Breast Screening Manual: A Guide for Health Departments and Providers

Provided by:

NC Breast and Cervical Cancer Control Program and
NC Women, Infant and Community Wellness Section

Revised July 2022

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES
Division of Public Health

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Division of Public Health

MEMORANDUM

NC BCCCP Providers

Attention: Nursing Directors/Supervisors

From: Susan Kansagra, M.D., MBA, Assistant Secretary for Public Health / State Health Officer, NC Division of Public Health *Dr. Susan Kansagra*

Date: July 19, 2022

Subject: Revised Edition (July 2022)
Breast Screening Manual: A Guide for Health Departments and Providers

Enclosed is the revised edition of the Breast Screening Manual: A Guide for Health Departments and Providers, February 2022. Please replace the previous manual, dated December 2016 with this edition. Revisions were made by the Division of Public Health through a collaborative effort of the Chronic Disease and Injury Section, and the Women and Children's Health Section. The Division of Public Health supports these guidelines as a model for the care of patients at the local level.

Numerous references have been consulted to assure that current standards and guidance on care of patients with abnormal breast findings are used. These references include the:

- Center for Disease Control and Prevention
- National Cancer Institute
- American Cancer Society
- U.S. Preventive Services Task Force
- American College of Obstetricians and Gynecologists
- American Academy of Family Physicians
- American Society of Breast Surgeons
- American College of Radiology

This Division of Public Health document is to be used as a model and template for writing policies and procedures to recruit, screen, diagnose and treat women for breast cancer. In keeping with our mission to work in partnership with local communities to improve the quality of life and save the lives of women in North Carolina, this manual will be helpful in delivery of health care services to the public. We thank you and appreciate the work you do to improve the quality of life for North Carolina women.

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF PUBLIC HEALTH

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Breast Screening Manual: A Guide for Health Departments and Providers
Revised July 2022

This NC Breast and Cervical Cancer Control Program (NC BCCCP) and NC Women, Infant and Community Wellness Section Women, Infant and Community Wellness Section, Breast Screening Manual: A Guide for Health Departments and Providers was reviewed and revised through the collaborative efforts of representatives of the following NC Division of Public Health sections and programs:

NC Breast and Cervical Cancer Control Program
NC Chronic Disease and Injury Section
NC Comprehensive Cancer Control Program
NC Medical Advisory Committee for the Breast and Cervical Cancer Control Program
NC Partnership to Increase Colorectal Cancer Screenings
NC Women's and Children's Health Section

The NC BCCCP and NC Women, Infant and Community Wellness Section Breast Screening Manual Committee expresses gratitude and appreciation to all individuals who worked toward the successful completion of the NC BCCCP and Women's Health Breast Screening Manual.

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Breast Screening Manual: A Guide for Health Departments and Providers

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TAB 1: Overview

OVERVIEW

Breast Health

The National Cancer Institute (NCI) estimates that women living in the United States have a 12.9%, or a 1 in 8, lifetime risk of being diagnosed with breast cancer (NCI, 2021). Estimated risk is an average risk for all women. Individual risk factors include age, family history, reproductive history, race and ethnicity, as well as other factors. NCI's Surveillance, Epidemiology, and End Results [SEER] Program, is based on breast cancer statistics for the years 2015 through 2017. If the current incidence rate remains the same, a woman born today in the United States has an approximate lifetime risk of 1 in 8 for being diagnosed with breast cancer at some time during her life. On the other hand, the chance that she will never have breast cancer is 87.1 or 7 in 8. For men born in the United States today, the lifetime risk of breast cancer is 0.13% based on breast cancer statistics for years 2015 – 2017, or a 1 in 800 chance of being diagnosed with breast cancer at some time in his life.

The SEER report (NCI, 2021) estimates the risk of developing breast cancer in 10-year age intervals. Per the current report, the risk that a woman will be diagnosed with breast cancer during the next 10 years, starting at the following ages is as follows:

Age 30	0.49 percent (or 1 in 204)
Age 40	1.55 percent (or 1 in 65)
Age 50	2.40 percent (or 1 in 42)
Age 60	3.54 percent (or 1 in 28)
Age 70	4.09 percent (or 1 in 24)

Women in North Carolina have the same lifetime risk as the national average. In their annual projections for North Carolina, the American Cancer Society (ACS) estimates that 9,850 women will be diagnosed with breast cancer in 2021, and an estimated 1,470 women will die of breast cancer. Breast cancer is the second leading cause of cancer deaths in North Carolina women. The burden of breast cancer falls heavily on low-income and minority women, particularly women in rural North Carolina. In 2019, North Carolina minority females were 47% more likely to die from breast cancer than white females (NCCCR, 2021).

Nationally, survival rates have increased over time for both white and African American women; however, the American Cancer Society reports the disparity in five-year survival rates between white women (91%) and African American women (81%) persists. Lower survival rates in African American women are hypothesized to be due to later stage detection of their breast cancers and the higher rate of more aggressive breast cancers in young African American women such as triple negative breast cancer and inflammatory breast cancer (ACS, 2021).

Early detection and treatment of breast cancer is saving lives. The American Cancer Society reported the decline of breast cancer mortality rates across the U.S. by more than 40% from 1989 – 2018 (ACS, 2021). With improvements in early detection, increased awareness, and

mammography screening as well as advances in treatment, more cases of breast cancer will be diagnosed and treated at earlier stages, and breast cancer mortality will continue to decrease (ACS 2021).

TAB 2: Breast Cancer Screening & Risk Factors

BREAST CANCER SCREENING AND BREAST CANCER RISK FACTORS

Breast Cancer Risk Factors

Scientists and physicians cannot explain why one woman gets breast cancer and another does not. Many things in our genes, our lifestyle, and the environment around us may increase or decrease our risk of developing cancer. Scientists are studying many ways to help prevent cancer, including ways to avoid or control things known to cause cancer, changes in diet and lifestyle, identifying precancerous conditions early, and chemoprevention and risk-reducing surgery. Per the National Cancer Institute (NCI), prevention is action taken to lower the chance of getting cancer. Lowering the risk factors and increasing the protective factors can be controlled so that the chance of developing cancer decreases (NCI, 2021). While risk factors can be avoided, avoidance does not necessarily guarantee a life free of breast cancer.

The National Cancer Institute Findings:

- Inherited changes in certain genes (including BRCA1, BRCA2, and others) increase the risk of breast cancer.
- Having a mother, sister and/or daughter with breast cancer increases the risk of developing breast cancer, especially if they were diagnosed before age 50.
- Women who have a high percentage of breast tissue that appears dense on a mammogram have a higher risk of breast cancer than women of similar age who have little or no dense breast tissue.
- Populations that eat a high-fat diet are more likely to die of breast cancer.
- Exercise, especially in young women, may decrease hormonal levels and decrease breast cancer risk.
- Breast feeding reduces breast cancer risk.
- Alcohol consumption may be associated with a slightly increased risk of breast cancer.
- Postmenopausal weight gain after natural menopause and/or after age 60 may increase breast cancer risk.
- Women who use combined estrogen and progestin menopausal hormone therapy for 5+ years have an increased chance of developing breast cancer (NCI, 2021).

The American Cancer Society Findings:

- Risk factors that are not easily changed:
    - Family history of breast cancer,
    - BRCA1/BRCA2 inherited gene mutations,
    - Having first period before twelve,
    - Not having children or not having first child until after age 30,

    - Late age at menopause, and
    - High breast tissue density.
- Modifiable risk factors:
    - Limiting the use of hormone replacement therapy (combined estrogen and progestin),
    - Reducing alcohol consumption,
    - Breast feeding your child/lactating,
    - Avoiding obesity, and/ or
    - Being physically active (ACS, 2021).

The link between breast cancer and other factors such as smoking, diet and vitamin intake and night shift work remain unclear with conflicting research findings. The 2014 Surgeon General's report concluded that there is "suggestive but not sufficient" evidence that smoking increases the risk of breast cancer (Glantz and Johnson, 2014). A 2017 study reported findings that smoking was associated with a modest but significantly increased risk of breast cancer, particularly among women who started smoking at adolescent or peri-monarcheal ages. The relative risk of breast cancer associated with smoking was greater for women with a family history of the disease (Jones, Shoemaker, Wright, Ashworth & Swerdlow, 2017). While diet and vitamin intake results remain inconsistent, maintaining a healthy weight reduces risks.

The Best Preventive Recommendations for Breast Cancer:

- Achieve and maintain a healthy weight.
- Be physically active.
- Maintain adequate and healthy sleep habits.
- Limit alcoholic beverages.
- Avoid exposure to chemicals.
- Reduce exposure to radiation.
- Consider the risks and benefits of hormonal replacement therapy with provider or as a provider.
- Screening for breast cancer. Although screening does not protect against breast cancer, it may detect cancer earlier and allow for earlier treatment and best prognosis (Center for Disease Control [CDC], 2021) (ACS, 2021).

Staying healthy throughout your life will lower your risk of developing cancer and improve your chances of surviving cancer if it occurs [Centers for Disease Control and Prevention (CDC), 2021).

Components of Breast Cancer Screening in North Carolina

There are two main components of breast cancer screening:

1. Clinical Breast Examination (CBE)
2. Age-appropriate mammogram

Current Recommendations for Breast Screenings for Average-Risk Women

Aside from genetics, personal or family history, and a patient's risk assessment results, there is no consensus on age for mammographic screening, especially for women ages 40 – 49.

Whether to do a clinical breast exam is currently a controversial issue. As of publication of this manual, NC BCCCP continues to recognize clinical breast examination as a NC BCCCP service component and a part of the screening process.

Guidance from a sampling of various government and health care organizations for routine mammographic screening in women at average risk for developing breast cancer follows:

Organization	**Clinical Breast Exam (CBE) recommendation**	**Mammogram recommendation**
American Cancer Society (ACS) (2021)	Among average risk women, CBEs to screen for breast cancer is not recommended.	Ages 40 – 44 option to start screening with mammogram every year. Ages 45 – 54 should get mammograms every year. Ages 55 plus can switch to mammogram every other year or choose to continue with yearly mammograms. Screenings should continue as long as a woman is in good health and expected to live at least 10 more years.
American College of Radiology (ACR) (2021)	No recommendation.	Annual screening beginning at age 40.
American Academy of Family Physicians (AAFP) (2017)	Current evidence is insufficient to assess the benefits and harms of CBE.	Ages 40 – 49 individualized decision making. Ages 50 – 74 screening mammograms every two years. Ages 75 plus – insufficient evidence to recommend screening.

