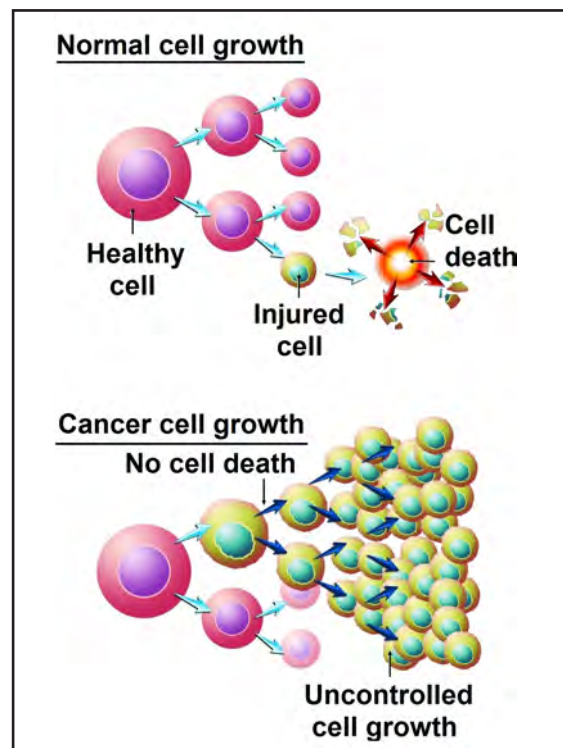


Figure 3.
Normal versus cancer cell growth

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Definitions:

Areola: A darker, circular area of the skin

Connective tissue: Supportive and binding fibers

Diagnosis: Identification of a disease

Ducts: Tubes that drain milk from the breast

Hormones: Chemicals in the body that activate cells or organs

Lobules: Glands in the breast that make milk

Lymph: A clear fluid containing white blood cells

Lymph nodes: Small groups of special immune cells

Metastasis: The growth of cancer beyond local tissue

Nipple: The darker, raised part of the breasts

Protein: Chains of amino acid

Puberty: The time when teens sexually develop

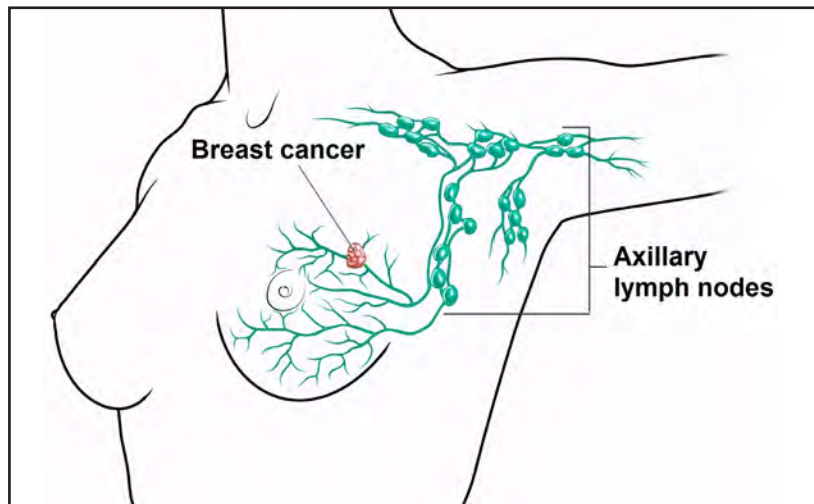


Figure 4. Lymph nodes near a breast with cancer

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Breast cancer begins in the cells of the breast. The cancer cells keep growing and dividing forming a tumor (Figure 4). Tumors usually first appear in the breast ducts or lobules. Some cancer cells may cross into the blood and lymph vessels in the breast and spread to other parts of the body. Breast cancer usually metastasizes first to the lymph nodes. When the breast cancer cells enter the axillary lymph nodes, they can continue to grow there, often causing swelling. Cancer cells may also be carried by lymph to the supraclavicular or internal mammary lymph nodes.

2.3 Causes of breast cancer

The cause of breast cancer is not known. However, a number of things increase your risk for breast cancer. Being a woman and older age are the most common risk factors. Other risk factors include:

- Someone in your family has had breast cancer, especially at a young age
- Your menstrual periods started at an early age
- You entered menopause at a late age
- You've taken hormone replacement therapy for a long time
- You had your first baby late in life

Women with a strong family history of breast cancer may wish to discuss their risk of getting breast cancer with their doctor and consider starting breast cancer risk reduction treatment. For more information on reducing your risk for breast cancer, see the NCCN Guidelines for Breast Cancer Risk Reduction, available at NCCN.org. These guidelines were written for your doctor, so he or she will likely be able to answer your questions about the information on risk reduction.

2.4 Common types of breast cancer

Common types of breast cancer are broadly grouped by whether the cancer is limited to or has grown beyond the ducts or lobules. Breast cancer confined to the ducts or lobules is called “noninvasive” or “carcinoma in situ.” Breast cancer that has spread beyond the walls of the ducts or lobules is called “infiltrating” or “invasive.” A single breast tumor often has areas with both of these cancer types. In other words, the tumor is a mix of noninvasive and invasive cancer.

Carcinoma in situ

Carcinoma is another word for cancer. Carcinoma in situ means that the cancer is still confined to the ducts or lobules where it started. It has not spread into nearby fatty tissues of the breast or to other organs. There are two kinds of breast carcinoma in situ:

Lobular carcinoma in situ (LCIS). Also called lobular neoplasia, LCIS is cancer restricted to the lobules. Breast cancer doctors do not think that LCIS becomes an invasive cancer. However, women with LCIS are at higher risk of having invasive cancer in either breast.

Ductal carcinoma in situ (DCIS). This is the most common kind of carcinoma in situ. In DCIS, cancer cells are only in the ductal walls. Doctors treat DCIS with surgery and sometimes radiotherapy, which usually cures the cancer. If DCIS is not treated, it will likely grow into an invasive cancer.

Definitions:

Axillary: On the side of the body near the armpit

Carcinoma in situ: Breast cancer that has not spread beyond the ducts or lobules

Hormone replacement therapy: Medicine to increase hormone levels

Internal mammary: Below the breastbone

Menopause: The end of menstrual periods

Menstrual periods: The flow of blood and tissue from the uterus

Radiotherapy: Treatment with radiation

Risk factors: Something that increases the chance of getting a disease

Supraclavicular: Near the collarbone

Tumor: A mass made from an abnormal growth of cells

Uterus: The female organ where babies grow during pregnancy; the womb

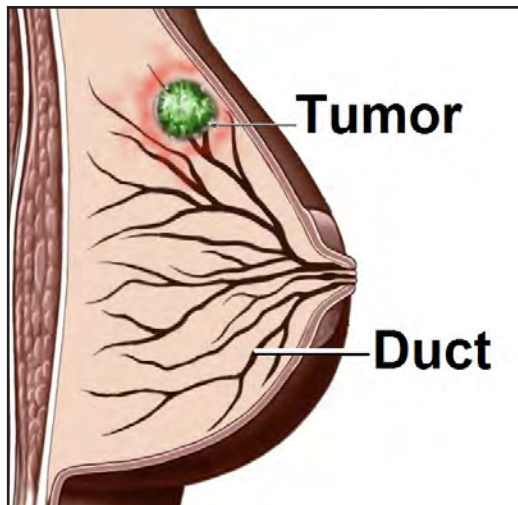


Figure 5. Invasive ductal carcinoma

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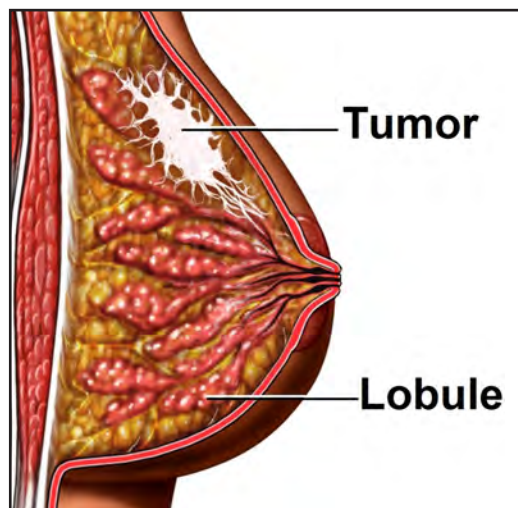


Figure 6. Invasive lobular carcinoma

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Invasive breast cancer

Invasive breast cancer is cancer that has spread from the ducts and lobules into the breast tissue. In some cases, it has spread to lymph nodes in or near the breast. There are many kinds of invasive breast cancer:

Invasive ductal carcinoma. About 80% of invasive breast cancers are invasive ductal carcinoma. This invasive cancer starts in the ducts but then spreads into the fatty tissue of the breast (Figure 5). Once in the fatty tissue, the cancer can spread to other parts of the body through lymph or blood vessels.

There are four special kinds of invasive ductal carcinoma:

- **Medullary cancer** accounts for about 5% of invasive breast cancers. The tumor has a fairly well-defined edge separating it from normal breast tissue. It also has immune cells at the edge of the tumor. Medullary cancer can be hard to tell apart from the more common invasive ductal carcinoma. Most breast cancer doctors believe that medullary cancer is very rare and should be treated as invasive ductal carcinoma.
- **Tubular carcinoma** accounts for about 2% of invasive breast cancers. Women with this kind of breast cancer have a better prognosis because the cancer is less likely to spread outside the breast than common invasive cancers of the same size.
- **Metaplastic tumors** are a very rare kind of invasive ductal carcinoma. These tumors include cells that are normally not found in the breast, such as skin or bone cells. These tumors are treated similarly to the common invasive ductal carcinomas.
- **Colloid carcinoma** is also called mucinous carcinoma. It is another rare kind of invasive ductal carcinoma. It is formed by mucus-producing cancer cells. Colloid carcinoma has a better prognosis and a lower chance of metastasis than common invasive cancers of the same size.

Invasive lobular carcinoma. About 10% – 15% of invasive breast cancers are invasive lobular carcinomas. This invasive cancer starts in the lobules and spreads into the fatty tissues of the breast (Figure 6). Like invasive ductal carcinoma, this cancer can then spread beyond the breast to other parts of the body.

Mixed tumors. Mixed tumors contain a variety of cell types, such as invasive ductal carcinoma combined with invasive lobular carcinoma. Mixed tumors are usually treated as an invasive ductal cancer.

Inflammatory breast cancer.

About 1% – 3% of all breast cancers are inflammatory breast cancer. This cancer is sometimes called by its abbreviation—IBC. In this disease, cancer cells have spread to the lymph node channels in the skin of the breast. The skin of the diseased breast is red, feels warm, and has the look of an orange peel (Figure 7). The diseased breast may also become larger, firmer, tender, or itchy. Inflammatory breast cancer is often mistaken for an infection in its early stages. It has a higher chance of spreading and worse prognosis than common invasive ductal or invasive lobular carcinomas.

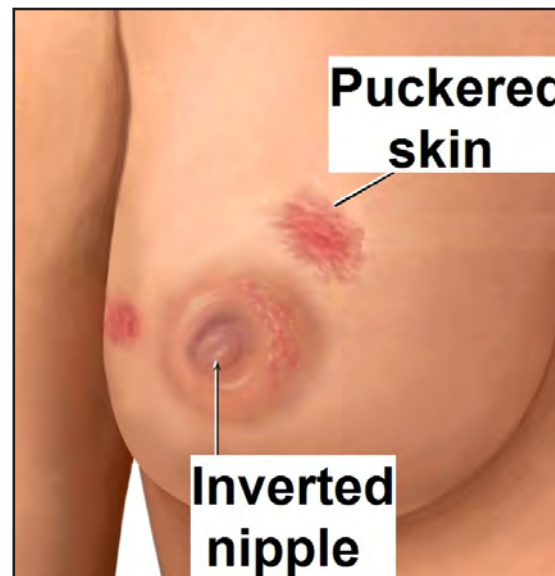


Figure 7.
Signs of inflammatory breast cancer

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Definitions:

Immune cells: Cells that defend the body against disease

Invasive breast cancer: Cancer that has spread into the fatty tissue of the breast

Mucus: A sticky, thick liquid that moisturizes or lubricates

Prognosis: The pattern and outcome of a disease

2.5 Breast cancer screening

Breast cancer screening is for all women so that any disease can be found early. Signs of breast cancer may be noticed by you or your doctor. You may detect a lump during a self-exam of your breasts. You may also notice fluid coming from your nipple or a change in the shape of your breasts. If you see any of these changes, tell your doctor.

Breast cancer may also be found by screening tests. Which screening tests you receive is based on your age, medical history, and other factors. Screening can include increasing breast awareness as well as the tests described below.

Medical history

The doctor will ask you questions about your general health and any symptoms you may have noticed. You will also be asked if anyone in your family has had cancer. If so, the doctor will ask about the types of cancer and how old your relatives were when their cancer was found.

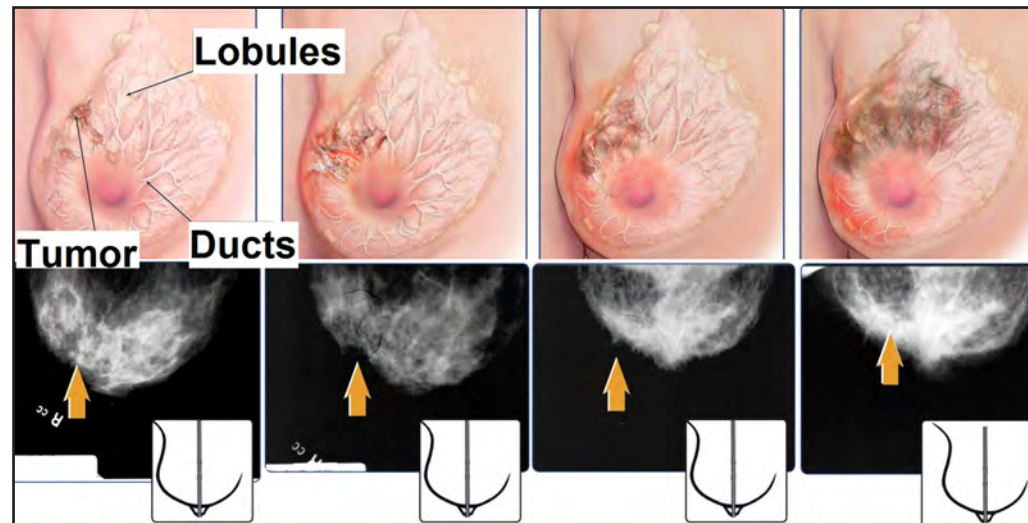


Figure 8. Pictures showing results of mammogram

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Clinical breast exam

Your doctor will feel your breasts to see whether there is a lump or thickening that is not like normal breast tissue. Your breasts may be felt while you sit or stand up as well as when you recline. Your doctor will also check for enlarged lymph nodes in your armpits and around the collarbone. Some women feel uncomfortable having their breasts touched by their doctor. Keep in mind that this exam provides important information and takes only a short time.

Risk assessment

Women may be at normal or increased risk for breast cancer. Risk is based on several conditions. For example, prior radiotherapy in the chest area, strong family history or genetic risk, and previous breast cancer may all increase your risk for getting breast cancer. Your doctor may recommend that you have certain screening tests at specific time points based on your breast cancer risk.

Screening mammogram

A mammogram uses x-rays to look at breast tissue (Figure 8). Screening mammograms usually take two views of the breast to try to find cancer when it's most likely curable. Radiologists look at the mammogram and report their findings to your doctor. The report will state whether the mammogram results were normal, uncertain, or showed cancer. Based on your results, your doctor may recommend either regular follow-up or more testing.

Screening magnetic resonance imaging

Magnetic resonance imaging (MRI) uses radio waves and powerful magnets to look at breast tissue. Also, a contrast material is injected to see abnormal areas of the breast and show areas that are not cancerous. For this reason, MRIs can result in a higher number of false alarms than mammography. Thus, deciding who gets an MRI involves careful thought. Women with a normal risk for breast cancer should not receive an MRI. If you are at high risk for breast cancer, an MRI in addition to a mammogram may be appropriate.

Ultrasound

Ultrasound is a test that uses sound waves to take pictures of the inside of the breast. The pictures allow doctors to evaluate an area for cancer. Ultrasound is very useful to see a solid mass from a fluid-filled cyst. A solid mass is more likely to be cancer than a cyst. There is some evidence that breast ultrasonography can be a useful screening test for high-risk women who have dense breasts. However, at this time, it is not recommended by the NCCN Breast Cancer Screening and Diagnosis Guidelines Panel. Breast scintigraphy and ductal lavage are also not recommended as regular screening tests.

Definitions:

Breast awareness:

Learning about your breasts

Contrast: A substance put into your body to make better pictures during imaging tests

Cyst: A closed sac in the body filled with air or fluid

Ductal lavage: A test used to collect cells from breast ducts

Genetic risk: The chance of having a disease passed down from parents

Imaging: Medical tests that take pictures of the inside of the body

Mammogram: A test using x-rays to look at breast tissue

Radiologist: A doctor who specializes in reading imaging tests

Scintigraphy: A test that uses radioactive tracers to view body parts

Screening: Regular tests used to detect a disease in someone without symptoms

Ultrasonography: A test that uses ultrasound to view body parts

Main Points

- More cancer tests are needed if you find a lump or have abnormal screening results.
- Tests of breast tissue are the only way to know if you have breast cancer. Needle biopsies of breast tissue are common and cause little pain.
- Tests that take pictures of your body can tell if the cancer has spread.
- Tumor tests can tell if hormones or HER2 proteins help your cancer grow.
- Tests of your genes can help tell if your cancer will come back after treatment.
- A pathologist looks at your cells with a microscope to decide test results.
- Breast cancers are grouped into stages 0 – IV based on how likely they are to act. Early stages of breast cancer are more likely to be cured.
- Breast cancers are also grouped into grades 1 – 3 based on how the cells look. A lower grade is less likely to spread.

3.1 Do I have breast cancer?

For many women over 40 years old, a lump in their breast or an abnormal mammogram is often the first sign of breast cancer. Other signs of breast cancer include breast thickening, fluid from the nipple, and skin changes of the breast. Your doctor will need more information if you have these signs. Results from screening and diagnostic tests will help decide if you have cancer.

Diagnostic mammogram

A diagnostic mammogram looks at the breast more carefully and gives more precise information about the tumor. It gives extra views of the breast by squeezing it in different ways and taking more x-rays. Only about 90% of breast cancers can be seen on mammograms. If the mammogram does not give enough information, an MRI or ultrasound may be needed.

Breast biopsy

A biopsy is needed if cancer is suspected. Most often, biopsies are benign. There are two types of biopsies. For both types, the doctor will numb the area to make the procedure as painless as possible.

Needle biopsy. Most often, doctors remove breast tissue with a needle inserted through the skin into the mass. This type of biopsy is called a needle biopsy. It causes less discomfort than other biopsies and provides important information for treatment decisions.



Figure 9. Stereotactic needle biopsy

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There are two types of needle biopsies: a core needle biopsy and fine-needle aspiration. The core needle biopsy is the more common and favored method. It obtains a larger tissue sample for testing. A fine-needle aspiration can be used to remove fluid from a cyst to check for cancer cells.

If your doctor can feel a lump, a needle biopsy can be done in the doctor's office. If not easily felt, your doctor will use imaging to help find where to place the needle. When mammography is used to guide the needle, it is called a stereotactic needle biopsy (Figure 9). Ultrasound-guided biopsy uses an ultrasound image.

Excisional biopsy. When your doctor needs a larger tissue sample, an excisional biopsy will be done. For this biopsy, your doctor will remove breast tissue with a scalpel. The whole mass along with some normal tissue, called a margin, will be removed. If the surgeon cannot feel a lump, a wire will be inserted into the mass using mammography. This is called a wire localization biopsy. It is usually done under local anesthesia and does not require an overnight stay.

Definitions:

Benign: A tumor that is not made of cancer cells

Biopsy: A medical procedure that collects tissue

Local anesthesia: A loss of feeling due to drugs in a specific area of the body

Margin: Normal tissue around the edge of a tumor that is removed during surgery

Pathologist: A doctor who specializes in testing cells to identify disease

Scalpel: A knife for surgery

3.2 Tests after diagnosis

If cancer is found, your doctor will likely order more tests. The tests are based on your tumor size, whether lymph nodes may be involved, and whether your cancer has metastasized. Most women with breast cancer do not need many more tests following diagnosis.

Lymph node tests

Breast cancer can spread beyond the breast to your lymph nodes. Needle biopsies of lymph node tissue before surgery may show if cancer cells are present. There are two needle biopsies that are commonly used:

Core needle biopsy. Similar to a core biopsy of the breast tumor, your doctor will insert a needle through your skin into your lymph node. The needle used in a core biopsy is able to remove a solid tissue sample. If your doctor can't feel the tumor, an ultrasound may be used to help guide the needle into your body.

Fine-needle aspiration. A fine-needle aspiration (FNA) can be used to remove either fluid from a cyst or a small group of cells from a tumor. This procedure usually doesn't cause pain and can be done in a few minutes.

Blood tests

There are two common tests that use blood samples. They are needed to plan surgery, look for evidence of metastases, and plan treatment after surgery.

These blood tests include:

Complete blood count. This test counts the different types of cells in the blood and tells whether the amount of each type is normal. This test is repeated often, particularly if chemotherapy is needed. It tells if you have enough red blood cells to carry oxygen to your tissues, white blood cells to fight infections, and platelets to make clots needed for healing injuries.

Chemical and enzyme tests. These tests look for signs of abnormal activity in other organs. Women with noninvasive cancer do not need these tests. Abnormal results may sway your doctor to order other tests, such as a bone scan, to see whether the cancer has spread to other organs.

