Oregon Breast & Cervical Cancer Program

Breast Cancer Diagnostic and Follow-Up Protocols

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Within this document there are gray text boxes highlighting information pertaining to women under 40, and pregnant/lactating women. See pages 31-32 for specifics.
ACKNOWLEDGMENT

In the fall of 1997, a panel of experts working with the Oregon Department of Human Services (DHS), Health Services representing the fields of Diagnostic Radiology, Medical Oncology, Surgical Oncology, Radiation Oncology, Epidemiology, Internal Medicine, and Public Health, were given permission by the Centers for Disease Control and Prevention to build upon a 1995 CDC Publication: Evaluation of Common Breast Problems: A Primer for Primary Care Providers. In 2001 efforts began to further revise these guidelines to address women under 40 and males presenting with breast symptoms. Additionally, much work was done to clarify the management of abnormal clinical breast exam (CBE) findings.

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BACKGROUND

WHAT IS THE OREGON BREAST AND CERVICAL CANCER PROGRAM?

In 1990, Congress passed the Breast and Cervical Cancer Mortality Prevention Act and authorized the National Centers for Disease Control and Prevention (CDC) to plan activities in partnership with state health departments and other national organizations. In 1994, DHS Health Services received a grant to establish this program in Oregon. The BCC Program promotes education and screening for early detection of breast and cervical cancer among medically underserved Oregon women. More information about the BCC Program can be found at http://www.healthoregon.org/bcc.

WHAT IS THE PURPOSE OF THIS DOCUMENT?

These guidelines are intended to aid program staff and primary care providers participating in the Oregon Breast and Cervical Cancer (BCC) screening program. They have also been written with the BCC Case Managers in mind. These guidelines are primarily directed towards women ages 40 and above; however, these guidelines also include men and women (under age 40) who present with symptoms. (At the time of publishing these guidelines, women under age 40 are no longer eligible for the BCC or Komen Breast Screening program.)

WHAT IS THE IMPACT OF BREAST CANCER IN OREGON?

According to the Oregon State Cancer Registry (OSCaR), in 2000, Oregon had 2,708 new cases of invasive breast cancer and 484 deaths due to breast cancer. Of these, 16 new cases of invasive breast cancer and two deaths were in males.²

The American Cancer Society estimates that in 2003, 2,600 Oregon women will be diagnosed with invasive breast cancer and 500 will die of breast cancer.³

INCIDENCE AND MORTALITY

Oregon’s average annual age-adjusted breast cancer rate for 2000 was 142.3 per 100,000. This rate is higher than the national 1995-1999 SEER (Surveillance, Epidemiology, and End Results) Registry rate of 135.1. The age-adjusted mortality rate for Oregon was 24.7 per 100,000, compared to the national rate of 26.7 per 100,000. Staging information as well as incidence and mortality charts are shown on the next page.²
BACKGROUND

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**Age Specific Rates**

**Female Breast Cancer**

**Oregon 2000**

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**Stage* at Diagnosis**

**Female Breast Cancer**

**Oregon 2000**

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*C by SEER Summary Stage (Surveillance, Epidemiology, and End Results)*

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Cancer in Oregon, 2000 (OSCaR)²
I. MEDICAL HISTORY

RISK ASSESSMENT

Evaluation should begin with a review of a woman’s major risk factors for breast cancer. These include: age, personal history of breast cancer, family history of breast cancer, and certain types of histologically diagnosed benign breast disease. However, it should be recognized that up to 80% of women with newly diagnosed breast cancer have no identifiable major risk factors other than age. The major risk factors are described below:

Age: In general, the most obvious and important risk factor for breast cancer is being female, followed by age. The incidence of breast cancer increases with age until at least age 80. Approximately 80% of women with new diagnoses of invasive breast cancer are over the age of 50. Breast cancer is relatively uncommon in younger women, though rates begin to significantly increase at approximately age 40.

For Women under Age 40: Breast cancer risk for most women under 40 is low, but not zero. The American Cancer Society estimates that by age 40, one woman in 225 will develop breast cancer. Breast cancer before age 40 represents 10% of breast cancer cases. Failure to diagnose breast cancer in young women has higher socioeconomic impact and therefore is a frequent cause for medical malpractice litigation. Pre-menopausal breasts are challenging to examine and screening mammography is less effective in this population. The normal characteristics of the young breast are often mistaken for dominant masses. Benign breast changes are much more common in younger women than women over 50. Fibroadenomas are the most common lesion in women age 15-35 and fibrocystic changes are the most common breast lesions in women age 35-50.

Personal History of Breast Cancer: Patients with a personal history of breast cancer should have medical follow-up with regularly scheduled clinical and imaging examinations. A woman with a personal history of breast cancer has a risk of developing a new primary breast cancer as high as 1% per year of remaining life. It is therefore important that the examiner ask about any previous biopsies and their results. A woman with a history of a prior breast cancer should be followed by a surgeon, oncologist, or provider knowledgeable about breast cancer.

Family History of Breast Cancer: A family history should identify any paternal or maternal relatives with breast cancer or ovarian cancer and the age at which the cancer developed. People who have a family history of breast cancer have a greater risk of developing breast cancer than the general population. The increased risk is of particular concern if family members were diagnosed with pre-menopausal breast cancer.
MEDICAL HISTORY

Seven to 10% of all breast and ovarian cancers are related to inherited genetic mutations. Mutations in the BRCA 1 & 2 genes are the most prevalent inherited mutations. A family history that is suspicious for a BRCA mutation includes breast cancer before the age of 50, family history of ovarian cancer, and a hereditary pattern that suggests autosomal dominant inheritance. Other suspicious findings include a family history of bilateral breast cancer and male breast cancer. BRCA mutations are more common in people of Jewish heritage. Women with BRCA mutations confront a dramatically increased risk of developing breast and ovarian cancer. Ten to 20% of women with a BRCA mutation will develop breast cancer by age 40 and have a lifetime risk of up to 60-70%. Breast masses in women known to be BRCA positive, or in women whose mutation status is unknown but have a family history suggestive of BRCA positivity, should be considered malignant until proven otherwise.

Half of all breast cancers under age 30 are related to inherited mutations. In addition to the BRCA 1 & 2 mutations, pre-menopausal breast cancer is commonly found in families with Li-Fraumeni Syndrome and Cowden Syndrome. A referral for genetic counseling is indicated for women from families at risk for hereditary cancer syndromes.

Women who carry such mutations are at very high risk of developing breast cancer and/or ovarian cancer, and should be referred for care to an expert in this area, typically either a medical or surgical oncologist. In women with familial syndromes, breast cancer tends to develop at a younger age; therefore, screening of these women should begin 10 years earlier than the age at which breast cancer was first diagnosed in their relatives.

For Women Under Age 40: It is important to refer women for genetic counseling if BRCA mutation is a concern.

Prior Radiation Therapy: While prior radiation therapy is not an issue for many women, radiation therapy to the chest (usually for Hodgkin’s disease during the teens-young adulthood) is a significant breast cancer risk factor.

Minor Risk Factors: Other less important but recognized risk factors for breast cancer include: nulliparity (never having been pregnant), age above 30-35 years at first live birth, early menarche, late menopause, regular alcohol use, post-menopausal obesity or hormone replacement therapy. These risk factors may be used by providers to develop risk profiles for individual patients but will not generally affect screening recommendations for women. The Gail Model Risk Assessment Tool is helpful for defining breast cancer risk in women over age 35 who undergo regular breast cancer screening. The total estimates 5-year and lifetime breast cancer risk taking minor and major risk factors into account.

Oral Contraceptives: In young women, oral contraceptive (OC) use confers a small short-term increase in breast cancer risk. This excess risk disappears by ten years after stopping OC.
**MEDICAL HISTORY**

### Who is considered to be high risk (and warrant screening) under age 40?

Women under age 40, who would be considered high risk include those who:

1. have a personal history of breast cancer (invasive and/or DCIS);
2. are known BRCA carriers;
3. have a history of LCIS and/or atypical hyperplasia on prior biopsy;
4. have the following family histories on either maternal or paternal side:
   - breast cancer under age 50 occurring in a pattern that suggests inheritance;
   - both breast and ovarian cancer (either the same woman or women from the same family line) (First degree relatives are of particular concern);
   - bilateral breast cancer;
   - male breast cancer.
5. are age 35-39 with a 5-year Gail Model Score of 1.67 or greater (the risk of the average 60-year old woman).

For the woman who perceives herself to be at high risk for breast cancer and has negative physical findings and/or imaging studies, a referral to a cancer risk assessment program can help define her breast cancer risk and identify appropriate risk reduction strategies.

### SYMPTOM ASSESSMENT

It is important to assess breast cancer risk in patients presenting with breast symptoms; however, most women diagnosed with breast cancer do not have significant risk factors. Many women present with breast symptoms, and others will reveal breast problems if they are questioned. The most common breast symptoms presented to the primary care provider include breast lumps, pain, and nipple discharge.

Benign breast symptoms, particularly fibroadenomas, generally occur in women of menstruating ages, whereas simple cysts are more common in the perimenopausal period. The incidence of benign breast symptoms appears to rise as women age, until 45 years of age, when the incidence declines sharply. Because the risk of breast carcinoma increases with age, clinicians need to be particularly suspicious of a dominant mass or asymmetric thickening in the breasts of post-menopausal women. Cystic findings become less common after menopause, although cysts, pain and discharge can be found in women taking hormone replacement therapy.

The provider should inquire about common symptoms such as breast mass, breast pain, skin or nipple changes, axillary lymph nodes, and nipple discharge. The patient should be asked about the duration of the symptoms and whether they are associated with the menstrual cycle. (More information on the diagnosis of suspicious findings and the management of these problems is covered in Sections II and III of this document.)
II. **Clinical Breast Examination (CBE)**

The importance of CBE lies in its ability to detect masses that may be missed on mammography (up to 15-18% of mammograms are negative in the presence of palpable cancer), detect interval lesions that may appear between the patient’s screening mammograms, or evaluate a lump discovered by the patient on breast self-examination (BSE). Clinical studies have shown that the most critical factor in distinguishing a normal nodularity from a discreet mass is the duration of the examination.

**Benign breast changes**: Risk factors for benign breast changes appear to be distinct from those of breast cancer. These risk factors include: history of premenstrual breast discomfort, irregular menses, spontaneous abortion, a family history of both benign and malignant breast disease, lack of use of oral contraceptives, obesity, small breast size, and late natural menopause. However, it is important to rule out cancer when a woman with a history of benign breast changes presents with new symptoms.

**Performing the Exam**

Ideally, the clinical breast exam (CBE) should take place one to two weeks past the onset of menstruation. The exam should be conducted unhurriedly in a setting that allows for minimal distraction and adequate patient privacy. The CBE technique must be thorough and organized to assure that the areas commonly missed (upper outer quadrant and axillary tail, retro-areolar complex, inframammary fold, along and under the clavicle) are adequately covered. The core competencies for breast physical examination include the following:

1. **Health History**: A thorough history should begin with a review of the patient’s concerns or symptoms and include risk factors such as reproductive history, family history and personal history of breast or ovarian cancer. (See page 7-9 of these protocols for more information on risk factors and symptom assessment).

2. **Visual Inspection**: Inspection of the breasts in different positions is an important component of CBE. Look for general contour, symmetry, color, texture, dimpling, or retraction. Positioning includes arms at the side, arms above the head, hands on hips to flex the pectoralis muscle, and leaning forward. The patient should turn side-to-side in each of these positions.

3. **Lymph Node Examination**: Examination of the supra- and infra clavicular lymph nodes needs to occur with the patient sitting. The optimal position for examination of the axillary lymph nodes is also the sitting position with each arm supported at the elbow, or with opposite hand supported on provider’s shoulder. Axillary nodes can be palpated in the lateral, medial, central, substernal and subscapular planes.

See Appendix A for graphics depicting the areas covered in a CBE.
4. **Positioning:** The goal is to spread the breast tissue evenly over the chest wall. The modified supine is either left or right lateral decubitus position. Newer techniques support the hip and lower back with the knees flexed in the contralateral direction. This position is particularly helpful with women who have larger breasts. Avoiding shifting the breast tissue during the examination is essential for a thorough exam.

5. **Perimeter:** Although many patients and some clinicians think of the breast as a circle, the area where breast tissue may be found is actually a pentagon, and extends from the mid-axillary line to the lateral edge of the sternum, and from the clavicle to the inframammary ridge. Covering the entire perimeter is essential in order to avoid missing areas where cancers are most likely to occur: the upper outer quadrant (50%) and the subareolar area (18%). See Appendix A for a diagram of the perimeter.