Organization	Clinical Breast Exam (CBE) recommendation	Mammogram recommendation
American Society of Breast Surgeons (ASBrS, 2019)	No recommendation.	Ages 40 and above – yearly screening mammography; cease when life expectancy is ≤ 10 years.
US Preventive Services Task Force (USPSTF, 2016, new recommendations under review)	No recommendation.	Ages 40 – 49 individual decision; may begin every 1 – 2 years. Ages 50 – 74 screening mammogram once every two years. Ages 75 plus – insufficient evidence of benefit.
American College of Obstetricians & Gynecologists (ACOG, 2018)	Ages 25 – 39 offered every 1 – 3 years. Ages 40 and above offered annually.	Ages 40 – 49 initiate after counseling every 1– 2 years if patient desires. Ages 50 – 75 recommend screening mammogram every 1– 2 years. Ages 75 plus – shared decision making about when to discontinue. Supports shared decision making between physician and patient. (ACOG, 2016)
National Breast and Cervical Cancer Early Detection Program (NBCCEDP, 2021)	No recommendation for average risk women.	Ages 40 – 64 every one to two years.
North Carolina Breast and Cervical Cancer Control Program (NC BCCCP, 2021)	Ages 40 – 64 annually.	Ages 40 – 49 annual or biennial screening mammogram (State Funds.) Ages 50 – 64 annual or biennial screening mammogram (Federal Funds). Ages 65 – 75 annual or biennial screening mammogram (State Funds).

1. American Cancer Society, 2021
2. American College of Radiology, 2021
3. American Academy of Family Physicians, 2016
4. American Society of Breast Surgeons, 2019
5. US Preventive Services Task Force, 2016
6. American College of Obstetricians and Gynecologists, 2018
7. National Breast and Cervical Cancer Early Detection Program, Center for Disease Control, 2021
8. North Carolina Breast and Cervical Cancer Control Program, Agreement Addendum, 2021 – 2022

Clinical Breast Examination (CBE)

The purpose of the clinical breast examination (CBE) is to assess breast health status. A CBE should be thorough. The examination may be done as part of a general exam or as a separate exam for asymptomatic or symptomatic women. In 2021 – 2022, NC BCCCP continues to recognize clinical breast examination as part of the screening process. Please refer to the recommendations table above.
If you plan to conduct clinical breast examinations, and need training on the vertical strip method, please contact NC BCCCP at 919-707-5300.

Mammography Screening

Mammography is the best way to detect breast cancer in its earliest, most treatable stage – an average of 1 – 3 years before a woman can feel the lump (Duffy, 2012; National Cancer Institute, 2021). Mammography also locates cancers too small to be felt during a clinical breast examination.

1. **Screening mammogram**
    a. **Definition:** A screening mammogram is performed on asymptomatic women to detect early, clinically unsuspected breast cancer. (American College of Radiology [ACR], 2016)
    b. **Purpose:** The purpose of screening mammograms is to find breast cancers before they cause symptoms. Early detection results in the diagnosis of breast cancer before there are palpable masses and symptoms. Breast cancers found during screening examinations are more likely to be small, confined to the breast, may not require chemotherapy or lymph node surgery, and increase the number of treatment options.

A screening mammogram consists of two views:

Mediolateral Oblique (MLO)	**Craniocaudal (CC)**
Visualizes: ✔ Pectoral Muscle ✔ Nipple ✔ Breast Tissue	Visualizes: ✔ Nipple ✔ Breast Tissue ✔ Includes medial tissue that may not be seen on the MLO view

1. **Diagnostic Mammogram**
    a. **Definition:** A diagnostic mammographic examination is used to evaluate certain clinical breast findings, such as an area of palpable concern, a persistent focal area of pain or tenderness, skin/nipple changes, or suspicious nipple discharge. Diagnostic mammography is indicated to evaluate abnormal imaging findings identified on a screening mammography (ACR, 2021).

*Please note that diagnostic mammograms are considered screening exams within NC BCCCP for data reporting purposes to the CDC.

- A second type of diagnostic examination must be performed on women with an abnormal mammogram (ACR, 2021).

- Asymptomatic women with augmented breasts may undergo screening mammography and depending upon individual risk factors and attending physician recommendations, may be recommended for diagnostic mammogram. For women who have undergone mastectomy and breast reconstruction, the attending physician and the patient have flexibility in choosing diagnostic mammograms or reverting back to screening mammograms (ACR, 2021).

b. Purpose: The purpose of diagnostic mammography is to identify the exact size and location of a breast abnormality, the surrounding tissue and lymph nodes. A diagnostic mammogram sometimes requires extra views, spot compression and magnification. Most diagnostic mammograms are likely to be benign. If an abnormality is suspicious, usually an ultrasound study follows and/or a biopsy may be ordered. If a woman has a clinically suspicious abnormality, a biopsy is the only way to determine with certainty whether she has breast cancer (National Breast Cancer Foundation, 2019).

Note: (1) When scheduling a mammogram, previous films should be requested and sent to the contracted radiology facility. Films should be requested at least two weeks prior to the woman's appointment. (2) Results of the CBE and history of any prior breast surgery should also be included on the referral form to the radiology facility.

NC BCCCP Guidance on Screening Mammography

The priority population for National Breast and Cervical Cancer Early Detection Program (NBCCEDP) (Federal Funds) screening mammography services is the group of women ages 50 – 64 who are low-income (less than 250% of federal poverty level) and who have not been screened in the past year. At the clinician's discretion, women aged 50 – 64 with a history of normal screening results and no significant risk factors may be put on an every-other-year screening cycle. The priority population for NC BCCCP State Funds is women ages 40 – 49 who are low-income (less than 250% of federal poverty level) and who have not been screened in the past year. Diagnostic mammograms may be provided for symptomatic women under 40 years of age using State Funds and under 50 years of age using Federal Funds (North Carolina Division of Public Health, Breast and Cervical Cancer Control Program,2021).

Federal BCCCP Screening Age Priorities:

Test Type	National Breast and Cervical Cancer Early Detection Program (NBCCEDP) Rules	Performance Indicator
Breast Cancer Screening	Screening mammograms to women 50 – 64 years of age every 1 – 2 years.	At least 75% of all initial mammograms paid with Federal Funds should be within this age group.
Breast Cancer Diagnostic Imaging	Mammograms provided for symptomatic women under 50 years of age who require a diagnostic work-up or who have a family history of breast cancer.	No more than 25% of all initial mammograms paid with Federal Funds should be within this age group.

NBCCEDP, 2021

NC (State) BCCCP Screening Age Priorities:

Test Type	NC Breast and Cervical Cancer Early Detection Program (NC BCCCP) Rules	Performance Indicator
Breast Cancer Screening	Screening mammograms to women aged 40 – 49 years and up to age 75 if no other source of payment is available every 1 – 2 years.	NC BCCCP funds cannot be used to screen asymptomatic women under the age of 40, even if considered to be at high risk for breast cancer.
Breast Cancer Diagnostic Imaging	Women aged 21 to 75 with gross incomes below 250% of Federal Poverty Level, who are uninsured or underinsured may be eligible subject to limitations; Eligible women ages 21 – 39 with an undiagnosed breast abnormality may receive NC BCCCP funded diagnostic services **if no other source of healthcare reimbursement is available.**	Eligible women ages 21 – 39 May be referred from Family Planning Services, outside clinics or through a self-referral for an undiagnosed abnormality.

NC BCCCP Training Manual, 2021

Breast Self-Examination (BSE)

A woman can notice changes by being aware of how her breasts normally look and feel and by feeling her breasts for changes, or by choosing to use a step-by-step approach and using a specific schedule to examine her breasts. Breast self-exam is no longer recommended by most professional organizations.

If your patients are interested in learning how to conduct breast self-exams, you may contact the NC BCCCP to set up a train-the-trainer instructional seminar.

TAB 3: Quality Assurance

QUALITY ASSURANCE

Quality Assurance Recommendations for Breast Cancer Screening

For breast cancer screening to be effective, health care providers must have systems in place to ensure that any abnormalities detected by clinical breast exam or mammography are followed up appropriately. Patients with abnormal test results should be notified promptly. Patients who need additional diagnostic tests or treatment should be tracked to assure they receive proper follow-up care.

Five key steps are necessary for managing the results of breast cancer screening:

1. Track any imaging studies until results are obtained.
2. Follow requirements for patient notification.
3. Document that notification has occurred.
4. Refer patients with any abnormalities on clinical breast exam or imaging for appropriate follow-up; and
5. Track referrals to make sure that patients have received follow-up.

Each clinic might have a different mechanism for ensuring that all these steps have occurred, but all clinics should have written guidelines, standards, and policies for management of breast cancer screening programs. Written policies must be accessible to staff. This manual contains recommendations that should be considered in the development of local policies. Policies should be reviewed at least annually and revised as needed.

The following integral elements are required for a follow-up system.

1. **Designation of a responsible person:** The person designated as having responsibility for follow-up (or supervision of follow-up) of breast cancer screening should be a registered nurse (RN) who has knowledge of breast cancer screening programs and familiarity with guidelines regarding follow-up of patients with abnormal breast cancer screening results.

2. **A referral plan:** The referral plan will contain written procedures for referring patients with abnormal findings, including referral resources, the process of referring and the preparation of eligibility forms, if applicable. All education and counseling protocols should be included, along with a list of educational materials used to assist the patient in understanding the abnormal test result or any additional diagnostic tests that may be done.

3. **A follow-up plan:** The follow-up plan should contain written procedures that ensure the patient was referred to a provider, needed services were provided if the patient agreed to the referral and the results of the referral were returned to the agency.

4. **A tracking system:** Clinical management of patients is improved with a tracking system. Tickler files, computerized databases or written logs are common methods of tracking patients. The system alerts staff of patients' status, especially abnormal breast screening, and provides a simple tool for follow-up. Any tracking system must be checked at predetermined intervals to ensure follow-up is completed. The following is a suggested general process for breast screening tracking:

    - All mammograms ordered are logged into a tracking system.
    - When results are received by the agency, the person responsible for follow-up reviews the reports.
    - Results requiring no intervention require patient notification. The report is initialed by the nurse or designee and filed in the medical record. The patient is contacted and notified of the results.
    - Results requiring follow-up are reviewed, the patient is notified, and the plan of care is determined based on this manual, local policy and consultation with the medical advisor.
    - The plan of care and notification of the patient are documented in the medical record.
    - The nurse responsible for patient follow-up enters information in the tracking system and monitors the progress of the patient until follow-up is complete.