Imaging tests

Bone scan. For this test, you will receive an intravenous injection of a radioactive dye. Several hours later, a scan will show whether there are areas of new bone growth. New growth suggests possible spread of breast cancer to the bone. However, many changes that appear on a bone scan are not cancer.

In early-stage breast cancer, your doctor will use this test only if there is some reason to think that cancer may have spread to the bone. Examples of reasons for a bone scan include changes in blood chemistry tests or bone pain. Your doctor may also order a bone scan if the cancer is locally advanced. However, if the cancer has spread to other organs, a bone scan is needed.

Computed tomography.

Computed tomography (CT) scans take many x-rays of the same body part from different angles to make detailed pictures (Figure 10). Except for the intravenous shot of dye, this test is painless. CT scans are used to determine if cancer has spread to other organs. If you have early-stage breast cancer, a CT scan is not needed. If the cancer appears more advanced, your doctor may order a CT of your chest and/or abdomen to see whether the cancer has spread.

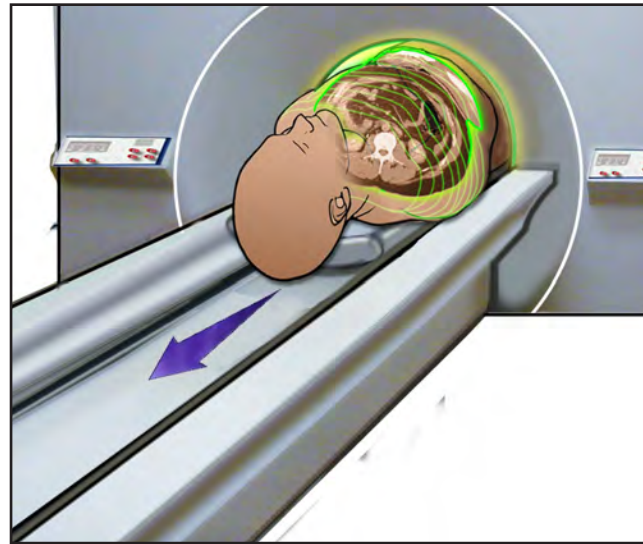


Figure 10. Computed tomography

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MRI. After diagnosis, an MRI is useful to look at the brain, spinal cord, and specific areas of the bone. Doctors also use it if the results of other imaging tests are unclear or if there is concern about exposure to radiation from other scans. Regularly given MRIs for all patients with breast cancer are not helpful and not needed.

Positron emission tomography. Positron emission tomography (PET) scans use a form of sugar (glucose) that contains a radioactive atom. A small amount of the radioactive sugar is injected into an arm. The patient is then put into the PET machine where a special camera can detect the radioactivity. Because of the high amount of energy that breast cancer cells use, areas of cancer in the body absorb large amounts of the radioactive sugar. Newer machines combine PET and CT scans.

Definitions:

Abdomen: The belly area between the chest and pelvis

Blood chemistry tests: Tests to show unusual amounts of chemicals in the body

Chemotherapy: Drugs that kill cancer cells

Early-stage cancer: Cancer that has not grown much in nearby tissues

Glucose: A natural sugar in the body used by cells for energy

Intravenous: Drugs given by needle through a vein

Locally advanced: Growth of cancer in nearby tissues and possibly lymph nodes

Radioactive: Containing a powerful energy called radiation

PET scans are helpful for finding unsuspected disease in locally advanced or metastatic breast cancer. Although PET scans can find cancer that has spread, a number of normal body activities also use large amounts of energy. As a result, false alarms are common. A positive PET scan result should be confirmed by another imaging test or biopsy.

Tumor tests

There are important tests that are used to examine the type of tumor you have. Tumor tests can help you decide which treatment choices are best for your cancer. The cancer tissue removed during the biopsy or surgical treatment is used for these tests.

Hormone receptor tests. Estrogen and progesterone are hormones the body makes that start the growth of breast tissue during puberty. In some types of breast cancer, these hormones also help tumors to grow. These types of tumors are called estrogen receptor–positive, progesterone receptor–positive, or both. They tend to grow more slowly and are less likely to spread to the lymph nodes.

To test for the effect of hormones, the tumor cells are stained. The stain shows estrogen and progesterone receptors on the cells. The more stained cells, the more strongly the tumor is hormone receptor–positive, and the more likely it is that the tumor needs hormones to grow.

DCIS and all invasive breast cancers should be tested for hormone receptors at the time of breast biopsy or surgery. These tests are important because certain drugs can stop the hormones that grow breast tumors. If you have a hormone receptor–positive tumor, you will likely take hormone therapy to decrease the chance of your cancer returning or growing. Ask your doctor for your tumor test results to keep with your personal records.

If your tumor does not have hormone receptors, it is called estrogen receptor–negative and progesterone receptor–negative (or hormone receptor–negative). Hormone therapy will not likely be helpful.

HER2 tumor tests. In the nucleus of a cell, there are coded instructions for building new cells. These instructions are called genes (Figure 11). The HER2 gene is a set of instructions for making HER2 protein. The HER2 protein is found on the edge of cancer cells and tells the cell to grow and divide. In normal cells, there are two copies of the HER2 gene. However, in HER2-positive tumors, the cells are different from normal cells in a number of ways:

- The number of copies of the HER2 gene is high.
- The amount of HER2 protein is high (i.e., “overexpressed”).
- There are more messages for the cell to grow and divide.
- The growth of cells can be fast.

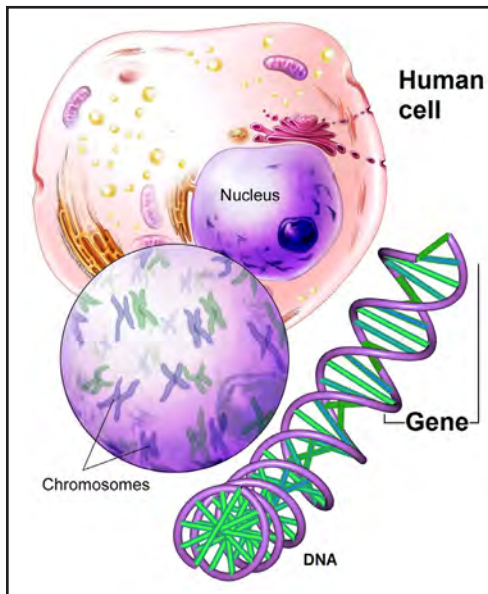


Figure 11.
Genes from a human cell

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The two ways of testing for HER2 tumor status are immunohistochemistry (IHC) and fluorescence in situ hybridization (FISH). IHC is a test that counts the number of HER2 protein receptors. In HER2-positive tumors, the amount of HER2 protein on the cell is above normal. FISH is a test that counts the number of HER2 genes.

In HER2-positive tumors, there are too many copies of the HER2 gene in cells. See Table 1 for test scores. An IHC score of 2+ is considered borderline and should be followed by a FISH test.

About 15% – 20% of women with breast cancer have HER2-positive tumors. Some breast cancers are less likely to be HER2-positive. For example, the majority of tubular cancers are hormone receptor–positive, but HER2-negative. HER2-positive tumors are viewed as aggressive. However, there are drugs that target this type of tumor. Due to costs and side effects of these drugs, it is very important to have tests that correctly show HER2 tumor status.

Definitions:

Estrogen: A hormone that develops female body traits

Genes: Instructions for making new cells

Nucleus: The control center of gene activity within a cell

Overexpressed: Gene activity is above normal resulting in too much protein

Progesterone: A hormone involved in female body organs

Receptor: A binding site on cells

Table 1. Test results for HER2 tumors

	Immunohistochemistry	Fluorescence in situ hybridization
HER2-negative tumor	0, 1+, 2+	2
HER2-positive tumor	3+	3 or more

Genetic tests

Doctors have recently started to use genetic tests to assess risk of breast cancer recurrence. Doctors look for specific genes known to be active in breast cancer. Based on the results, tumors can be grouped into low and high risk of recurrence.

21-gene test. The NCCN Guidelines Panel recommends consideration of a 21-gene test (oncotype DX[®]) for some women with breast cancer. This test has been found to predict which women will have a recurrence of breast cancer. In general, women with node-negative, hormone receptor–positive, HER2-negative tumors are at low risk. However, the 21-gene test can show which of these women are most likely to benefit from chemotherapy. See part 7.2.4 for more information. In contrast, women with hormone receptor–negative or HER2-positive tumors tend to have a higher risk of recurrence. For these women, the 21-gene test usually does not provide information that would change their treatment.

This test looks at 21 genes to give a score of high, intermediate, or low risk. It is clear what to do if the score is low or high, but less clear if the score is intermediate. A low recurrence score below 18 means you can safely skip chemotherapy but still must take hormone therapy.

A high recurrence score of 31 or higher means that chemotherapy should be taken with hormone therapy. An intermediate score is between 18 and 30. A score in this range means that you and your doctor should carefully discuss whether to take chemotherapy and hormone therapy. Your decision can be based on a number of factors including your age and personal preferences.

3.3 Risk assessment tool

There are online tools to help decide whether a woman should undergo chemotherapy. Adjuvant! Online is a tool for women with hormone receptor–negative disease, or with positive lymph nodes and either positive or negative hormone receptors. Its web address is www.adjuvantonline.com. Your doctor will type your information into the Adjuvant! Online program for you. This program will assess many factors specific to you and your cancer to give an estimate on the benefit of chemotherapy. This program was made before HER2 status became an important factor in choosing treatment. Thus, information about the benefits of drugs for HER2 tumors is not included. The program is currently being updated to include HER2 status.

3.4 The pathology report

The tissue removed during the biopsy or surgical treatment is reviewed by a pathologist. A pathologist is a doctor who specializes in looking at cells to identify disease. First, the pathologist prepares the tissue to be looked at under a microscope. The tissue is covered in a waxy material and cut into very thin slices. The slices are then stained with dyes to help see the differences between parts of a single cell and differences between multiple cells. These stained samples are placed on glass slides and then examined under a microscope.

Next, the pathologist writes a report for your doctor. Usually, there are at least two reports. The first report is about the biopsy sample. The second report is about the tissue removed during treatment. There may be more reports if other surgeries are needed.

The pathology report has several parts. The first report says whether cancer cells were found in the tissue and, if so, what types of cancer cells. Common cancer cell types are ductal, lobular, and nipple. The pathology reports will address whether the cancer is noninvasive or invasive, hormone receptor–positive, and HER2–positive. The cancer is also assigned a stage and grade, which are described later.

The process of preparing the tissue, evaluating it, and reporting it to your doctor usually takes 1 or 2 days. At times, the pathologist may have questions and request a 2nd opinion from another pathologist. This can take extra time.

It is a good idea to ask for a copy of the pathology reports. If you have questions, do not hesitate to talk with your doctor. It is important that you understand the reports and how they will be used for treatment decisions. You can also request that your tissue samples be reviewed by a pathologist at an NCCN Member Institution or other specialist suggested by your doctor.

Definitions:

Aggressive cancer: A cancer that spreads quickly

Genetic tests: Tests to assess risk for a disease based on genes

Node-negative: Lymph nodes that do not have cancer cells

Recurrence: The return of cancer after successful treatment

3.5 Stages of breast cancer

Breast cancer is divided into different groups called stages. There are five main stages based on the tumor size, how many lymph nodes are involved, and how far the cancer has spread (Figure 12). Your doctors will decide your cancer stage based on physical exams and the tests described in Parts 3.1 and 3.2.

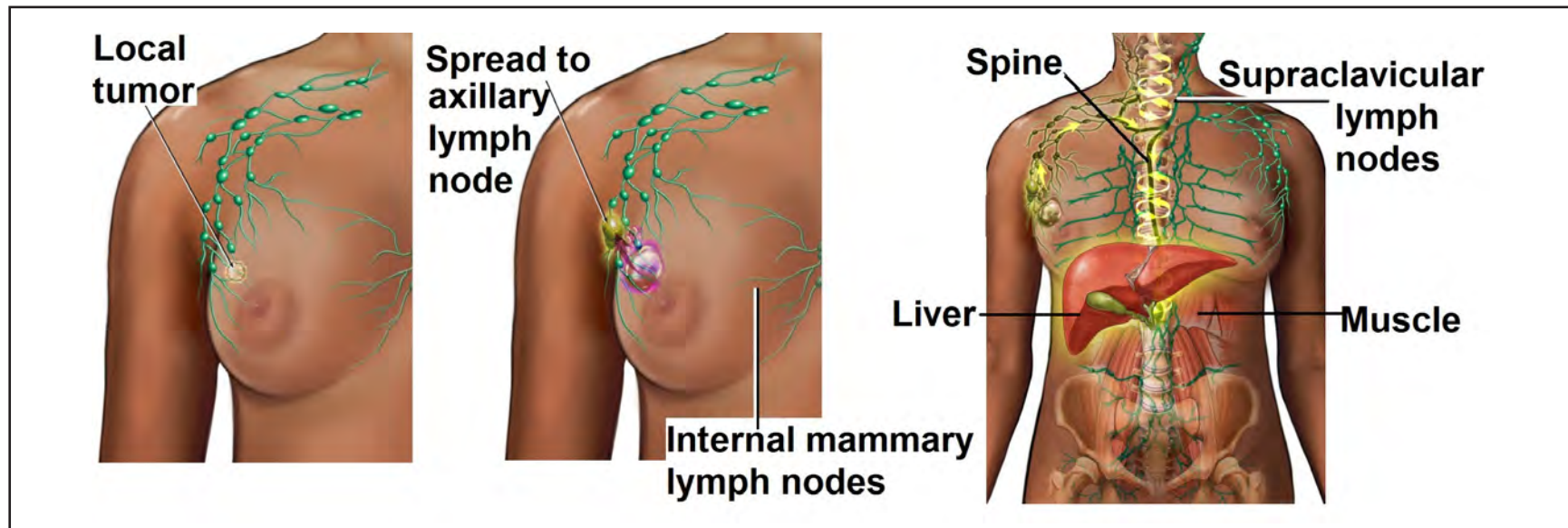
Using information from thousands of patients, cancer doctors developed the criteria for cancer staging. Your cancer stage is important. However, it is based on large numbers of patients and may not tell the outcome for an individual person. Some people will do better than

expected. Others will do worse. Other factors are very important in determining your prognosis. Some of these factors include your age, general state of health, and the HER2 and hormone receptor status of the tumor.

This section provides very specific information on breast cancer staging. It may have more details than some women want, but others may wish to know the details. The stage of a cancer is one of the most important factors in choosing treatment options and predicting how long patients will live. To follow the treatment guide in Part 7, you will need to know your cancer stage. Be sure to ask your cancer care team to explain this to you if you have any questions.

Figure 12. Areas of possible breast cancer growth

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System to define cancer stage

The system most often used to describe the extent of breast cancer is the TNM staging system. In this system, each of the letters— T, N, and M—describes the growth of the cancer. The T category describes the size of the tumor measured in centimeters (2.54 cm = 1 inch) and growth into nearby tissues. The N category specifies the extent of the cancer in the lymph nodes. The M category tells if the cancer has spread to distant organs. The extent of cancer growth for the T category is as follows:

- T0:** No primary tumor
- Tis:** Tumor is only in the breast lobules or ducts
- T1:** Tumor is 2 cm or smaller in diameter (about $\frac{3}{4}$ inch)
- T2:** Tumor is larger than 2 cm but no larger than 5 cm in diameter
- T3:** Tumor is larger than 5 cm in diameter
- T4:** Tumor has spread to the chest wall or skin

The N category has two sets of descriptions. The first set is marked with the letter “c” for clinical stage:

- cN0:** No growth to lymph nodes
- cN1:** Tumor growth to ipsilateral, unattached axillary lymph nodes
- cN2:** Tumor growth to ipsilateral, attached axillary lymph nodes or internal mammary lymph nodes
- cN3:** Tumor growth to ipsilateral supraclavicular lymph nodes or both the ipsilateral axillary and internal mammary lymph nodes

Definitions:

Chest wall: The layer of muscles, bones, and tissue on the outer part of the chest

Clinical stage: A cancer stage given by your doctor before surgery

Ipsilateral: On the same side of the body as the tumor

The second set is marked with the letter “p” for pathologic stage:

- pN0:** No growth to lymph nodes
- pN1:** Tumor growth to 1 to 3 axillary lymph nodes
- pN1mi:** Lymph node tumor is 2.0 mm or smaller in size
- pN2:** Tumor growth to 4 to 9 axillary lymph nodes
- pN3:** Tumor growth to 10 or more axillary lymph nodes or growth to lymph nodes in other areas around the breast

The M category includes:

- M0:** No distant cancer spread
- M1:** Cancer has spread to distant organs

The 5 stages of breast cancer

The information from each TNM category is combined to assign the cancer a stage (Table 2). Each stage is represented by Roman numerals ranging from 0 to IV. The stages identify tumor types that have a similar prognosis and thus are treated in a similar way.

Your cancer will likely be assigned a stage two times. First, the clinical stage will be decided by the physical exam and tests for diagnosis. Second, the pathologic stage will be based on the tissue samples taken during surgery. Most of the time, the pathologic stage is the most important stage. This is because your lymph nodes can only be completely examined under a microscope.

Table 2. Staging of breast cancer

Anatomic stage/prognostic groups			
0	Tis	N0	M0
IA	T1	N0	M0
IB	T0	N1mi	M0
	T1	N1mi	M0
IIA	T0	N1	M0
	T1	N1	M0
	T2	N0	M0
IIB	T2	N1	M0
	T3	N0	M0
IIIA	T0	N2	M0
	T1	N2	M0
	T2	N2	M0
	T3	N1	M0
	T3	N2	M0
IIIB	T4	N0	M0
	T4	N1	M0
	T4	N2	M0
IIIC	Any T	N3	M0
IV	Any T	Any N	M1

Used with the permission of the American Joint Committee on Cancer (AJCC), Chicago, Illinois. The original source for this material is the AJCC Cancer Staging Manual, Seventh Edition (2010) published by Springer Science+Business Media LLC; www.springer.com.

Stage 0. Noninvasive breast cancers are considered stage 0. LCIS and DCIS tumors are labeled as Tis (is = in situ). In stage 0, there is no cancer growth to the lymph nodes or distant sites.

Stage I. The breast tumor is invasive in stage I. Its size is 2 cm (about ¾ inch) or smaller in diameter. The cancer has either not spread to or there are very small tumors in the lymph nodes. When there are very small tumors, the cancer is stage IB. In stage IA and IB, the cancer has not spread throughout the body.

Stage II. Compared to stage I, the tumor is larger, there more are cancer cells in the lymph nodes under the arms, or both features are present. However, the cancer has still not metastasized. Stage II breast cancers are divided into two groups. These two groups are called stage IIA and stage IIB.

In stage IIA, there is either no primary tumor in the breast or the tumor is no larger than 2 cm, but cancer cells are in the axillary lymph nodes. The N1 criterion for clinical staging is the presence of cancer cells in the ipsilateral axillary lymph nodes. These lymph nodes are not attached to one another or nearby tissue. The pathologic N1 criterion is cancer in 1 to 3 axillary lymph nodes. Also for stage IIA, the tumor size can range from 2.1 to 5 cm but the lymph nodes are cancer free.

In stage IIB, the tumor size can range from 2.1 to 5 cm with affected axillary lymph nodes. Stage IIB breast cancer also includes tumors larger than 5 cm with no spread to the lymph nodes. The tumor has not grown into the chest wall or skin.

Definitions:

Criterion: A standard for making a decision

Pathologic stage:
A cancer stage given by a pathologist based on surgery samples

Stage III. Stage III is divided into three groups—IIIA, IIIB, and IIIC. Stage IIIA includes a tumor larger than 5 cm and cancer in the ipsilateral axillary nodes. Stage IIIA also includes a smaller tumor or no tumor and a greater impact of cancer on the lymph nodes. The N2 criterion for clinical staging is malignant ipsilateral axillary nodes, which are attached to one another or nearby tissue. Otherwise, cancer in the internal mammary lymph nodes also meets the criterion. The pathologic N2 criterion is cancer in 4 to 9 axillary lymph nodes.

In stage IIIB, the tumor has grown into the chest wall or skin but there may or may not be cancer in the lymph nodes. In stage IIIC, there may or may not be a tumor but the cancer has spread far into the nearby lymph nodes. The N3 criterion for clinical staging is cancer in the supraclavicular lymph nodes or cancer in both the ipsilateral axillary and internal mammary lymph nodes. The pathologic N3 criterion is cancer in 10 or more axillary lymph nodes or cancer in other lymph nodes around the breast. To note, inflammatory breast cancer is always staged as stage IIIB unless it has metastasized.

Stage IV. This stage is characterized by the spread of breast cancer to distant organs. It includes tumors of any size, any affected lymph nodes, and metastasis.

3.6 Breast cancer grade

Your breast cancer will also be grouped by how closely the cancer cells look like normal cells. This is called the grade. The pathologist assigns a grade from 1 to 3. Grade 1 is assigned when the cancer cells look the most like normal cells. Grade 3 is assigned when the cancer cells look the least like normal cells. The grade of the cancer helps predict whether you have a more or less aggressive cancer. In general, a lower grade suggests a cancer that is less likely to spread.

The tumor grade is most important for women with node-negative small tumors. Women with low-grade tumors may require no further treatment, while women with moderate- to high-grade tumors may need genetic testing. Genetic testing can assess the risk of breast cancer recurrence and benefit of hormonal therapy or chemotherapy.

LCIS may not be given a grade and DCIS is given a nuclear grade. A nuclear grade describes how abnormal the nuclei of the cancer cells look. Sometimes other traits of DCIS are also used to decide cancer grade.