6. **Pattern:** The vertical strip pattern is optimal and provides the most comprehensive coverage of the breast perimeter and area within.

7. **Palpation:** Use the pads (rather than the less sensitive tips) of the three middle fingers, with the hand slightly bowed. Move in slightly overlapping dime size circles.

8. **Pressure:** The breast tissue should be examined at each palpation point with three sequential depths of pressure in a spiraling dime size circle.
   - Superficial (skin) - just barely moving the surface of the skin
   - Medium (fat) - to the mid-level of the tissue
   - Deep (bone) - to the chest wall or ribs

9. **Patient education:** Principles of BSE are similar to CBE and the area for palpation is identical. Women learn best through observation and demonstration of the technique and the provider’s feedback. However there is no evidence that BSE reduces breast cancer mortality.

10. **Plan of action:** Suggest appropriate intervals for early detection (BSE, CBE and mammography) based on the patient’s individual risk factors and unique needs. Clinician reinforcement of the importance of periodic screening is the most important factor in patient compliance.

**DOCUMENTATION**

Use of a standardized form with a diagram of the breast is optimal. Both normal and abnormal findings need to be documented. There are three aspects of the physical exam to be recorded:

1. **Lymph Nodes:** Record whether the lymph nodes are clinically negative. If they are palpable, indicate their consistency, whether the nodes are single or multiple, and whether movable or fixed. Be sure to note all three areas (supra- and infra clavicular and axillary).
2. **Skin Changes/Abnormalities**: Document skin changes or abnormalities in breast symmetry and contour, color, skin texture; nipple/areolar complex; skin retraction or dimpling. Note how long the skin change has been present.

3. **Discrete Masses**: For discrete masses, it is prudent to document:
   - **Location**: distance from base of nipple, quadrant (or clock face), and depth (superficial, mid-level, deep)
   - **Size**: in millimeters or centimeters
   - **Shape**: usually communicated as round, oval, irregular, flat
   - **Mobility**: fixed, tethered, or mobile
   - **Consistency or texture**: rock hard, hard, firm, soft, rubbery, or spongy
   - **Tenderness**: present or absent, focal or diffuse, persistent or only when palpated

**Management of CBE Findings**

Ten years ago, one in 10 patients referred to breast specialists were found to have a carcinoma. Recent studies show that only 1 in 15 referrals are diagnosed with malignancy. The examining clinician uses judgment to distinguish a benign vs. abnormal exam. When the area in question is felt to be probably benign, a repeat breast exam can be done. The best time to do the repeat breast exam is one week after the end of the menstrual cycle. For women who are not menstruating, or who are irregular, a consistent time of the month is preferred. If the index of suspicion is high, immediate referral for workup is indicated. The CBE is one method of detection - not an independent diagnostic tool.

For continuity of care, include specific, clear, written breast examination findings along with diagram with the referral to mammography and breast specialists. Primary care providers should track the referral, including results, and use these clinical protocols to refine their clinical judgment. Patients must be informed of options for clinical workup and participate in the decision-making process.

Current guidelines aim to categorize referrals (absolute and relative) and reduce the number of unnecessary referrals to breast specialists.

**Classification System for Breast Abnormalities**: The classification system described below is helpful in describing breast changes, and determining whether the exam is benign or suspicious. Documentation of the features mentioned in the classification system on a breast diagram is useful for repeat CBE and continuity between clinicians. There are eight categories of breast findings listed in this section.

1. **Enlarged Lymph Nodes, Lymphadenopathy**: Examine the patient in the upright position, with arm relaxed, focusing on the tissue between the pectoralis and latisimus muscles, and below the arm crease and deep in the apex of the axilla. Push the tissue against the chest wall with the examining hand. Possible causes of
enlarged lymph nodes include both benign (mastitis, breast infection, trauma, inflammatory conditions of soft tissues or nodes) and malignant (tumors of the breast, other organs, or nodes themselves) conditions.

**Benign Features:**
- No enlarged lymph nodes

**Suspicious Features:**
- Enlarged Nodes with/without tenderness

**Management of Lymphadenopathy:** If enlarged nodes with or without tenderness and no other symptoms are palpated, a complete imaging workup with diagnostic mammogram and/or ultrasound, and either a repeat breast exam within 1 month or surgical referral based on the degree of clinical suspicion. Obvious injury or infections will require a repeat breast exam within 1 month, and surgical referral if NOT resolved completely within 2-4 weeks with treatment.

2. **Skin Changes:** A visual inspection of the breast in different positions will reveal skin changes such as dimpling, retraction, or changes in contour, symmetry, color, and/or texture. It is important to assess how long the change has been present, and whether the skin change is associated with a mass. The degree of suspicion is much higher when the skin change is unilateral.

Ecema is usually bilateral and the nipple may be spared. This can be confused with Paget’s disease (carcinoma in situ of the nipple) which is typically unilateral and the nipple is always involved. Although ecema often involves the nipple, it rarely involves the areola. Timing of onset of breast skin changes/nipple retraction is of paramount importance. Long-standing nipple inversion (over many years) can be normal; but recent, even slight, nipple retraction has more serious implications.

**Benign Features:**
- Long-standing bilateral nipple inversion;
- Red, oozing and crusted nipples due to dermatologic conditions (e.g. psoriasis, seborrheic dermatitis, contact dermatitis, neuro-dermatitis and atopic dermatitis.)
- Bruising (ecchymosis) from known trauma.

**Suspicious Features:**
- Nipple retraction or distortion of recent or sudden onset;
- Red and crusted nipple-areolar complex that does not permanently respond to topical steroids (Paget’s disease can temporarily respond to steroids);
- Change in skin texture (orange peel/peau d’orange);
- Warmth, erythema;
- Unilateral dimpling (may or may not be associated with a mass).
**Management of Skin Changes or Nipple Retraction:** Unilateral breast skin changes or nipple retraction need close follow-up. Bilateral mammography and/or targeted ultrasound are the first line investigations. Suspected dermatologic changes of breast skin that do not completely resolve with treatment should be referred to a dermatologist or other specialist and considered for skin biopsy. A woman with skin changes in or around the nipple area that has not resolved with conservative treatment (such as antibiotics, steroids, warm compresses, or observation) should be considered to have Paget’s disease until proven otherwise, and should be referred to a breast specialist for possible biopsy.

3. **Infections and inflammations including trauma:** Infection and/or inflammation, including erythema, breast abscess, Mondor’s disease, mastitis, mammary duct ectasia and edema are characteristic of some benign breast conditions. Assess for redness, warmth, tenderness and lumpiness. Caution! Inflammation that does not respond to antibiotics should be worked up for inflammatory breast cancer.

Benign Features:
- Inflammation that has responded to antibiotics and is completely resolved within 10-14 days;
- Mastitis in women who are breast-feeding that resolves with treatment.
- Trauma-related swelling and erythema with later changes in the stages of ecchymoses (bruising) that completely resolves within 6 weeks.

Suspicious Features:
- Inflammation or erythema that has NOT responded to antibiotics and/or other conservative measures, especially in post-menopausal women or women who are not pregnant or lactating;

**Management of inflammation or infections:** Signs of inflammation can be treated with a 10-day course of antibiotics, but if unresponsive, inflammatory carcinoma must be excluded by further workup (including biopsy) and the patient must be seen promptly by a surgeon.

4. **Nipple discharge:** Nipple discharge is usually divided into three types: pseudo, physiologic, and true.

   a. **Pseudo** nipple discharges can be associated with inverted nipples, eczema, or infection. If the discharge is being caused by a disease, it is more likely to be benign than cancerous. Endocrine causes of galactorrhea (milky discharge) include pregnancy, hypothyroidism, brain tumors, and amenorrhea syndromes. Medications such as birth control pills, antihypertensives, phenothiazines, and tranquilizers may also cause these types of nipple discharge.
b. Bilateral nipple discharges usually have **physiological** causes, such as hyperprolactinemia, mammary duct ectasia (a benign condition occurring in post-menopausal women and is characterized by dilation of the ducts) and periductal inflammation. These types of discharge are typically yellow, gray, or green in color ("earth colors") and thick or sticky.

It is important for the clinician to note if the discharge is spontaneous, unilateral vs. bilateral, number of ducts involved, consistency and color of the discharge, medications being taken, and whether the discharge is associated with a lump.

c. A **suspicious** nipple discharge is one originating in one or few duct(s), unilaterally, and not earth colored (especially clear, bloody, and/or gelatinous). It is usually reported by the woman as having begun spontaneously (not in response to stimulation) and staining her bra, bed sheet or sleeping garment.

<table>
<thead>
<tr>
<th>Discharge</th>
<th>Benign</th>
<th>Suspicious</th>
</tr>
</thead>
<tbody>
<tr>
<td>Side</td>
<td>Bilateral</td>
<td>Unilateral</td>
</tr>
<tr>
<td>Spontaneous?</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td># Ducts</td>
<td>Multiductal</td>
<td>Uniductal</td>
</tr>
<tr>
<td>Color</td>
<td>Earth tones</td>
<td>Clear, bloody, black</td>
</tr>
</tbody>
</table>

**Management of Suspicious Discharge:** A bloody, black, gelatinous, or clear spontaneous discharge is most worrisome and a diagnostic mammogram is warranted. However, even if the results of the diagnostic mammogram are normal, the patient should still be referred to a surgeon and considered for galactography. If a woman with a nipple discharge has a mammographic abnormality, the provider should assess whether the abnormality corresponds with the quadrant from which the discharge originates. An abnormality that does not correspond to the quadrant may represent a separate lesion, needing further workup.

If a nonsuspicious nipple discharge is present, diagnostic mammography is of little benefit, but screening mammography should be performed if appropriate for the patient’s age. Medical workup of galactorrhea (including careful history, complete exam, and prolactin level) is appropriate for persistent milky discharge. Slide cytology on nipple discharge is usually unhelpful and not recommended. Use of hemoccult cards is recommended to check for occult blood.

5. **Cyclic swelling and tenderness:** Physiologic features brought on by the menstrual cycle are considered normal and are not to be classified as a syndrome requiring treatment.
Benign Features:
- Generalized swelling, tenderness or pain brought on by the menstrual cycle;
- During pregnancy, the milk-producing glands become swollen and the breasts may feel lumpier than usual (usually symmetrical).

Suspicious Features:
- Persistent, generalized swelling, tenderness or pain not cyclic or not related to HRT therapy;
- Persistent swelling in a woman who is breast feeding (and when CBE done after both breasts emptied of milk);
- Unilateral swelling, especially if minimal or non-tender.

Management of suspicious swelling or tenderness: Surgical referral.

6. Mastalgia: Breast pain is extremely common; two out of three women suffer from breast pain at some time in their lives. It is important to define the pattern and frequency of pain. In severe mastalgia, the pain can be frequent and diffuse, constant and localized, or persistent and lasting for years. It may or may not be cyclic. Distinguish severity, focal vs. diffuse, unilateral vs. bilateral, and whether the pain is episodic or constant. The most common cause is the physiologic action of estrogen and progesterone on breast tissue.

Women with breast pain should have a careful physical exam and a mammogram if age 40 or older. If these are negative, an explanation of the effects of hormonal cycling will reassure most patients. A trial of non-narcotic analgesics such as ibuprofen, acetaminophen, or aspirin and the use of a brassiere that provides good support are suggested. Some women gain relief from breast pain with oil of primrose, 3 grams a day,9 which can be obtained at health food stores. The elimination of caffeine, chocolate, or salt from the diet has no scientifically proven benefit, although some women may experience relief of pain with caffeine and sodium restriction. Although the use of danocrine is popular in Europe, most American patients find the virulizing side effects less tolerable than their breast symptoms, and there is little role for therapy with male hormones.

Benign Features:
- Mild discomfort in the week prior to menstruation is the most frequent finding and is considered normal;
- Bilateral

Suspicious Features:
- Pain deemed significant and interfering with everyday activities;
- Pain associated with a lump;
- Pain that has failed to be alleviated by simple measures (such as wearing a well-supporting bra), and oral agents commonly used for symptom relief;
- Unilateral persistent pain.
Management of Pain: Pain associated with a mass does not eliminate the possibility of cancer. Refer the patient to a surgeon if there is persistent localized pain (with or without a mass) that is not responsive to conservative measures.