    Tracking systems remind staff to:

    - Document all patient contacts.
    - Obtain results of all referrals.
    - Contact patients with incomplete short-term follow up.
    - Navigate patients to additional work-up/referrals as indicated.
    - Develop procedures to overcome patient-related barriers to follow-up, for example, telephone reminders or mailing reminders.
    - Attempt to contact patients three times for results that have not been communicated, including a certified letter as the third attempt for lost to follow-up.

5. **Internal quality assurance:** On an annual basis, a minimum of five (5) in-house chart audits should be performed to track the percent of women with abnormal results who receive definitive diagnostic and therapeutic procedures. Documentation of findings and corrective action should be on file.

Patient Notification Requirements

Mammography Quality Standards Act (MQSA)

MQSA requires the radiology facility that performed the mammogram to send the provider a report of the examination via hard copy and or electronic copy and send the patient a lay letter of the examination. The expectations for patient notification are as follows:

- If the mammogram is interpreted as Category 0: Incomplete, the radiologist will obtain additional imaging view and/or compare with prior mammograms. No report will be sent out until further imaging is complete.

- No additional follow-up is required if the mammogram is interpreted as
  Category 1: Negative or
  Category 2: Benign

  The radiology facility is required to send a written mammography report within 30 days for categories 1 and 2. (Positive mammography reports should be available within three business days).

- If the mammogram is interpreted as Category 3: Probably benign, the radiologist will recommend a short-term follow up mammogram, usually in six months and send a written report within 5 to 3 business days.

- The following are required if the mammogram is interpreted as either
  Category 4 – Suspicious or
  Category 5 – Highly Suggestive of Malignancy

The facility is required to notify the patient and health care provider of positive examinations as soon as possible (as guidance, within 3 to 5 business days) (Federal Drug Administration, 2021). In the case of verbal communication, this may be done by documenting such communication in the mammography report or in logs. In the case of written communication, see two bulleted items below:

- The facility is required to send written lay summaries to the patients themselves. This may be done by having copies of the lay summary available within five business days. If the facility does not keep copies of the patients' lay reports, they may document such communication in the mammography report, or in logs, or by stating in the facility's Quality Assurance (QA) manual that the lay summary is provided within the appropriate time frames.

- NC BCCCP strongly encourages the ordering provider to notify the patient of mammography results, positive or negative and document appropriately (NC Division of Public Health, Breast and Cervical Cancer Control Program, 2021).

NC Screening Provider Quality Assurance

1. Responsibilities of all Breast Screening Providers
- Notify patients who have normal (negative) mammograms of their results. (Radiologists as well as providers provide documentation.)
- Ensure follow-up of abnormal screening results with the patient.
- All results from any referral will be documented in the patient's medical record.
- Documentation will include all contacts with patients regarding appointments for referral and appointments not kept.

2. Additional Responsibilities of Providers (NC BCCCP and Women's Health)
- The screening provider assures follow-up on patients with abnormal screening results is completed within 60 days of the patient's initial screening examination.
- Three attempts are required to contact patients with abnormal screening results. The third attempt to notify a patient with abnormal screening results must be by certified mail.
- The NC BCCCP and/or NC Women's Health provider will ensure clinical standards of care will be used to manage abnormal test results. Contracts with outside medical providers will specify program expectations.
- All NC BCCCP and/ or Women's Health providers will ensure eligible women, who have abnormal results for any covered test are followed by the Nurse Navigator until:

    1. A qualified provider determines that the patient does not have cancer; or
    2. Until the patient is under care for a diagnosed cancer; or
    3. The Nurse Navigator is unable to contact the patient; or
    4. The patient declines services.

- The follow-up process includes correct entry of clinical information to support NC BCCCP's requirements for CDC for submission and timely data reports or other mandated reports for Women's Health programs.

- The follow-up process also includes a local protocol that recalls the agency BCCCP patient for appropriate re-screening for breast and cervical cancer or other NC Women's Health programs.

TAB 4: Management of Abnormal Clinical Findings

MANAGEMENT OF ABNORMAL CLINICAL FINDINGS

If an abnormality is found on clinical breast examination or screening mammography, further diagnostic workup is necessary to diagnose the nature of the abnormality. See **Algorithm for Management of Findings on Breast Screening and Algorithm for Management of Category 3 Mammogram** summarizing key management decisions is provided.

Abnormal Clinical Findings

1. Palpable Mass

Any patient with a solid, well-defined palpable mass (or an ill-defined mass) should be referred for breast imaging. If additional imaging does not explain the clinical finding, a surgical referral must be made. If cyclical cysts are suspected, a repeat CBE at a different point in a woman's menstrual cycle (within a month) may be offered.

Women who are 30 years old or older should be referred for a diagnostic mammogram and follow-up ultrasound at the discretion of the radiologist. Mammograms can be more difficult to interpret after diagnostic procedures such as fine needle aspirations, so it should be ensured that the mammogram appointment takes place prior to surgical evaluation. The location and nature of any breast abnormality detected on examination should be noted on the mammogram referral.
Women who are less than 30 years old should be referred for breast ultrasound. Again, the imaging should take place prior to surgical evaluation, and abnormal findings on breast examination should be noted on the ultrasound referral.

Referral to a surgeon should occur if breast imaging (mammogram and/or breast ultrasound) does not explain the clinical finding, and if the finding persists greater than two weeks. A negative mammogram in a patient with a palpable mass does not rule out breast cancer. Any questionable pathologic findings or pathologic findings that do not correlate with the imaging are indications for biopsy by excision to rule out the presence of occult malignancy in the region of the mammographic abnormality (US Department of Health and Human Services, NIH, 2019).

Mammography may miss some cancers in women with dense breasts (American Cancer Society, 2021). When a patient has an area of palpable concern that is limited by dense tissue, and the mammogram and spot compression magnification are unremarkable, ultrasound is performed.

Procedures a woman might undergo when referred to a surgeon include fine needle aspiration, core needle biopsy or surgical excisional biopsy. Fine needle aspiration (FNA) is particularly useful for a patient in whom it is suspected that a breast mass is a simple cyst. The procedure consists of inserting a 22 or 24 gauge needle into the mass and removing any fluid. Fluid is sent for laboratory analysis to assess for malignancy. Core needle biopsy consists of inserting a larger gauge needle into the mass and removing tissue for evaluation by a pathologist. Excisional biopsy consists of surgically

removing the entire mass for evaluation by a pathologist (US Department of Health and Human Services, NIH, 2019).

2. Non-palpable Masses Found on Mammography

Abnormalities on mammography are categorized by a system designed by the American College of Radiology called BI-RADS®, or the Breast Imaging Reporting and Data System (ACR BI-RADS Atlas, 2013). A mammogram report will contain one of seven designations:

Category 0: Incomplete: Need Additional Imaging Evaluation

Category 1: Negative

Category 2: Benign Category

Category3: Probably Benign

Category 4: Suspicious

Category 5: Highly Suggestive of Malignancy

Category 6: Known Biopsy-Proven Malignancy

Patients with normal breast exams whose mammograms report Category 1 or 2 findings do not require further follow-up and can be rescreened in one to two years.

Patients with screening mammograms that report Category 0 or diagnostic mammograms that report Category 3 findings should follow-up as suggested by the radiologist's recommendations. This might include immediate referral for additional imaging, referral for additional imaging or referral to a surgeon for biopsy.

Patients with mammograms that report Category 4 or 5 findings should always be referred for a biopsy. This referral should take place within five business days. The results of the mammogram should be made available to the surgeon to whom the patient is referred.

Patient Navigation must be initiated for NC BCCCP patients with this finding.

3. Vague Thickening or Nodularity Not Suspicious for Cancer

<u>Premenopausal Women</u>

Management of premenopausal women with vague thickening not suspicious for cancer depends on multiple factors. For women who are young, without family history of breast cancer, no known genetic risks, no known changes in breast texture (by clinical exam and/or patient history), etc., clinician judgment will dictate whether a follow-up exam and/or mammogram is indicated. For women who are at increased risk (due to age, family history, ethnicity, etc.) or who may be less likely to be attentive to changes in their breasts, it is appropriate to repeat clinical breast examination mid-cycle after one or two menstrual cycles. If a localized area remains abnormal on repeated examination, the

patient should be referred to a surgeon for evaluation. Mammography is ordered in such women just as described above under "The Palpable Mass."

Postmenopausal Women

Postmenopausal women with a questionable clinical breast examination should be referred for imaging and surgical evaluation per the recommendations above under “The Palpable Mass.”

4. Nipple Discharge or Skin Changes

The nature of nipple discharges should be defined by a careful patient history. A patient with a spontaneous, single duct discharge, even when non-bloody, is potentially pathologic and should be referred to a surgeon. However, bilateral milky, green or grey nipple discharge is typically benign. Medical work-up of galactorrhea may be appropriate for persistent milky discharge (Beaumont Breast Cancer Services, 2021).

Patients with any skin breakdown require treatment and follow up. A trial of topical treatment (e.g., steroid cream) may be appropriate for a limited amount of time with re-evaluation in 1 – 2 weeks. Patients without complete resolution or with recurring symptoms require a surgery referral. Biopsy of the nipple may be necessary to differentiate eczema of the nipple from Paget’s disease (cancer of the nipple) in certain cases (Beaumont Breast Cancer Services, 2021).

5. Breast Pain

Breast pain includes any discomfort or pain of the breast, such as premenstrual tenderness. Breast pain is typically benign. The question is how tolerable (or intolerable) the pain is for the woman. There are many causes of breast pain, including hormonal fluctuations related to menstruation or pregnancy, where some degree of pain is normal. With menopause, breast tenderness often goes away, unless a woman is taking hormone replacement therapy.

Other causes of breast pain include fibrocystic breast changes, mastitis (blocked or infected milk duct), premenstrual syndrome (PMS), alcoholism with liver damage and injury. There are certain medications that cause breast pain including digitalis preparations, aldomet, aldactone and other potassium-sparing diuretics, anadrol and chlorpromazine.

If the clinical breast examination is normal, reassure the patient and explain the hormonal causes of breast pain. Typically, the patient's mind is put at ease. The provider may recommend a trial of non-narcotic analgesics such as acetaminophen, or topical or oral NSAIDs. The use of a well-fitting bra that provides good support, or the use of warm compresses may also be recommended. Although there is no clear evidence in the literature that shows reducing dietary caffeine, salt or fat improves breast pain, some women report anecdotal benefits from these changes. Stress,

caffeine, smoking, lactation frequency, and benign disorders have been found as factors detected to be related with mastalgia. A significant relation between mastalgia and malignant breast disease has been detected in the literature (Eren, Aslan, Ozemir, Baysal, Sagiroglu, Elenci, Alimoglu, 2016). If the pain persists, a repeat breast exam and mammogram may be provided.