Part 4: Treating breast cancer

Main Points

- Consider your health and personal feelings when choosing your treatment.
- Getting a second opinion is suggested.
- One or more lymph nodes may be removed to see if the cancer has spread.
- Surgery and radiotherapy treat cancer in or near the breast.
- Systemic therapy treats cancer beyond the breast. It includes chemotherapy, hormone therapy, and targeted therapy.
- Systemic therapy is also used to shrink tumors for surgery.
- There may be research on new treatments that you can take part in.

Definitions:

Malignant: A tumor with cancer cells

Medical oncologist: A physician who specializes in all types of cancer

Radiation oncologist: A doctor who specializes in the treatment of cancer with radiation

Surgeon: A doctor who specializes in operations

4.1 Choosing your treatment

Cancer care is a team effort. Your primary doctor will refer you to one or more doctors who specialize in cancer. Surgeons and radiation oncologists provide local treatment to the breast. Medical oncologists give drug treatments to destroy cancer cells that may have spread beyond the breast. A list of questions about treatment that you may want to ask your doctors can be found in Part 9.

Treatments for breast cancer include surgery, radiotherapy, chemotherapy, hormone therapy, and targeted therapy. In addition, there may be clinical trials testing new treatments. The treatment plan suggested by your doctors will be based on your type of breast cancer. Hormone receptor status, HER2 status, how the cancer cells look under a microscope, tumor size, and how far the cancer has spread are important factors for deciding the best treatments for you.

Like other women, your treatment choice might depend on your age, body image, hopes and fears, and stage of life. Some women select surgery that spares breast tissue for body image reasons. Other women may choose surgery that removes the whole breast because of less time or perceived need for radiotherapy. Still others may select treatment based on possible side effects.

There is no single treatment practice that is best for all patients. This is very true for women with inflammatory breast cancer. Among these women, treatment is tailored differently to meet the needs of each woman. Your final decision will require talking about the possible results and your personal feelings toward treatment. Your cancer care team can help you sort through the choices.

4.2 Getting a 2nd opinion

The time around a cancer diagnosis is very stressful. Often people with cancer want to get treated as soon as possible. They want to make their cancer go away before it spreads further. It is important to know that while cancer can't be ignored, there is time to think about treatment choices and decide which treatment plan is best for you.

You may wish to have another doctor review your test results and the treatment plan your doctor has recommended. This is called getting a 2nd opinion. Breast cancer is a serious disease and new information may have been published about which treatments are most effective and safe. While you may completely trust your doctor, it is sometimes helpful to get a 2nd opinion on which treatment is right for you.

Your doctor will need to give copies of the pathology report and other test results to the other doctor. Some people feel uncomfortable asking their doctor for help. However, a 2nd opinion is a normal part of cancer care. Even when doctors are diagnosed with cancer, most will consult with more than one doctor before choosing their treatment. Furthermore, some health plans require a 2nd opinion. If your health plan does not cover the cost of a 2nd opinion, you have the choice of paying for it yourself.

Choosing your cancer treatment is a very important decision. It can have consequences for your length and quality of life. There are few cancers that are so aggressive that you can't take a few weeks to get a 2nd opinion and select the best treatment for you.

4.3 Treatments for breast cancer

The treatments for breast cancer are described in this section. Knowing what these treatments involve will help you read the treatment guide in Part 7. Not all women receive every type of treatment listed. Also, the order of treatment can differ between women. There are several terms used to describe when treatment is given. For example, some women receive chemotherapy before surgery. After surgery, they start hormone therapy. In this case, chemotherapy is the neoadjuvant treatment, surgery is the primary treatment, and hormone therapy is an adjuvant treatment.

Terms describing the order of a treatment

Adjuvant treatment

Treatment that follows primary treatment

First-line regimen

First round of chemotherapy

Neoadjuvant treatment

Treatments given before the primary treatment

Primary treatment

The main treatment for cancer

Second-line regimen

Second round of chemotherapy

Definitions:

Clinical trial: Research that compares new treatments to the best current treatment to find out which is better

Side effect: An unplanned physical or emotional response to treatment

Surgery

Most patients with breast cancer will have surgery. There are two common types of surgery for removing tumors in the breast tissue: a lumpectomy and a mastectomy. Also, women usually have at least one lymph node surgically removed. This surgery is called a lymphadenectomy.

Lumpectomy. The entire breast lump with some normal breast tissue is removed in a lumpectomy (Figure 13). This is a breast-conserving surgery (also called breast-conserving therapy). Your surgeon will work with the pathologist to make sure that there are no signs of cancer. If cancer cells are found at the outside edge of the removed tissue, more surgery is usually needed. Most often, surgery for this positive margin is another lumpectomy but sometimes a mastectomy is needed.

Mastectomy. A mastectomy surgically removes either a large part of or the whole breast. There are many types of mastectomy. Three common types are a total (simple) mastectomy, a modified radical mastectomy, and a partial (segmental) mastectomy. A modified radical mastectomy is the most common type of mastectomy done today. In this surgery, the entire breast is removed but the chest muscles remain (Figure 13).

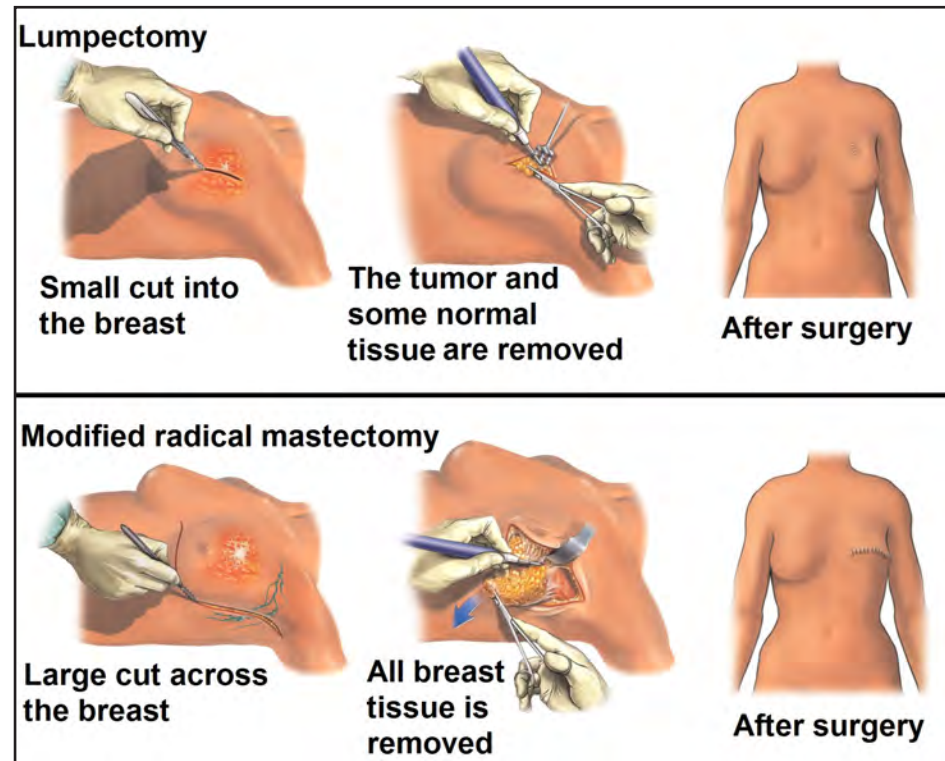


Figure 13. Common surgeries for breast cancer

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Saving the chest muscles preserves the strength in the arm. Following a mastectomy, there is a horizontal scar across the chest where the breast was. A mastectomy is required in some cases, but some women choose mastectomy over lumpectomy.

Quadrantectomy. A quadrantectomy removes one-fourth of the breast. It is a breast-conserving surgery like a lumpectomy and a partial mastectomy. However, the quadrantectomy and partial mastectomy remove more breast tissue than a lumpectomy.

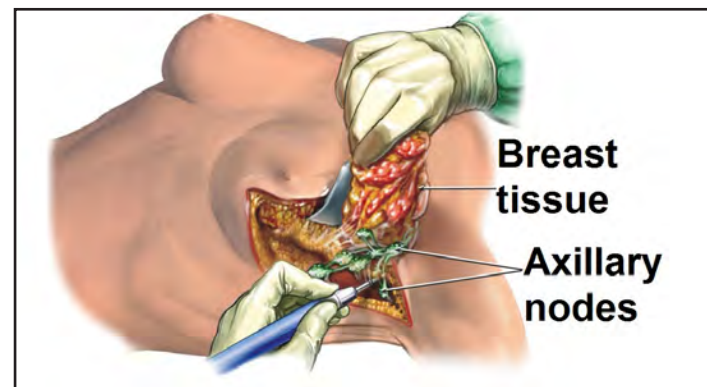
Lymphadenectomy. The only way to know for certain if the cancer has spread to your lymph nodes is to view them under the microscope. There are two common surgeries to remove lymph nodes. They include:

Sentinel lymph node biopsy. A sentinel lymph node biopsy is now a common surgery. It is used to examine lymph nodes more closely when no signs of cancer are noted by initial lymph node tests. A radioactive substance or dye is injected into the lymph vessel. The dye follows the path the lymph takes when it leaves the breast. The dye allows the surgeon to find the first lymph node to which lymph travels. The surgeon then removes that node and sends it to the pathologist. A sentinel lymph node biopsy should only be done by a surgical team experienced with this method. If the sentinel lymph node is cancer free, no more surgery is needed. If cancer is present, the surgeon will remove more lymph nodes to see how many have cancer. This information will help plan the best treatment.

Axillary lymph node dissection. Axillary lymph node dissection is required for women with signs of malignant lymph nodes. In this surgery, all the lymph nodes in your armpit are removed. (Figure 14). This method can clearly show if the cancer has spread to your lymph nodes. It can be done at the same time as the tumor removal or several days later. Importantly, one recent clinical trial suggested that when fewer than three sentinel lymph nodes have cancer, removing more lymph nodes may only cause worse symptoms and not improve treatment results.

Figure 14.
Axillary lymph node dissection during tumor surgery

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Definitions:

Lumpectomy: Surgery to remove the whole breast lump and some normal breast tissue

Lymphadenectomy: Surgery to remove lymph nodes

Mastectomy: Surgery to remove the whole breast

Positive margin: The normal-looking tissue around the tumor has cancer cells

Scar: A permanent mark on the skin after an injury or surgery

Sentinel lymph node: The first lymph node lymph travels to after leaving the breast

Radiotherapy

Radiotherapy uses a beam of high-energy rays (or particles) to destroy cancer cells. It is needed to kill any cells left behind after surgery. Cancer cells may remain in the breast, chest wall, or lymph nodes. Radiotherapy can be given in two ways:

External beam radiation therapy (EBRT). EBRT delivers radiation from a machine outside the body. This type of radiation therapy is most often given after lumpectomy. Radiation is given to the entire breast with an extra dose (or “boost”) to the site of the tumor. It is usually given 5 days a week for 6 to 7 weeks.

Brachytherapy. Brachytherapy is also called interstitial radiation. It involves placing radioactive objects in or near to where the tumor was removed. Brachytherapy may also be given to boost EBRT in women who received a lumpectomy.

The extent of radiotherapy depends on 2 things: (1) which type of surgery was received and (2) whether the lymph nodes have cancer. After a lumpectomy, the whole breast will receive radiation to destroy any remaining cancer cells. Also, the area where the cancer was removed will get an extra boost to prevent the cancer from returning. After a mastectomy, radiation will be given to the remaining skin and muscle if the tumor was larger than 5 cm or if there was not a small margin around the removed tumor.

After surgery, more radiation may be needed if the cancer has spread to the lymph nodes. Radiation may be given to the area just above the collarbone and along the breastbone. The radiated area depends on the number and location of involved lymph nodes.

Partial breast irradiation. Recently, some doctors have given radiation only to the lumpectomy site instead of the whole breast. This is called a partial breast irradiation. If breast cancer recurs, the most common place is the site of the original tumor. Outside of a clinical trial, partial breast irradiation is an option for women who are over 60 years old and do not have the *BRCA1* or *BRCA2* mutation, have small tumors with negative margins, and have favorable ductal cancer. For other women, the NCCN Guidelines Panel encourages women to take part in clinical trials studying partial breast irradiation.

Systemic therapy

Breast cancer is able to spread to other parts of the body. Doctors use drugs to treat cancer cells that may have spread beyond the breast and nearby tissues. This drug treatment is called systemic therapy. It includes chemotherapy, hormone therapy, and targeted therapy. Some drugs are pills that are swallowed and other drugs are injected into the body with a needle. In most cases, systemic treatment follows soon after surgery.

If you had surgery for early-stage cancer, it is impossible to be 100% sure that cancer cells did not spread before surgery. If they did spread, these cells could grow to become metastatic breast cancer. The goal of systemic adjuvant therapy is to prevent this. Except for women with very small tumors and low risk of recurrence, most women with invasive breast cancer receive systemic adjuvant therapy.

Women with breast cancer that has spread to other parts of the body have metastatic breast cancer. For these women, local treatments are not able to get rid of all the cancer. While advanced breast cancer is unlikely to be cured, long-term cancer control is often possible with systemic treatment. All the types of systemic treatment may be used at some point for advanced cancer. When one treatment stops working, another drug or combination of drugs can be used. Some women with metastatic breast cancer live for years and even decades with a high quality of life.

Chemotherapy. Chemotherapy is the use of drugs to kill cancer cells. When talking about chemotherapy, many people commonly refer to it as “chemo.” It is given orally as a pill or intravenously into a vein with a needle. Either way, the drugs travel in the blood to kill cancer cells throughout the body. Sometimes chemotherapy is used as a neoadjuvant treatment to make it easier to remove the cancer. Also, chemotherapy can be used to shrink tumors larger than 5 cm that would be otherwise unfit for surgery. Otherwise, chemotherapy is used as an adjuvant treatment for early-stage breast cancer. In metastatic breast cancer, the goal is to control the cancer so that women can live longer with the best quality of life possible.

Sometimes chemotherapy is one drug, called a single agent. Other times a mix of drugs is used. This is called a chemotherapy regimen. A regimen increases the odds that more cancer cells will be killed since different drugs work in different ways. The treatment goal of chemotherapy is used to help decide which chemotherapy drug(s) will be used. In many cases, doctors will use a single agent because it provides good control with fewer side effects. If your disease is very aggressive, your doctors may use regimens to control the disease faster but with more side effects.

Definitions:

BRCA mutations:

Changes in genes that normally help prevent tumor growth

Boost: An extra dose of radiation to a specific area

Partial breast irradiation:

Radiation to the lumpectomy site

Particles: Small pieces of matter

Chemotherapy is given in cycles of treatment days followed by days of rest. These cycles vary in length depending on which drugs are used. Typically, the cycles are 14, 21, or 28 days long. These cycles give the body a chance to recover before the next treatment. Thus, a regimen of 3 to 6 months has rest periods between treatments. See Table 3 for a list of common chemotherapy and other drugs for breast cancer.

Often, neoadjuvant or adjuvant chemotherapy is most effective when drug regimens are used. There are several effective combinations. For metastatic cancer, a drug or regimen is used until it stops working and then is changed to another. A woman may take one regimen right after another until three regimens in a row have failed to work. If the cancer is HER2 positive, combinations that include trastuzumab will be used.

Table 3. Common systemic drugs for breast cancer

Generic name	Brand name	Drug class
Early stage		
Anastrozole	Arimidex [®]	Selective nonsteroidal aromatase inhibitor
Capecitabine	Xeloda [®]	Antimetabolite
Carboplatin	Paraplatin [®]	Platinum alkylating agent
Cyclophosphamide	Cytoxan [®]	Alkylating agent
Docetaxel	Taxotere [®]	Microtubule inhibitor
Doxorubicin	Adriamycin [®]	Antineoplastic anthracycline
Epirubicin	Ellence [®]	Antineoplastic anthracycline
Exemestane	Aromasin [®]	Irreversible steroidal aromatase inactivator
Fluorouracil	5-FU	Antimetabolite
Letrozole	Femara [®]	Competitive nonsteroidal aromatase inhibitor
Paclitaxel	Taxol [®]	Microtubule inhibitor
Tamoxifen	Nolvadex Istubal Valodex	Nonsteroidal antiestrogen
Trastuzumab	Herceptin [®]	Anti-human HER2 monoclonal antibody

Part 4: Treating breast cancer

Late stage		
Anastrozole	Arimidex®	Selective nonsteroidal aromatase inhibitor
Bevacizumab	Avastin®	Anti-vascular endothelial growth factor (VEGF) antibody
Carboplatin	Paraplatin®	Platinum alkylating agent
Capecitabine	Xeloda®	Antimetabolite
Cisplatin	Platinol®	Platinum alkylating agent
Cyclophosphamide	Cytoxan®	Alkylating agent
Docetaxel	Taxotere®	Microtubule inhibitor
Doxorubicin	Adriamycin®	Antineoplastic anthracycline
Doxorubicin injection	Doxil®	Antineoplastic anthracycline
Epirubicin	Ellence®	Antineoplastic anthracycline
Eribulin	Halaven™	Microtubule inhibitor
Etoposide	VePesid®	Topoisomerase II inhibitor
Exemestane	Aromasin®	Irreversible steroidal aromatase inactivator
Fluorouracil	5-FU	Antimetabolite
Fulvestrant	Faslodex®	Estrogen receptor antagonist
Gemcitabine	Gemzar®	Antimetabolite: Pyrimidine antagonist
Ixabepilone	Ixempra®	Microtubule inhibitor
Lapatinib	Tykerb®	Inhibitor of intracellular kinase domain of epidermal growth factor receptor (EGFR) and human epidermal growth factor receptor 2 (HER2)
Letrozole	Femara®	Competitive nonsteroidal aromatase inhibitor
Paclitaxel	Taxol®	Microtubule inhibitor
Tamoxifen	Nolvadex Istubal Valodex	Nonsteroidal antiestrogen
Toremifene	Fareston®	Nonsteroidal antiestrogen
Trastuzumab	Herceptin®	Anti-human HER2 monoclonal antibody
Vinblastine	–	Microtubule inhibitor; Vinca alkaloid
Vinorelbine	Navelbine®	Microtubule inhibitor; Vinca alkaloid

The listed chemotherapy drugs have been shown in clinical trials to work well and be safe. It is important to know that even the best drugs do not always work. Also, while these drugs are safe, you may have side effects, even serious ones. Chemotherapy kills cancer cells, but it also damages some normal cells. Your doctor must keep a careful balance of doses high enough to kill the cancer cells but low enough to avoid destroying too many healthy cells. Every drug has possible side effects, so it is important to take only the ones that are most likely to work.

Hormone therapy. If your breast cancer is hormone–receptor positive, hormone therapy will likely be part of your treatment. Estrogen is a hormone made by the ovaries and in small amounts by the adrenal glands and fat. It can cause breast cancer cells that have hormone receptors to make more cancer cells. Blocking estrogen from working or lowering estrogen levels can help stop breast cancer from returning. There are three types of hormone therapy.

Antiestrogen drugs. Antiestrogens stop the effect of estrogen on cancer cell growth. They work by blocking the receptor for estrogen located on the edge of the cell. Tamoxifen is the antiestrogen drug most commonly used for women who have not reached menopause. Toremifene and fulvestrant are options for postmenopausal women with metastatic breast cancer. Fulvestrant reduces the number of estrogen receptors.

Aromatase inhibitors. Other drugs called aromatase inhibitors lower estrogen levels in the body. These drugs work by blocking a protein that makes estrogen in postmenopausal women. They cannot stop the ovaries of premenopausal women from making estrogen. For this reason, these drugs only work in postmenopausal women. Three drugs in this category are used for treatment of breast cancer: anastrozole, letrozole, and exemestane.

Ovarian ablation. The ovaries are the main source of estrogen in premenopausal women. Removing them stops most estrogen from being made. Surgery that removes the ovaries is called an oophorectomy. Radiotherapy to the ovaries also stops the ovaries from making estrogen. A third ablation choice is drugs called luteinizing hormone–releasing hormone (LHRH) agonists. These drugs block estrogen production by the ovaries by stopping LHRH from being made in the brain.

In early-stage breast cancer, hormonal drugs are often given for at least 5 years to prevent breast cancer from returning. Often, both hormone therapy and chemotherapy are used as adjuvant therapy for hormone receptor–positive breast cancer with a significant risk of recurrence. Your doctor may switch your therapy to an aromatase inhibitor if you are first take tamoxifen for several years and you reach menopause. It is important to finish and not stop taking hormone therapy without telling your doctor. These drugs work better when taken for long periods of time.

Hormone therapy is often the first treatment used for advanced breast cancer, especially for hormone–receptor positive tumors. However, hormone therapy is also used for hormone-negative receptors that act like hormone–receptor positive disease. It is also first used for bone metastases, symptom-free metastases, or metastases not affecting the organs needed for living.

Different hormone therapies are successful in treating metastatic breast cancer. When one stops working, others can be tried. Often, switching from one hormone therapy to another can control the disease for a long time. This is not the case if your disease is quickly advancing. If your cancer has not responded to three hormone therapies in a row, your doctor may recommend changing to chemotherapy.

Hormone therapy and menopause. As discussed earlier, aromatase inhibitors are not recommended for premenopausal women. For this reason, deciding whether a woman is postmenopausal is important for making treatment decisions. This is not as simple as it may sound. Menstrual periods can stop because of cancer treatment while the ovaries continue to make estrogen. Also, at times chemotherapy stops the ovaries from making estrogen for awhile, but they can start making estrogen again after treatment. To know your menopausal status, your doctor may order blood tests to check for related hormone levels.