7. Nodularity, significant lumpiness, both cyclic and noncyclic: There may be a discrepancy between what the patient perceives as a breast mass and what the examiner finds on careful physical examination of the breast. Where the patient feels a “lump”, the examiner may find only lobular normal breast tissue. The patient may note the “lump” during the premenstrual phase. It may be a diffuse, poorly defined thickening that may or may not be matched in the opposite breast, or an area of irregularity or prominence such as normal, but nodular, breast tissue. Physiologic nodularity may be stable or fluctuate with the menstrual cycle. It may involve a specific area of the breast, often the tail and/or upper outer quadrant, or involve the entire breast. Bilateral palpation to look for symmetry is an important tool in determining the degree of suspicion for an abnormal exam.

Benign Features:
- Bilateral and symmetrical diffuse lumpiness;
- Bilateral and symmetrical areas of lumpiness/fibrocystic areas.

Suspicious Features:
- Asymmetrical nodularity that persists after menstruation or after a repeat breast exam in women no longer cycling.

Management of Suspicious Nodularity:

All women will require a surgical referral or a repeat breast exam within 2 months if there is any degree of suspicion by the clinician performing the CBE. Management of suspicious nodularity will be similar to that of Palpable Masses described below.

A negative ultrasound performed by a breast imager and correlated with the area of clinical concern (“targeted ultrasound”), can increase the confidence of the patient and the referring provider that the palpable findings are normal. When vague palpable findings are due to cancer, the ultrasound will frequently be positive even when the mammogram is negative. The areolar margin, the area beneath the inframammary fold, and the upper outer quadrant may contain a number of small palpable nodules of normal breast tissue that are not suspicious and do not require biopsy. If the patient is concerned or anxious, it is good medical practice to advise her to return bimonthly or quarterly for a repeat examination until she and the examiner are convinced of the benign nature of the findings. In menstruating women, return visits should occur the week after her menstrual period.
8. **Dominant Masses (lumps):** The most common types of dominant lumps are simple cysts, galactoceles, and fibroadenomas. Such benign lumps are often distinct, persistent, and relatively unchanging. However, because breast cancer may be present in such a variable manner, there are no physiological exam features which reliably distinguish benign from malignant masses.

**Simple cysts** are the most common type of dominant lump and are characterized as a fluid-filled sac within the breast tissue. While they may be found in younger women, they are most commonly found between the ages of 35 and 50. Simple cysts may be painful or asymptomatic, may be palpable, or only visible on ultrasound. With a small amount of fluid, they may appear soft and fluctuant, but when the cyst is tense, it may feel like a solid mass. Cysts are often solitary, but may be multiple. The clinical breast exam cannot reliably distinguish a solid mass vs. a cyst. The common practice of describing a mass on CBE as a cyst should be avoided. Some cysts are complex, and may also be cancerous. Accordingly, ultrasound is key in confirming whether a mass is cystic or solid, and whether the cyst is simple or complex.

**Galactoceles** are a simple, milk-filled cyst, probably formed by overdistention of a lactiferous duct, usually appearing as a firm, nontender mass in the breast tissue. These can be present long after breast feeding.

**Fibroadenomas** are the most common tumor of the breast and are made up of both structural (fibro) and glandular (adenoma) tissues. They occur most frequently in the third decade of life but may occur anytime after puberty, even during menopause. Fibroadenomas are hormonally responsive and may increase in size during the end of the menstrual cycle and during pregnancy. Characteristically, fibroadenomas are painless, well-circumscribed, freely movable tumors with a rounded, lobulated, or discoid configuration. They are usually rubbery feeling, but may appear hard, particularly when calcified. Often times they are described as an area of thickening that feels “ropey” or “granular”, and can often be felt in the area around the nipple and areola and in the upper-outer part of the breast.

**Cancer,** when palpated, generally feels discrete, firm or hard, unilateral, irregular, and is typically nontender. It may be mobile or fixed to adjacent tissue. Occasionally a cancer will present as an area of thickening, asymmetry, or focal persistent pain. Therefore, any asymmetrical finding may be a cause for concern, and particularly in women over 50, should be considered cancer until proven otherwise.

**Benign Features:**
- Round, or oblong that is bilateral and symmetrical;
- Fluctuance that is bilateral and symmetrical;
- Previously determined by diagnostic workup (ultrasound, biopsy or surgical referral) to be benign (but not a diagnosis of atypia).
Suspicious Features:
- Unilateral;
- Fixed to adjacent tissue (may be mobile);
- Discrete;
- Firm or hard;
- Nontender (but may have focal pain);
- New lump in pre-existing nodularity;
- Cyst that recurs more than two times within four to six weeks, displays bloody fluid on aspiration, or leaves a residual palpable mass post-aspiration.

**Management of Palpable Masses:** Workup beyond a diagnostic mammogram is often required. If the CBE finding has been proven by ultrasound to be a simple cyst, further workup is unnecessary although the cyst may still be aspirated to relieve symptoms. In some rural areas there may be a delay scheduling diagnostic imaging. Providers may choose to aspirate the cyst before diagnostic imaging, but it’s important to inform the radiologist.

9. **Breast Examinations That Are Difficult:** All patients age 40 and older should have regular clinical breast examinations and screening mammography. The patient should be referred to a surgeon for evaluation when the breast examination is difficult, for example, because she: 1) has had a reduction mammoplasty or augmentation implantation; 2) has extremely large, dense, or multi nodular breasts; 3) has had multiple biopsies with multiple scars; or, 4) is pregnant or lactating.

**Pregnant or Lactating Women:** Physical diagnosis of breast cancer in pregnant or lactating women may be extremely difficult. Any pregnant or lactating woman with a clinically suspicious lesion should be referred to a surgeon without delay. Approximately 1 in 3,000 pregnant or lactating women develop breast cancer, and 1% to 2% of breast cancers are diagnosed in pregnant women. Ultrasound imaging of a palpable mass or thickening can confirm a fluid-filled or complex mass (e.g. cyst or galactoceles), a solid mass requiring biopsy, or a drainable abscess. Mammography is generally less helpful in women who are pregnant or lactating, but should be obtained in cases of high suspicion and is safe after the 1st trimester.
III. Screening and Diagnostic Imaging

Mammography

Breast imaging has very different roles in the asymptomatic (without symptoms) woman and in the woman with a breast lump. In the asymptomatic woman, screening mammography is the primary means of detecting early breast cancer. Clinically suspicious findings warrant a diagnostic mammogram and (often) ultrasound. Providers need to be specific as to the type of mammogram they order. Where percutaneous biopsy is available, breast imaging can accomplish both detection and diagnosis.

The function of a true screening mammography program is to screen a large pool of apparently normal and asymptomatic women to find the few who have findings suggestive of early breast cancer. If an abnormality is suspected with screening mammography, additional mammographic views and/or ultrasound are performed. Most suspected abnormalities detected on a screening mammogram are resolved by further imaging. Most often the abnormality is found to be glandular tissue, a cyst, or benign calcifications. Occasionally a mass or suspicious finding is confirmed by imaging, requiring biopsy.

After the imaging workup is complete, the mammogram report should give some indication of the radiologist’s level of concern about the findings. The American College of Radiology (ACR) has published a grading system which indicates the level of concern. The grading system is as follows:11

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Incomplete: need additional imaging evaluation or comparison to old films. Patient will be called back for additional imaging, such as special mammographic views or ultrasound. A final score (1-5) is assigned after comparing old films or obtaining additional views.</td>
</tr>
<tr>
<td>1</td>
<td>Negative.</td>
</tr>
<tr>
<td>2</td>
<td>Benign. Usually cysts, fibroadenomas, benign calcifications, or benign lymph nodes.</td>
</tr>
<tr>
<td>3</td>
<td>Probably benign. Benign features on imaging but lack specific identifying features. These findings have an approximately 2% or less risk of being malignant, and may be managed by short term imaging usually at 6 months. Palpable findings need evaluation by surgeon.</td>
</tr>
<tr>
<td>4</td>
<td>Suspicious. These lesions require biopsy; the rate of malignancy ranges between 13-16%.12</td>
</tr>
<tr>
<td>5</td>
<td>Highly suggestive of malignancy. These lesions require biopsy; the malignancy rate is 59-74%.12</td>
</tr>
</tbody>
</table>

“Percutaneous” means “through the skin.” This biopsy method uses needles or needle-like devices to obtain slivers (cores) of tissue for diagnosis. This is as opposed to an “open” biopsy, which is done by a surgeon in the operating room. When used appropriately by a trained specialist, percutaneous biopsy has a success rate of 95% or greater.
It is important to remember that a normal breast imaging examination does not exclude breast cancer. Between 10-20% of palpable cancers are not visible on mammograms. This false negative rate is considerably reduced when high-resolution ultrasound is added to the workup. Any mass that is clinically suspicious and which is unexplained by the imaging studies should be biopsied. **All PALPABLE masses must be explained. The ACR emphasizes that a negative mammogram in the presence of suspicious ultrasound or CBE warrants a fine needle aspirate (FNA) or biopsy.**

**Under age 30:** No consensus has been reached by the ACR on the appropriateness of diagnostic mammography in women under 30.

**Women age 30+:** For women over 30 with a palpable mass, the ACR recommends the use of diagnostic mammography with supplemental mammographic views, stating that mammography has been found to be the most sensitive screening procedure for detecting cancer.

### Ultrasound

The traditional role of ultrasound is to distinguish between a benign cyst and a solid mass. This is true for both palpable breast masses and nonpalpable mammographically detected masses. Palpation-guided aspiration of a cyst may occasionally fail because the target is deep or “feels” larger than it actually is, impairing accurate localization. In these cases, ultrasound can make the diagnosis or aid in aspiration. Ultrasound-guided cyst aspiration may be preferable to “blind” aspiration, because an unsuccessful clinical aspiration can cause hemorrhage into the cyst which complicates the ultrasound appearance, making the lesion look solid. Ultrasound guided cyst aspiration is a quick and simple procedure which should be done whenever a cystic-looking lesion cannot be confidently diagnosed as a simple cyst based upon its sonographic appearance, or when either the patient or provider desire aspiration. Many complex lesions are actually benign cysts, and when aspirated to disappearance, follow-up imaging or biopsy is unnecessary. Lesions suspected of being complex cysts should always undergo aspiration, because mucinous carcinoma occasionally has the ultrasound appearance of a complex cyst.

An increasingly important role for ultrasound is to detect a mass when there are findings on palpation but the mammogram is negative. The mammogram may be negative in the following situations:

- A mass is present but it is obscured because the breast is mammographically dense.
- The palpable findings are due to invasive lobular carcinoma, which can infiltrate tissues without making an image-detectable mass.
- The palpable findings represent prominent normal fibrous or fatty tissue.
SCREENING & DIAGNOSTIC IMAGING

Ultrasound will frequently detect palpable masses in the first and second cases. Failure of ultrasound to detect palpable findings suggests but does not prove that the findings are due to prominent normal tissues (third case). These cases must be managed based on the degree of clinical concern.

Ultrasound can occasionally be helpful in evaluating focal areas of breast pain as well as mammographic findings such as focal asymmetric densities, areas of architectural distortion, or areas of new or increasing density that are unexplained by the clinical history. In these cases, when there is no mass or abnormal shadowing detected at ultrasound and the CBE is negative, the imager has greater confidence that the mammographic findings are benign.

The ability of ultrasound to characterize a solid mass as probably benign is still being explored. Ultrasound is increasingly being used in the conservative (non-surgical) management of fibroadenomas.

Ultrasound has an important role in guiding interventional breast procedures. These include fine needle aspiration, core needle biopsy and needle localization for surgical biopsy. Ultrasound is the imaging modality of choice for women younger than age 30 who have a dominant breast lump.

Ultrasound has no defined role in screening asymptomatic women of any age. This is true regardless of risk factors, personal history of breast disease or breast density on mammography. For a thoughtful editorial regarding the use of ultrasound in patients with negative or equivocal breast exams, see Hall.

Women Under Age 35: The ACR notes that women age 30-35 may be best served by having ultrasound performed initially. Although mammography has been found on retrospective review to be abnormal in 86-90% of symptomatic young women subsequently diagnosed with breast cancer, a negative mammogram in the presence of a suspicious CBE does not change the recommendation to evaluate the CBE findings further.