If the follow-up breast examination and mammogram are normal and breast pain persists, refer the woman to a breast specialist for further evaluation. For women with breast pain who have a palpable mass or mammographically detected abnormality, the work-up is identical to that of women with palpable mass. Though breast cancers are usually painless, the presence of pain cannot reliably rule out breast cancer. There are a small percentage of breast cancers that present as painful or uncomfortable.

6. Special Considerations

Women Identified as High Risk

The Centers for Disease Control and Prevention (CDC) has mandated that the North Carolina Breast and Cervical Cancer Control Program assess and report risk of patients for breast cancer.

Definition of high risk:

For breast cancer, high risk is defined as:

- Those who have a known genetic mutation such as BRCA 1 or 2,
- Those who have first-degree relatives with premenopausal breast cancer or known genetic mutations,
- Those who have a history of radiation treatment to the chest area before the age of 30 (typically for Hodgkin's lymphoma), or
- Those who have a lifetime risk of 20% or more for development of breast cancer based on risk assessment models that are largely dependent on family history.

Impact on local agencies: NC BCCCP providers are required to assess NC BCCCP patients for breast cancer risk, and to counsel high risk patients regarding risk reduction.

What you need to do:

1. Assess NC BCCCP patients for risk of breast cancer.
    a. If a patient has one of the following factors, she is considered at high risk:
        - Known genetic mutation such as BRCA1 or BRCA2.
        - First-degree relatives with premenopausal breast cancer or known genetic mutations.
        - History of radiation treatment to the chest area before the age of 30

(typically for Hodgkin's lymphoma).

b. If the patient has none of the risk factors listed above, calculate risk using the GAIL Model at https://bcrisktool.cancer.gov/calculator.html or Tyrer-Cuzick risk assessment tools at https://ibis-risk-calculator.magview.com .These risk assessment tools are recommended by the NC Cancer Prevention and Control Branch and NC BCCCP medical advisors. A calculated lifetime risk of 20% or more for development of breast cancer is considered high risk using the GAIL Model as well as the Tyrer-Cuzick Model. The Tyrer-Cuzick model is used to calculate a person's likelihood of carrying the BRCA1 or BRCA2 mutations and for developing breast cancer in 10 years (NCI, 2021).

2. Document your assessment in the patient's medical record and report in data sent to NC BCCCP.
3. Counsel NC BCCCP patients about risk reduction strategies if they are at high risk.
    a. Women who are at high risk for breast cancer (including those women who are age 21 – 39 should be advised to have a mammogram annually, beginning at age 30. NC BCCCP will cover this annual screening.
    b. Women who are at high risk for breast cancer may also consider obtaining a breast MRI in conjunction with the annual mammogram. NC BCCCP does not cover MRI screening based on risk alone. MRI may only be covered as a diagnostic service in certain circumstances with pre-approval. Call your NC BCCCP nurse consultant to obtain prior authorization. MRI done without prior authorization is not covered for any reason.
4. For additional information on screening for breast cancer and for follow-up recommendations, please see the following:

NC BCCCP Risk Assessment Policy

The Breast Cancer Risk Assessment Tool is based on a statistical model known as the Gail Model. The Gail Model has been tested in large populations of white women and has been shown to provide accurate estimates of breast cancer risk. The model was tested for Asian and Pacific Islander women, black/African American, and Hispanic women using data from the Women's Health Initiative. It performed well but may underestimate risk in black/African American women with previous biopsies and Hispanic women born outside the United States. The model needs further validation for Hispanic women and other subgroups. Researchers are conducting additional studies to gather more data to test and improve the model. The Tyrer-Cuzick model is used to calculate a person's likelihood of carrying the BRCA1 or BRCA2 mutations. It estimates the likelihood of a woman developing breast cancer in 10 years and over the course of her lifetime. The tool is used to assist a person's decision making for genetic testing and counseling (NCI, 2021).

Fibrocystic Breasts – Fibrocystic changes are the most common cause of non-cancerous breast lumps (Mayo Clinic, 2021). They affect at least 50% of women at some point in their lives, most commonly at ages 30 – 50. Fibrocystic breasts are usually not a risk factor for

breast cancer, but women with fibrocystic breasts may have diffusely lumpy breasts, making detection of underlying breast cancer more difficult. If there is any uncertainty about clinical breast exam in a patient with fibrocystic breasts, the patient may be referred for mammography, ultrasound, and/or a consultation with a breast specialist.

Fibroadenoma – A noncancerous rubbery mass in the breast that is usually painless and moves around easily when palpated. Fibroadenomas cannot be diagnosed with mammography, sonography or histopathology. Fibroadenomas can only be diagnosed with a biopsy.

Pregnant and Lactating Women – These women often experience breast tenderness and engorgement, which can make detection of masses more difficult. Clogged pores and/ or ducts may also be the culprit of breast pain or tenderness and it is recommended that if this is thought to be a problem that adequate time be given for this to resolve prior to intervention. Lactating women should empty their breasts prior to a mammogram.

If a palpable abnormality is found on CBE, diagnostic evaluation with ultrasound and mammography may need to be performed. Ultrasound is the first line imaging modality to be used in these patients since most of these findings are benign. However, if a suspicious mass/mass highly suggestive of malignancy is detected with ultrasound then bilateral diagnostic mammogram is recommended for further evaluation/extent of disease.

Mammography is thought to be safe to perform during pregnancy. The amount of radiation needed for a digital breast mammogram is small and focused only on the breast. A lead shield is placed over the lower part of the body for protection. Scientists cannot be certain about the effects of radiation on an unborn baby, however diagnostic evaluation should not be delayed for abnormal and suspicious findings during pregnancy as pregnancy-associated breast cancer (PABC) is increasing due to more women delaying childbearing into the fourth decade of life (ACS, 2021; ACR, 2018). Mammograms should only be used to evaluate distinct, dominant masses. The radiologist should always be informed if the woman is pregnant. A referral to a breast surgeon should be made for a definitive diagnosis.

Other Patients with a Difficult Breast Examination

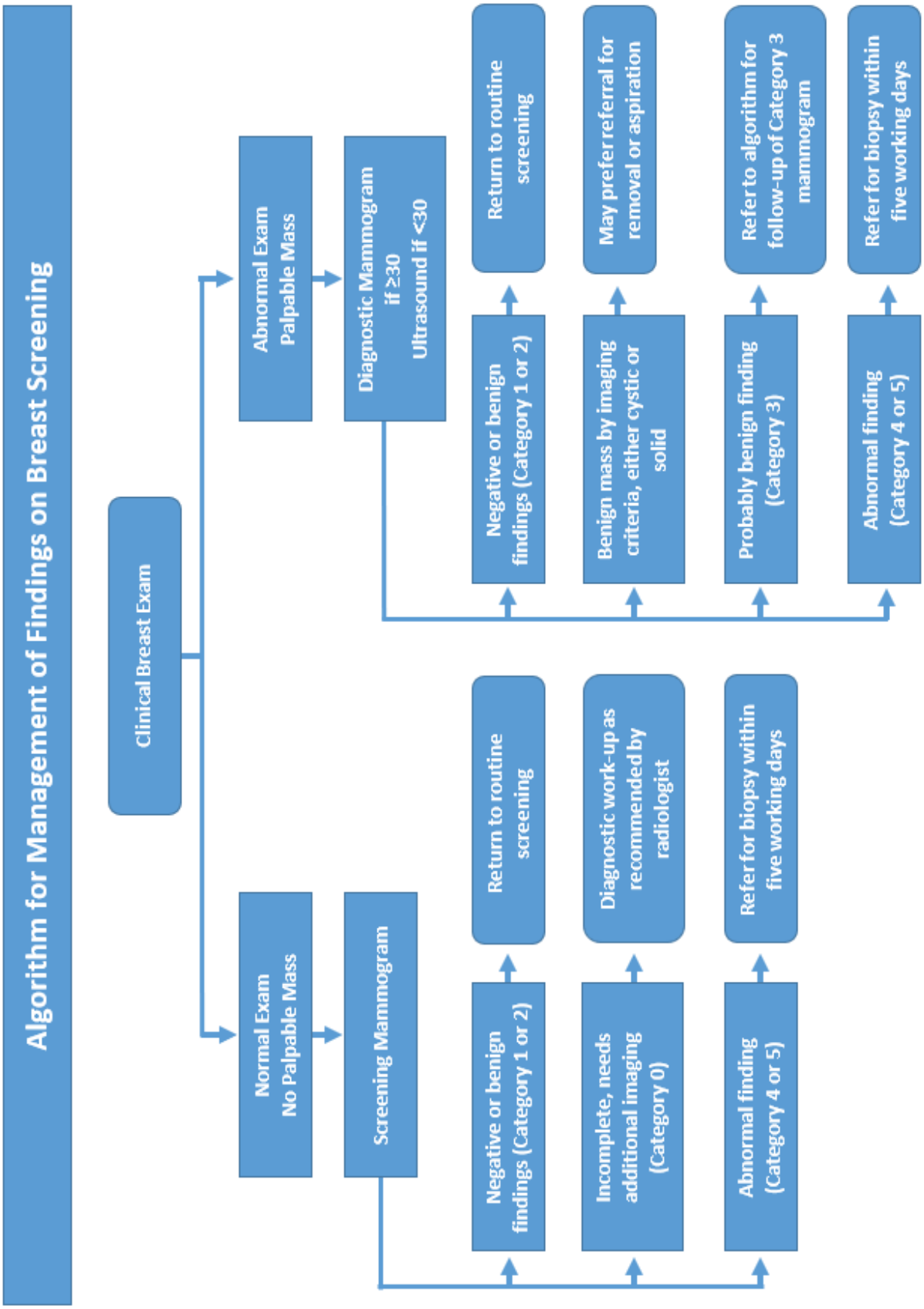
Some women may have a difficult clinical examination that requires further evaluation. This group may include:

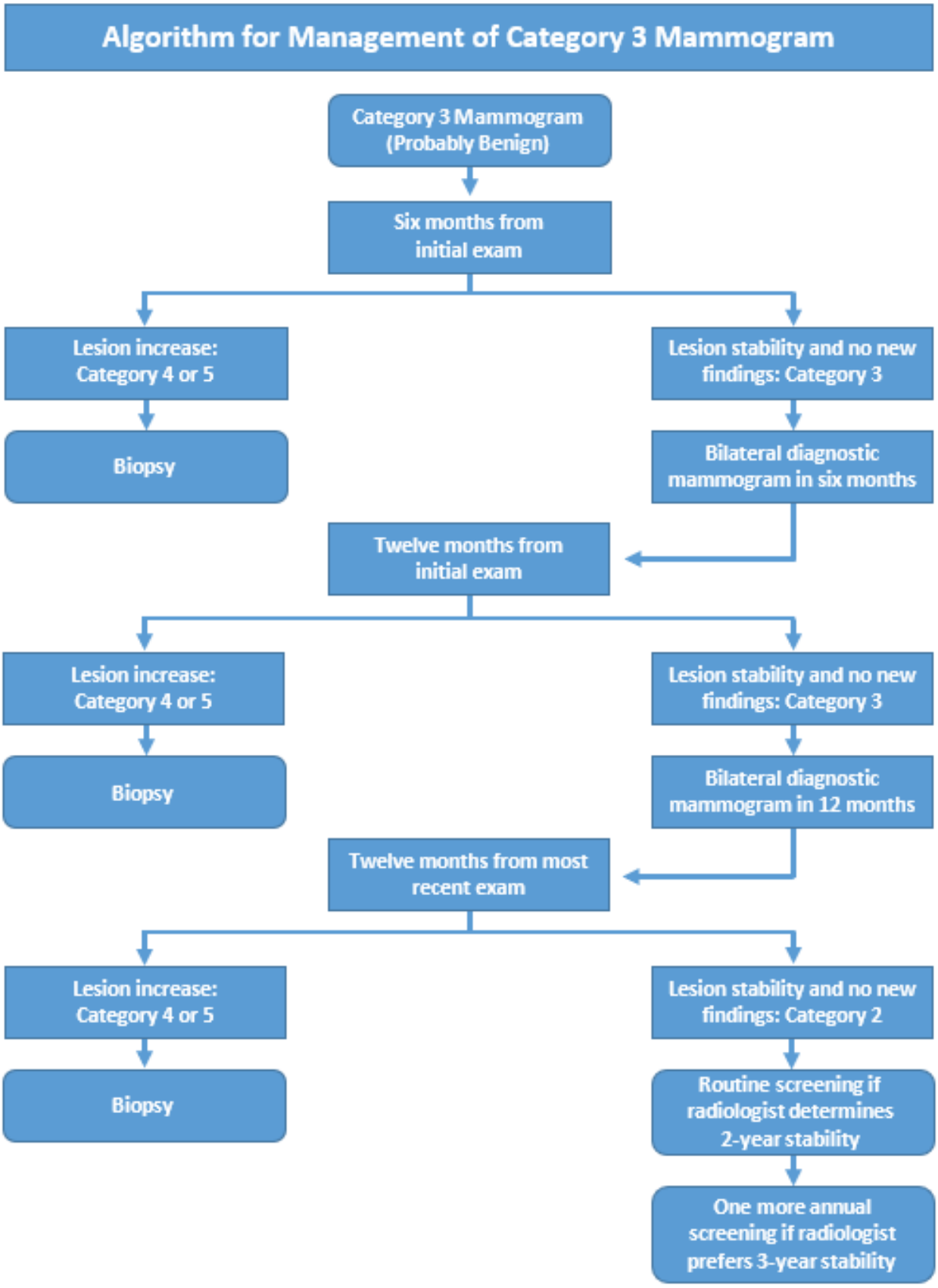
- Women who have had breast reduction surgery.
- Women with multiple previous biopsies and scarring.
- Women with breast implants.

Women who have had a Mastectomy

If a clinician is unsure of the significance of findings on clinical examination in any of the above situations, a referral to a mammography or breast specialist should be made.

Algorithm for Management of Findings on Clinical Breast Screening (both screen and diagnostic are on the diagram) (See next page)


Algorithm for Management of Findings on Breast Screening
Clinical Breast Exam
Abnormal Exam
Palpable Mass
Diagnostic Mammogram
if ≥30
Ultrasound if <30
Negative or benign findings (Category 1 or 2)
Return to routine screening
Benign mass by imaging criteria, either cystic or solid
May prefer referral for removal or aspiration
Probably benign finding (Category 3)
Refer to algorithm for follow-up of Category 3 mammogram
Abnormal finding (Category 4 or 5)
Refer for biopsy within five working days
Normal Exam
No Palpable Mass
Screening Mammogram
Negative or benign findings (Category 1 or 2)
Return to routine screening
Incomplete, needs additional imaging (Category 0)
Diagnostic work-up as recommended by radiologist
Abnormal finding (Category 4 or 5)
Refer for biopsy within five working days


Algorithm for Management of Category 3 Mammogram
Category 3 Mammogram (Probably Benign)
Six months from initial exam
Lesion increase: Category 4 or 5
Biopsy
Lesion stability and no new findings: Category 3
Bilateral diagnostic mammogram in six months
Twelve months from initial exam
Lesion increase: Category 4 or 5
Biopsy
Lesion stability and no new findings: Category 3
Bilateral diagnostic mammogram in 12 months
Twelve months from most recent exam
Lesion increase: Category 4 or 5
Biopsy
Lesion stability and no new findings: Category 2
Routine screening if radiologist determines 2-year stability
One more annual screening if radiologist prefers 3-year stability

TAB 5: Interpretation of Mammography Reports

INTERPRETATION OF MAMMOGRAPHY REPORTS

Organization of the Mammography Report Reporting System (ACR BI-RADS ATLAS, 2013)

The reporting system should be concise and organized using the following structure. If a comparison to previous studies is made, this should be indicated in the report.

A. INDICATION FOR EXAMINATION
   1. A brief description of the indication for examination.
      a. Screening for an asymptomatic woman.
      b. Recall for additional work-up of an abnormal finding.
      c. Evaluation of a clinical finding, specifying the finding and its location.
      d. Follow-up of a probably benign lesion or cancer treated with breast conservation.
   2. If an implant is present, both standard and implant-displaced views will be indicated.

B. SUCCINCT DESCRIPTION OF THE OVERALL BREAST COMPOSITION
   1. Breast density helps indicate the relative possibility that a lesion could be obscured by normal tissue.
   2. Mammography does not identify all breast cancers. Clinical breast examination (CBE) is an important element of screening. Abnormal CBE findings should never be ignored and may be especially important in dense breasts.
   3. If breasts are not equally dense, the denser breast should be used to categorize composition
   4. The categories of density are:
      a. Almost entirely fatty.
      b. Scattered areas of fibroglandular density.
      c. Heterogenously dense. If some areas are relatively dense but other areas are primarily fatty, a second sentence will describe the location(s) of the denser tissue. This category may obscure small masses.
      d. Extremely dense. Mammography sensitivity is lowest in this category.

C. DESCRIPTION OF ANY IMPORTANT FINDINGS THAT MAY BE SUSPICIOUS FOR CANCER

1. Mass:
   a. Size
   b. Morphology (shape, margin)
   c. Density
   d. Associated calcifications
   e. Associated features
   f. Location
2. Calcifications:
   a. Morphology — describe typically benign type or describe shape of particles
   b. Distribution (may not be appropriate for typically benign calcifications)
   c. Associated features
   d. Location
3. Architectural Distortion:
   a. Associated calcifications
   b. Associated features
   c. Location
4. Asymmetries (asymmetry, global asymmetry, focal asymmetry, developing asymmetry):
   a. Associated calcifications
   b. Associated features
   c. Location
5. Intramammary lymph node (rarely important): Location
6. Skin lesion (rarely important): Location
7. Solitary dilated duct (rarely present): Location (ACR, 2013).

D. COMPARISON TO PREVIOUS EXAMINATION(S), IF DESIRED
Comparison to previous examination may assume importance if the finding of concern requires an evaluation of change or stability. Comparison is not important when a finding has unequivocally benign features. Comparison may be irrelevant when the finding is inherently suspicious for malignancy (ACR, 2013).

E. ASSESSMENT

1. The incorporation of an assessment category in the overall summary is mandated by the Food and Drug Administration, Mammography Quality Standards, Final Rule.
2. Assessment categories are described on pages 30 to 31 (ACR, 2013).

F. MANAGEMENT

1. If a suspicious abnormality is identified, the report should indicate that a biopsy should be performed in the absence of clinical contraindication.
2. See algorithm on page 27 and 28 for follow-up recommendations (ACR, 2013).

G. OTHER

Any verbal discussions between the interpreting physician and the referring clinician or patient should be documented in the original report, or as an addendum to the report (ACR, 2013).

Mammography Assessment Categories

Mammographic Assessment is Incomplete

Category 0: Incomplete: Need additional imaging evaluation and/or prior mammograms for comparison. This is most commonly used in a screening situation. Additional imaging may include spot compressions (with or without magnification), additional views, or ultrasound. Category 0 may also be used to indicate the need for comparison with previous study(ies). When those prior examinations have been compared, there should be an addendum to the initial mammography report that includes a revised assessment (ACR, 2013).

Mammography Assessment is Complete

Category 1: Negative. This is a normal exam and there is nothing to comment on (ACR, 2013).

Category 2: Benign. Like Category 1, this category indicates there is no mammographic evidence of malignancy, and routine mammographic screening is recommended. However, the interpreting physician has chosen to describe one or more characteristically benign findings such as:

- Involuting calcified fibroadenomas,
- Skin calcifications,
- Metallic foreign bodies such as core biopsy and surgical clips,
- Fat-containing lesions such as oil cysts, lipomas, galactoceles and mixed-density hamartomas,
- Intramammary lymph nodes,
- Vascular calcifications,
- Implants, and/or
- Architectural distortion clearly related to prior surgery (ACR, 2013).

Category 3: Probably benign. A finding in this category indicates less than 2% likelihood of malignancy, but greater likelihood than a characteristically benign finding. It is not expected to change over the period of surveillance, but the interpreting physician prefers to establish stability before recommending routine screening.

Commonly reported probably benign findings include:

- Non-calcified circumscribed solid mass
- Focal asymmetry
- Solitary group of punctate calcifications

This category should never be used to assess an initial screening mammogram without obtaining a complete diagnostic imaging evaluation. It should also not be used in the presence of a palpable lesion; nor should it be used for a finding that is either new or increasing in size or extent.

Most category 3 findings will be managed with short-term (six months) mammographic follow-up, followed by additional mammograms until long-term (2 – 3 years) stability has been established. Patient preference or overriding clinical concern may lead to biopsy rather than short term follow-up (ACR, 2013).