Targeted therapy. Some cancer treatments are made to affect only cancer cells and not normal cells. This is called targeted therapy. Trastuzumab is an example of a targeted therapy for cancer cells with high amounts of HER2 protein. Trastuzumab may be given in a neoadjuvant drug regimen to shrink the tumor for easier removal. Studies indicate that it is an effective treatment for HER2-positive, early-stage breast cancer and HER2-positive metastatic breast cancer. Adjuvant trastuzumab is most often given by needle (intravenously) for 1 year. It is commonly started when chemotherapy starts and is continued after chemotherapy has been completed. If the drug regimen is not finished before surgery, it may be completed afterward.

Definitions:

Adrenal glands: The pair of glands above each kidney that make hormones

LHRH: A hormone made in the brain that causes the pituitary gland to make luteinizing hormone

Oophorectomy: Surgery to remove the ovaries

Ovaries: The pair of organs in females that makes ova (eggs)

Postmenopausal: The state of no menstrual periods for at least 12 months

Premenopausal: The state of having regular menstrual periods

Tamoxifen: A drug that lowers the amount of estrogen in the body

4.4 What are clinical trials?

Many new cancer treatments are available because patients have been willing to take part in clinical trials. In these studies, new treatments are compared to current treatments, such as those described in Part 4.3. The purpose of the clinical trial is to find out if the new or current treatment is better at fighting cancer better. Clinical trials may also look at new ways to diagnose or prevent a disease, make current treatments better, or assess whether a new treatment is safe. NCCN believes that the best management for any patient with cancer is in a clinical trial.

Your doctor may ask you if you would like to be in a clinical trial. There are several benefits. First, you will receive the most current cancer care according to a very specific treatment plan. Second, doctors who work with clinical trials know the newest cancer treatments. They also track the results of treatment—both good and bad—and compare their results with other doctors to improve treatment.

There are many decisions to make after your diagnosis of cancer, and one may be whether or not a clinical trial is right for you. Here we will give you a brief review of clinical trials. Talking with your cancer care team, your family, and your friends can help you make the best treatment choice for you.

The purpose of clinical trials

Clinical trials are done to test new treatments to see whether they are better than the current treatments. A clinical trial is only done when there is good reason to believe that a new treatment, test, or procedure may be better than the current one. Treatments tested in clinical trials are often found to have benefits and may become tomorrow's standard treatment. However, there is no way to know whether this will be the case before the results of the trial have been confirmed.

Clinical trials can focus on many things, such as:

- New uses of medications that are already approved by the U.S. Food and Drug Administration (FDA). For example, drugs that are used in one type of cancer may be tested in another type of cancer.
- Different ways of giving chemotherapy, such as by mouth instead by a needle in the arm.
- New drugs that have not yet been approved by the FDA. For example, research to know the best dose that treats the disease and has the fewest side effects.
- Alternative medicines, such as herbs and vitamins.
- New diagnostic tests, such as genetic tests, to assess which patients are the best candidates for certain treatments.
- Medicines or procedures to relieve symptoms.

Phases of clinical trials

There are four phases of clinical trials, which are numbered I, II, III, and IV. The phases are described below using the example of a drug treatment:

- **Phase I clinical trials** are done to find the best way to safely give a new treatment to patients. The cancer care team closely watches patients for any harmful side effects. In phase I studies, the drug has already been tested in lab and animal studies but needs to be tested in humans to understand the best dose for treatment with the fewest side effects. Since phase I trials are usually the first type of trial in humans, most patients in these trials have been previously treated with current treatments. Doctors start by giving very low doses of a new drug to the first patients and increasing the doses for later groups of patients until side effects appear or the desired treatment effect is seen. Doctors are hoping to help patients, but the main purpose of a phase I trial is to test the safety of the drug. If a drug is found to be reasonably safe in phase I studies, it can be tested in a phase II clinical trial.
- **Phase II clinical trials** test if a drug works for a specific type of cancer and are done in larger groups of patients when standard treatments are not working. Often, phase II trials test new combinations of drugs. Patients are closely watched to see if the treatment has an effect, such as shrinking of the tumor. The cancer care team also looks for side effects. If a drug or combination of drugs is found to be effective in phase II studies, it can be tested in a phase III clinical trial.
- **Phase III clinical trials** include large numbers of patients. Often, these studies are randomized. This means that patients are put into a treatment group by chance. There can be more than two treatment groups in a clinical trial. The control group gets the standard treatment and the other groups get a new treatment. Neither you nor your physician can pick which group you would get assigned. This may make you feel uneasy. Your doctor will explain to you the exact reason for the clinical trial and the risks and benefits of all treatments. Every patient in phase III studies is

Definitions:

Alternative medicine:

Treatments used in place of ones usually given by doctors

Food and Drug Administration (FDA):

A federal government agency that regulates drugs and food

watched closely. The study will be stopped early if the side effects of the new treatment are too severe or if one group has much better results than the others. Phase III clinical trials are usually needed before the FDA will approve a new drug for use by the general public

- **Phase IV clinical trials** study new drugs approved by the FDA and made available to all patients. In phase IV studies, the treatment is tested in a very large number of patients with different types of cancer. This way more can be learned about short-lived and long-lasting side effects and safety. For example, some rare side effects may only become apparent in phase IV studies. Doctors can also learn more about how well the drug works and if it might be helpful when used in other ways, such as in combination with other treatments.

Deciding to enter a clinical trial

If you would like to take part in a clinical trial, you should begin by asking your doctor if clinical trials are available where you have decided to get treatment. If clinical trials are available, you will be evaluated to see if you meet specific conditions of the study. In clinical trials, study participants are usually similar in terms of their tumor and general health. The purpose is to know that any improvement is because of treatment and not because of differences between patients. Even if you meet the conditions of the study, it is still your choice to participate.

All study participants need to sign a paper called an informed consent form (ICF). The ICF describes the study in detail including the risks and benefits. Your doctor will explain why the clinical trial may be right for you, and the ICF will be reviewed completely before you decide whether to participate.

How can I find out more about clinical trials that might be right for me?

You can get a list of clinical trials by calling the National Cancer Institute (NCI) Cancer Information Service toll free at 1-800-4-CANCER (1-800-422-6237) or by visiting the NCI clinical trials website at www.cancer.gov/clinicaltrials. Based on information about your cancer, this service can put together a list of clinical trials that may match your medical needs. The service will also ask where you live and whether you are willing to travel so a nearby treatment center can be found.

Definitions:

Control group: Research participants who do not receive a new treatment

Informed consent form (ICF): A document describing a study and requiring a signature from participants after review

Randomized: Assignment to a group by chance

Part 5: Treating signs and symptoms

Main Points

- All treatments for breast cancer can cause unwanted signs and symptoms.
- Not all women have the same symptoms or severity of symptoms.
- Some side effects of treatment are serious and need to be checked on a regular basis.
- If you wish to have babies in the future, talk with a fertility doctor before starting treatment.
- Talk with your treatment team about ways to treat symptoms of breast cancer and its treatment.
- Surgery to create new breasts is an option for many women.
- If you do not want treatment for breast cancer, you can still receive treatment for symptoms.

5.1 Common side effects

Each treatment for breast cancer has possible side effects. Side effects are unpleasant physical or emotional conditions or symptoms. How your body responds to cancer and its treatment is as unique as your fingerprints. Knowing your cancer's stage and your treatment choices can help you have better expectations about any health problems you may face. However, no one can be certain how you will respond. Women can have different side effects although they are on the same treatment. Also, the severity of side effects can vary between women. This part describes the more common side effects of breast cancer treatment.

Side effects of surgery

Pain and swelling can be side effects of surgeries that remove the tumor in the breast. Both symptoms usually fade away in the weeks following surgery. If your symptoms bother you, talk to your doctor or nurse about treatment.

Both axillary lymph node dissection and sentinel lymph node biopsy have side effects. However, side effects are much more common and severe with lymph node dissection. Lymphedema is the most important of these side effects and may be permanent. Lymphedema is swelling due to buildup of lymph. It occurs in the arms after node removal. Most women find lymphedema bothersome but not disabling. There is no way to know who will develop it or when it will develop. It can happen just after surgery or months to years later. Significant lymphedema occurs in about 1 in 10 women who have axillary lymph node dissection and in up to 1 in 20 of those who have sentinel lymph node biopsy.

Side effects of radiotherapy

Side effects most likely to occur from radiation are swelling and heaviness in the breast, sunburn-like skin changes in the treated area, and fatigue. Changes in the breast tissue and skin usually go away in 6 to 12 months. In some women, the breast may become smaller and firmer after radiotherapy. There may also be some aching in the breast. Rarely, a rib fracture or second cancer may be caused by radiation.

Side effects of chemotherapy

Side effects of chemotherapy depend on the drug type, amount taken, length of treatment, and the person. Some women have many side effects. Other women have few. Some side effects can be very serious while others can be unpleasant but not serious. Side effects include:

Heart damage. Doxorubicin and epirubicin may cause heart damage, but this is uncommon in people without heart disease. Trastuzumab can also cause heart damage in some women. If you might have heart disease, your doctor may recommend a heart test before starting treatment. If your heart is weakened, your doctor may use chemotherapy drugs that are not known to harm the heart. Fortunately, heart damage, although serious, is not common.

Infections, fevers, and low white blood cell counts.

Many of the common chemotherapy drugs can cause these side effects because they target cells that quickly make new cells. White blood cells are among the fastest of these, so they are very vulnerable to chemotherapy. Neutrophils are important white blood cells that fight bacterial infections. Your doctor will monitor the number of these and other blood cells before each chemotherapy cycle. If too low, a dose of chemotherapy might be delayed or the amount of chemotherapy might be reduced.

Blood counts are the lowest several days after chemotherapy. As a result, your body's ability to fight off an infection is weakened during this time. You should contact your doctor immediately if you have a fever of 101°F or higher because this is a sign of infection. For some regimens where low white blood cell counts are expected, your doctor may give other drugs called growth factors that increase white blood cells.

Bleeding and bruising. Platelets are another type of blood cell. They stop a wound from bleeding by forming blood clots. A shortage of platelets is fairly common during chemotherapy. Your doctors will check your platelet count and change your cancer treatment if needed.

Nausea and vomiting. These side effects are fairly common. However, your doctor can order drugs that greatly reduce these problems. Your doctor may recommend drugs for nausea and vomiting before taking chemotherapy. If so, it is important to take them. Preventing nausea and vomiting is much easier than stopping them once they start.

Common side effects

Surgery to remove tumor		
Swelling	Pain	Scar
Lymph node surgery		
Short- or long-term numbness in skin or upper arm	Lymphedema	Smaller, firmer breasts
Short-term limited movement of arm and shoulder	Radiotherapy	Fatigue
	Swelling, aches, heaviness in the breast	Fractured rib
	Sunburn-like skin changes	Second cancer
Chemotherapy		
Heart damage	Nausea, vomiting	Fatigue
Infections, fevers, low white blood cell counts	Early menopause	Mouth sores
	Loss of appetite	Hair loss
Bleeding, bruising		
Hormone therapy		
Hot flashes, vaginal discharge, mood swings	Venous thromboembolism (blood clots)	Osteoporosis, bone fractures, joint pain
Endometrial cancer, uterine sarcoma		
Targeted therapy		
Heart problems		

Notes:

Menopause and infertility. Pre-menopausal women may develop early menopause from chemotherapy drugs. Even if they have menstrual periods, they may be unable to have babies. The older a woman is when she receives chemotherapy, the more likely that these side effects will happen. Some chemotherapy drugs are more likely to cause early menopause than others.

Do not depend on chemotherapy to prevent pregnancy. Becoming pregnant while on chemotherapy can lead to birth defects in your baby and interfere with your cancer treatment. If you had menstrual periods before chemotherapy, use birth control while on it.

Other side effects. Short-lived side effects often include loss of appetite, fatigue, mouth sores, and hair loss. Your doctor or nurse can suggest ways to help with them.

Side effects of hormone therapy

For many women, tamoxifen causes symptoms of menopause. Menopausal symptoms include hot flashes, vaginal discharge, and mood swings. Tamoxifen has two rare but more serious side effects: 1) a slight increased risk for endometrial cancer and uterine sarcoma; and 2) a slightly increased risk for venous thromboembolism (Figure 15). Tell your doctor about any abnormal vaginal bleeding. This may be a sign of endometrial cancer. Report swelling and pain in a leg or arm to your doctor promptly. These may be signs of venous thromboembolism. For most women with breast cancer, the benefits of taking tamoxifen far outweigh the risks.

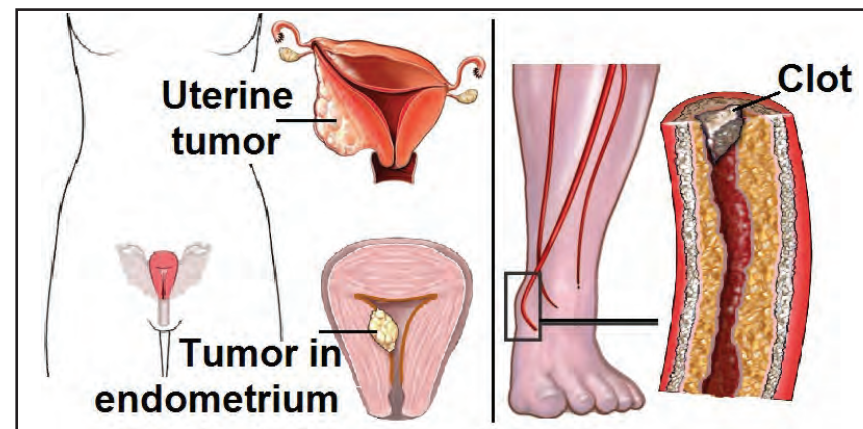


Figure 15.
Rare but serious side effects of hormone therapy

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The aromatase inhibitors have been compared with tamoxifen as adjuvant hormone therapy. They have different side effects than tamoxifen because they don't cause uterine cancer and very rarely cause blood clots. They can cause osteoporosis and bone fractures. This is because they remove all estrogen from the body of a postmenopausal woman. Checking your bone health with regular bone mineral density tests can show bone weakness before fractures occur. Your doctor can order medicine to strengthen your bones if necessary.

Aromatase inhibitors also cause hot flashes and sometimes joint pain. Although these are considered less serious side effects, some women find them severe enough to think about stopping therapy. If you have these thoughts, talk with your doctor about taking another drug that may have the same benefit but with fewer side effects.

Side effects of trastuzumab

Trastuzumab can harm the heart. It should be used with caution when combined with doxorubicin or epirubicin, which can also affect the heart. You may need to undergo regular testing to check your heart while on this drug.

5.2 Can I still have babies?

Many younger women with breast cancer are concerned about their ability to have babies after cancer treatment. Chemotherapy can cause menstrual periods to stop, but they usually return within 2 years of finishing chemotherapy. Of importance, menstrual periods do not predict 100% whether you will become pregnant. There is no valid way to make certain that fertility will return after treatment. Some women are able to get pregnant and others are not. If you wish to get pregnant in the future, it may be helpful to talk with a fertility doctor before starting chemotherapy.

Definitions:

Birth defect: A physical, mental, or chemical abnormality in a newborn baby

Endometrial cancer: Cancer in the lining of the uterus

Infertility: Physically unable to have babies

Osteoporosis: A disease that causes thinning, weakened bones

Uterine sarcoma: Cancer of the uterus

Venous thromboembolism: Dangerous blood clot in a vein

You should not become pregnant while undergoing radiation, hormone therapy, or chemotherapy. Although menstrual periods may stop during tamoxifen, it may still be possible to become pregnant. For this reason, it is important to use a reliable method of birth control. Birth control with hormones should not be used during and after breast cancer treatment. Other birth control methods are intrauterine devices, barrier methods, or, if you are done having babies, tubal ligation for you or a vasectomy for your partner (Figure 16).

Some women discover they have breast cancer while they are pregnant. Women in their 1st trimester of pregnancy may think about ending the pregnancy and focus on their treatment. Others will decide to stay pregnant, have a mastectomy and axillary staging, and wait until the 2nd trimester to start chemotherapy. This waiting period is needed because during the 1st trimester the baby is growing fast and is very sensitive to chemicals that can cause birth defects. In the 2nd and 3rd trimesters, the baby is less likely to be harmed by chemotherapy.

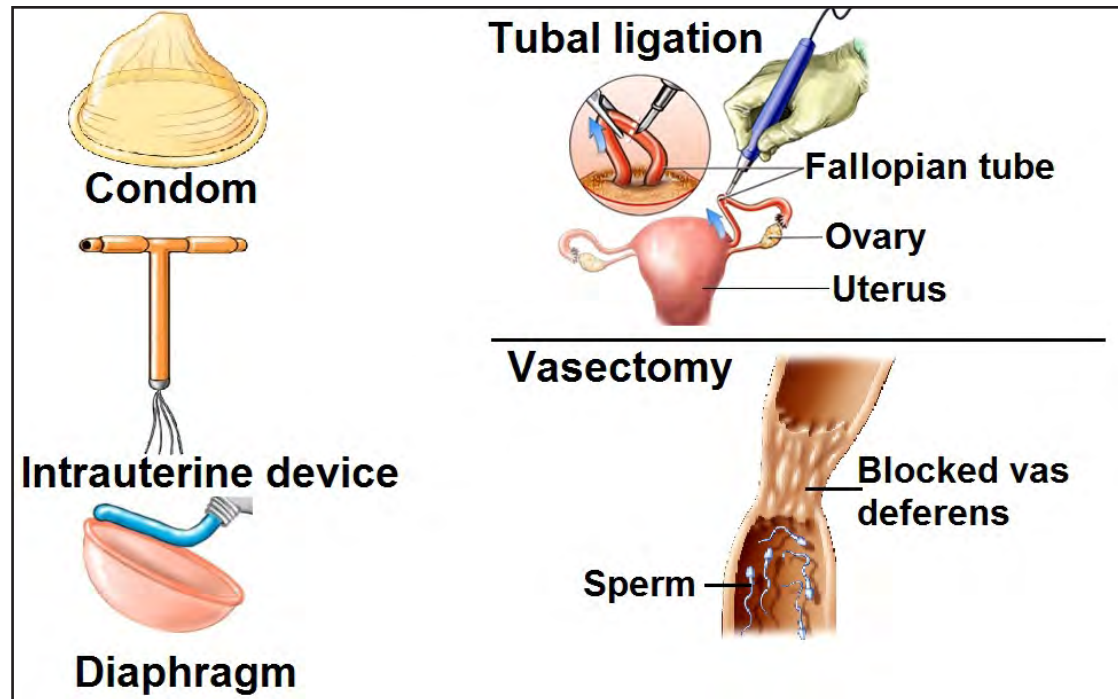


Figure 16. Birth control for women with breast cancer and their partners

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Women who discover they are pregnant in the 2nd or 3rd trimester can have either mastectomy or breast conserving surgery followed by chemotherapy. If needed, chemotherapy before surgery can be given in the 2nd or early 3rd trimester. In any case, radiotherapy and hormone therapy should be done after your baby is born.

Breast feeding babies is okay following breast-conserving therapy. However, the quantity and quality of the milk may be low. You should not breast feed if you are still undergoing chemotherapy or hormone therapy.

5.3 Symptom control

Most of these guidelines cover ways to treat breast cancer. However, maintaining your quality of life is also a very important goal. You may be able to help yourself feel better by taking an active role in your care. If you know the side effects of treatment, you are more likely to quickly notice them and tell your treatment team.

There are effective and safe ways to treat many symptoms of breast cancer and the problems caused by its treatment. Changes in behavior, diet, or over-the-counter medications may be helpful. For example, steps can be taken to avoid or control lymphedema, including:

- Avoiding having blood drawn from the arm on the same side as the lymph node surgery.
- Also, avoiding wearing blood pressure cuffs on and having needles placed into that arm.
- Wearing a well-fitted rubber sleeve that squeezes the arm.
- Wearing gloves when your arm might get cut.
- Telling your doctor immediately if your arm or hand feels tight or swollen.
- When properly given, medications can relieve symptoms without causing other symptoms. For example, drugs like denosumab, zoledronate, and pamidronate can treat bone loss. These are usually given with calcium and vitamin D supplements.

Symptom relief can help you to be more active and may, indirectly, help you to live longer. Don't hesitate to discuss your symptoms or any other quality-of-life concerns with your cancer care team. If you don't tell your treatment team, they may not figure out how you are feeling.

Definitions:

Barrier methods: Devices that prevent sperm from entering the uterus

Fallopian tube: The female organ that helps eggs travel from an ovary to the uterus

Intrauterine devices: Objects in the uterus that release medicine to prevent pregnancy

Tubal ligation: Surgery to stop eggs from traveling through the fallopian tubes to the uterus

Vas deferens: A male organ that helps sperm travel from the testicles to the penis

Vasectomy: Surgery to stop sperm from traveling through the vas deferens to the penis

5.4 Breast reconstruction

A mastectomy removes the whole breast. After a mastectomy, a woman may want to have her breast remade so that her breast looks more normal (Figure 17). Breast reconstruction requires more surgery after a mastectomy. You can have immediate reconstruction — at the same time as the mastectomy—or delayed reconstruction — days after the mastectomy. Your surgeon may use saline-filled implants or tissue from other parts of your body to reconstruct the breast.

Deciding the type of reconstruction and when to do it depends on several factors:

- Your personal preferences
- Your breast size and shape
- Your body size and shape
- How much you exercise
- The details of your medical situation (e.g., how much skin was removed)
- Whether you need chemotherapy or radiation

You and your doctor will make the decision together. If you are thinking about breast reconstruction, it is important to tell your doctor when planning cancer treatment.