OTHER IMAGING MODALITIES

The only imaging modality proven to be effective for breast cancer screening is mammography. However, magnetic resonance imaging (MRI) is considered the gold standard for the evaluation of implant rupture. Implant rupture can also sometimes be diagnosed with ultrasound. The role of MRI in the diagnosis of breast cancer is still being defined, although it may hold promise for differentiating tumor from scar tissue and fibrocystic breast changes. Computerized tomography (CT) has no practical role in the evaluation of the breast although in rare instances it can be helpful in localizing lesions for biopsy. The role of breast scintigraphy and positron emission tomography as adjuncts to mammography are yet to be determined.
**CAD or Computer Assisted Diagnosis**, in the form of “R-2” or similar machine, can be a major aid to Mammographers, as an impartial “second reader”. It will indicate changes on a mammogram that may need extra evaluation by the Radiologist. It does not diagnose, but does act as extra eyes looking for subtle changes on the images. The mammogram image is scanned with a laser beam and converted into a digital signal. The computer highlights the suspicious areas on a monitor.

**MANAGEMENT OF PALPABLE FINDINGS**

When a woman has a **palpable mass**, imaging is for diagnosis, not screening, and therefore must be interpreted in the context of the clinical breast exam. The workup of the patient with a dominant mass should include a diagnostic mammogram and may also include ultrasound or cyst aspiration. Ultrasound should be strongly considered when the mammogram is negative, because palpable cancers that are not visible on the mammogram are frequently visible on ultrasound. In this way, the mammogram and ultrasound are complementary. Invasive lobular carcinoma is frequently not visible on the mammogram, but may be very conspicuous with ultrasound.

In the setting of a dominant palpable mass, imaging may occasionally lead to a diagnosis, such as simple cyst, calcified fibroadenoma, or obvious spiculated cancer. Often, however, imaging findings will be nonspecific or even negative. In this setting, palpable findings are managed clinically, usually by a breast surgeon, and the role of imaging is more to screen the surrounding breast and opposite breast for nonpalpable breast cancer. While imaging of the symptomatic patient frequently fails to provide a specific diagnosis, it can provide important predictive information by determining the extent or multifocality of the palpable abnormality.

**Correlation of Palpable Findings with Imaging Study**: Correlation of the palpable mass to the imaging workup is key. It is important for the provider to communicate his/her CBE findings when abnormal, to the imaging facility. It is essential that the diagnostic mammogram and ultrasound specifically address the palpable findings, and the report must contain evidence that this has occurred. Here are two examples of reports that correlate the palpable and imaging findings:

1. The breasts are moderately dense. A BB was placed on the palpable lump in the left upper outer quadrant at 2 o’clock approx 4 cm from base of nipple. The palpable lump consists of a well-circumscribed 2 cm mass that is solid at ultrasound. ACR Category 3: Probably benign, recommend 6-month follow-up.
2. A marker was placed on the palpable lump in the right breast upper outer quadrant at 3 o’clock, approx 8 cm from base of nipple. The breasts are heterogeneously dense. The palpable mass is obscured by dense breast tissue and is not visible on the mammogram. Ultrasound of the palpable mass reveals a 1 cm simple cyst. ACR Category 2: Benign findings.

Here is a report that does not correlate the palpable and imaging findings:

“History: Palpable mass. Findings: cyst in the left outer breast, otherwise negative.”

Newer technologies such as CAD and digital mammography are not covered procedures by the BCC Program at this time.
SCREENING & DIAGNOSTIC IMAGING

It is impossible to determine from this last report if the cyst corresponds to the palpable lump or if it is an incidental finding and the lump of concern (chief complaint) has not been adequately visualized.

The ultrasound should be added at the discretion of the radiologist. If only fatty tissue is detected mammographically at the site of a palpable abnormality, ultrasound may be unnecessary. If the palpable finding is an obvious cancer mammographically, ultrasound may be unnecessary but might yield additional information about the extent of the tumor. In most other cases, high resolution ultrasound should be performed after the mammogram.

For Women Under 30: When a woman younger than age 30 has a dominant palpable lump, the imaging modality of choice is ultrasound. However, imaging studies rarely affect management decisions in this age group. In this age group, cysts are more rare, and the most common masses are fibroadenomas and fibrocystic change.

The American College of Radiology (ACR) Appropriateness Criteria for imaging workup of palpable breast masses differentiates between women less than 30 years old and older than 30. In women less than 30 with a palpable mass, ultrasound was determined to be the most appropriate imaging test. According to the ACR, ultrasound has been found to be the most sensitive procedure for determining benign breast disease and provides the most accurate diagnosis of any solid palpable mass.

Young women in their teens or twenties with a discrete palpable mass most likely have a fibroadenoma. Mammography rarely affects management decisions in these young women. If imaging is performed, it should be ultrasound rather than mammography. The combination of fine needle aspiration (FNA), clinical breast exam, and sonography (modified triple test) can be very helpful.

Morrow, et al recommend a directed ultrasound of the area of the mass in women under 40 because of the low specificity of mammograms and whole breast ultrasound in young women. Morrow and colleagues recommend that a woman with a clinically suspicious mass undergo a mammogram and FNA, followed by definitive surgery if the mass is malignant.

Palpable Breast Mass During Pregnancy: 1 in 3000 women will be diagnosed with breast cancer during pregnancy. Pregnancy creates special challenges to the practitioner charged with evaluating a palpable mass. Mammography is less accurate because the breasts have an increase in gland tissue and water content and a decrease in fatty tissue. Ultrasound is the first imaging procedure of choice. Ultrasound is safe and can be useful in determining whether the mass is cystic or solid. Mammography is fairly safe after the first trimester. A histologic breast biopsy (core biopsy or surgical biopsy) may be necessary to determine whether the mass is malignant, but is technically difficult, harder to interpret, and more likely to cause a hematoma or milk fistula. FNA may prove a helpful alternative.
SCREENING & DIAGNOSTIC IMAGING

The breast imaging workup may yield any of the following results:

- **Cyst.** The palpable mass is found to represent a cyst. Cysts are common in the pre- and perimenopausal age groups.
  - **Simple Cyst:** If the mass is a simple cyst by ultrasound diagnostic criteria, no further workup is necessary. Simple cysts are characterized on ultrasound as fulfilling four criteria: (1) round or oval, (2) sharply defined margins, (3) lack of internal echoes (“anechoic”) and (4) posterior acoustic enhancement. Whenever margins are not described in a report as being smooth or circumscribed, more clarification is needed from the radiologist. Simple cysts require only routine follow-up. However, the cyst may be aspirated if it is painful. Aspirated cysts sometimes recur.

- **Complex Cyst:** Complex cysts with debris or thickened material inside need to be aspirated for definitive diagnosis because of the possibility of mucinous carcinoma. Occasionally the radiologist will categorize the complex cyst as “probably benign” finding, i.e. perfectly smooth margins, and then it is safe to either aspirate it or follow it for 2 years except, in the presence of a discrete palpable mass, in which case an aspiration is required. If the margins are not described in the report, clarification is needed. Usually aspiration is preferred unless it will be technically difficult or unusually uncomfortable (behind the nipple, for instance).

- **Cyst Aspiration and Reoccurrence:** If a cyst recurs more than two times within four to six weeks, is grossly bloody or leaves a residual mass after aspiration, cytological examination and surgical referral for biopsy and/or excision is warranted. If the mass disappears with aspiration, then it was a simple cyst and no further workup is necessary. If there is residual soft tissue left after a diagnostic aspiration, this should be biopsied. If the suspected cyst turns out to be solid and does not aspirate, (a situation that can often be avoided by pre-aspiration ultrasound), its management depends on its morphology after imaging workup. See “Solid mass” below. Aspirated cyst fluid should be discarded unless it is bloody or clear/gelatinous on the initial/first pass of the needle. Bloody or clear/gelatinous fluid should be sent to cytology. Although multiple cysts commonly occur, women should be advised to seek medical advice every time a new lump arises.

- **Solid mass** detected by mammogram and/or ultrasound. A surgical referral is necessary even if the mass has been categorized as a ACR 2-Benign or ACR 3-Probably Benign. Management of a solid mass will vary depending on its imaging characteristics and ACR category. If the finding is ACR 4-Suspicious or ACR 5-Highly Suggestive of Malignancy, the lesion should be biopsied. Occasionally the patient may desire removal of any solid palpable mass, whatever its risk of malignancy. Alternative strategies are available, however, in selected cases. These include nonsurgical biopsy by FNA, core needle, or MammoTone biopsy. These strategies are discussed in Section IV of this document. A woman’s desire to have a mass excised, regardless of nonsurgical
alternatives suggested by her provider, should be determined from the outset; in such a case, a needle biopsy would be an unnecessary procedure and cost.

- **Mass not detected** by mammogram OR ULTRASOUND. These are usually reported as Category 1 (Negative). These cases require additional clinical follow-up, which may consist of a repeat CBE at a short interval in the cases of low clinical concern, or surgical referral in the cases of higher clinical concern. The surgeon will decide when a biopsy is indicated despite negative imaging findings. *A negative mammogram should not deter the clinician from arranging FNA biopsy or tissue biopsy of a palpable mass because 15-18% of mammograms are normal in the presence of a palpable cancer.*

**MANAGEMENT OF NON-PALPABLE FINDINGS**

Most abnormalities detected on a screening mammogram are resolved by further imaging. Most often the abnormality is found to be focally prominent glandular tissue, a cyst, or benign calcifications. The mammogram will then be reported as ACR 1-Negative or ACR 2-Benign and the patient will resume routine screening. If the mammogram result is ACR 3-Probably Benign—short interval follow-up suggested, the lesion is almost certainly benign, with an approximately 2% or less risk of cancer.21

Options for follow-up of a category 3 study should be presented to the woman and include close imaging follow-up or referral for a surgical consultation. The radiologist should recommend the interval and type of imaging follow-up; this will generally be at 6 months and may include ultrasound examination. If the lesion is stable and continues to look benign after 6 months, the patient has another imaging follow-up at 6 months, and then again in a year (6,12, and 24 months). If the lesion continues to be stable and look benign, the patient resumes routine screening.

When a BIRADS 3 mammogram is followed in this fashion, the low but measurable risk for a delayed diagnosis of breast cancer should be clearly communicated to the patient. If she is unwilling to accept this risk (<2%) or if she is a high-risk patient, the woman should be referred to a surgeon for consideration of biopsy. This may be an image-detected core biopsy or a surgical biopsy, depending on the local practice. Nonpalpable ACR 3-Probably Benign lesions may be suitable for either stereotactic or ultrasound guided core biopsy.

Alternatively, if the nonpalpable finding is ACR 4-Suspicious ACR 5-Highly Suggestive of Malignancy, the lesion should be biopsied. In centers where image-guided core biopsy is available, the biopsy can be performed as part of the imaging workup. Where image-guided biopsy is not available or is deemed inappropriate by the imager or not acceptable by the patient, needle-localized surgical excisional biopsy should be performed. If image-guided core biopsy is done, it is the responsibility of the radiologist performing the biopsy to correlate the pathology result with the imaging findings.
If the pathology result does not explain the imaging findings, or if atypical ductal hyperplasia is the result, surgical excisional biopsy should be performed. Further, it is important for both the patient and provider to remember that image guided and needle-localized surgical biopsy are not always mutually exclusive; if the image guided biopsy shows malignancy and the patient desires breast preservation, a wire-localized biopsy to excise the lesion will then be required. If the core biopsy result is benign and is concordant with the imaging findings, the patient will be advised to enter imaging follow-up at 6, 12, and 24 months. When core biopsy of a mass yields the concordant diagnosis of fibroadenoma, the patient may resume routine screening.22

Nonpalpable cysts detected by mammography and confirmed to be simple cysts by ultrasound need not be aspirated except for relief of pain. A nonpalpable cyst not fulfilling complete imaging criteria for a simple cyst may be aspirated for diagnosis using image guidance. If the area has suspicious characteristics by ultrasound, an imaging-directed biopsy, either image-guided (FNA or core) biopsy or needle-localized surgical excisional biopsy, should be performed.

Occasionally, the patient will desire removal of any solid mass, whatever its risk of malignancy. The patient should be informed that alternative strategies are available in selected cases, and these include imaging follow-up, or nonsurgical biopsy by FNA or large core needle. If a woman desires to have a mass excised, regardless of nonsurgical alternatives suggested by her provider, this should be determined from the outset, because in such a case, a needle biopsy would be an unnecessary cost.