Category 4: Suspicious. This category indicates findings that do not have the classic appearance of malignancy but are sufficiently suspicious to recommend biopsy. The likelihood of a Category 4 finding being malignant ranges from greater than 2% to less than 95%. To narrow this range and better guide patients and clinicians regarding management, Category 4 findings may be subdivided into additional categories:

- 4A: low suspicion for malignancy (>2% – 10% likelihood)
- 4B: intermediate suspicion of malignancy (>10% – 50% likelihood)
- 4C: moderate concern, but not classic for malignancy (>50% – <95% likelihood) (ACR, 2013).

Category 5: Highly Suggestive of Malignancy. Findings in this category have at least a 95% likelihood of being malignant. This category is typically established after an inconclusive percutaneous biopsy and will likely result in a recommendation for repeat biopsy (usually surgical) (ACR, 2013).

Category 6: Known Biopsy-Proven Malignancy. This category is reserved for examinations performed after biopsy proof of malignancy. It describes imaging performed after a percutaneous biopsy but prior to a complete surgical excision, in which there are no mammographic abnormalities other than the known cancer (ACR, 2013).

TAB: 6: APPENDICES

TAB 7: Appendix A

APPENDIX A: Breast Cancer Glossary

A

Abscess
An enclosed collection of pus in tissues, organs or confined spaces in the body. An abscess is a sign of infection and is usually swollen and inflamed.

Adenoma
A tumor that is not cancer. It starts in gland-like cells of the epithelial tissue (thin layer of tissue that covers organs, glands, and other structures within the body).

Adjunct agent
In cancer therapy, a drug or substance used in addition to the primary therapy.

Adjuvant therapy
Additional cancer treatment given after the primary treatment to lower the risk that the cancer will come back. Adjuvant therapy may include chemotherapy, radiation therapy, hormone therapy, targeted therapy, or biological therapy.

Areola
The area of dark-colored skin on the breast that surrounds the nipple.

Aspiration
Removal of fluid or tissue through a needle. Also, the accidental breathing in of food or fluid into the lungs.

Axilla
The underarm or armpit.

Axillary dissection
Surgery to remove lymph nodes found in the armpit region. Also called axillary lymph node dissection.

Axillary lymph node
A lymph node in the armpit region that drains lymph from the breast and nearby area.

Axillary lymph node dissection
Surgery to remove lymph nodes found in the armpit region, axillary dissection.

B

Benign
Not cancer. Benign tumors may grow larger but do not spread to other parts of the body. Also called nonmalignant.

Benign breast disease
A group of conditions marked by changes in breast tissue that are benign (not cancer). There are different types of benign breast disease, including some types caused by an increase in the number of cells or by the growth of abnormal cells in the breast ducts or lobes. Signs and symptoms of benign breast disease include irregular lumps or cysts, breast swelling or discomfort, skin redness or thickening and nipple discharge. Most benign breast conditions do not increase the risk of breast cancer. Also called mammary dysplasia.

BI-RADS
A method used by radiologists to interpret and report in a standardized manner the results of mammography, ultrasound, and MRI used in breast cancer screening and diagnosis. Also called Breast Imaging Reporting and Data System.

Bilateral
Affecting both the right and left sides of the body.

Bilateral prophylactic mastectomy
Surgery to remove both breasts to reduce the risk of developing breast cancer.

BRCA 1
A gene on chromosome 17 that normally helps to suppress cell growth. A person who inherits certain mutations in a BRAC 1 gene has a higher risk of getting breast, ovarian, prostate, and other types of cancer.

BRCA 2:
A gene on chromosome 13 that normally helps to suppress the cell growth. A person who inherits certain mutations (changes) in a BRCA 2 gene has a higher risk of getting breast, ovarian, prostate, and other types of cancer.

Breast cancer in situ
Abnormal cells that are confined to the ducts or lobules in the breast. There are two forms: ductal carcinoma in situ (DCIS) and lobular carcinoma in situ (LCIS). In situ means in its original place. For example, in ductal carcinoma in situ, cells are found only in the place where they first formed. They have not spread.

Breast density
A term used to describe the amount of dense tissue compared to the amount of fatty tissue in the breast on a mammogram. There are different levels of breast density ranging from little or no dense tissue to very dense tissue. The more density, the harder it may be to find tumors or other changes on a mammogram.

Breast implant
A silicone gel-filled or saline-filled sac placed under the chest muscle to restore breast shape.

Breast reconstruction
Surgery to rebuild the shape of the breast after a mastectomy.

Breast self-exam
An exam by a woman of her breast to check for lumps or other changes.

Breast conserving surgery and Breast-sparing surgery
An operation to remove the breast cancer but not the breast itself. Types of breast conserving surgery include lumpectomy (removal of a lump), quadrantectomy (removal of one quarter, or quadrant of the breast), and segmental mastectomy (removal of the cancer as well as some of the breast tissue around the tumor and the lining over the chest muscles below the tumor).

C

Calcification
Deposits of calcium in the tissues. Calcification in the breast can be seen on a mammogram but cannot be detected by touch. There are two types of breast calcifications, macrocalcifications and microcalcification. Macrocalfications are large deposits and are usually not related to cancer. Microcalcifications are specks of calcium that may be found in an area of rapidly dividing cells. Many microcalcifications clustered together may be a sign of cancer.

Carcinoma
Cancer that begins in the skin or in tissues that line or cover internal organs.

Carcinoma in situ
A group of abnormal cells that remain in the place where they first formed. They have not spread. These abnormal cells may become cancer and spread into nearby normal tissue. Also called stage 0 disease.

Chemotherapy
Treatment that uses drugs to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing. Chemotherapy may be given by mouth, injection, or infusion, or on the skin, depending on the type and stage of the cancer being treated. It may be given alone or with other treatments, such as surgery, radiation therapy, or biologic therapy.

Clinical breast exam
An exam of the breast performed by a health care provider to check for lumps or other changes. Also called CBE.

Clinical trial
A type of research study that tests how well new medical approaches work in people. These studies test new methods of screening, prevention, diagnosis, or treatment of a disease. Also called a clinical study.

Complementary and alternative medicine (CAM)
Forms of treatment that are used in addition to (complementary) or instead of (alternative) standard treatments. These practices generally are not considered standard medical approaches. Varying quality and quantity of research are available to substantiate the safety and effectiveness of CAM. CAM may include dietary supplements, mega dose vitamins, herbal preparations, special teas, acupuncture, massage therapy, magnet therapy, spiritual healing, and meditation.

Core biopsy
The removal of a tissue sample with a large (typically 11 – 18 gauge) needle for examination under a microscope.

Cyst
A closed sac-like pocket of tissue that can form anywhere in the body. It may be filled with fluid, air, pus or other materials. Most cysts are benign (not cancer).

D

Diagnosis
The process of identifying a disease, condition or injury from its signs and symptoms. A health history, physical exam, and tests (e.g., blood tests, imaging tests and biopsies) may be used to help make a diagnosis.

Diagnostic mammogram
An X-ray of the breast to check for breast cancer after a lump or other sign or symptom of breast cancer has been found.

Digital mammography
The use of a computer, rather than X-ray film, to create a picture of the breast.

Ductal carcinoma
The most common type of breast cancer. It begins in the lining of the milk ducts (thin tubes that carry milk from the lobules of the breast to the nipple). Ductal carcinoma may be either ductal carcinoma in situ (DCIS) or invasive ductal carcinoma. DCIS is a non-invasive condition in which abnormal cells are found in the lining of a breast duct and have not spread outside the duct to other tissues in the breasts. In some cases, DCIS may become invasive cancer. In invasive ductal carcinoma, cancer has spread outside the breast duct to surrounding normal tissue. It can also spread through the blood and lymph system to other parts of the body.

Ductal carcinoma in situ
A noninvasive, precancerous condition in which abnormal cells are found in the lining of a breast duct. The abnormal cells have not spread outside the duct to the tissues in the breast. In some cases, ductal carcinoma in situ may become invasive cancer and spread to other tissues, although it is not currently known how to predict which lesions will become invasive; intraductal carcinoma.

Ductal ectasia
A benign condition. Mammary duct ectasia occurs when a milk duct beneath the nipple widens, the duct walls thicken and the duct fills with fluid. The milk duct may become blocked or clogged with a thick, sticky substance. The condition often causes no symptoms, but some women may have nipple discharge, breast tenderness or inflammation of the clogged duct (periductal mastitis) (Mayo Clinic, 2020). The condition is more common in women who are getting close to menopause.

Ductal lavage
A method used to collect cells from milk ducts in the breast. A hair-size catheter (tube) is inserted into the nipple, and a small amount of salt water is released into the duct. The water picks up breast cells and is removed. The cells are checked under a microscope. Ductal lavage may be used in addition to clinical breast examination and mammography to detect breast cancer.

Dysplasia
A term used to describe the presence of abnormal cells within a tissue or organ. Dysplasia is not cancer, but it may sometimes become cancer. Dysplasia can be mild, moderate, or severe, depending on how abnormal the cells look under a microscope and how much of the tissue or organ is affected.

E

Endocrine Therapy
Treatment that adds, blocks, or removes hormones. For certain conditions (such as diabetes or menopause), hormones are given to adjust low hormone levels. Hormones can also cause certain cancers (such as prostate and breast cancer) to grow. To slow or stop the growth of cancer synthetic hormones or other drugs may be given to block the body's natural hormones. Sometimes surgery is needed to remove the gland that makes a certain hormone; hormonal therapy; hormone therapy; and hormone treatment (Cancer Dictionaries, 2021).

Estrogen
A type of hormone made by the body that helps develop and maintain female sex characteristics and the growth of long bones. Estrogen can also be made in the laboratory. They may be used as a type of birth control and to treat symptoms of menopause, menstrual disorders, osteoporosis, and other disorders.

Estrogen receptor
A protein found inside the cells of the female reproductive tissue, some other types of tissue, and some cancer cells. The hormone estrogen will bind to the receptors inside the cells and may cause the cells to grow. Also called ER.

F

Fibroadenoma
A benign (not cancer) tumor that most often forms in the breast and is made up of fibrous (connective) tissue and glandular tissue. A fibroadenoma is usually painless. It often feels like a hard, round lump with a smooth, well-defined border that moves easily under the skin of the breast. Fibroadenomas may go away on their own or may need to be removed. They often get smaller after menopause. Fibroadenomas are the most common type of benign breast tumor. They can occur at any age but are more common in younger women. Most fibroadenomas do not increase the risk of breast cancer.

Fibrocystic breast changes
A common condition marked by benign (not cancer) changes in breast tissue. These changes may include irregular lumps or cysts, breast swelling or discomfort, sensitive nipples, and itching. These symptoms may change throughout the menstrual cycles and usually stop after menopause. Fibrocystic breast changes can occur at any age but are most common in younger women. This condition does not increase the risk of breast cancer.