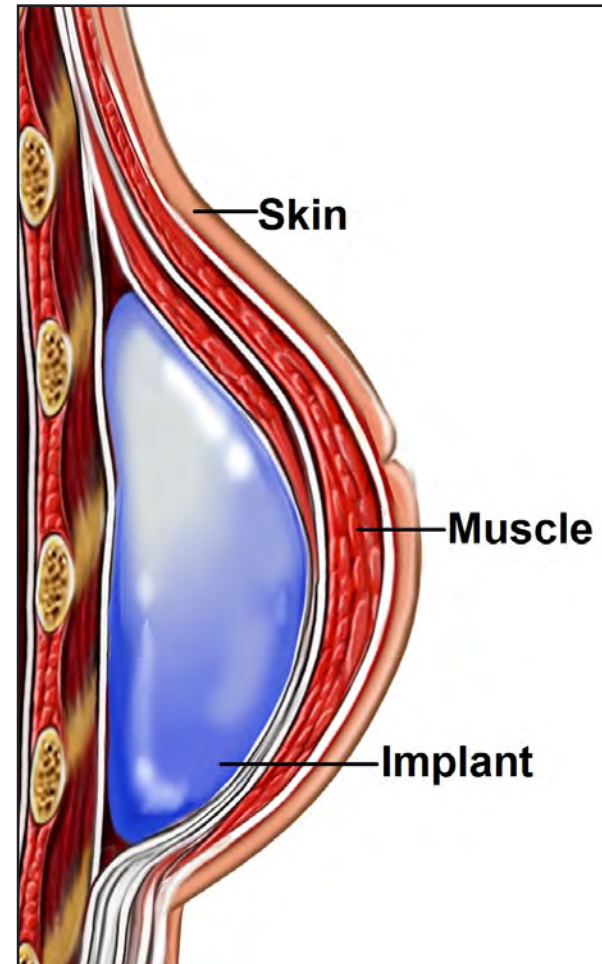


Figure 17.
Reconstructed breast with implant

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Main Points

- Tell your doctor about any alternative and complementary medicines you are taking.
- There is help for the many challenges you will face as a patient with cancer.
- Caregivers who don't ignore their own needs will likely give better care to their loved ones.

6.1 Aren't there other treatments?

You may hear about other treatments from your family and friends. They may suggest complementary and alternative medicine (CAM), such as vitamins, herbs, or stress reduction, as a treatment for your cancer or to help you feel better. CAM is a group of various treatments that are not usually given by doctors. There is a great deal of interest today in CAM for cancer.

Complementary medicines are treatments given along with usual medical treatments. Examples include acupuncture for pain management or yoga for relaxation. Many CAMs are being studied to find out if they are truly helpful. While some of these treatments may not be designed to kill cancer cells, they may be helpful if they improve your comfort and well-being.

Alternative medicine is used in place of usual medicine. Some alternative medicines are promoted as cures, though typically they have not been proven to work. If there was good evidence that CAM or other treatments cured cancer, it would be included in these guidelines.

It is important that you let your cancer care team know of any CAMs that you are using for two key reasons: (1) Your cancer care team can help you figure out which CAMs may be helpful and which have no benefit; and (2) Some CAMs may limit how well treatment for your cancer or other medical conditions works.

6.2 What else can I do?

For most patients with cancer, their primary concern is that their treatment works. However, having cancer is complex and brings many physical and emotional challenges. It is important to know these challenges, talk about them with your cancer care team, and use what support is available. Don't wait until you feel overwhelmed to ask questions or raise issues. There are ways of dealing with most of the problems you will face.

It is also important to know that there is no norm for how people cope with their cancer. Everyone reacts differently. Your reaction can be shaped by your type of cancer, personality, overall health, the support you have, and other factors. You can help yourself by knowing potential challenges and taking an active role in managing them. Below are some of the issues you may face, and in Part 9, there is a list of suggestions for taking care of yourself.

Anxiety and depression

Feelings of anxiety and depression are common among patients with cancer. Many women experience anxiety before their biopsy and while waiting to hear if they have breast cancer. For some women, this may be a minor problem, such as the normal anxiety felt while sitting in the doctor's office. It may also be a passing depression related to a difficult part of treatment. However, for some, it is a longer lasting, more serious distress that limits the ability to live and interact with people.

If you are having anxiety or depression, tell your treatment team. Too many people hesitate to talk about emotional concerns when there is excellent help available. This might include support groups, “talk” therapy, or medication. Some women also benefit from physical exercise, talking with family or friends, and using relaxation and meditation techniques. Your cancer care team has information to help you.

Fatigue

Fatigue is one of the most common problems that patients with cancer have. It can occur during treatment and beyond, and can have a serious impact on life. Cancer-related fatigue differs from normal tiredness in that it comes on suddenly and is not relieved by sleep. Some women have described it as paralyzing. Researchers are not sure what causes cancer-related fatigue. Surprisingly, clinical trials have found that physical exercise can help with cancer-related fatigue. Talk with your treatment team about an exercise program that is right for you.

Be aware of your energy levels and try to conserve your energy. Plan ahead, rest, limit activities, and prioritize. Good nutrition and stress management can also be helpful. Also remember that there are many fun activities that do not require much energy. Solving puzzles, visiting with friends, reading books, watching TV or movies, and even sitting outside can help how you feel. If you are experiencing fatigue, talk with your treatment team and work with them to develop an individual plan to help you.

Nutrition

Some women with breast cancer lose weight while others gain weight during treatment. In every case, good nutrition is always important. Depending on your type of cancer and treatment, you may have changes in taste, loss of appetite, problems eating and digesting food, or you may become much less active. For some women, their eating is related to stress or anxiety. Be aware of your dietary needs during and after treatment and plan to talk to a nutritional specialist. Meeting your calorie needs, getting plenty of fluids, and eating a balanced diet are all important.

Exercise

Until very recently, most patients with cancer were told not to exercise during treatment. New data, however, have shown that many patients benefit from moderate exercise. Exercise helps women maintain muscle tone and overall health, build good nutritional habits, and lower stress. Exercise programs vary depending on each woman's situation, so talk with your treatment team about what exercises would be good for you.

Being a survivor

Cancer survivorship begins on the day you learn of your breast cancer and continues throughout life. For many women, the end of active treatment signals a time of celebration but also of great anxiety. This is a very normal response. You may need support to address issues that arise from not being in treatment and not having regular visits with your treatment team.

You may have different challenges than the ones listed. It is important to remember that everyone has strengths and talents. Use yours to help cope with cancer and its treatments. Maintain warm relationships with family and friends. Make a list for them of things that would help you. Most people would be happy to hear what you need. If you are a person of faith, your personal faith and your faith community can help. There are also experienced professionals in mental health services, social work services, and pastoral services who are able to assist you in coping with your illness. You can also start attending support groups, which would allow you to receive help from other cancer survivors. Visit NCCN's cancer resources page (NCCN.com) for more information.

Main Points

- Initial tests for possible breast cancer include mammograms and tissue biopsies.
- Noninvasive lobular cancer is usually treated with a surgical biopsy and possible risk reduction treatment.
- Noninvasive ductal cancer is treated with either breast-conserving therapy or mastectomy followed by possible risk reduction treatment.
- Surgery to remove the tumor and lymph nodes with possible radiotherapy is used for local invasive breast cancer.
- Adjuvant hormone therapy is common for hormone receptor–positive local tumors and trastuzumab for HER2-positive local tumors. Adjuvant chemotherapy is used when there is a higher risk of recurrence.
- Breast-conserving therapy may be possible for large, local invasive tumors following neoadjuvant systemic treatment.
- Advanced and inflammatory breast cancers are treated with a series of medicines. These medicines include surgery for tumors, radiotherapy, chemotherapy, hormone therapy, and/or trastuzumab.
- Breast reconstruction can occur at the time of the tumor surgery or afterward.
- Follow-up tests for breast cancer include clinical breast exams and mammograms.

The treatment guide for breast cancer can be found on the next pages. The goal of this guide is to increase your understanding of the treatment pathways for breast cancer. These pages will show step-by-step how you along with your doctor can arrive at the decisions you need to make about your treatment.

On the following pages there are charts to display the flow of events and explanations of each chart. Every effort has been made to make this treatment guide easy to read. Some words that may not be familiar to you are defined on the page, and there is also a dictionary in Part 8 that you can check. For more information about tests and treatments in this guide, read Parts 2 through 6.

The treatment guide is organized by clinical stage, so make sure that you know this information. Keep in mind that this guide is meant to be used with your doctor who knows your situation, medical history, and personal preferences. In Part 9, there is a personal treatment record that you may want to print out and bring with you to your next doctor's visit.

7.1 Carcinoma in situ

Part 7.1 of the treatment guide is for women with stage 0 tumors. The two types of stage 0 breast cancer are lobular and ductal carcinoma in situ. Tumors of this kind are located only in the lobules or ducts of the breast.

7.1.1 Lobular carcinoma in situ

Initial tests and treatment

Tests	Treatment
<ul style="list-style-type: none"> • Medical history and physical exam, • Diagnostic bilateral mammogram, and • Pathology review of biopsy sample 	<ul style="list-style-type: none"> → Observation if surgical biopsy → Surgery if needle biopsy

For LCIS, your doctor will assess your medical history and perform a physical exam. A diagnostic bilateral mammogram will tell whether there are other abnormal areas in either breast. A review of tissue samples by a pathologist will confirm if the diagnosis is LCIS. The pathologist will rule out invasive breast cancer and other conditions.

Definitions:

Bilateral: Both sides of the body; both breasts

Carcinoma in situ: Breast cancer that has not spread beyond the ducts or lobules

Invasive breast cancer: Cancer that has spread into the fatty tissue of the breast

Mammogram: A test using x-rays to look at breast tissue

Needle biopsy: Insertion of a needle into the body to remove tissue

Observation: Signs of cancer are checked for regularly

Pathologist: A doctor who specializes in testing cells to identify disease

LCIS is usually not treated with surgery other than the excisional biopsy of the breast (Figure 18). If you had a needle biopsy instead, the tumor will be surgically removed. A lymph node biopsy is not needed for LCIS. After surgery, most women choose observation since LCIS is not an invasive cancer. Even so, women with LCIS have an increased risk of developing invasive breast cancer in either breast.

After LCIS treatment

Ways to reduce your risk of breast cancer returning are important options to consider. Your doctors may counsel you about your options. If you are premenopausal, taking tamoxifen for 5 years will lower your recurrence risk. Postmenopausal women can take either tamoxifen or raloxifene.

Having many family members with breast cancer puts you at very high risk for invasive breast cancer. If you are at high risk, a prophylactic bilateral mastectomy is another treatment option. Your doctor can help you decide whether to have this treatment. You should undergo genetic tests before deciding to have a prophylactic mastectomy. Breast reconstruction can be done at the same time as the mastectomy or at a later date.

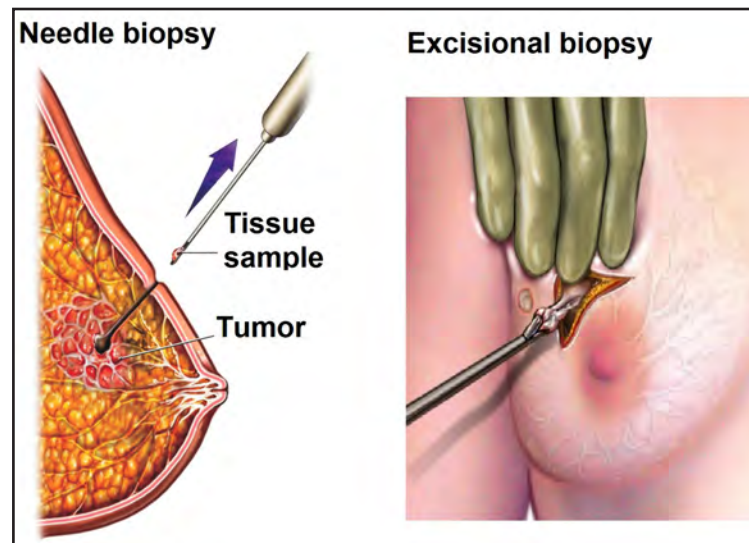


Figure 18.
Biopsies of breast tumors

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Risk reduction	Follow-up tests
Observation only	<ul style="list-style-type: none"> → Yearly mammogram, and → Clinical breast exam every 6 to 12 months
Hormone therapy	<ul style="list-style-type: none"> → Postmenopausal women with intact uterus on tamoxifen <ul style="list-style-type: none"> • Yearly mammogram, and • Clinical breast exam every 6 to 12 months → Other women <ul style="list-style-type: none"> • Yearly mammogram, and • Clinical breast exam every 6 to 12 months
Bilateral mastectomy	→ As clinically indicated

For invasive breast cancer, see Part 7.2.
For recurrence, see Part 7.7.

Whether you choose observation only or hormone therapy, the follow-up tests are the same. You should receive a yearly mammogram and a physical exam every 6 to 12 months after cancer treatment. The exception is for postmenopausal women with a uterus who are on tamoxifen. Tamoxifen increases the risk for endometrial cancer for these women. If this describes you, get a pelvic exam each year and report any vaginal bleeding to your doctors at once. Women who have had a bilateral mastectomy only need to undergo follow-up testing if there are signs of cancer.

7.1.2 Ductal carcinoma in situ

Initial tests and treatment

Tests	Treatment
<ul style="list-style-type: none"> • Medical history and physical exam, • Diagnostic bilateral mammogram, • Pathology review of biopsy sample • Hormone receptor test, and • Possible genetic counseling 	<ul style="list-style-type: none"> → Lumpectomy only → Lumpectomy followed by whole breast radiotherapy → Total mastectomy with or without breast reconstruction

For DCIS, your doctor will assess your medical history and perform a physical exam. A diagnostic bilateral mammogram will tell whether there are other abnormal areas in either breast. A review of the breast tissue samples by a pathologist will confirm if the diagnosis is DCIS. The pathologist will rule out invasive breast cancer and other conditions. Testing for hormone receptor–positive tumors should also be done. If anyone in your family has had breast cancer, especially at a young age, your doctor may recommend genetic testing. Genetic testing can show if you are at high risk for invasive breast cancer.

Definitions:

Breast reconstruction:

Surgery to create new breasts

Endometrial cancer:

Cancer of the lining of the uterus

Excisional biopsy:

Surgery to remove the tumor and some normal tissue

Genetic tests:

Tests to assess the risk for a disease based on genes

Lymph nodes:

Small groups of special immune cells

Postmenopausal:

The state of no menstrual periods for at least 12 months

Prophylactic:

A medical procedure to prevent disease

Raloxifene:

A drug that blocks the effects of estrogen on breast tissue

Tamoxifen:

A drug that lowers the amount of estrogen in the body

Lymph node surgery is generally not done with DCIS. However, the pathologist may find that you have invasive cancer and a sentinel lymph node biopsy would not be possible after some surgeries. Thus, having a lymph node biopsy before such surgeries may help decide which treatment you need.

The margin in the breast tissue sample should be more than 1 mm. If DCIS is in only 1 area and the margin is cancer free, your surgical choices are a lumpectomy or total mastectomy. If you have a low risk of recurrence, radiotherapy may not be needed after a lumpectomy. For other women, radiotherapy to the whole breast with a boost to the tumor site can help prevent recurrence. Fully discuss excluding radiotherapy with your doctor. If interested in partial breast irradiation, the NCCN Guidelines Panel suggests taking part in a clinical trial. After lumpectomy, a mammogram is suggested to ensure that the entire area of DCIS has been removed. Studies have shown that women treated with lumpectomy and radiotherapy for DCIS are in no greater danger of dying from breast cancer than those who have a mastectomy.

If DCIS can't be completely removed with a lumpectomy, a mastectomy is recommended. There are 2 other reasons to receive a mastectomy for DCIS. First, it is recommended if cancer cells are found in the tissue margin from a lumpectomy. Second, a mastectomy is needed if the biopsy shows 2 or more areas of DCIS that can't be removed with 1 surgical cut into the breast. Radiotherapy is not needed following a mastectomy unless cancer cells are found in the tissue margin.

Following a mastectomy, you may decide to have breast reconstruction. Reconstruction can be done at any time. A skin-sparing mastectomy keeps some skin to allow the breast to look more natural after breast reconstruction.

Reconstruction should be performed by an experienced breast surgery team. To reduce your risk of recurrence, tamoxifen is an option. If you were treated with lumpectomy, consider taking tamoxifen for 5 years, especially if you have an estrogen receptor–positive tumor. For any woman with DCIS, use of tamoxifen for 5 years can reduce the risk of breast cancer developing in the other breast.

After DCIS treatment

Risk reduction	Follow-up
Consider tamoxifen for 5 years for: <ul style="list-style-type: none"> • DCIS treated with lumpectomy especially if estrogen-positive DCIS • Risk reduction for opposite breast 	Medical history and physical exam every 6 months for 5 years then every year, Yearly mammograms starting 6-12 months after finishing radiotherapy, if received, and Yearly gynecologic exam for women taking tamoxifen
For invasive breast cancer, see Part 7.2. For recurrence, see Part 7.7.	

To reduce your risk of recurrence, tamoxifen is an option. If you were treated with lumpectomy, consider taking tamoxifen for 5 years, especially if you have an estrogen receptor–positive tumor. For any woman with DCIS, use of tamoxifen for 5 years can reduce the risk of breast cancer developing in the other breast.

Regular follow-up is suggested following primary treatment for DCIS. Follow-up includes getting mammograms every year. Every 6 months, your doctor should check your medical history and conduct a physical exam, and after 5 years, these evaluations can be done once a year. Like LCIS, a pelvic exam every year is suggested for postmenopausal women with a uterus on tamoxifen. Unusual vaginal bleeding should be promptly reported.

Definitions:

Boost: An extra dose of radiation

Hormone receptor–positive: Cancer cells that use hormones to grow

Lumpectomy: Surgery to remove the whole breast lump and some normal breast tissue

Margin: Normal tissue around the edge of a tumor that is removed during surgery

Mastectomy: Surgery to remove the whole breast

Partial breast irradiation: Radiation to the lumpectomy site

Radiotherapy: Treatment of a disease with radiation

Recurrence: The return of cancer after successful treatment

7.2 Local invasive breast cancer

Part 7.2 of the treatment guide is for women with local tumors. Tumors in stage I, II, and IIIA with a TNM classification of T3, N1, M0 are considered local. These tumors have not grown into the chest wall or skin. Also, the cancer has not spread beyond the axillary lymph nodes, and the affected lymph nodes are not attached to each other.

7.2.1 Initial tests and treatment

Clinical stage	Tests	Neoadjuvant treatment	Primary treatment
Stage IA T1, N0, M0 Stage IB T0, N1mi, M0 T1, N1mi, M0 Stage IIA T0, N1, M0 T1, N1, M0 T2, N0, M0 Stage IIB T2, N1, M0 T3, N0, M0 Stage IIIA T3, N1, M0	<ul style="list-style-type: none"> • Medical history and physical exam, • Complete blood count and platelets, • Liver and alkaline phosphatase tests, • Diagnostic bilateral mammogram; ultrasound (US) and MRI of breasts if needed, • Pathology review of biopsy sample, • Hormone receptor and HER2 tests, and • Genetic counseling if needed <p>Other tests based on stage and symptoms:</p> <ul style="list-style-type: none"> • Bone scan, • Abdominal and pelvis CT, US, or MRI scan, • Chest imaging, • PET scan, and • Fertility discussion 	Consider chemotherapy if tumor is larger than 2 cm and breast-conserving therapy is wanted	<ul style="list-style-type: none"> → Lumpectomy and lymph node surgery → Mastectomy and lymph node surgery with or without breast reconstruction

For radiotherapy after surgery, see Part 7.2.2 or 7.2.3.
 For neoadjuvant chemotherapy, see Part 7.3.
 For more advanced breast cancers, see Parts 7.4 - 7.7.

There are several initial tests for women with local invasive breast cancer. Recommended tests are listed in the chart. The list starts with tests that are suggested for all women with local disease. Blood, imaging, and tumor tests are included. A breast MRI with dedicated breast coil may be needed if you have breasts that can't be seen well with mammography or ultrasound. If you are at high risk for hereditary breast cancer, your doctor may counsel you about genetic tests.

The chart lists other tests your doctor might order based on your stage of cancer and symptoms. A bone scan may be done if there is bone pain or there are abnormal blood tests. An abdominal and pelvis CT, ultrasound, or MRI scan is possible if you have unusual lab results or symptoms, or if the physical exam suggests possible spread of cancer. If the tumor is large and has spread to one or more lymph nodes, chest imaging and/or a PET (or PET-CT) scan may be needed. Also, chest imaging is recommended if you have symptoms of lung disease, such as persistent coughing. If you want to have babies in the future, talk with your doctor about your options.

The surgical options for stage I and II tumors are either a lumpectomy or mastectomy. Lumpectomy is possible for most of these tumors. If you have a larger tumor, your doctor may give neoadjuvant systemic treatment to shrink the tumor. Shrinking the tumor makes surgery easier. Generally, a lumpectomy is not recommended for tumors larger than 5 cm. However, shrinking the tumor with neoadjuvant treatment may allow you to have breast-conserving therapy instead of a mastectomy. Part 7.3 reviews this type of treatment plan.

Definitions:

Abdomen: The belly area between the chest and pelvis

Alkaline phosphatase: A protein found in most tissues of the body

Breast-conserving therapy: Lumpectomy followed with radiotherapy

Fertility: The ability to have babies

HER2 protein: A protein that tells a cell to grow and divide

Invasive breast cancer: Breast cancer that has spread into the breast tissue

MRI: Use of radio waves and powerful magnets to see the breast

PET-CT scan: Use of radioactive material to see the shape and function of body parts

Ultrasound: A test that uses sound waves to take pictures of the inside of the breast

Breast-saving therapy is not appropriate if the following qualities describe you:

- Had prior radiotherapy to the breast with cancer or nearby chest area
- Have signs of cancer throughout the breast
- Have multiple tumors that can't be removed with one cut into the breast
- Can't have a lumpectomy to remove all the cancer while keeping an acceptable look of the breast
- Have connective tissue disease involving the skin (e.g., scleroderma or lupus)
- Have tumors that need radiation when pregnant
- Have tumors larger than 5 cm that can't be shrunk by neoadjuvant treatment

When deciding between lumpectomy and mastectomy, consider all the facts. A woman may want a mastectomy to “take it all out as quickly as possible.” However, a mastectomy does not provide a better prognosis in most cases. Large research studies have found that breast-conserving therapy works as well as a mastectomy. A benefit of breast-conserving surgery is that the look of your breast is kept. A disadvantage is the need for several weeks of radiation therapy after surgery. However, some women who have a mastectomy will still need radiotherapy.