**Correlation of Non-Palpable Findings with Imaging Study:** Just as it is essential that the diagnostic mammogram and ultrasound specifically address the palpable findings (see page 23), the same principle applies when ultrasound is performed for a screening-detected nonpalpable mass: the report must correlate the ultrasound findings with the mammogram and indicate whether any cyst found is the cause of the nodule on the mammogram.

Correlating imaging findings with clinical or mammographic findings is the responsibility of the breast imager, not of the referring provider. However, the referring provider must provide specific documentation about any areas of concern to assist the breast imager.
IV. Diagnostic Work-Up Beyond Imaging

Biopsy or FNA Recommended by Radiologist

For nonpalpable lesions detected by mammography, especially Category 4 lesions, the breast imager is best able to assess whether core biopsy or excisional biopsy is more appropriate. In general, discrete focal lesions, especially masses, can be accurately diagnosed with large core needle biopsy, whereas “field abnormalities” such as large areas of microcalcifications or radial scars, should be excised. In some practice environments, surgical consultation for Category 4 and 5 lesions is obtained only if there is a diagnosis of cancer, while in others all patients with abnormal mammograms are referred to the surgeon. With either strategy, most Category 5 lesions will require surgical referral.

Fine Needle Aspiration

Fine needle aspiration (FNA) can safely and reliably diagnose a breast mass as a benign cyst if the mass completely resolves after aspiration and the aspirated fluid is benign in appearance (i.e. not grossly bloody, clear or gelatinous). Benign-appearing cyst fluid should be discarded and not sent for cytologic evaluation. If there is a residual mass either by palpation or by imaging, if no fluid is aspirated, or if the fluid is clear, gelatinous, or grossly bloody, then further evaluation is necessary.

FNA of solid breast masses is a valuable diagnostic tool when done by experts and interpreted by experienced cytopathologists. However, in part because the expertise of FNA performance and interpretation is highly variable, FNA of solid lesions has a relatively high rate of false negative diagnoses (1.8% to 33%). Accordingly, a negative or benign result should be interpreted in the setting of the physical examination and imaging findings23 and the Triple test (discussed on page 29 of this document).

Large Core Needle Biopsy

Cutting needle biopsy of the breast provides a core of tissue for histologic evaluation and when properly done in appropriately selected patients is a safe, well-tolerated and cost-effective alternative to surgical biopsy. Large core needle biopsy specimens can be interpreted by any pathologist, and they can provide specific histologic diagnosis. When a mass is palpable, this kind of biopsy is sometimes done by a surgeon. A nonpalpable mass detected at screening mammography can be biopsied by a radiologist using ultrasound or mammographic (stereotactic) guidance. In many centers, large core needle biopsy is replacing open surgical biopsy for the diagnosis of screening-detected nonpalpable mammographic lesions.
Core biopsy is a sampling technique and is not intended to remove the lesion (with the possible exception of Mammo-tome biopsy). The histologic result must explain or be consistent with the imaging findings. If it does not, rebiopsy is mandatory. Core biopsy patients with benign histology which is concordant with the imaging findings should be followed with imaging for two years after biopsy in order to exclude the 1-2% sampling error rate\textsuperscript{24-27} of this type of biopsy. The radiologist or surgeon who performs the biopsy is responsible for comparing the histology results with the imaging findings and for making follow-up recommendations.\textsuperscript{28,29} The follow-up interval will usually be the same as for a category 3 lesion, i.e.: 6, 12 and 24 months. When a fibroadenoma is diagnosed by core biopsy, the 6-month follow-up may be omitted. If histologic results from a core biopsy include atypical hyperplasia or radial scar, follow-up with excisional biopsy is mandatory.\textsuperscript{27,30,31}

**TRIPLE TEST (TT)**

The diagnostic triple test of (1) imaging, (2) CBE, and (3) needle biopsy allows the surgeon to reduce the number of surgical biopsies for palpable breast lumps that prove to be benign, while at the same time effectively diagnosing cancer. In the “classic” TT strategy, the surgeon correlates the clinical breast exam, mammogram, and FNA results to assess whether a palpable mass may be followed clinically instead of requiring open biopsy. If all three are interpreted as benign (“concordant-benign”), the mass can be safely followed without excision. If all are malignant (“concordant-malignant”) the patient can proceed directly to definitive therapy without the need for intervening confirmatory open biopsy. If the three components are not in agreement (“disconcordant”), the mass should be histologically biopsied (core or surgical biopsy) for further evaluation.\textsuperscript{23}

**MODIFIED TRIPLE TESTING (MTT):**

Because of the relative higher accuracy of ultrasound over mammography in women younger than 40 (especially for the evaluation of a dominant finding on CBE), the TT is modified (MTT) in these patients to use ultrasound instead of mammography. There is also a role for the MTT in men (see page 33). The algorithm is then the same as described in the above section.\textsuperscript{32}

**OPEN SURGICAL BIOPSY**

Surgical removal of a breast lesion is the gold standard against which other diagnostic techniques are compared. It is routinely performed for dominant palpable masses. Non-palpable screening-detected lesions may also undergo surgical biopsy, however, large core needle biopsy is now being used more frequently in the evaluation of these lesions. Needle-localized surgical biopsy for nonpalpable breast lesions has a 2-3% error rate,\textsuperscript{33-36} which is similar to the sampling error of large core needle biopsy.\textsuperscript{24-27}
Indications for surgical biopsy instead of core needle biopsy include:

- Patient preference for surgical excision.
- A nonpalpable mammographic lesion, which is not amenable to image-guided core biopsy, as determined by the radiologist.
- Lesion which mammographically is highly suspicious for cancer (BIRAD #5), and surgeon or patient do not desire preoperative tissue diagnosis.
- Core biopsy is unavailable.
- Lesion previously biopsied by core needle technique which histology shows atypical hyperplasia, radial scar, or where the imaging findings are not concordant with the histology results.

Surgical removal of a nonpalpable breast lesion requires a needle localization procedure prior to biopsy. This is a mammographic or ultrasound procedure done by the radiologist. After the biopsy, the surgical specimen should be imaged with mammography or ultrasound to ensure that the lesion has been removed.

Histologic diagnosis is a sampling technique; the pathologist does not evaluate the entire volume of the biopsy specimen. Therefore, it is important that the histologic diagnosis be correlated with the clinical and imaging findings. The radiologist and/or the surgeon perform this correlation. If the clinical and imaging findings are discordant with a benign histologic diagnosis, the pathologist should do further tissue sectioning because the initial sections may have missed the lesion. If they continue to be discordant, mammography should be repeated to see if the lesion was actually removed. Occasionally rebiopsy may be necessary.

In summary, the best diagnostic evaluation of breast problems occurs when the primary care physician, radiologist, surgeon, and pathologist have an open and cooperative relationship.
V. Special Populations

**IMPLANTS**

Women with implants should receive regular mammography according to accepted screening guidelines. The mammogram can often be optimized by a technique called “push back” views. Palpable masses can be evaluated with routine TT (triple test) or MTT (modified triple test), with the exception that it is usually prudent to do all indicated needle biopsies by ultrasound or stereotactic guidance, to avoid implant rupture. Suspected implant rupture is best evaluated by MRI or ultrasound. The presence of implants is not known to increase the risk of breast cancer. Women with implants who are diagnosed with breast cancer can choose lumpectomy and radiation therapy (if clinically appropriate) and thus be treated with the implant in place. The presence of an implant does not seem to significantly impact the effectiveness of radiation, although radiation does slightly increase the risk of subsequent implant rupture.

**PREGNANT WOMEN**

Because of age and physiology issues, pregnant women do not typically undergo screening mammography. However, dominant masses noted on breast self-examination (BSE) or clinical breast examination (CBE) should be evaluated by TT or MTT, realizing that diagnostic mammography is fairly safe after the 1st trimester. Open surgical biopsy should be avoided whenever possible because of the risk of milk fistula; fine needle aspiration (FNA) and core biopsy are good alternatives.

Cancers diagnosed during pregnancy or up to a year after delivery are termed “pregnancy associated” and usually present at a higher stage than cancers in non-pregnant patients. The stage-for-stage prognosis of pregnancy-associated and non-pregnancy-associated breast cancers may be the same, although this is controversial. There is no evidence to suggest that therapeutic abortion is necessary or improves the prognosis when breast cancer is diagnosed in a pregnant women. Any discussion to abort the fetus should be between the woman and her provider; ultimately, the decision resides with the patient and possibly her partner. If the fetus is kept, chemotherapy is generally safe after the second trimester, and breast preservation is an option if technically appropriate, as long as the radiation is delayed until after delivery.

More information on screening and diagnostic workup for women who are pregnant or lactating can be found in highlighted text as follows:

- Difficult breast exam .............................................................. page 19
- Imaging workup ........................................................................ page 24
**SPECIAL POPULATIONS**

**YOUNG WOMEN (<40 YEARS OF AGE)**

Screening and workup of breast lesions in these women have been previously discussed. Some, but not all, data suggest that stage-for-stage prognosis of breast cancer is slightly worse for younger women compared to women older than 40. Breast preservation may be associated with a higher local recurrence rate in younger women, although it should still be offered as long as the woman is aware of this risk. Young women with very good prognosis lesions, including DCIS, should consider bilateral mastectomy and reconstruction to reduce further risk of new lesions, especially when there is a family history or risk.

More information on screening and diagnostic workup for women who are under age 40 can be found in highlighted text as follows:
- Risk Assessment by Age .............................................................. page 7
- BRCA Counseling ........................................................................ page 8
- High Risk under age 40, and screening frequency ....................... page 9
- Appropriateness of diagnostic mammogram ............................... page 21
- Ultrasound in women under age 35 ............................................ page 22
- Imaging in women with a discrete palpable mass ....................... page 24

**MALES (MALE BREAST CANCER)**

The male breast is normally only a small disk of ductal tissue behind the nipple areolar complex. Enlargement of this tissue, either unilateral or bilateral, especially when soft or firm (not hard) and tender, is most commonly due to [gynecomastia](https://en.wikipedia.org/wiki/Gynecomastia), a benign enlargement of male breast tissue with many causes (including any condition causing relative hyperestrogenism and several medications).

**Risk Factors:**

Predisposing male breast cancer risk factors appear to include:\(^{37,38}\)
- Radiation chest wall exposure, particularly radiation given for the treatment of childhood malignancies.
- Estrogen administration, and diseases associated with hyperestrogenism, such as cirrhosis or Klinefelter’s syndrome.\(^{39}\)
- There are definite familial tendencies, with an increased incidence seen in men who have a number of female relatives with breast cancer.
- An increased risk of male breast cancer has been reported in families in which the BRCA 1 or 2 mutation on chromosome 13q has been identified.
- Prolonged heat exposure (e.g. iron smelter or foundry worker) which may have a suppressive effect on testicular function.
- Advanced age.
Gynecomastia is a definite risk factor, probably because elevated levels of estrogen increase the risk for both gynecomastia and for breast cancer. Drugs that can cause gynecomastia include the following (the list is by no means complete):

- Ketoconazole, a synthetic imidazole derivative, is an azole antifungal agent.
- Spironolactone is a potassium-sparing diuretic.
- Phenothiazines are antipsychotic agents, specific members of this class of drugs include: Chlorpromazine, Chlorpromazine Hydrochloride, Fluphenazine Decanoate, Fluphenazine Hydrochloride, Mesoridazine Besylate, Perphenazine, Prochlorperazine, Prochlorperazine Edisylate, Prochlorperazine Maleate, Thoridazine, Thoridazine Hydrochloride, Trifluoperazine Hydrochloride, Trifluromazine Hydrochloride.
- Isoniazid is a synthetic, isonicotinic acid-derivative antituberculosis agent.
- Digoxin, a cardiac glycoside. Cardiac glycosides are used principally in the prophylactic management and treatment of heart failure and to control the ventricular rate in patients with atrial fibrillation or flutter.
- Rauwolfia alkaloids, used in the management of mild to moderate hypertension.

**Symptoms:**

- Approximately 20-30% present with bloody nipple discharge and pain
- Approximately 70% present with a painless mass.

**Signs:**

Signs evident on physical examination are similar to those described in female breast cancer. Nipple discharge in a male is more often associated with cancer than in females, and should trigger a surgical evaluation.