Fine-needle aspiration
The removal of tissue or fluid with a small needle for examination under a microscope; needle biopsy.

G

Gene
The functional and physical unit of heredity passed from parent to offspring. Genes are pieces of DNA and most genes contain the information for making a specific protein.

Gland
An organ that makes one or more substances, such as hormones, digestive juices, sweat, tears, saliva, or milk. Endocrine glands release the substances directly into the blood stream. Exocrine glands release the substances into a duct or opening to the inside or outside of the body.

H

HER2/neu
A protein involved in normal cell growth. HER2/neu may be made in larger than normal amounts by some types of cancer cells, including breast, bladder, pancreas, and stomach cancers. This may cause cancer cells to grow more quickly and spread to other parts of the body. Checking the amount of HER2/neu on some types of cancer cells may help plan treatment. Also called c-erb B-2, HER2, hyman EFG receptor 2, and human epidermal growth factor receptor 2.

HER2/neu gene
The gene that makes the human epidermal growth factor receptor 2. The protein produced is HER2/neu, which is involved in the growth of some cancer cells; c-erbB-2.

Hormone
One of many substances made by glands in the body. Hormones circulate in the bloodstream and control the actions of certain cells or organs. Some hormones can also be made in a laboratory.

Hormone receptor
A cell protein that binds to a specific hormone. The hormone receptor may be on the surface of the cell or inside the cell. Many changes take place in a cell after a hormone binds to its receptor.

Hormone replacement therapy
Treatment with hormones to replace natural hormones when the body does not make enough. For example, hormone replacement therapy may begin when the thyroid gland does not make enough thyroid hormone or when the pituitary gland does not make enough growth hormone. Or it may be given to women after menopause to replace the hormones estrogen and progesterone that are no longer made by the body. Also called HRT.

Hormone therapy
Treatment that adds, blocks, or removes hormones. For certain conditions (such as diabetes or menopause), hormones are given to adjust low hormone levels. Hormones can also cause certain cancers (such as prostate and breast cancer) to grow. To slow or stop the growth of certain cancers, synthetic hormones or other drugs may be given to block the body's natural hormones. Surgery is used to remove the gland that makes a certain hormone. Also called endocrine therapy, hormonal therapy, and hormone treatment.

I

Immunotherapy
A type of therapy that uses substances to stimulate or suppress the immune system to help the body fight cancer, infections, and other diseases. Some types of immunotherapy only target certain cells of the immune system. Others affect the immune system in a general way. Types of immunotherapies include cytokins, vaccines, bacillus Calmette-Guerin (BCG) and some monoclonal antibodies.

Incidence
The number of new cases of a disease diagnosed each year.

Incisional biopsy
A surgical procedure in which a portion of a lump or suspicious area is removed for diagnosis. The tissue is then examined under a microscope to check for signs of disease.

Intraductal breast carcinoma
A noninvasive condition in which abnormal cells are found in the lining of a breast duct. The abnormal cells have not spread outside the duct to other tissues in the breast. In some cases, intraductal breast carcinoma may become invasive cancer and spread to other tissues. At this time there is no way to know which lesions could become invasive. Also called DCIS and ductal carcinoma in situ.

Invasive cancer
Cancer that has spread beyond the layer of tissue in which it developed and is growing into surrounding, healthy tissues, infiltrating cancer.

L

LCIS
A condition in which abnormal cells are found in the lobules of the breast. This condition seldom becomes invasive cancer. However, having LCIS in one breast increases the risk of developing breast cancer in either breast. Also called lobular carcinoma in situ.

Lobe
A portion of an organ, such as the liver, lung, breast, thyroid, or brain.

Lobular carcinoma
Cancer that begins in the lobules (milk glands) of the breast. Lobular carcinoma may be either lobular carcinoma in situ (LCIS) or invasive lobular carcinoma. LCIS is a noninvasive condition in which abnormal cells are found in the lobules of the breast. LCIS rarely becomes invasive cancer but having LCIS in one breast increases the risk of developing invasive cancer in either breast. In invasive lobular carcinoma, cancer has spread from the lobules to surrounding normal tissue. It can also spread through the blood and lymph system to other parts of the body.

Lymph node
A small bean-shaped structure that is part of the body's immune system. Lymph nodes filter substances that travel through the lymphatic fluid and they contain lymphocytes (white blood cells) that help the body fight infection and disease. There are hundreds of lymph nodes found throughout the body. They are connected to one another by lymph vessels. Clusters of lymph nodes are found in the neck, axilla (underarm), chest, abdomen and groin. For example, there are 20 – 40 lymph nodes in the axilla. Also called lymph gland.

Lymph node mapping
The use of dyes and radioactive substances to identify lymph nodes that may contain tumor cells. Also called lymphatic mapping.

Lymphedema
A condition in which extra lymph fluid builds up in tissues and causes swelling. It may occur in an arm or leg if lymph vessels are blocked, damaged, or removed by surgery.

M

Magnetic resonance imaging (MRI)
A procedure in which radio waves and a powerful magnet linked to a computer are used to create detailed pictures of areas inside the body. The pictures can show the difference between normal and diseased tissue. Magnetic resonance imaging makes better images of organs and soft tissue than other scanning techniques, such as computed tomography (CT) or X-ray. Magnetic resonance imaging is especially useful for imaging the brain, the spine, the soft tissue of joints, and the inside bones. Also, called nuclear magnetic resonance imaging, MRI.

Malignant
Cancerous. Malignant tumors can invade and destroy nearby tissue and spread to other parts of the body.

Mammogram
An X-ray of the breast.

Mammography
The use of film or a computer to create a picture of the breast.

Margin
The edge or border of the tissue removed in cancer surgery. The margin is described as negative or clean when the pathologist finds no cancer cells at the edge of the tissue, suggesting that all the cancer has been removed. The margin is described as positive or involved when the pathologist finds cancer cells at the edge of the tissue, suggesting that all the cancer has not been removed.

Mastectomy
Surgery to remove part or all of the breast. There are different types of mastectomies that differ in the amount of tissue and lymph nodes removed.

Menarche
A young woman's first menstrual period.

Menopause
The time of life when a woman's ovaries stop producing hormones and menstrual periods stop. Natural menopause usually occurs at age 50. A woman is said to be in menopause when she hasn't had a period for 12 months in a row. Symptoms of menopause include hot flashes, mood swings, night sweats, vaginal dryness, trouble concentrating and infertility.

Metastasis
The spread of cancer cells from the place where they first formed to another part of the body. In metastasis, cancer cells break away from the original (primary) tumor, travel through the blood or lymph system and form a new tumor in other organs or tissues of the body. The new, metastatic tumor is the same type of cancer as the primary tumor. For example, if breast cancer spreads to the lung, the cancer cells in the lung are breast cancer cells, not lung cancer cells.

Microcalcification
A tiny deposit of calcium in the breast that cannot be felt but can be detected on a mammogram. A cluster of these very small specks of calcium may indicate that cancer is present.

N

Needle biopsy
The removal of tissue or fluid with a needle for examination under a microscope. When a wide needle is used, the procedure is called a core biopsy. When a thin needle is used, the procedure is called a fine needle aspiration biopsy.

Needle-localized biopsy
A procedure to mark and remove tissue when the doctor cannot feel a lump. An imaging device is used to guide a thin wire with a hook on the end through a hollow needle to place the wire in or around the abnormal area. Once the wire is in the right place, the needle is removed, and the wire is left in so the doctor will know where the abnormal tissue is. The wire is removed at the time the biopsy is done.

Neoadjuvant therapy
Treatment given as a first step to shrink a tumor before the main treatment, which is usually surgery, is given. Examples of neoadjuvant therapy include chemotherapy, radiation therapy, and hormone therapy. It is a type of induction therapy.

Nipple discharge
Fluid that is not milk coming from the nipple.

Nonmalignant
Nonmalignant tumors may grow larger but do not spread to other parts of the body. Also called benign.

O

Oncologist
A doctor who has special training in diagnosing and treating cancer. Some oncologists specialize in a particular type of cancer treatment. For example, a radiation oncologist specializes in treating cancer with radiation.

Oncology
A branch of medicine that specializes in the diagnosis and treatment of cancer. It includes medical oncology (the use of chemotherapy, hormone therapy and other drugs to treat cancer), radiation oncology (the use of radiation therapy to treat cancer), and surgical oncology (the use of surgery and other procedures to treat cancer).

P

Palpation
Examination by pressing on the surface of the body to feel the organs or tissues underneath.

Pathologist
A doctor who has special training in identifying diseases by studying cells and tissues under a microscope.

Pathology report
The description of cells and tissues made by a pathologist based on microscopic evidence, and sometimes used to make a diagnosis of a disease.

Patient Navigation
Patient Navigation was founded by Harold P. Freeman, M.D. in 1990, when he initiated and developed the first Patient Navigation program in Harlem to reduce disparities in access to diagnosis and treatment of cancer, particularly among poor and uninsured people. The core principles of the concept which focus upon saving lives from cancer and chronic diseases, include informing patients about the need for certain recommended examinations and provide timely access to such examinations; to eliminate barriers to timely diagnoses and treatment in patients who have abnormal or suspicious findings; eliminating barriers to timely care across the entire health care continuum (i.e., prevention, detection, diagnosis, treatment, and supportive to end-of-life care) (Harold P Freeman Institute, 2021).

Prevention
In medicine, action taken to decrease the chances of getting a disease or condition. For example, cancer prevention includes avoiding risk factors (such as smoking, obesity, lack of exercise, and radiation exposure) and increasing protective factors (such as getting regular physical activity, staying at a healthy weight, and having a healthy diet).

Progesterone
A type of hormone made by the body that plays a role in the menstrual cycle and pregnancy. Progesterone can also be made in the laboratory. It may be used as a type of birth control and to treat menstrual disorders, infertility, symptoms of menopause, and other conditions.

Progesterone receptor (PR)
A protein found inside the cells of the female reproductive tissue, some other types of tissue, and some cancer cells. The hormone progesterone will bind to receptors inside the cells and may cause the cells to grow. Also called PR.

Prognosis
The likely outcome or course of a disease; the chance of recovery or recurrence.

Prophylactic mastectomy
Surgery to reduce the risk of breast cancer by removing one or both breasts before disease develops. Prophylactic mastectomy may be done in people who have a very high risk of developing breast cancer. Also called preventive mastectomy and risk-reducing mastectomy.