After lumpectomy or mastectomy, your axillary lymph nodes may be examined for cancer. You may not need to have your lymph nodes checked if the following qualities describe you:

- Your cancer tumor is small
- Your cancer is unlikely to spread to the lymph nodes
- Having your lymph nodes removed would not affect whether to have adjuvant treatment
- You are of older age
- You have serious medical conditions other than cancer

The two choices for checking the lymph nodes are sentinel lymph node biopsy and axillary lymph node dissection. Sentinel lymph node biopsy is not right for all women. It should only be used when the size of the nodes is normal and the nodes appear cancer free when breast cancer is first diagnosed. If a sentinel lymph node biopsy finds no cancer then no other lymph node surgery is needed. If results suggest that cancer is in the lymph nodes, a complete axillary dissection is usually done. If a sentinel lymph node biopsy is not right for you, you will only have a complete axillary lymph node dissection.

Lymph node surgery is usually done at the same time as the tumor surgery. In a mastectomy, lymph nodes are removed through the same opening used to remove the tumor (Figure 19). In a lumpectomy, it is usually done through a second opening. If your lymph nodes have cancer, radiotherapy to these areas may be given, depending on the number of involved nodes. Discuss your situation with your doctor.

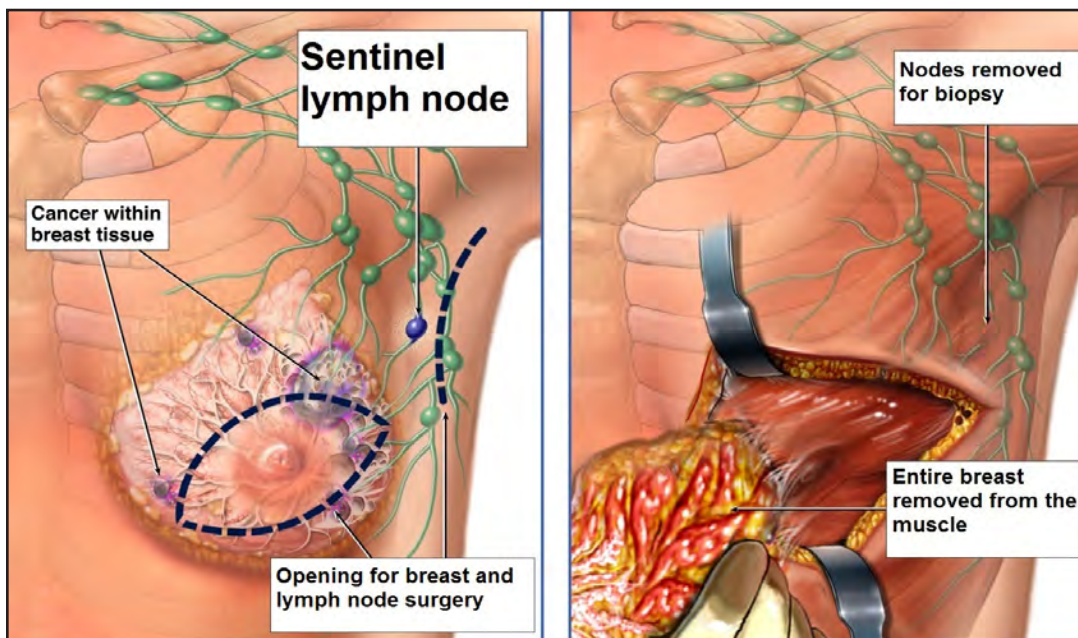


Figure 19. Sentinel lymph nodes removed during mastectomy

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Definitions:

Axillary: On the side of the body near the armpit

Axillary lymph node dissection: Surgery to remove all axillary lymph nodes

Prognosis: The outcome of a disease

Sentinel lymph node biopsy: Surgery to remove the first lymph nodes to which cancer cells travel after leaving the breast

7.2.2 Radiotherapy after lumpectomy

Spread to lymph nodes	Radiotherapy after lumpectomy
No cancer spread to lymph nodes	<p>If needed, chemotherapy should be given before radiotherapy</p> <p>Radiation therapy to the entire breast with or without added boost to tumor site, or for some women, partial breast radiation.</p>
Cancer spread to 1 to 3 lymph nodes	<p>Radiation therapy to the entire breast with or without added boost to tumor site; Possible radiotherapy to the area above and below the collarbone</p>
Cancer spread to 4 or more lymph nodes	<p>Radiation therapy to the entire breast and area above and below the collarbone with or without added boost to tumor site</p>
For adjuvant treatment, see Part 7.2.4.	

Following lumpectomy, radiotherapy is used to kill any cancer that may remain near or in the breast. For most women, radiotherapy is a part of breast-conserving therapy for invasive cancer. However, some women may be able to go without it. You may be able to have a lumpectomy without radiation therapy if the following qualities describe you:

- You are 70 years old or older
- Your breast tumor was smaller than 2 cm and was completely removed
- Your tumor was hormone receptor–positive
- No cancer was found in your lymph nodes
- You were given hormone therapy

If you are to have radiotherapy, the extent of treatment depends on how many of your lymph nodes have cancer. The chart shows the recommended radiotherapy based on the lymph node test results. If needed, adjuvant chemotherapy is given after surgery but before radiotherapy.

7.2.3 Radiotherapy after mastectomy

Spread to lymph nodes	Radiotherapy after mastectomy
	If needed, chemotherapy should be given before radiotherapy
No cancer spread to lymph nodes, tumor 5 cm or smaller, no cancer in large margin	→ No radiotherapy
No cancer spread to lymph nodes, tumor 5 cm or smaller, no cancer in small margin	→ Radiotherapy to the chest wall
No cancer spread to lymph nodes, tumor larger than 5 cm, cancer in margin	→ Possible radiotherapy to chest wall with or without radiation to area above the collarbone; possible radiotherapy to lymph nodes next to breast bone
Cancer spread to 1 to 3 lymph nodes	→ Strongly consider radiotherapy to chest wall and area above the collarbone; if radiotherapy is given, possible radiotherapy to lymph nodes next to breast bone
Cancer spread to 4 or more lymph nodes	→ Radiotherapy to chest wall and area above collarbone; possible radiotherapy to lymph nodes next to breast bone

For adjuvant treatment, see Part 7.2.4.

The extent of radiotherapy after mastectomy is based on how many of your lymph nodes have cancer. Information on lymph node surgery is discussed in Part 7.2.1. If you are to receive adjuvant chemotherapy, it is given prior to radiotherapy. The one exception is when the chemotherapy regimen is a combination of

cyclophosphamide/methotrexate/fluorouracil (CMF). CMF and radiation can be given together. Following mastectomy, most women will receive radiotherapy to the chest wall. See the chart for radiotherapy recommendations based on your tumor and lymph node results.

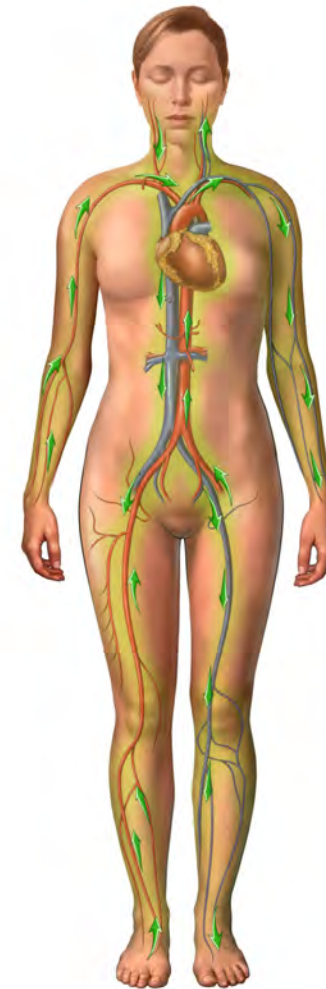
7.2.4 Adjuvant systemic treatment

Most women with invasive breast cancer receive some type of adjuvant systemic therapy. The recommendations for adjuvant therapy are based on various characteristics of your breast cancer. The size of the tumor and hormone receptor and HER2 status are important factors for deciding which treatment is best for you. The type of breast cancer cells is another factor.

Usually, women with hormone receptor–positive disease receive hormone therapy. Targeted therapy with trastuzumab is used only for tumors that are HER2-positive. Chemotherapy is used when there is a higher risk for recurrence.

The use of adjuvant chemotherapy for women over the age of 70 has been questioned. Few clinical trials have included large numbers of older women, so information is limited. In older women, the recurrence of breast cancer can take a long time. Thus, the odds that chemotherapy will prevent a life-threatening recurrence in older women are small. Plus, there are unwanted side effects of chemotherapy. What's more, other health problems may be more serious than the need to treat recurrent breast cancer with chemotherapy. If you are 70 years old or older, think about the risks and benefits when deciding whether to undergo chemotherapy.

Recommendations for adjuvant systemic treatment are presented next. Ductal, lobular, mixed, or metaplastic cancers follow the same decision path. They are presented together in order of hormone receptor and HER2 status. Afterward, recommendations for tubular or colloid cancers are given.



Ductal, lobular, mixed, and metaplastic breast tumors

Hormone receptor and HER2 negative

Tumor size		Adjuvant treatment
Microinvasive or breast tumors ≤0.5 cm	No cancer in lymph nodes	No further treatment
	Lymph node tumors ≤2 mm	Possible chemotherapy
Breast tumors 0.51 – 1.0 cm		Possible chemotherapy
Breast tumors >1.0 cm		Chemotherapy
	Lymph node tumors >2 mm	Chemotherapy

For follow-up tests, see Part 7.6.

Due to their hormone– and HER2-negative status, hormone therapy and trastuzumab are not treatment options for these tumors. For the smallest of these breast tumors with no cancer cells found in the lymph nodes, no adjuvant treatment is needed. For breast tumors of the same size with tiny lymph node tumors, chemotherapy may be helpful. You may also be given chemotherapy if the size of your breast tumor is larger than 0.5 cm but smaller than 1.0 cm. The NCCN Guidelines Panel recommends chemotherapy for women with breast tumors larger than 1.0 cm or with tumors larger than 2 mm in one or more lymph nodes.

Definitions:

Adjuvant treatment:
Treatment that follows primary treatment

Hormone therapy:
Treatment used to stop hormones from working in the body

Side effect: An unplanned physical or emotional response to treatment

Systemic treatment:
Drugs used to destroy cancer cells throughout the body

Targeted therapy:
Treatment used to that stop cancer cells without changing normal cells

Hormone receptor positive, HER2 negative

Tumor size	21 gene test	Adjuvant treatment
Microinvasive or breast tumors ≤ 0.5 cm	No cancer in lymph nodes	No further treatment
	Lymph node tumors ≤ 2 mm	Possible hormone therapy
Breast tumors > 0.5 cm	Not done or Score of 18 – 30	Hormone therapy with or without chemotherapy
	Score < 18	Hormone therapy
	Score > 31	Hormone therapy and chemotherapy
	Lymph node tumors > 2 mm	Hormone therapy and chemotherapy

For follow-up tests, see Part 7.6.

Hormone therapy is suggested for all but the smallest of these tumors due to their hormone receptors. However, hormone therapy may be helpful if you have small breast and lymph nodes tumors. The 21 gene test may be used to decide whether the addition of chemotherapy for breast tumors larger than 0.5 cm would help. A low recurrence risk score of 18 suggests that hormone therapy alone is enough. If you have a moderate risk score of 18 to 30, you may need chemotherapy in

addition to hormone therapy. This combined treatment may also prevent recurrence in women whose risk is unknown since they didn't take the test. High scores above 31 suggest that both hormone therapy and chemotherapy would help stop recurrence. Likewise, hormone therapy and chemotherapy are recommended for women with tumors larger than 2 mm in 1 or more lymph nodes. If needed, chemotherapy should be given before hormone therapy. Table 4 lists chemotherapy regimens for HER2-negative tumors.

Table 4. Chemotherapy regimens for HER2-negative tumors

Abbreviations	Combinations
Preferred adjuvant regimens	
TAC	docetaxel/doxorubicin/cyclophosphamide with filgrastim support
AC	doxorubicin/cyclophosphamide
Dose-dense AC followed by paclitaxel	doxorubicin/cyclophosphamide with paclitaxel every 2 weeks
AC followed by paclitaxel	doxorubicin/cyclophosphamide followed by weekly paclitaxel
TC	docetaxel and cyclophosphamide
Other adjuvant regimens	
FAC/CAF	fluorouracil/doxorubicin/cyclophosphamide
FEC/CEF	cyclophosphamide/epirubicin/fluorouracil
CMF	cyclophosphamide/methotrexate/fluorouracil
AC followed by T	doxorubicin/cyclophosphamide followed by docetaxel every 3 weeks
EC	epirubicin/cyclophosphamide
A followed by T followed by C	doxorubicin followed by paclitaxel followed by cyclophosphamide every 2 weeks with filgrastim support
FEC followed by T	cyclophosphamide/epirubicin/fluorouracil followed by docetaxel
FEC followed by paclitaxel	cyclophosphamide/epirubicin/fluorouracil followed by weekly paclitaxel

Hormone receptor negative, HER2 positive

Tumor size	Adjuvant treatment
Microinvasive or breast tumors ≤ 0.5 cm	No cancer in lymph nodes → No further treatment
	Lymph node tumors ≤ 2 mm → Possible trastuzumab and chemotherapy
Breast tumors 0.51 – 1.0 cm	→ Possible trastuzumab and chemotherapy
Breast tumors >1.0 cm	→ Trastuzumab and chemotherapy
Lymph node tumors >2 mm	→ Trastuzumab and chemotherapy

For follow-up tests, see Part 7.6.

No more treatment is needed for node-negative breast tumors 0.5 cm or smaller. Trastuzumab and chemotherapy may be helpful for node-positive breast tumors ≤ 0.5 cm and breast tumors between 0.51 and 1.0 cm. Trastuzumab with chemotherapy is suggested

by the NCCN Guidelines Panel for women with breast tumors larger than 1.0 cm or with tumors larger than 2 mm in one or more lymph nodes. Table 5 lists chemotherapy regimens for HER2-positive tumors.

Table 5. Chemotherapy regimens for HER2-positive tumors

Abbreviations	Combinations
Preferred adjuvant regimens	
AC	doxorubicin/cyclophosphamide followed by paclitaxel + concurrent trastuzumab
TCH	docetaxel, carboplatin, trastuzumab
Other adjuvant regimens	
Docetaxel + trastuzumab followed by FEC	docetaxel + trastuzumab followed by cyclophosphamide/epirubicin/fluorouracil
Chemotherapy followed by trastuzumab	chemotherapy followed by trastuzumab sequentially
AC followed by docetaxel + trastuzumab	doxorubicin/cyclophosphamide followed by docetaxel + trastuzumab
Neoadjuvant regimen	
T + trastuzumab followed by CEF + trastuzumab	paclitaxel plus trastuzumab followed by cyclophosphamide/epirubicin/fluorouracil

Hormone receptor and HER2 positive

Tumor size	Adjuvant treatment
Microinvasive or breast tumors ≤ 0.5 cm	No cancer in lymph nodes \rightarrow Possible hormone therapy Lymph node tumors ≤ 2 mm \rightarrow Hormone therapy with or without chemotherapy and trastuzumab
Breast tumors > 0.5 cm	Lymph node tumors > 2 mm \rightarrow Trastuzumab, hormone therapy, and chemotherapy

For follow-up tests, see Part 7.6.

Trastuzumab and hormone therapy are suggested for all these tumors with the exception of node-negative breast tumors ≤ 0.5 cm. Chemotherapy may help treat women who have small breast and lymph node tumors. Adding chemotherapy to the adjuvant regimen is recommended for all women with breast tumors larger than 0.5 cm or with tumors larger than 2 mm in one or more lymph nodes.

Tubular or colloid breast tumors

Hormone status	Tumor size	Adjuvant treatment
Hormone positive	Breast tumors <1.0 cm with no or ≤2 mm lymph node tumors	→ No further treatment
	Breast tumors 1.0 – 2.9 cm with no or ≤2 mm lymph node tumors	→ Possible hormone therapy
	Breast tumors ≥ 3.0 cm with no or ≤2 mm lymph node tumors	→ Hormone therapy
	Lymph node tumors >2 mm	→ Hormone therapy and possible chemotherapy
Hormone negative, repeat test	→ Treat as ductal, lobular, mixed, or metaplastic breast cancer if 2 nd test is negative	

For follow-up tests, see Part 7.6.

Tubular or colloid breast cancers have a more favorable prognosis than other types of breast cancer. For these tumors, hormone receptor status is an important factor in deciding treatment. HER2 status is not important since these tumors are usually HER2 negative. In fact, you should question a tubular diagnosis if test results show your tumor is hormone receptor–negative or HER2-positive. The chart displays the treatment

recommendations of the NCCN Guidelines Panel. Hormone therapy is suggested for tumors larger than 3.0 cm. For node-positive disease, chemotherapy with hormone therapy has better benefits. The one exception is if you are over the age of 60 and already taking hormone therapy. The benefits of chemotherapy for you may be small, so choose your treatment based on your situation.

7.3 Breast-saving treatment for large local tumors

Part 7.3 of the treatment guide is for women with large local tumors who want to save as much of their natural breast as possible. Breast-conserving treatment is usually not recommended for large tumors. However, systemic treatments may shrink the tumor to allow for a lumpectomy.

7.3.1 Initial tests

Clinical stage	Tests	Lymph node tests
Stage IIA T2, N0, M0 Stage IIB T2, N1, M0 T3, N0, M0 Stage IIIA T3, N1, M0	<ul style="list-style-type: none"> • Medical history and physical exam, • Complete blood count and platelets, • Liver and alkaline phosphatase tests, • Diagnostic bilateral mammogram; ultra-sound (US) and MRI of breasts if needed, • Pathology review of biopsy sample, • Hormone receptor and HER2 tests, and • Genetic counseling if needed <p>Other tests based on stage and symptoms:</p> <ul style="list-style-type: none"> • Bone scan, • Abdominal and pelvis CT, US, or MRI scan, • Chest imaging, • PET scan, and • Fertility discussion 	<p>If your doctor doesn't feel enlarged lymph nodes, possible:</p> <ul style="list-style-type: none"> • Sentinel lymph node test <p>If your doctor feels enlarged lymph nodes, possible:</p> <ul style="list-style-type: none"> • Core needle biopsy, • Fine needle aspiration (FNA), or • If FNA or core biopsy is negative, sentinel lymph biopsy test

For neoadjuvant treatment, see Part 7.3.2.
 For more advanced breast cancers, see Parts 7.4 - 7.7.

The initial tests discussed in Part 7.2.1 are also recommended for women wanting breast-conserving therapy. In addition, you will need to have lymph node tests. If your lymph nodes are of normal size, a sentinel lymph node biopsy may be done before chemotherapy. If your lymph nodes are enlarged suggesting that cancer is present, one of the two types of needle biopsies can be done instead.

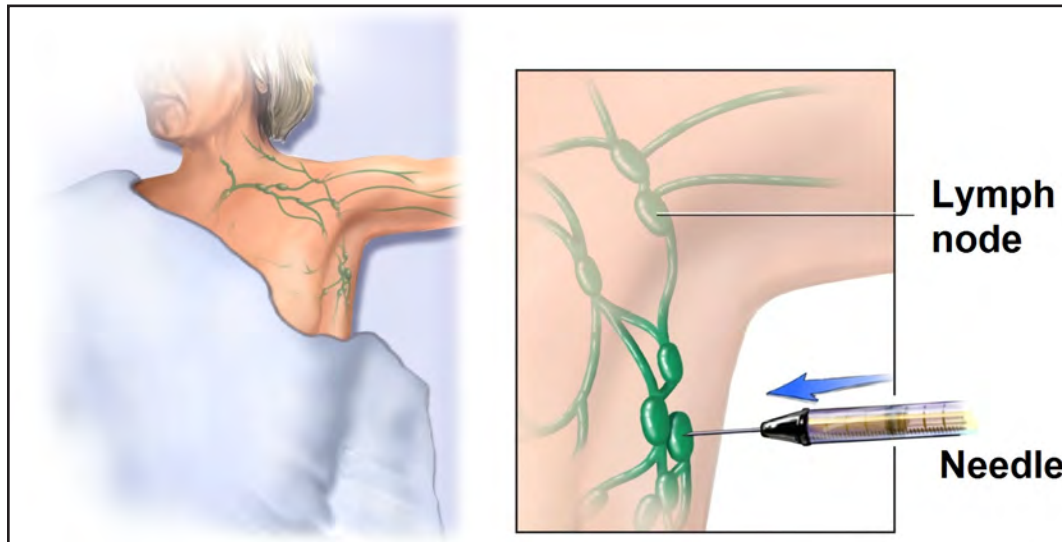


Figure 20. Lymph node needle biopsy

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Use of sentinel lymph node biopsy for women having neoadjuvant chemotherapy is debated. This is because the chemotherapy may change a positive sentinel node to a negative one. Your doctors may then miss that your cancer has spread outside the breast. As a result, your surgeon may remove the sentinel node before chemotherapy or will perform an axillary lymph node dissection. Another option is to have a needle biopsy of your lymph nodes (Figure 20). If the biopsy finds no cancer, a sentinel lymph node biopsy is still possible. Healing from a sentinel lymph node biopsy may be easier, but it should only be done by a team of doctors that has experience doing this procedure.