**Evaluation:**

A male patient presenting with above-mentioned findings should be evaluated with physical examination initially (as described on pages 10-11). Physical examination alone has a sensitivity of nearly 100%; however, by itself it will usually not be sufficient to categorically identify malignancy. Imaging of the breast will often provide relevant diagnostic information in MBC. If MBC is suspected on the physical exam, a mammogram and conventional diagnostic breast imaging workup can usually distinguish breast cancer (rare) from gynecomastia (common). Ultrasound is occasionally helpful in conjunction with the mammogram. FNA with expert cytological evaluation and core biopsy are also helpful in assessing suspicious lesions in the male breast. In the case of MBC a high degree of suspicion is necessary in the evaluation of the patient in order to avoid delays in treatment.
SPECIAL POPULATIONS

Treatment:

Small tumors (less than 2 cm) may occasionally be considered for less radical procedures such as partial mastectomies, although given the anatomy of the male breast the distribution of tumors might preclude such interventions. Lymph node dissection should be entertained for staging in most tumors, particularly larger lesions. Also, adjuvant radiotherapy should be considered. Larger tumors will require mastectomy and possibly irradiation for local control. Adjuvant chemotherapy should be provided to those with large tumors and positive axillary nodes. This has been recommended by some researchers with some degree of success. Most tumors in MBC are hormone receptor positive allowing for hormonal therapy to be applied effectively.

Survival:

Historically, MBC is known for increased mortality but current clinical data suggest that overall five-year survival is comparable, stage to stage, to female breast cancer. In early stage disease, survival varies from 71 to 100%. In advanced stages it can be as low as 20%.
Algorithm for Palpable Breast Mass

**AGES 40 AND ABOVE**

Palpable Breast Lump on CBE by Provider

Breast imaging workup: diagnostic mammogram with ultrasound & cyst aspiration if indicated. Ultrasound should be performed in most cases, especially when mammogram is negative.¹

No mass detected by imaging² (ACR 1)³

- Simple cyst (ACR 2)
  - Aspirate if symptomatic
    - Resume Screening
  - Aspirate³
    - Aspiration Benign⁴
      - Moderate or High suspicion (ACR 4/5)
      - Refer: for possible Biopsy⁵
    - Probably benign by imaging (ACR 3)
      - Repeat CBE Suspicious²
        - Yes
          - Referral: for Biopsy
        - No
          - CBE and Imaging FU at 6 months
      - Refer: for Biopsy

Complex cyst

- Aspirate⁴
  - No
    - Solid mass
  - Yes
    - Aspiration Benign⁴
      - Moderate or High suspicion (ACR 4/5)
      - Refer: for Biopsy

**IMPORTANT**

¹ Breast imaging work-up may include special views, ultrasound & cyst aspiration as indicated. See pages 21–26 of text for more information.

² Caution: Lobular carcinoma and some other tumors may be invisible on mammogram. Surgical referral is needed when a dominant palpable mass is not visualized.

³ See page 20 for a description of the ACR categories.

⁴ Bloody or clear cyst fluid should be sent for cytology. See pages 28 for more information.

⁵ Biopsy includes open surgical biopsy, stereotactic core biopsy, ultrasound-guided core biopsy and/or fine needle aspiration biopsy.
Algorithm for Palpable Breast Mass

**Women Under age 40**

**Presenting Palpable Breast Lump to Provider**

- **CBE Normal or Benign**
  - CBE Normal or Benign
  - Continue Concern on CBE

- **Probably¹ Benign CBE**
  - Repeat CBE in 1 or 2 months, preferably one week after the end of the menstrual cycle²
  - CBE Normal or Benign

- **CBE is Suspicious for Malignancy**
  - Age < 30
    - Ultrasound
    - Not a Simple Cyst³
      - Aspiration Benign⁴
      - Refer to Surgeon or Breast Imaging Specialist
    - Simple Cyst (ACR 2)⁵
      - Aspirate if symptomatic

  - Age ≥ 30
    - Ultrasound and/or Mammogram

**IMPORTANT**

¹ See the CBE Guide (Appendix B) for more information on findings that require more workup.

² The best time to do the repeat breast exam is one week after the end of the menstrual cycle. For women who are not menstruating, or who are irregular, a different time of the month is preferred.

³ Anything that is not confirmed by ultrasound to be a simple cyst would need a referral. This includes normal imaging (ACR 1), solids and complex cysts.

⁴ Bloody or clear cyst fluid should be sent for cytology. See page 28 for more information.

⁵ See page 20 for a description of the ACR categories.

**AT EVERY STAGE THERE SHOULD BE DISCUSSION BETWEEN THE WOMAN AND PROVIDER.**
Algorithm for Non-Palpable Abnormality Detected on Mammogram

**Abnormal Screening Mammogram (ACR 0, 4, 5)**

- Breast Imaging Workup: 1
  - Diagnostic Mammogram, other imaging as needed

  **At every stage there should be discussion between the woman and provider.**

1. **Definitely benign (Category 2)**
   - Routine Screening

2. **Probably benign (Category 3)**
   - CBE and risk factor assessment by provider 3

3. **Moderate suspicion (Category 4)**
   - Imaging guided Core Biopsy 4
   - Surgical referral for biopsy 5

4. **High suspicion (Category 5)**
   - Surgical referral for biopsy 5

**IMPORTANT**

1. Breast imaging work-up may include special views, ultrasound & cyst aspiration as indicated. See pages 21-26 of text for more information.
2. See page 20 for a description of these categories.
3. The choice of follow-up versus biopsy depends upon the patient's level of concern, her risk factors and the likelihood of adequate follow up.
4. Image-Guided FNA or Core Biopsy stereotactic or ultrasound-guided.
5. Biopsy includes open surgical biopsy, stereotactic core biopsy, ultrasound-guided core biopsy, and/or fine needle aspiration biopsy.
CBE DIAGRAMS

The perimeter of the breast to be examined is more of pentagon than a square. Covering the entire perimeter is essential in order to avoid missing areas where cancers are most likely to occur: the upper outer quadrant and subareolar area.

Below is a diagram of the 5 nodal chains to palpate during a CBE.

1. Low axillary, Level I
2. Mid-axillary, Level II
4. Supraclavicular

Three and 5 are behind bone and usually not palpable.

This finding might be described as “Right breast: 2 o’clock position, approx 1 cm from base of nipple. Palp at chest wall: 1 cm, round, soft, non-tender, mass fixed to chest wall.”

Using this type of diagram to show both front and side views of clinical findings is useful.
### SUGGESTIONS FOR DOCUMENTING BREAST CHANGES NOTED ON CLINICAL BREAST EXAMINATION

<table>
<thead>
<tr>
<th>BREAST CHANGES</th>
<th>DESCRIPTION</th>
<th>ASSESSMENT / DOCUMENTATION</th>
</tr>
</thead>
</table>
| Physiological, cyclic swelling and tenderness      | ■ Generalized bilateral swelling, tenderness or pain brought on by the menstrual cycle.  
■ During pregnancy, the milk-producing glands become swollen and the breast feels more nodular than usual.                                      | □ Unilateral vs. bilateral;  
□ Symptoms;  
□ Hormone cycle;  
□ Medications;  
□ Caffeine intake.                                                                                      |
| Nodularity, fibrocystic changes, significant lumpiness, both cyclic and non-cyclic | ■ Will usually present as persistent diffuse lumpiness.  
■ May be stable or fluctuate with the menstrual cycle.  
■ May involve a specific area of the breast (often the tail, and upper outer quadrant) or involve the entire breast. Bilateral palpation to look for symmetry is an important tool in determining the degree of suspicion for an abnormal exam. Benign features are bilaterality and symmetry. Suspicious features are asymmetrical nodularity that persists after menstruation or after the repeat breast exam in a non-cycling woman. | □ Size, shape, location, texture, tenderness (especially focal);  
□ Presence or absence of symmetry;  
□ Menstrual cycle or hormone status.                                                                       |
| Mastalgia, severe pain, both cyclic and non-cyclic | ■ Mastalgia (breast pain) is extremely common (two out of three women suffer from breast pain at some time in their lives.)  
■ May or may not be cyclic and may or may not be associated with a breast lump (less than 5% of painful lumps are malignant.)  
■ Unilateral persistent focal pain in post-menopausal women is suspicious. | □ Pattern of pain;  
□ Unilateral vs bilateral;  
□ Severity;  
□ Association with a lump;  
□ Focal vs. diffuse;  
□ Recent trauma and/or how long the pain has been problematic;  
□ Medications;  
□ R/O costochondritis.                                                                                       |

**Note:** American Cancer Society (ACS) and CDC are currently in the process of developing national recommendations for maximizing performance and reporting of clinical breast exams. Once those recommendations are completed, these protocols may be revised to reflect those recommendations.
### Simple Cyst
- May be painful or asymptomatic, may be palpable, or only visible on ultrasound.
- With a small amount of fluid, may appear soft and fluctuant, but when the cyst is tense, it may feel like a solid mass.
- Cysts are often solitary, but may be multiple.
- The CBE cannot distinguish solid vs. fluid-filled, simple vs. complex (possibly cancerous).

### Galactoceles
- Are a simple, milk-filled cysts, probably formed by over-distention of a lactiferous duct, usually appearing as a firm, nontender mass in the breast tissue.

### Fibroadenomas
- Are the most common benign solid lesions and are made up of both structural (fibro) and glandular (adenoma) tissues.
- Occur most frequently in the third decade of life but may occur anytime after puberty, even during menopause.
- Are hormonally responsive and may increase in size during the end of the menstrual cycle.
- Characteristically, painless, well-circumscribed, freely movable tumors with a rounded, lobulated, or discoid configuration.
- Usually rubbery feeling, but may appear hard and, when calcified, may be stone hard. Often times they are described as an area of thickening that feels “ropey” or granular”, and often felt in the area around the nipple and areola and in the upper-outer quadrant of the breast.

### Cancer
- Typically singular, unilateral, discrete, firm, typically non-tender, persistent, unchanging and generally fixed to adjacent tissue. It can feel similar to a fibroadenoma or could be a cyst that persistently refills or leaves a dominant mass after being aspirated.
- Because breast cancer may present in such a variable manner, there are no physical exam features which reliably distinguish benign from malignant masses.

<table>
<thead>
<tr>
<th>DOMINANT MASS (PROMINENT, DISTINGUISHABLE)</th>
<th>DESCRIPTION</th>
<th>ASSESSMENT / DOCUMENTATION</th>
</tr>
</thead>
</table>
| Simple Cyst                              | - May be painful or asymptomatic, may be palpable, or only visible on ultrasound.  
- With a small amount of fluid, may appear soft and fluctuant, but when the cyst is tense, it may feel like a solid mass.  
- Cysts are often solitary, but may be multiple.  
- The CBE cannot distinguish solid vs. fluid-filled, simple vs. complex (possibly cancerous).  

**Galactoceles** are a simple, milk-filled cysts, probably formed by over-distention of a lactiferous duct, usually appearing as a firm, nontender mass in the breast tissue.

**Fibroadenomas** are the most common benign solid lesions and are made up of both structural (fibro) and glandular (adenoma) tissues.
- Occur most frequently in the third decade of life but may occur anytime after puberty, even during menopause.
- Are hormonally responsive and may increase in size during the end of the menstrual cycle.
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- Usually rubbery feeling, but may appear hard and, when calcified, may be stone hard. Often times they are described as an area of thickening that feels “ropey” or granular”, and often felt in the area around the nipple and areola and in the upper-outer quadrant of the breast.

**Cancer** is typically singular, unilateral, discrete, firm, typically non-tender, persistent, unchanging and generally fixed to adjacent tissue. It can feel similar to a fibroadenoma or could be a cyst that persistently refills or leaves a dominant mass after being aspirated.
- Because breast cancer may present in such a variable manner, there are no physical exam features which reliably distinguish benign from malignant masses.

**ALL PALPABLE MASSES REQUIRE FURTHER INVESTIGATION UNTIL PROVEN BENIGN!**
### BREAST CHANGES

<table>
<thead>
<tr>
<th>Nipple Discharge</th>
<th><strong>DESCRIPTION</strong></th>
</tr>
</thead>
</table>
| - Non-lactating woman with a unilateral, spontaneous nipple discharge (whether clear, serous, bloody or black) should be referred for diagnostic breast imaging (mammography, ultrasound guided imaging, and/or galactography).  
- Diagnostic mammograms in these instances may be negative but should not deter surgical referral.  
- If a woman with a nipple discharge has a mammographic abnormality, the abnormality should correspond with the quadrant from which the discharge originates. An abnormality that does not correspond to the quadrant may represent a separate lesion. Even an abnormality that does correspond might be a separate lesion, needing further work-up. |
| **ASSESSMENT / DOCUMENTATION** |
| - Unilateral vs. bilateral; spontaneous or expressed;  
- Color;  
- Number of involved ducts. |

<table>
<thead>
<tr>
<th>Infection, inflammations, erythema: including subareolar abscess, lactational mastitis, breast abscess, and Mondor's disease.</th>
<th><strong>DESCRIPTION</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>- Infection and/or inflammation, including mastitis and mammary duct ectasia, are characteristics of some benign breast conditions. Mammary duct ectasia (scarring of the nipples; can result in secondary pain, inflammation, and infection) is most common in women nearing menopause. Inflammation that does not respond to antibiotics should be worked up for inflammatory breast cancer. Hydroaenitis, (painful lump under arm) related to shaving / deodorant use, are common during warm weather.</td>
<td></td>
</tr>
<tr>
<td><strong>ASSESSMENT / DOCUMENTATION</strong></td>
<td></td>
</tr>
</tbody>
</table>
| - Redness;  
- Warmth;  
- Tenderness;  
- Lumpiness;  
- Nipple discharge;  
- Response to antibiotics after 7-10 days. |

<table>
<thead>
<tr>
<th>Nipple or areolar scaliness and/or skin dimpling or retraction</th>
<th><strong>DESCRIPTION</strong></th>
</tr>
</thead>
</table>
| - Unilateral breast skin changes or nipple retraction need close follow-up.  
- Bilateral mammography and/or targeted ultrasound are the first line investigation.  
- A woman with skin changes in or around the nipple area that has not resolved with conservative treatment (such as antibiotics, steroids, warm compresses, or observation) should be considered to have Paget's disease until proven otherwise, and should be referred to a breast specialist for possible biopsy.  
- Providers are encourage to refer to a dermatologist to confirm diagnosis of seborrhoeic dermatitis if the provider is not experienced in this area.  |
| **ASSESSMENT / DOCUMENTATION** |
| - Degree of symmetry in contour;  
- Skin color;  
- Nipple retraction or distortion, including how long change has been present;  
- Nipple eczema that does not respond to topical steroids after 7-10 days;  
- Change in skin texture (orange peel or peau d’orange) |

---

*Based upon: Clinical Breast Examination: Proficiency and Risk Management. A Continuing Education Program of the California Department of Health Services (Revised July 16, 2002)*
## Guide to Clinical Breast Exam (CBE) Results and Management

<table>
<thead>
<tr>
<th>Breast Exam Findings</th>
<th>Benign Characteristics</th>
<th>Suspicious (or Probably Benign) Characteristics</th>
<th>Management of Suspicious Findings</th>
</tr>
</thead>
</table>
| Lymph-Adenoapthy, Enlarged Lymph Node(s) (axillary, supra/infra clavicular) | ■ Painless enlarged lymph node(s)  
■ Painful enlarged lymph node(s) | ■ Mastitis or infection in breast, hand/arm, major systemic infection, not resolved within 2-3 weeks w/treatment | (1) Repeat breast exam < than 1 month  
(2) Surgical referral |
| Nipple or Areolar Scaliness And/or Skin Dimpling or Retraction | ■ Long-standing present bilateral nipple inversion or unilateral IF since breast development. | ■ Nipple retraction or distortion of recent or sudden onset.  
■ Change in skin texture (orange peel/peau d’orange)  
■ Unilateral dimpling, puckering | (1) Diagnostic mammogram  
(2) Surgical referral |
| Nipple Discharge                         | ■ Bilateral  
■ Non-spontaneous  
■ Multi-ductal & non-spontaneous  
■ Cloudy, green, yellow, brown or blue | ■ Spontaneous discharge  
■ Unilateral & spontaneous  
■ Clear, gelatinous, black or bloody  
■ Persistent in a single duct | (1) Diagnostic mammogram  
(2) Surgical referral |
| Infection, Inflammation Erythema, Lactational Mastitis, Breast Abscess & Mondor’s Disease | ■ Inflammation  
■ Infection  
■ Erythema  
■ Mastitis in women who are breastfeeding  
■ Bruising and lump associated with trauma | ■ Breast abscess  
■ Mondor’s disease  
■ Erythema | (1) Repeat breast exam < 1 month  
(2) Surgical referral if NOT resolved completely within 2-4 weeks with treatment. |
### Guide to Clinical Breast Exam (CBE) Results and Management

<table>
<thead>
<tr>
<th>Breast Exam Findings</th>
<th>Benign Characteristics</th>
<th>Suspicious (or Probably Benign) Characteristics</th>
<th>Management of Suspicious Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Swelling Tenderness</strong></td>
<td>Generalized swelling, tenderness or pain bought on by menstrual cycle; Bilateral swollen milk-producing glands during pregnancy or breastfeeding (symmetrical).</td>
<td>Persistent, generalized swelling, tenderness or pain not cyclic or HRT. Persistent swelling in women who are breastfeeding (and when CBE done after both breast emptied of milk).</td>
<td>(1) Surgical Referral</td>
</tr>
<tr>
<td><strong>Mastalgia Severe pain</strong></td>
<td>Mild discomfort in the week prior to menstruation</td>
<td>Significant pain interfering with everyday activities (bilateral or unilateral). Pain associated with a lump. Intractable pain not responding to simple measures, and common drugs. Unilateral persistent pain.</td>
<td>(1) Surgical Referral</td>
</tr>
<tr>
<td><strong>Nodularity (physiologic), Diffuse or Significant Lumpiness, Fibrocystic</strong></td>
<td>Bilateral and symmetrical diffuse lumpiness Bilateral and symmetrical areas of lumpiness/increased nodularity/fibrocystic tissue</td>
<td>Asymmetrical nodularity/lumpiness/fibrocystic areas that persist after menstruation or after a repeat breast exam in women no longer cycling.</td>
<td>(1) Diagnostic mammogram and/or (2) Ultrasound, and (3) either repeat breast exam within 1 month or surgical referral based on degree of clinical and imaging suspicion.</td>
</tr>
<tr>
<td><strong>Dominant Masses (discrete)</strong></td>
<td>Bilateral mirrored/symmetrical discrete nodularity Previously determined by diagnostic workup (ultrasound, biopsy/FNA, or surgical consult) to be benign.</td>
<td>Unilateral Firm or hard Fixed to adjacent tissue New lump in pre-existing nodularity Cyst diagnosed by ultrasound, that recurs more than 2 times within 4-6 weeks, or leaves a residual palpable mass post-aspiration</td>
<td>Discrete Non-tender, may have local pain</td>
</tr>
</tbody>
</table>
APPENDIX C: TREATMENT CONSIDERATIONS

TREATMENT OF BREAST CANCER

This section was developed to assist the Case Managers in the BCC Program. It will be important for the case manager to understand the pathology report, and assist the patient in understanding their diagnosis. The specialist will have gone over this information with the woman, but it is usually difficult for the patient to “take it all in.” Repeated explanations are very helpful to the patient. It is important that the Case Manager also understands the implications of the pathology report and thus can help guide client advocacy. For this reason, this section has been structured to provide some basic information on the following topics:

- Types of Breast Cancer (Tumor Histology)
  - Invasive
  - Non-invasive

- Grading
  - Nottingham for Invasive
  - Van Nuys for DCIS

- Reading the Pathology Report - Implications
  - Hormone Receptivity
  - Oncogenes
  - Margins
  - Ductal Architecture

- Staging
  - Tumor Size
  - Degree of Nodal Involvement
  - Metatases

- Treatment
  - Goals of Treatment
  - Factors Involved in the Treatment Decision

- Treatment Options
  - Surgical treatment
  - Radiation therapy
  - Chemotherapy

- Checklist for the Patient
APPENDIX C: TREATMENT CONSIDERATIONS

TYPES OF CANCER (TUMOR HISTOLOGY)

Invasive:

- **Ductal Carcinoma** - cancer originating from the lining of the ducts of the breast which has grown through the walls of the ducts and into the surrounding breast tissue, with the potential for spreading to adjacent lymph nodes and other body systems, (most commonly the bones, lungs, liver and brain). May be mildly to extremely aggressive, depending on prognostic factors.

- **Lobular Carcinoma** - cancer originating in the lobules of the breast which has grown through the walls of the lobules and into the surrounding tissue with the potential for spreading to adjacent lymph nodes and other body systems. May be mildly to extremely aggressive, depending on prognostic factors.

- **“Variant” Cancers** - the additional forms of invasive breast cancer are seen less frequently. They are generally considered less aggressive, although this depends on other prognostic factors.
  - **Medullary** - breast cancer which is surrounded by a rim of white blood cells (medulla).
  - **Mucinous/colloid** - mucous-making form of invasive ductal carcinoma.
  - **Paget’s Disease** - cancer of the nipple that presents as itching or scaling; it is a form of DCIS but may also be associated with an underlying invasive ductal cancer.
  - **Tubular** - cancer that form tubules microscopically.
  - **Papillary** - cancer that appears as little polyp-like projections under the microscope. There are invasive or DCIS forms of papillary cancers.

- **Inflammatory** - this cancer starts in the breast and invades the skin lymphatics; presents with redness and warmth. Poor prognosis; treated with multi-modal therapy (chemotherapy, surgery, and radiation therapy).

Non-invasive:

- **Ductal Carcinoma In Situ (DCIS)** - precancerous cells originating from the lining of the ducts of the breast. May be mildly to extremely aggressive.

**High Risk Lesions** - certain lesions, especially lobular carcinoma in situ (LCIS) and atypical hyperplasia (lobular or ductal), are markers for increased risk for subsequent breast cancers. They are usually found incidentally on biopsies done for other reasons. Despite their names, they are not cancers and do not require specific therapy. *Atypical hyperplasia found by core biopsy should always be followed by excisional biopsy to rule out DCIS.*

---

Ductal Carcinomas make up for 70% of all breast cancers in women.

Lobular Carcinomas make up to 10% of all breast cancers in women.

**Note:** The type of invasive cancer, while interesting, is not generally regarded as independently prognostic, and therefore is not as important as the other prognostic factors discussed below.
APPENDIX C: TREATMENT CONSIDERATIONS

GRADING

Grading (determining the degree of cellular abnormality in the tumor on microscopic examination) of the breast cancer is suggestive of prognosis and guides treatment. Diagnosing and grading of breast cancer requires histologic material obtained by at least one of the following procedures: core needle biopsy, excisional biopsy, or lumpectomy.

There are two different grading systems: (1) Nottingham combined (for invasive cancers) and (2) Van Nuys (for non-invasive cancers [DCIS]). Charts for both grading systems are included below.

### Histological grade (Nottingham combined)

<table>
<thead>
<tr>
<th>ELEMENT</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. Tubule Analysis</strong></td>
<td>Elements A, B &amp; C are each scored as 1, 2 or 3.</td>
</tr>
<tr>
<td>[ ] Good tubule formation</td>
<td>[ ] Moderate tubule formation</td>
</tr>
<tr>
<td><strong>B. Regularity of Nucleus</strong></td>
<td>Sum of Scores</td>
</tr>
<tr>
<td>[ ] Regular</td>
<td>B</td>
</tr>
<tr>
<td><strong>C. Dividing Characteristics of Nucleus</strong></td>
<td>[ ] Normal mitosis/nucleus to cytoplasm ratio</td>
</tr>
</tbody>
</table>

### Van Nuys Prognostic Index for grading DCIS

<table>
<thead>
<tr>
<th>ELEMENT</th>
<th>Treatment Options</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. Size</strong></td>
<td>Elements A, B &amp; C are each scored as 1, 2 or 3.</td>
</tr>
<tr>
<td>[ ] 0-14 mm</td>
<td>[ ] 15-40 mm</td>
</tr>
<tr>
<td><strong>B. Cell type and necrosis</strong></td>
<td>Sum of Scores</td>
</tr>
<tr>
<td>[ ] Low &amp; intermediate nuclear grade w/out necrosis</td>
<td>B</td>
</tr>
<tr>
<td><strong>C. Extent of Clear Margins</strong></td>
<td>[ ] &gt; 10 mm</td>
</tr>
</tbody>
</table>

3-5 = GI (Well differentiated)  
6-7 = G2 (Moderately differentiated)  
8-9 = G3 (Poorly differentiated)  
5, 6, 7 = Excision with Radiation  
8, 9 = Mastectomy is Recommended


**APPENDIX C: TREATMENT CONSIDERATIONS**

**READING THE PATHOLOGY REPORT-IMPLICATIONS**

**Hormone Receptivity**

<table>
<thead>
<tr>
<th>Estrogen</th>
<th>Progesterone</th>
</tr>
</thead>
</table>

*Positive Hormone Receptors:* Anti-estrogen therapy such as Tamoxifen or Arimilex, is usually part of the treatment plan. Some physicians recommend hormone suppression even on hormone negative tumors if the patient is young and the tumor aggressive, but evidence does not support this.