Definitions:

Core needle biopsy: Use of a needle to remove a large tissue sample

Fine needle aspiration: Use of a thin needle to remove fluid or tissue from the body

7.3.2 Neoadjuvant treatment

Neoadjuvant treatment	Results	Next steps
Neoadjuvant treatment may consist of: <ul style="list-style-type: none"> • Chemotherapy • Hormone therapy • Trastuzumab 	<ul style="list-style-type: none"> → Tumor shrinks and can be removed → Tumor shrinks but can't be removed → Tumor doesn't shrink after 3-4 cycles → Tumor gets larger 	<ul style="list-style-type: none"> → Lumpectomy → Consider changing chemotherapy and test tumor size again, or → Mastectomy if tumor doesn't shrink enough

For primary and adjuvant treatment, see Part 7.3.3.

It is recommended that the breast tumor area be marked before neoadjuvant treatment. Marking should be done so that the area can be found if the tumor completely disappears on tests. While shrinkage of the tumor is good, surgery is still needed to remove the remaining tissue from the breast since it may have cancer cells.

Neoadjuvant treatment prior to breast-conserving therapy can be chemotherapy, hormone therapy, or targeted therapy. If your tumor is HER2-positive, trastuzumab should be added to chemotherapy.

If your tumor is hormone receptor-positive, hormone therapy is sometimes used instead of chemotherapy. After the tumor shrinks from neoadjuvant treatment, the next step is lumpectomy. If the tumor doesn't shrink enough for a lumpectomy or gets larger, another type of chemotherapy may be given or a mastectomy will be needed. A maximum of 6 to 8 cycles of chemotherapy should be received to shrink the tumor.

7.3.3 Primary and adjuvant treatment

Primary treatment	Adjuvant treatment
<p>Lumpectomy with or without lymph node surgery and with or without breast reconstruction</p> <p>Mastectomy with or without lymph node surgery and with or without breast reconstruction</p>	<ul style="list-style-type: none"> • Adjuvant radiotherapy after surgery based on affected nodes as shown in Parts 7.2.2 and 7.2.3, • Hormone therapy if hormone receptor–positive, and • Finish up to 1 year of trastuzumab if HER2 positive
<p>Consider a clinical trial of chemotherapy</p>	
<p>For follow-up tests, see Part 7.6.</p>	

Surgery to remove your lymph nodes should be done along with a lumpectomy or mastectomy. However, this is not necessary if a sentinel lymph node biopsy was done before chemotherapy and showed no evidence of cancer. A lumpectomy or mastectomy may be followed by breast reconstruction. After surgery, any chemotherapy that was planned but not finished may be continued. On the other hand, your doctor may suggest more chemotherapy

as part of a clinical trial depending on your tumor size and number of positive lymph nodes. Adjuvant therapy should consist of radiotherapy to the breast or surgical area and sometimes to the nearby lymph nodes. The decision to treat the lymph nodes with radiation is based on the affected lymph nodes as shown in Part 7.2.2 and 7.2.3. Other adjuvant treatment depends on hormone/HER2 status.

7.4 Locally advanced invasive breast cancer

Part 7.4 of the treatment guide is for women with tumors that have not metastasized but have grown large locally. All stage III breast cancers with the exception of T3, N1, M0 are considered locally advanced. These tumors have either grown into the chest wall or skin, or the cancer has advanced in the lymph nodes. The axillary lymph nodes may be matted together or to other tissue, or the cancer has spread to the internal mammary or supraclavicular lymph nodes.

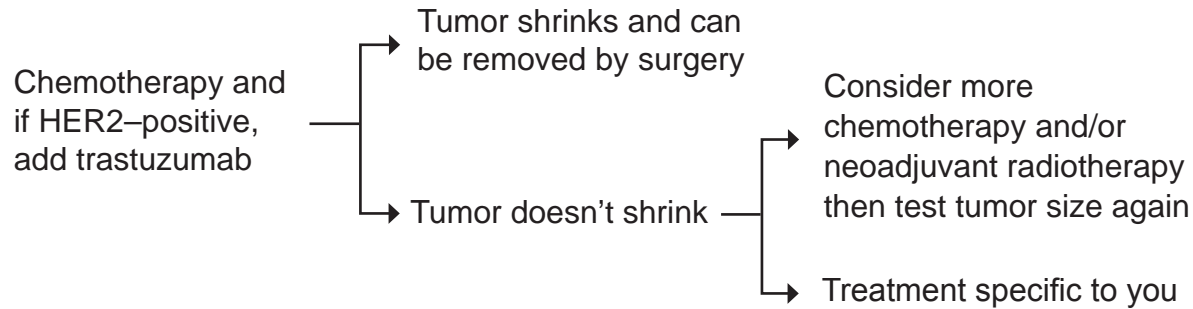
The initial tests for women with locally advanced breast cancer are the same as for local invasive breast cancers. See the chart for the list. Blood, imaging, and tumor tests are recommended for all women with locally advanced disease. Other possible tests are based on stage and symptoms. They may include a bone scan and imaging of the abdomen, pelvis, or chest.

7.4.1 Initial tests

Clinical stage	Tests
Stage IIIA T0, N2, M0 T1, N2, M0 T2, N2, M0 T3, N2, M0 Stage IIIB T4, Any N, M0 Stage IIIC Any T, N3, M0	→ <ul style="list-style-type: none"> • Medical history and physical exam, • Complete blood count and platelets, • Liver and alkaline phosphatase tests, • Diagnostic bilateral mammogram; ultrasound (US) and MRI of breasts if needed, • Pathology review of biopsy sample, • Hormone receptor and HER2 tests, and • Genetic counseling if needed Other tests based on stage and symptoms: <ul style="list-style-type: none"> • Bone scan, • Abdominal and pelvis CT, US, or MRI scan, • Chest imaging, • PET scan, and • Fertility discussion
For neoadjuvant treatment, see Part 7.4.2. For inflammatory breast cancer, see Part 7.5. For recurrent or metastatic cancer, see Part 7.7.	

7.4.2 Neoadjuvant treatment

Neoadjuvant treatment



The treatment for locally advanced breast cancer starts with chemotherapy given before surgery. The neoadjuvant treatment should also include trastuzumab if the tumor is HER2-positive. If the tumor shrinks, surgery may be done. Otherwise, you may receive more neoadjuvant treatment and be tested again for tumor size. If neoadjuvant treatment fails, treatment specific for your situation will be planned.

7.4.3 Primary and adjuvant treatment

Primary treatment	Adjuvant treatment
<p>Possible lumpectomy with lymph node surgery</p> <p>Mastectomy and lymph node surgery with or without breast reconstruction at a later time</p>	<p>Radiotherapy to the chest wall and lymph nodes above the collarbone and perhaps internal nodes next to breastbone</p> <ul style="list-style-type: none"> • Finish chemotherapy if you didn't before surgery, • Hormone therapy if hormone-receptor positive, and • Finish up to 1 year of trastuzumab if HER2 positive
<p>For follow-up tests, see Part 7.6.</p>	

If your tumor shrinks enough, you may undergo either a lumpectomy or mastectomy with lymph node surgery. This is followed by radiotherapy to the breast or chest wall, to the supraclavicular nodes, and, if enlarged, to the internal mammary nodes. Breast reconstruction can be done later if desired. After surgery, any planned chemotherapy not received yet should be completed. If your cancer is hormone receptor-positive, adjuvant hormone therapy is recommended. If the tumor is HER2-positive, take trastuzumab. If you need trastuzumab, it can be taken at the same time as radiotherapy and hormone therapy.

Definitions:

Internal mammary:
Near the breastbone

Supraclavicular:
Near the collarbone

7.5 Inflammatory breast cancer

Part 7.5 of the treatment guide is for women with inflammatory breast cancer. This breast cancer is very aggressive. It causes one-third or more of the breast skin to be red and usually feels warm. The breast may also be swollen. The redness and swelling of the breast are caused by small cell clusters that slow down the flow of lymphatic fluid in the breast tissue. Inflammatory breast cancer is a type of invasive breast cancer, but there are differences in treatment because of its aggressive nature.

7.5.1 Initial tests

Clinical stage	Tests
Stage IIIB T4, Any N, M0	<ul style="list-style-type: none"> • Medical history and physical exam, • Complete blood count and platelets • Liver tests, • Diagnostic bilateral mammogram; ultrasound (US) and MRI of breasts if needed, • Pathology review of biopsy sample, • Hormone-receptor and HER2 tests, • Genetic counseling if needed, • Bone scan, • CT scan of chest, abdomen, and pelvis, • Chest imaging, and • PET scan

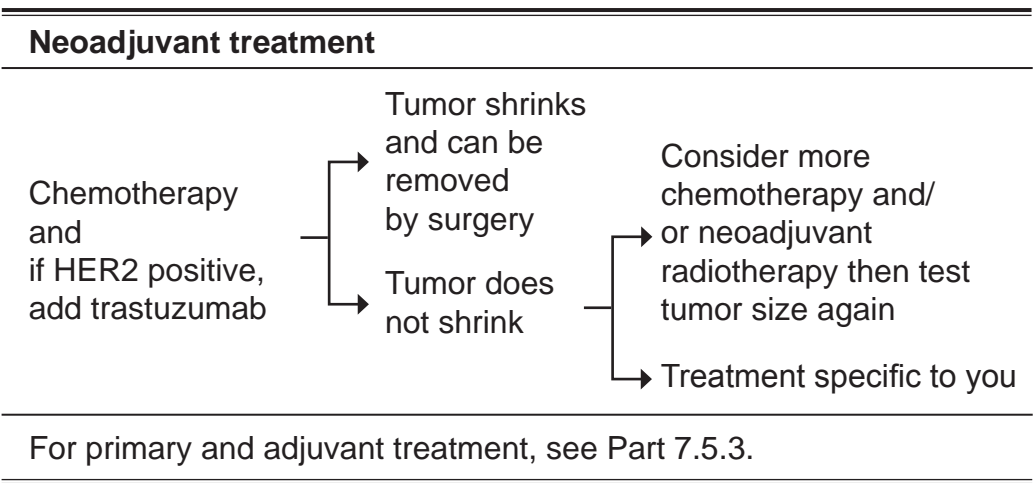
For neoadjuvant treatment, see Part 7.5.2.

For recurrent or metastatic cancer, see Part 7.7.

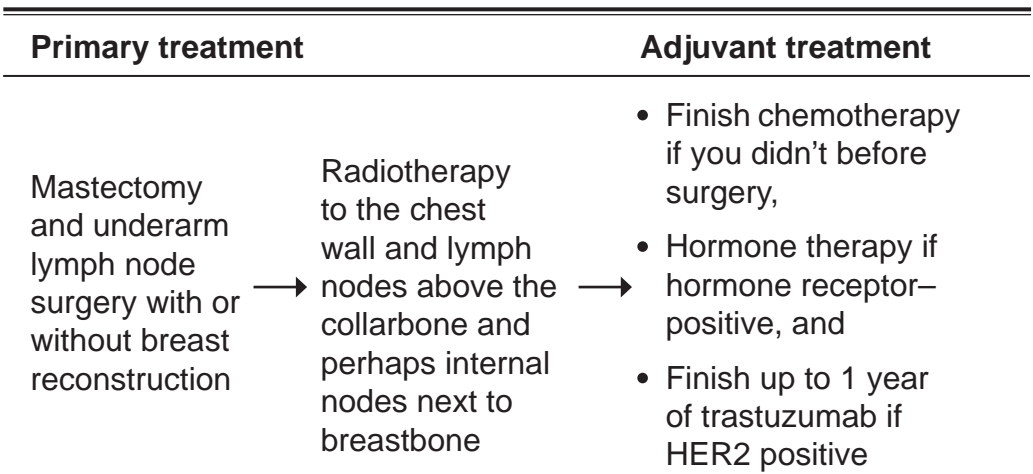
Tumor size is not always used as the rule for staging inflammatory breast cancer. In some cases, no tumor mass will be found, so staging is based on how far the cancer has spread in the body. If there is no spread to distant organs, it is called stage IIIB. If the breast cancer cells have metastasized, it is called stage IV and it is treated like other types of metastatic breast cancer. Part 7.6 reviews treatment for metastasized breast cancer.

The initial tests for inflammatory breast cancer are listed in the chart. A physical exam is included but your doctor may not feel a lump inside your breast. Only a biopsy of the breast tissue or skin can be used to confirm this disease. Before treatment begins, multiple tests will be needed to know whether the cancer has spread. For stage IIIB, tumor size and hormone receptor and HER2 status will help decide the best treatment.

7.5.2 Neoadjuvant treatment



7.5.3 Primary and adjuvant treatment



For follow-up tests, see Part 7.6.

No one treatment plan is right for all women with inflammatory breast cancer. Treatment is tailored to each woman. Because it is a fast-growing cancer, you are likely to receive multiple types of treatment. Usually, chemotherapy is given first. It is likely to be either doxorubicin or epirubicin, and paclitaxel or docetaxel. If your tumor is HER2-positive, trastuzumab will likely be added to the neoadjuvant regimen. If your tumor does not get smaller, a different chemotherapy, radiation therapy, or both will be tried. If the tumor responds to this 2nd treatment, surgery will take place. If not, your doctor can recommend treatment based on your personal situation.

If your tumor shrinks after neoadjuvant treatment, the next step will be a mastectomy with radiation to the chest and lymph nodes around the collarbone. Following surgery, chemotherapy will be completed if it hadn't been before surgery. Also, if the tumor has hormone receptors, hormone therapy will be started. Likewise, if the tumor is HER2-positive, one year of trastuzumab will be completed. Reconstruction, if wanted, will be performed at a later date.

7.6. Follow-up tests for first invasive cancer

Tests

- Medical history and physical exam every 4 to 6 months for 5 years then every year,
- Yearly mammogram,
- Yearly gynecologic exam for women with uterus on tamoxifen,
- Women starting an aromatase inhibitor or early menopause should have bone mineral density tests at start and regularly after,
- Continue to take hormone therapy for entire time suggested by your doctor, and
- Maintain active lifestyle and healthy body weight (20 – 25 body mass index)

For follow-up tests, see Part 7.6.

All women successfully treated for invasive breast cancer should have regular follow-up testing. Follow-up tests include medical history, physical exam, and a mammogram. Tests and schedules are listed in the chart. If you take tamoxifen, a pelvic exam is needed each year since this drug can increase your risk of uterine cancer. Tell your doctor if you have any abnormal vaginal bleeding. Women on an aromatase inhibitor or who reach menopause early should have bone mineral density tests regularly. If you take hormone therapy, it is very important that you don't stop taking it. Otherwise, your risk for cancer returning may be higher.

7.7 Metastatic or recurrent breast cancer

Part 7.6 of the treatment guide is for women with tumors that have metastasized or returned after a disease-free period. Recurrent breast cancer may return either near the breast or to distant organs. Metastasized breast cancers are categorized as stage IV.

7.7.1 Tests for recurrence and metastases

Tests

- Medical history and physical exam,
- Complete blood count and platelets,
- Liver tests,
- Chest imaging,
- Bone scan,
- X-ray of bones that hurt and weight-bearing bones that are abnormal on bone scan,
- Abdominal CT or MRI may be suggested,
- Biopsy of first recurrence,
- Hormone receptor and HER2 tests if status unknown or were negative before, and
- Genetic counseling if needed

For treatment of local recurrence, see Part 7.7.2.
For treatment of lymph node recurrence, see Part 7.7.3. For treatment of metastases, see Part 7.7.4.

The NCCN Guidelines Panel recommends specific tests if your cancer metastasizes or returns. See the chart for the test list. In addition to blood and physical tests, there should be x-rays of bones when the bone scan is not normal or when weight-bearing bones are painful. CT or MRI scans of the abdomen, chest, or head should be done if there are signs of recurrence in these areas. Another option is a PET scan. A biopsy should be done to confirm the recurrence if possible. If HER2 testing was negative or never done, a biopsy sample is needed. Also, hormone receptor tests should be done. If you have a strong family history of breast or ovarian cancer, think about getting genetic tests.

7.7.2 Treatment for local recurrence

Treatment for first cancer		Treatment for current cancer	
Lumpectomy and radiotherapy	→	Mastectomy and lymph node surgery] → Consider systemic therapy
Mastectomy and radiotherapy	→	Surgery to remove the tumor if possible	
Mastectomy	→	Surgery to remove the tumor if possible and radiotherapy to chest wall and area above the collarbone	

Treatment for a local recurrence depends on your prior treatment. If you had breast-conserving therapy, you will need a mastectomy with lymph node surgery. If you had a mastectomy and radiotherapy, the recurrent cancer should be removed by surgery if possible. If previously treated with mastectomy alone, treatment should consist of surgery with radiotherapy to the chest wall and area above the collarbone. In any case, adjuvant treatment of chemotherapy, hormone therapy, or trastuzumab should be considered. Try to have a healthy lifestyle including a healthy weight to increase your chance of good outcomes.

7.7.3 Treatment for lymph node recurrence

Lymph node recurrence	Treatment	
Axillary lymph nodes	→ If possible, surgery to remove the tumor and radiotherapy to the chest wall, axilla, and supraclavicular and infraclavicular lymph nodes	} Consider systemic therapy
Supraclavicular lymph nodes	→ If possible, radiotherapy to the chest wall and supraclavicular and infraclavicular lymph nodes	
Internal mammary lymph nodes	→ If possible, radiotherapy to the chest wall and internal mammary, supraclavicular, and infraclavicular lymph nodes	

Your cancer may return to your lymph nodes with or without a local recurrence. If cancer is found in your lymph nodes under your arms, surgery and radiotherapy is recommended. Radiotherapy should target your chest wall, the side of your body under the armpit, and the lymph nodes above and below your collar bone. When cancer is found in either your supraclavicular or internal mammary lymph nodes, radiotherapy alone is suggested. For supraclavicular recurrence, radiation should be given to your chest wall and your lymph nodes near the collar bone. For internal mammary recurrence, radiation should be given to your chest wall and your lymph nodes by the collar bone and breastbone. Following radiotherapy for any lymph node recurrence, chemotherapy, hormone therapy, or trastuzumab should be considered.

7.7.4 Treatment for metastases

This part of the guide reviews treatment for breast cancer that has grown beyond the breast or nearby lymph nodes. This includes women with recurrent metastatic cancer or women first diagnosed with metastatic cancer. Your treatment choices are based on whether or not the tumor is hormone receptor–positive and whether the tumor has limited or extensive spread. However, for metastatic breast cancer, hormone therapy may be recommended for women whose tumor is hormone receptor–negative. This may seem wrong since, earlier in this guide, only women with hormone receptor–positive tumors were recommended to have hormone therapy. Sometimes, a tumor that tests negative may act like a hormone–positive tumor. This can happen when there has been a long period of time between the initial treatment and the recurrence. Therefore, hormone therapy can sometimes help with tumors that are believed to be hormone receptor–negative. Also, hormone therapy has fewer side effects than chemotherapy. Since chemotherapy does not cure cancer that has spread outside the breast, treatments with the fewest side effects that can still control the cancer are recommended. In breast cancer that has spread, women often take different treatments over time.

Your bones are at risk for injury and disease when breast cancer spreads to them. Such medical problems include bone fractures, bone pain, spinal cord compression, and hypercalcemia. Bisphosphonates or denosumab may stop these problems from happening. On the other hand, these drugs have been linked to osteonecrosis—bone tissue death—of the jaw. If you take these drugs, you may be at higher risk of jaw osteonecrosis if you are on chemotherapy or corticosteroids, or if you have medical problems in your mouth. Examples of oral problems include periodontal disease and dental abscess. You should have a dental exam and get treatment for any dental problems before starting bisphosphonate or denosumab for bone metastases. Your doctor may also suggest taking calcium and vitamin D with these drugs.

Definitions:

Dental abscess: Pus trapped in the tissues near the jaw

Periodontal disease:
A disease of the gums in the mouth

Hypercalcemia: High levels of calcium in the blood

Osteonecrosis: Death of bone tissue

Periodontal disease:
A disease of the gums in the mouth

Spinal cord compression:
The bundle of nerves in the spine is squeezed causing pain

HER2 negative and hormone negative/refractory

Spread of cancer	Treatment
Denosumab or bisphosphonate if bone metastases	
Bone or soft tissue only or no symptoms of spread	<ul style="list-style-type: none"> → Consider different hormone therapy unless no response to 2 or 3 back-to-back therapies → Chemotherapy
Symptoms of cancer in internal organs	<ul style="list-style-type: none"> → Chemotherapy
<ul style="list-style-type: none"> → Consider supportive care only if no response to three regimens or in poor general health 	
<p>For hormone therapy, see the next chart. For follow-up hormone therapy, see Part 7.7.5.</p>	

The first chart is for women with tumors that are HER2 negative and hormone receptor–negative or that have not responded to hormone therapy. You have 2 treatment choices if your cancer has spread only to the bones or soft tissues, or if your cancer has spread to other organs that are still working well (e.g., liver, lungs). Your choices are hormone therapy or chemotherapy. Hormone therapy is not recommended if your tumor has not responded to 3 hormone therapies in a row. Chemotherapy alone is recommended if your cancer has spread beyond the bone or soft tissue, or has spread to other organs that are not working well. If the tumor does not shrink after 3 different chemotherapy regimens, stopping chemotherapy and receiving supportive care may be your best option. Table 6 lists chemotherapy regimens for recurrent or metastatic breast cancer.