**Oncogenes**

<table>
<thead>
<tr>
<th>Her-2-neu</th>
</tr>
</thead>
</table>

*Positive =* More likely to recur

**Margins**

- Clear
- Not clear
- Focally clear

*Effect treatment recommendations*

**Ductal Architecture**

- Papillary
- Cribriform
- Comedo

*Comedo =* More aggressive

**STAGING (TNM)**

Staging correlates with outcome. The American Joint Committee on Cancer (AJCC) has a system of staging breast cancer for prognostic features. Though the Committee’s system is provided in this handbook, staging is the responsibility of the provider involved in the initial diagnosis of breast cancer and the hospital’s tumor registrar. The Case Manager may refer to the definitions for clarification, or where staging is not specified to match the client’s medical report to the new classification system.

Staging includes both clinical (c) evaluation and pathological (p) evaluation. Any staging element determined by clinical exam will be preceded by a “c,” while those staging components determined by pathology will be preceded by a “p.” Additional specifications indicate other pathologic measurements.

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Staging and grading are not the same. Grading gives you an indication of how aggressive the cells look under the microscope. Staging involves both clinical and pathologic measurements that provide information on the anatomical extent of the lesion and implications on prognosis.
APPENDIX C: TREATMENT CONSIDERATIONS

Staging of breast cancer involves determining:

1. **Tumor size (T)** either by clinical exam or imaging, or pathological (biopsy, surgical removal).
2. **Degree of nodal involvement (N)** either by clinical (adenopathy) or pathological (sentinel node biopsy and/or axillary node dissection).
3. **Degree of metastasis (M)** T such as bone scan, CT scan of chest, abdomen and MRI of the brain.

Below are tables to illustrate how to code each component, and finally, how determine or estimate the stage of the invasive breast cancer based on pathological or clinical results.

### Primary Tumor (T)

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>TX</td>
<td>Primary tumor cannot be assessed</td>
</tr>
<tr>
<td>T0</td>
<td>No evidence of primary tumor</td>
</tr>
<tr>
<td>Tis (DCIS)</td>
<td>Ductal carcinoma in situ</td>
</tr>
<tr>
<td>Tis (LCIS)</td>
<td>Lobular carcinoma in situ (not a real cancer)</td>
</tr>
<tr>
<td>Tis (Paget’s)</td>
<td>Paget’s disease of the nipple with no underlying tumor</td>
</tr>
<tr>
<td>T-1</td>
<td>Tumor 2 cm or less in greatest dimension (T ≤ 2 cm)</td>
</tr>
<tr>
<td>T-2</td>
<td>Tumor more than 2 cm but not more than 5 cm in greatest dimension (2 cm &lt; T ≤ 5 cm)</td>
</tr>
<tr>
<td>T-3</td>
<td>Tumor more than 5 cm in greatest dimension (T &gt; 5 cm)</td>
</tr>
<tr>
<td>T-4</td>
<td>Tumor of any size with direct extension to (a) chest wall or (b) skin, edema (including peau d’orange) or ulceration of the skin of the breast, or satellite skin nodules confined to the same breast. Includes inflammatory carcinoma.</td>
</tr>
</tbody>
</table>

### Regional Lymph Nodes (N)

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>NX</td>
<td>Regional lymph nodes cannot be assessed (e.g. previously removed or not biopsied)</td>
</tr>
<tr>
<td>N0</td>
<td>No regional lymph node metastasis</td>
</tr>
<tr>
<td>N1</td>
<td>Metastasis to movable ipsilateral <strong>axillary lymph node(s) (not fixed or matted)</strong></td>
</tr>
<tr>
<td>N2</td>
<td>Metastasis in ipsilateral <strong>axillary</strong> lymph nodes <strong>fixed or matted</strong>, or in clinically apparent ipsilateral internal mammary nodes in the absence of clinically evident axillary lymph node metastasis (clinically apparent is defined as detected by imaging studies or by clinical examination or grossly visible pathologically)</td>
</tr>
<tr>
<td>N3</td>
<td>Metastasis in ipsilateral <strong>infraclavicular</strong> lymph nodes <strong>with or without axillary lymph node involvement</strong>, or in clinically apparent ipsilateral internal mammary lymph node(s) and in the presence of clinically evident axillary lymph node metastasis; or metastasis in ipsilateral supraclavicular lymph node(s) with or without axillary or internal mammary lymph node involvement.</td>
</tr>
</tbody>
</table>
### Distant Metastasis (M)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>MX</td>
<td>Cannot be assessed</td>
</tr>
<tr>
<td>M0</td>
<td>No distant metastasis. A negative clinical history and examination is sufficient for early stage disease; extensive imaging or other testing is not required for stages IIB and III.</td>
</tr>
<tr>
<td>M1</td>
<td>One or more distant metastasis.</td>
</tr>
</tbody>
</table>

When nodes are negative, M is often assumed to be “M0.”

### Staging Based on the Three Components (TNM)

<table>
<thead>
<tr>
<th>Stage</th>
<th>Tumor Size (T)</th>
<th>Regional Nodes (N)</th>
<th>Metastasis (M)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Tis</td>
<td>N0</td>
<td>M0</td>
</tr>
<tr>
<td>I</td>
<td>T1</td>
<td>N0</td>
<td>M0</td>
</tr>
<tr>
<td>II A</td>
<td>T0/T1</td>
<td>N1</td>
<td>M0</td>
</tr>
<tr>
<td></td>
<td>T2</td>
<td>N0</td>
<td>M0</td>
</tr>
<tr>
<td>II B</td>
<td>T2</td>
<td>N1</td>
<td>M0</td>
</tr>
<tr>
<td></td>
<td>T3</td>
<td>N0</td>
<td>M0</td>
</tr>
<tr>
<td>III A</td>
<td>T0/T1/T2</td>
<td>N2</td>
<td>M0</td>
</tr>
<tr>
<td></td>
<td>T3</td>
<td>N1/N2</td>
<td>M0</td>
</tr>
<tr>
<td>III B</td>
<td>T4</td>
<td>N0/N1/N2</td>
<td>M0</td>
</tr>
<tr>
<td>IV</td>
<td>Any T</td>
<td>Any N</td>
<td>M1</td>
</tr>
<tr>
<td>II C</td>
<td>Any T</td>
<td>N3</td>
<td>M0</td>
</tr>
</tbody>
</table>

**Common difficulties in staging:** Sometimes metastatic workups are incomplete, lymph nodes are not checked because of patient ill health or refusal, etc. Staging is not complete without all the information. If neoadjuvant chemotherapy is done prior to excision and nodal dissection, pre-treatment mammogram or ultrasound are relied upon for estimate of size (i.e. size at diagnosis is used to stage, not post-chemo size). This is known as “clinical staging” as opposed to “pathological staging.” Cancer can “skip” nodes, so even a negative sentinel node does not guarantee lack of nodal involvement (possible false negative), although it does increase the likelihood of nodes being negative.

The staging information here is abbreviated for case managers. For more information please refer to the American Joint committee on Cancer (AJCC) Cancer Staging Manual and Handbook, Sixth Edition.
APPENDIX C: TREATMENT CONSIDERATIONS

TREATMENT

Goals of Treatment:
The treatment of breast cancer involves both local and systemic therapy. Because it is believed that breast cancer may be a cancer that spreads early through the lymphatic and vascular systems, systemic treatment (chemotherapy and/or hormonal that treats the whole body) may be part of even the treatment of early breast cancers. In terms of local therapy, studies have shown that lumpectomy followed by radiation is as effective a local treatment for breast cancer as mastectomy. Many prognostic and technical factors go into the decisions of how to treat breast cancer.

Factors involved in the Treatment Decision:
The decision the individual will make with her/his breast specialist regarding the appropriate treatment will depend on the characteristics (discussed above) specific to the patient, including:

- Nuclear Grade
- Type of Cancer
- Hormone Receptivity
- Personal preference of the patient.
- Oncogene Expression
- Overall health of the patient.
- Margins
- (“performance status”)
- Degree of invasion
- Staging
- Degree of invasion
- Staging
- Staging

TREATMENT OPTIONS

Surgical treatment (considered “local” treatment):

- Lumpectomy: surgical removal of breast mass and the immediately surrounding tissue; axillary lymph node staging is often done (by sentinel lymph node biopsy and/or axillary dissection) through a separate incision during the same operation. May be preceded (neoadjuvant) or followed (adjuvant) by additional treatments. At present, neoadjuvant therapy is preferred over adjuvant only for locally advanced cancers or on a study.

- Mastectomy: surgical removal of the breast (simple or total); the breast and some axillary lymph nodes (modified radical); the breast, axillary lymph nodes and chest wall musculature (radical, rarely done); may be preceded (neo adjuvant) or followed (adjuvant) by additional treatments.

Six randomized clinical trails have shown lumpectomy (with radiation) and mastectomy to be equally effective for the local control of early stage breast cancer.
**Radiation therapy** (considered “local” treatment):

- The use of computer-directed radioactive particles, placed very precisely to destroy cancer cells which may remain in the tissue following surgery. Usually used after lumpectomy as an alternative to mastectomy.

- The use of an electron beam or the temporary implantation of tubes containing a shallow-penetrating radioactive substance used to “boost” the radiation treatment specifically at the surgical site, when used after lumpectomy, is part of the treatment.

**Chemotherapy** (systemic/total body treatment):

- The intravenous and/or oral administration of anticancer drugs which are intended to destroy cancer cells both at the surgical site and wherever they may have migrated (metastasized) within the body.

- The administration of hormone antagonists (e.g. Tamoxifen, Arimidex) which bind to receptor sites in breast cells. This blocks the estrogen from stimulating the tumor cell. Only works in estrogen receptor positive tumors.

- The use of oncogene antibodies (e.g. Herceptin) for the treatment of recurrence in her2neu over-expressing cancers.
APPENDIX C: TREATMENT CONSIDERATIONS

CHECKLISTS FOR THE PATIENT

When Your Diagnosis is Cancer
☐ Talk to a breast specialist
☐ Ask questions
☐ Understand your pathology report
☐ Research your options
☐ Gather information/internet
☐ Get a second opinion
☐ Consider clinical trials
☐ Find a support group
☐ Decide on a treatment plan
☐ Stay Involved in your Treatment

Know Your Pathology Report
☐ Histopathology grade I, II, or III
☐ Cell differentiation
☐ Ductal architecture
☐ Hormone receptors +/-
☐ Oncogene/Her2neu +/-
☐ Margins clear/not clear
☐ Lymph node involvement +/-
☐ Other factors

Know Your Cancer
☐ In situ ductal (DCIS)
☐ Paget’s disease
☐ Infiltrating (invasive) ductal
☐ Infiltrating (Invasive) lobular
☐ Medullary
☐ Mucinous/colloid
☐ Paget’s disease
☐ Tubular
☐ Papillary
☐ Inflammatory
☐ Adenocystic
☐ Carcinosarcoma

Know Your Staging
☐ Stage 0
☐ Stage 1
☐ Stage 2a
☐ Stage 2b
☐ Stage 3a
☐ Stage 3b
☐ Stage 3c
☐ Stage 4

Know Your Adjuvant Therapy Options
☐ Radiation
☐ Chemotherapy
☐ Hormonal antagonists(Tamoxifen)
☐ Oncogene antagonists

Know Your Surgical Options
☐ Lumpectomy
☐ Sentinel node biopsy
☐ Axillary node dissection
☐ Lumpectomy w/:
☐ Sentinel node biopsy
☐ Axillary node dissection
☐ Mastectomy (Simple/Total) w/
☐ Sentinel node biopsy
☐ Axillary node dissection
☐ Re-excisions for clear margins
☐ Quadructomies/partial mastectomy
☐ Radical mastectomy

Know About Complimentary Therapies
☐ Vitamins & minerals
☐ Herbology
☐ Naturapathy
☐ Positive affirmations
☐ Meditations
☐ Group support
☐ Play

Be involved. Your life depends on it.
REFERENCES

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