Table 6. Chemotherapy regimens for recurrent or metastatic breast cancer

Preferred agents	Preferred combinations
Doxorubicin	CAF/FAC (cyclophosphamide/doxorubicin/fluorouracil)
Epirubicin	FEC (fluorouracil/epirubicin/cyclophosphamide)
Pegylated liposomal doxorubicin	AC (doxorubicin/cyclophosphamide)
Paclitaxel	AT (doxorubicin/docetaxel or doxorubicin/paclitaxel)
Docetaxel	CMF (cyclophosphamide/methotrexate/fluorouracil)
Albumin-bound paclitaxel	Docetaxel/capecitabine
Capecitabine	GT (gemcitabine/paclitaxel)
Gemcitabine	Other combinations
Vinorelbine	Ixabepilone and capecitabine
Eribulin	Preferred agents for HER2-positive tumors
Paclitaxel with bevacizumab	Trastuzumab and paclitaxel with or without carboplatin
Other agents	Trastuzumab and docetaxel
Cisplatin	Trastuzumab and vinorelbine
Carboplatin	Trastuzumab and capecitabine
Cyclophosphamide	Preferred agents for trastuzumab-treated HER2-positive tumors
Mitoxantrone	Lapatinib and capecitabine
	Trastuzumab with different chemotherapy drug than was used before
	Trastuzumab and capecitabine
	Trastuzumab and lapatinib (with no other chemotherapy)

HER2 positive and hormone negative/refractory

Spread of cancer	Treatment
	Denosumab or bisphosphonate if bone metastases
Bone or soft tissue only or no symptoms of spread	<p>Consider different hormone therapy unless no response to 2 or 3 back-to-back therapies</p>
Symptoms of cancer in internal organs	<p>Trastuzumab with or without chemotherapy</p> <p>Trastuzumab with or without chemotherapy</p>
	<p>Use different chemotherapy or trastuzumab with lapatinib</p>
	<p>Consider supportive care only if no response to three regimens or in poor general health</p>
<p>For hormone therapy, see the next chart. For follow-up hormone therapy, see Part 7.7.5.</p>	

This chart is for women with tumors that are HER2-positive and hormone receptor—negative or that have not responded to hormone therapy. Hormone therapy may be given if your cancer has spread only to the bones or soft tissues, or your cancer has spread to other organs that are still working well. Otherwise, since the tumor is HER2 positive, trastuzumab may be given either alone or with chemotherapy. If your cancer still grows, trastuzumab may be continued with

a different chemotherapy drug. Another choice is to try a combination of lapatinib with more trastuzumab or with another chemotherapy drug. If the tumor does not shrink after three different chemotherapy regimens, stopping chemotherapy and receiving supportive care may be your best option. If you have bone metastases, treat dental problems first before taking bisphosphonate or denosumab.

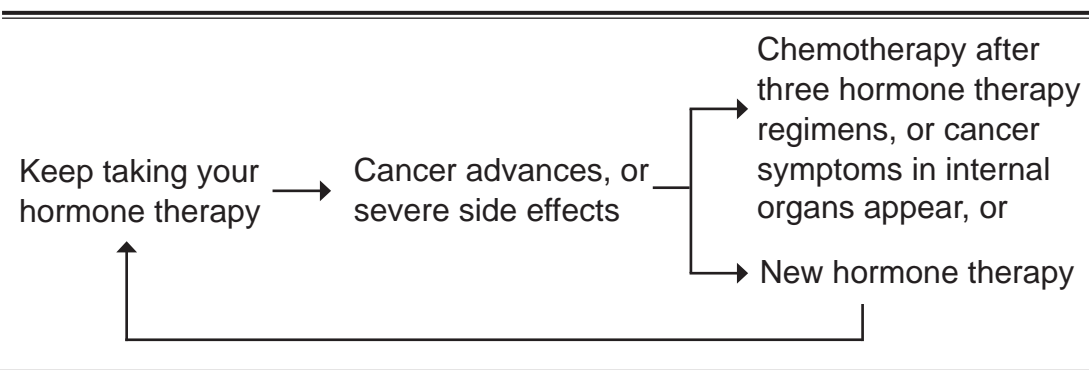
Hormone positive and any HER2 status

Status	Treatment
	Denosumab or bisphosphonate if bone metastases
Premenopause	If hormone therapy in past year, ovarian ablation therapy with other hormone therapy If no hormone therapy in past year, ovarian ablation therapy with other hormone therapy or antiestrogen alone
Postmenopause	Antiestrogen or aromatase inhibitor alone if no hormone therapy in past year
Symptoms of cancer in internal organs	Consider chemotherapy

For follow-up hormone therapy, see Part 7.7.5.

This chart is for women with tumors that are hormone receptor–positive. Bone metastases may be treated with bisphosphonate or denosumab. Other treatment will be based on your previous treatment and menopausal status. If you are premenopausal, ovarian ablation therapy and then use of hormone therapy similar to that used for postmenopausal women is suggested. You should be tested to make sure that you are postmenopausal before starting such therapy. If you were not treated with hormone therapy within the past year, an antiestrogen alone is an option. Tamoxifen for 2 to 3 years is recommended. For postmenopausal women, an aromatase inhibitor or antiestrogen would be the first treatment choice. Women with symptoms of cancer in their internal organs can consider chemotherapy.

7.7.5 Follow-up hormone therapy



If hormone therapy causes your cancer to shrink or not grow, it should be continued. If your cancer begins to grow again or you have bad side effects, another hormone therapy may be tried. The NCCN Guidelines Panel recommends trying at least three different hormone treatments until no benefit is seen or symptoms of cancer in internal organs appear. At that point, chemotherapy is recommended.

Part 8: Dictionary

Abdomen

The belly area between the chest and pelvis.

Adjuvant treatment

Treatment that follows primary treatment.

Adrenal glands

The pair of glands above each kidney that makes hormones.

Aggressive cancer

A cancer that spreads quickly.

Alkaline phosphatase

A protein found in most tissues of the body.

Alternative medicine

Treatments used in place of ones usually given by doctors.

Areola

A darker, circular area of the skin.

Axillary lymph node dissection

Surgery to remove all axillary lymph nodes.

Axillary

On the side of the body near the armpit.

Barrier methods

Devices that prevent sperm from entering the uterus.

BRCA mutation

Changes in genes that normally help prevent tumor growth

Benign

A tumor that is not made of cancer cells.

Bilateral

Both sides of the body; both breasts.

Biopsy

A medical procedure that collects tissue.

Birth defects

A physical, mental, or chemical abnormality in newborn babies.

Blood chemistry tests

Tests to show unusual amounts of chemicals in the body.

Boost

An extra dose of radiation to a specific area.

Breast awareness

Learning about your breasts.

Breast reconstruction

Surgery to create new breasts.

Breast-conserving therapy

Lumpectomy followed with radiotherapy.

Carcinoma in situ

Breast cancer that has not spread beyond the ducts or lobules.

Chemotherapy

Drugs that kill cancer cells.

Chest wall

The layer of muscles, bones, and tissue on the outer part of the chest.

Clinical staging

A cancer stage given by your doctor before surgery.

Clinical trial

Research that compares new treatments to the best current treatment to find out which is better.

Connective tissue

Supportive and binding fibers.

Contrast

A substance put into your body to make better pictures during imaging tests.

Control group

Research participants who do not receive a new treatment.

Core needle biopsy

Use of a needle to remove a large tissue sample.

Criterion

A standard for making a decision.

Cyst

A closed sac in the body filled with air or fluid.

Dental abscess

Pus trapped in the tissues near the jaw.

Diagnosis

Identification of a disease.

Ductal lavage

A test used to collect cells from breast ducts.

Ducts

Tubes that drain milk from the breast.

Early-stage cancer

Cancer that has not grown much in nearby tissues.

Endometrial cancer

Cancer in the lining of the uterus.

Estrogen

A hormone that develops female body traits.

Excisional biopsy

Surgery to remove the tumor and some normal tissue.

Fallopian tube

The female organ that helps eggs travel from an ovary to the uterus.

Fertility

The ability to have babies.

Fine needle aspiration

Use of a thin needle to remove fluid or tissue from the body.

Food and Drug Administration (FDA)

A federal government agency that regulates drugs and food.

Genes

Instructions for making new cells.

Genetic risk

The chance of having a disease passed down from parents.

Genetic tests

Tests to assess risk for a disease based on genes.

Glucose

A natural sugar in the body used by cells for energy.

HER2 protein

A protein that tells a cell to grow and divide.

Hormone receptor–positive

Cancer cells that use hormones to grow.

Hormone replacement therapy

Medicine to increase hormone levels.

Hormone therapy

Treatment used to stop hormones from working in the body.

Hormones

Chemicals in the body that activate cells or organs.

Hypercalcemia

High levels of calcium in the blood.

Imaging

Medical tests that take pictures of the inside of the body.

Immune cells

Cells that defend the body against disease.

Infertility

Physically unable to have babies.

Informed consent form (ICF)

A document describing a study and requiring a signature from participants after review.

Internal mammary

Near the breastbone.

Intrauterine devices

Objects in the uterus that release medicine to prevent pregnancy.

Intravenous

Drugs given by needle through a vein.

Invasive breast cancer

Cancer that has spread into the fatty tissue of the breast.

Ipsilateral

On the same side of the body as the tumor.

Lobules

Glands in the breast that make milk.

Local anesthesia

A loss of feeling due to drugs in a specific area of the body.

Locally advanced

Growth of cancer in nearby tissues and possibly lymph nodes.

Lumpectomy

Surgery to remove the whole breast lump and some normal breast tissue.

Luteinizing hormone-releasing hormone

A hormone made in the brain that causes the pituitary gland to make luteinizing hormone.

Lymph nodes

Small groups of special immune cells.

Lymph

A clear fluid containing white blood cells.

Lymphadenectomy

Surgery to remove lymph nodes.

Malignant

A tumor with cancer cells.

Mammogram

A test using x-rays to look at breast tissue.

Margin

Normal tissue around the edge of a tumor that is removed during surgery.

Mastectomy

Surgery to remove the whole breast.

Medical oncologist

A physician who specializes in all types of cancer.

Menopause

The end of menstrual periods.

Menstrual periods

The flow of blood and tissue from the uterus.

Metastasize

The growth of cancer beyond local tissue.

Magnetic resonance imaging (MRI)

Use of radio waves and powerful magnets to see the breast.

Mucus

A sticky, thick liquid that moisturizes or lubricates.

Needle biopsy

Insertion of a needle into the body to remove tissue.

Nipple

The darker, raised part of the breasts.

Node-negative

Lymph nodes that do not have cancer cells.

Nucleus

The control center of gene activity within a cell.

Observation

Signs of cancer are checked for regularly.

Oophorectomy

Surgery to remove the ovaries

Osteonecrosis

Death of bone tissue.

Osteoporosis

A disease that causes thinning, weakened bones.

Ovaries

The pair of organs in females that makes ova (eggs).

Overexpressed

Gene activity is above normal resulting in too much protein.

Partial breast irradiation

Radiation to the lumpectomy site.

Particles

Small pieces of matter.

Pathologic staging

A cancer stage given by a pathologist based on surgery samples.

Pathologist

A doctor who specializes in testing cells to identify disease.

Periodontal disease

A disease of the gums in the mouth.

Positron emission tomography-computed tomography (PET-CT)

Use of radioactive material to see the shape and function of body parts.

Positive margin

The normal-looking tissue around the tumor has cancer cells.

Postmenopausal

The state of no menstrual periods for at least 12 months.

Premenopausal

The state of having regular menstrual periods.

Progesterone

A hormone involved in female body organs.

Prognosis

The pattern and outcome of a disease.

Prophylactic

A medical procedure to prevent disease.

Protein

Chains of amino acid.

Puberty

The time when teens sexually develop.

Radiation oncologist

A doctor who specializes in the treatment of cancer with radiation.

Radioactive

Containing a powerful energy called radiation.

Radiologist

A doctor who specializes in reading imaging tests.

Radiotherapy

Treatment of a disease with radiation.

Raloxifene

A drug that blocks the effects of estrogen on breast tissue.

Randomized

Assignment to a group by chance.

Receptor

A binding site on cells.

Recurrence

The return of cancer after successful treatment.

Risk factors

Something that increases the chance of getting a disease.

Scalpel

A knife for surgery.

Scar

A permanent mark on the skin after an injury or surgery.

Scintigraphy

A test that uses radioactive tracers to view body parts.

Screening

Regular tests used to detect a disease in someone without symptoms.

Sentinel lymph node biopsy

Surgery to remove the first lymph nodes to which cancer cells travel after leaving the breast.

Side effect

An unplanned physical or emotional response to treatment.

Spinal cord compression

A painful squeezing of the nerves in the spine.

Supraclavicular

Near the collarbone.

Surgeons

A doctor who specializes in operations.

Systemic treatment

Drugs used to destroy cancer cells throughout the body.

Tamoxifen

A drug that lowers the amount of estrogen in the body.

Targeted therapy

Treatment used to stop cancer cells without changing normal cells.

Tubal ligation

Surgery to stop eggs from traveling through the fallopian tubes to the uterus.

Tumor

A mass made from an abnormal growth of cells.

Ultrasonography

A test that uses ultrasound to view body parts.

Ultrasound

A test that uses sound waves to take pictures of the inside of the breast.

Uterine sarcoma

Cancer of the uterus.

Uterus

The female organ where babies grow during pregnancy; the womb.

Vas deferens

A male organ that helps sperm travel from the testicles to the penis.

Vasectomy

Surgery to stop sperm from traveling through the vas deferens to the penis.

Venous thromboembolism

Dangerous blood clot in a vein.

9.1 Questions to ask about testing for breast cancer

- Where will the procedure take place? Will I have to go to the hospital?
- How long will it take? Will I be awake?
- Will it hurt? Will I need local anesthesia?
- What are the risks? What are the chances of infection or bleeding afterward?
- What if I am pregnant?
- How do I prepare for it? Will I need to avoid taking aspirin to reduce the chance of bleeding? Should I not eat beforehand?
- Should I bring a list of my medications?
- Should I bring someone with me?
- How long will it take for me to recover? Will I be given an antibiotic or other medicine afterward?
- How soon will I know the results and who will explain them to me? If a biopsy is done, will I get a copy of the pathology report?
- If I do have cancer, who will talk to me about the next steps? When?

9.2 Questions to ask about treating breast cancer

- What are the available treatments for breast cancer?
- What are the risks and benefits of each treatment for breast cancer?
- How will my age, general health, stage of breast cancer, and other medical conditions influence treatment choices?
- Would you help get a second opinion?
- What can I do to prepare for treatment?
- How soon should I start treatment?
- How much will the treatment cost and how can I find out how much my insurance company will cover?
- How likely is it that I'll achieve remission with treatment?
- What symptoms should I look out for while taking medications for breast cancer?
- What is the chance that my cancer will progress to advanced phases?

9.3 Questions to ask about clinical trials

- Is there a clinical trial that I could take part in?
- What is the purpose of the study?
- What kinds of tests and treatments does the study involve?
- What does this treatment do? Has it been used before?
- Will I know which treatment I receive?
- What is likely to happen in my case with, or without, this new treatment?
- What are my other choices and their advantages and disadvantages?
- How might the study affect my daily life?
- What side effects can I expect from the study? Can the side effects be controlled?
- Will I have to stay in the hospital? If so, how often and for how long?
- Will the study cost me anything? Will any of the treatment be free?
- If I am harmed as a result of the research, to what treatment might I be entitled?
- What type of long-term follow-up care is part of the study?
- Has the therapy been used to treat other types of cancers?

9.4 Suggestions for taking care of yourself

- Let other people help you. This is the time to take advantage of offers for rides, meals, childcare, or just good company.
- Be as healthy as you can—eat well, get enough rest, exercise, stop smoking.
- Talk with your family and friends about your concerns and needs. Let them know what is important to you, including, your feelings about end-of-life decisions.
- Do the things that help you cope—keep a journal, garden, play music, take that trip you have been wanting to take.
- Don't be afraid to take medications that can help your emotional and physical symptoms. Let your cancer care team help you.
- Talk with your treatment team about what you are experiencing. Don't wait until you are feeling overwhelmed.
- Know the resources that are available to you and use them.
- Be your own advocate—ask questions, take notes, and be active in your treatment.

9.5 Suggestions for taking care of caregivers

- Take the time to understand your loved one's cancer and its treatment. Educating yourself will help you know what to expect and how you can be supportive.
- Help provide eyes and ears and sometimes a voice for your loved one. It is extremely useful for patients to have someone with them at doctor's visits to listen, ask questions, take notes, process what is said, and sometimes speak up on their behalf.
- Talk about the important issues. Do it from the very beginning. Don't wait until a patient is too sick or has lost too much ability to address important matters.
- Help develop a treatment plan, and if appropriate, an advance directive. Such plans help everyone involved understand what is important to the patient in terms of treatment goals and end-of-life decisions.
- Take care of yourself. Find the time to get away—take a walk, have lunch with a friend, see a movie, and do something that feels normal. In addition, eat well, try to sleep well, and exercise. You will be a better caregiver if you are taking care of yourself.
- Let other people help you. Take advantage of those offers to make a meal, provide a ride, watch the kids, or just give you a break. Let your friends know what they can do.
- Take advantage of the resources that are available. There are many approaches to dealing with the complex issues that you may face as a caregiver. You should know what support is there for you and use these resources.
- Understand that caregivers are survivors just as much as patients. Cancer is life-changing whether you are the patient or the person caring for the patient.

9.6 Personal treatment record

GENERAL INFORMATION

Patient information

Name: _____ Hospital ID number: _____
Emergency contact: _____ Emergency telephone: _____

Provider Information

Name: _____ Address: _____ Telephone: _____
Name: _____ Address: _____ Telephone: _____
Name: _____ Address: _____ Telephone: _____
Name: _____ Address: _____ Telephone: _____

CLINICAL ASSESSMENT

Tests

Name/Date: _____ Result: _____
Name/Date: _____ Result: _____
Name/Date: _____ Result: _____
Name/Date: _____ Result: _____
Name/Date: _____ Result: _____

Cancer information

Cancer site: _____ Diagnosis date: _____
(T)umor score: _____ (N)ode score: _____ (M)etastasis score: _____
Stage: _____ Histology: _____

TUMOR TREATMENT

Name: _____ Start date: _____ End date: _____
Name: _____ Start date: _____ End date: _____
Name: _____ Start date: _____ End date: _____
Name: _____ Start date: _____ End date: _____

SYMPTOM TREATMENT

Name: _____ Start date: _____ End date: _____
Name: _____ Start date: _____ End date: _____
Name: _____ Start date: _____ End date: _____
Name: _____ Start date: _____ End date: _____

POST-TREATMENT PLAN

Describe: _____

NCCN Member Institutions

**City of Hope
Comprehensive Cancer Center**

Los Angeles, California
800.826.4673
www.cityofhope.org

**Dana-Farber/Brigham and
Women's Cancer Center |
Massachusetts General Hospital
Cancer Center**

Boston, Massachusetts
800.320.0022
www.dfbwcc.org • www.massgeneral.org/cancer

Duke Cancer Institute

Durham, North Carolina
888.275.3853
www.cancer.duke.edu

Fox Chase Cancer Center

Philadelphia, Pennsylvania
888.369.2427
www.fccc.edu

**Huntsman Cancer Institute
at the University of Utah**

Salt Lake City, Utah
877.585.0303
www.huntsmancancer.org

**Fred Hutchinson Cancer Research Center/
Seattle Cancer Care Alliance**

Seattle, Washington
206.288.7222 • www.seattlecca.org
206.667.5000 • www.fhcr.org

**The Sidney Kimmel Comprehensive
Cancer Center at Johns Hopkins**

Baltimore, Maryland
410.955.8964
www.hopkinskimmelfcancercenter.org

**Robert H. Lurie Comprehensive Cancer
Center of Northwestern University**

Chicago, Illinois
866.587.4322
www.cancer.northwestern.edu

Memorial Sloan-Kettering Cancer Center

New York, New York
800.525.2225
www.mskcc.org

**H. Lee Moffitt Cancer Center
& Research Institute**

Tampa, Florida
800.456.3434
www.moffitt.org

**The Ohio State University Comprehensive
Cancer Center - James Cancer Hospital
and Solove Research Institute**

Columbus, Ohio
800.293.5066
<http://cancer.osu.edu>

Roswell Park Cancer Institute

Buffalo, New York
877.275.7724
www.roswellpark.org

**Siteman Cancer Center at Barnes-
Jewish Hospital and Washington
University School of Medicine**

St. Louis, Missouri
800.600.3606
www.siteman.wustl.edu

**St. Jude Children's Research Hospital/
University of Tennessee Cancer Institute**

Memphis, Tennessee
901.595.4055 • www.stjude.org
877.988.3627 • www.utcancer.org

Stanford Cancer Institute

Stanford, California
877.668.7535
www.cancer.stanfordhospital.com

**University of Alabama at Birmingham
Comprehensive Cancer Center**

Birmingham, Alabama
800.822.0933
www.ccc.uab.edu

**UCSF Helen Diller Family
Comprehensive Cancer Center**

San Francisco, California
800.888.8664
<http://cancer.ucsf.edu>

**University of Michigan
Comprehensive Cancer Center**

Ann Arbor, Michigan
800.865.1125
www.mcancer.org

**UNMC Eppley Cancer Center at
The Nebraska Medical Center**

Omaha, Nebraska
800.999.5465
www.unmc.edu/cancercenter

**The University of Texas
MD Anderson Cancer Center**

Houston, Texas
877.632.6789
www.mdanderson.org

Vanderbilt-Ingram Cancer Center

Nashville, Tennessee
800.811.8480
www.vicc.org

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Chronic Myelogenous Leukemia, Malignant Pleural
Mesothelioma, Melanoma, and Multiple Myeloma.



The same authoritative source referenced by physicians and other health care professionals is now available for patients at NCCN.com.



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