Prosthesis
A device such as an artificial leg, that replaces a part of the body.

Punctate
Having small pinpoint calcium deposits.

R

Radiation
Energy released in the form of particles or electromagnetic waves. Common sources of radiation include radon gas, cosmic rays from outer space, medical X-rays, and energy given off by a radioisotope (unstable form of a chemical element that releases radiation as it breaks down and becomes more stable). Radiation can damage cells. It is used to diagnose and treat some types of cancer.

Radiation oncologist
A doctor who specializes in using radiation to treat cancer.

Radiation therapy
The use of high-energy radiation from X-rays, gamma rays, neutrons, protons, and other sources to kill cancer cells and shrink tumors. Radiation may come from a machine outside the body (external-beam radiation therapy), or it may come from radioactive material placed in the body near cancer cells (internal radiation therapy, or brachytherapy). Systemic radiation therapy uses a radioactive substance, such as radiolabeled monoclonal antibody, that travels in the blood to tissues throughout the body. Also called irradiation and radiotherapy.

Radical mastectomy
Surgery for breast cancer in which the breast, chest muscles, and all the lymph nodes under the arm are removed. For many years, this was the breast cancer operation used most often, but it is used rarely now. Doctors consider radical mastectomy only when the tumor has spread to the chest muscles, the Halsted radical mastectomy.

Radiologist
A doctor who has special training in creating and interpreting pictures of areas inside the body. The pictures are made with X-rays, sound waves, or other types of energy.

Reconstructive surgeon
A doctor who can surgically reshape or rebuild (reconstruct) a part of the body, such as a woman's breast, after surgery for breast cancer.

Recurrence
Cancer that has recurred (come back), usually after a period during which the cancer could not be detected. The cancer may come back to the same place as the original (primary) tumor or to another place in the body. Also called recurrent cancer.

Remission
A decrease in or disappearance of signs and symptoms of cancer. In partial remission, some, but not all, signs and symptoms of cancer have disappeared. In complete remission, all signs and symptoms of cancer have disappeared, although cancer still may be in the body.

Risk factor
Something that increases the chance of developing a disease. Some examples of risk factors for cancer are age, a family history of certain cancers, use of tobacco products, being exposed to radiation or certain chemicals, infection with certain viruses or bacteria and certain genetic changes.

S

Scintimammography
A type of breast imaging test that is used to detect cancer cells in the breasts of some women who have had abnormal mammograms, or who have dense breast tissue. It is not used for screening, or in place of a mammogram. In this test, a woman receives an injection of a small amount of a radioactive substance called technetium 99, which is taken up by the cancer cells, and a gamma camera is used to take pictures of the breasts. Also called Miraluma test and sestamibi breast imaging.

Screening
Checking for disease when there are no symptoms. Since screening may find diseases at an early stage, there may be a better chance of curing the disease. Examples of cancer screening tests are the mammogram (for breast cancer), colonoscopy (for colon cancer) and the Pap test and HPV tests (for cervical cancer). Screening can also include doing a genetic test to check for a person’s risk of developing an inherited disease.

Screening mammogram
X-rays of the breast taken to check for breast cancer in the absence of signs or symptoms.

Sentinel lymph node mapping
The use of dyes and radioactive substances to identify the first lymph node to which cancer is likely to spread from the primary tumor. Cancer cells may appear first in the sentinel node before spreading to other lymph nodes and other places in the body.

Sonogram
A computer picture of areas inside the body created by high-energy sound waves. The sound waves are bounced off internal tissues or organs and make echoes. The echoes form a picture of the body tissues on a computer screen. A sonogram may be used to help diagnose disease, such as cancer. It may also be used during pregnancy to check the fetus (unborn baby) and during medical procedures, such as biopsies. Also called ultrasound.

Stage
The extent of a cancer in the body. Staging is usually based on the size of the tumor, whether lymph nodes contain cancer and whether the cancer has spread from the original site toother parts of the body.

Stem cell
A cell from which other types of cells develop. For example, blood cells develop from blood-forming stem cells.

Stereotactic biopsy
A biopsy procedure that uses a computer and a 3-dimensional scanning device to find a tumor site and guide the removal of tissue for examination under a microscope.

Surgical oncologist
A surgeon who has special training in performing biopsies and other surgical procedures in cancer patients.

T

Tamoxifen
A drug used to treat certain types of breast cancer in women and men to prevent invasive breast cancer in women who have had ductal carcinoma in situ (abnormal cells in the ducts of the breasts), and to prevent cancer in women who are at high risk of developing the disease. It is also being studied in the treatment of other types of cancers. Tamoxifen citrate blocks the effects of the hormone estrogen in breast tissue, which may help keep breast cancer cells from growing. It is a type of selective estrogen receptor modulator (SERM). Tamoxifen is the active ingredient of tamoxifen citrate. Also called Soltamox.

Tissue flap reconstruction
A type of breast reconstruction in which a flap of tissue is surgically moved from another area of the body to the chest and formed into a new breast mound.

Tumor
An abnormal mass of tissue that forms when cells grow and divide more than they should or do not die when they should. Tumors may be benign (not cancer) or malignant (cancer). Benign tumors may grow large but do not spread into, or invade, nearby tissues or other parts of the body. Malignant tumors can spread into or invade, nearby tissues. They can also spread to other parts of the body through blood and lymph systems. Also called neoplasm.

Tumor grade
A description of tumor based on how abnormal the cancer cells and tissue look under a microscope and how quickly the cancer cells are likely to grow and spread. Low grade cancer cells look more like normal cells and tend to grow and spread more slowly than high grade cancer cells. Grading systems are different for each type of cancer. They are used to help plan treatment and determine prognosis. Also called histologic grade.

U

Ultrasound
A procedure that uses high energy sound waves to look at tissue and organs inside the body. The sound waves make echoes that form pictures of the tissues and organs on a computer screen (sonogram). Ultrasound may be used to help diagnose diseases such as cancer. It may also be used during pregnancy to check the fetus (unborn baby) and during medical procedures, such as biopsies. Also called ultrasonography.

X

X-ray
A type of radiation used in the diagnosis and treatment of cancer and other diseases. In low doses, X-rays are used to treat cancer.

NCI, 2021. Dictionary of Cancer Terms. Retrieved on September 29, 2021 from https://www.cancer.gov/publications/dictionaries/cancer-terms

TAB 8: Appendix B

APPENDIX B: NC BCCCP and NC Women, Infant and Community Wellness Section Eligibility

NC BCCCP – Eligible Population

Priority Populations

1. The priority population for NC BCCCP mammography services is women who are low-income (below 250% of federal poverty level), who have not been screened in the past year and:
    a. For federally funded services, the priority population is ages 50 – 64.
    b. For state-funded services, the priority population is ages 40 – 64.
2. The priority population for NC BCCCP cervical cancer screening services is women who are low-income (below 250% of federal poverty level), who have not been screened in the past year and:
    a. For federally funded services, the priority population is ages 40 – 64.
    b. For state-funded services, the priority population is ages 21 – 64.
3. Another priority population is women of ethnic minorities and women who are uninsured or underinsured which should be considered for enrollment of women in NC BCCCP.

Eligible Population

1. Women 21 – 75 years of age with gross incomes that are below 250% of the federal poverty level, according to the Federal Poverty Guidelines, and who are uninsured or underinsured, may be eligible for breast and cervical services, subject to the limitations and exceptions listed below.
2. Women enrolled in Medicare (Part B) and/or Medicaid programs are not eligible for program-funded services.
3. Women receiving Family Planning (Title X) services are not eligible for NC BCCCP-funded services that are available through Title X funding. Eligible women 21 – 39 with an undiagnosed breast or cervical abnormality may be able to receive NC BCCCP - funded diagnostic services if no other source of health care reimbursement is available.
4. Eligible women ages 21 – 39 with an undiagnosed breast or cervical abnormality may receive NC BCCCP funded diagnostic services if no other source of healthcare reimbursement is available.

5. Breast Services: At least 75% of all initial mammograms provided through NC BCCCP using federal funds must be for women ages 50 – 64. No more than 25% may be provided for symptomatic women under the age of 50.
6. Symptomatic women under the age of 50: NC BCCCP funds can be used to reimburse for Clinical Breast Exams (CBE) for symptomatic women under the age of 50. If the findings of the CBE are considered abnormal, including a discrete mass, nipple discharge, and skin or nipple changes, a woman can be provided a diagnostic mammogram and a referral for a surgical consult.
7. Screening women ages 40 – 49: NC BCCCP funds may be used to provide a clinical breast exam. If the CBE is abnormal, follow-up may be provided. If the CBE is normal, the woman is not eligible for a screening mammogram through NC BCCCP using federal funds until she is age 50. Programs receiving NC BCCCP state funds may use those funds to provide screening mammograms for women aged 40 – 49 and up to age 75.
8. Asymptomatic women under the age of 40: NC BCCCP funds cannot be used to screen asymptomatic women under the age of 40, even if they are considered high risk (e.g., women who have a personal history of breast cancer or first-degree relative with pre-menopausal breast cancer) for breast cancer.
9. Cervical Services: At least 20% of all enrolled women screened for cervical cancer shall meet the definition of never or rarely screened (more than five – 5 - years ago).
10. At least 75% of the initial Pap tests using federal funds must be provided to women ages 40 – 64.
11. No more than 25% of the Pap tests using federal funds may be provided to women less than 40 years of age.
12. Documented citizenship is not required for screening through NC BCCCP.
13. Income eligibility must be reassessed annually based on the revised federal poverty level.

North Carolina Women, Infant and Community Wellness Section Programs Eligibility

North Carolina Women, Infant and Community Wellness Section Funding Associated with Breast and Cervical Cancer Screening Services

Two Funding Sources: 1. Title X, 2. Heathy Mothers/ Healthy Children

Services:

- Patients who seek services at local health clinics that receive funding from the NC Women, Infant and Community Wellness Section may receive physical exams that include clinical breast exams and cervical cancer screening. Follow-up services for abnormal breast findings and/or abnormal cervical findings are not covered by NC Women, Infant and Community Wellness Section funding.

Eligibility:

- All patients seeking family planning services at clinics funded by Title X and Healthy Mothers/Healthy Children are eligible for services, including breast and cervical cancer screening.

Billing/Fees:

- Patients with incomes below 100% of the Federal Poverty Level are not charged for family planning services, including clinical breast exams and cervical cancer screening.
- Patients with incomes from 101% to 250% of the Federal Poverty Level are charged for family planning services on a sliding fee scale per the Federal schedule of discounts, including charges for clinical breast exams and cervical cancer screening.
- Patients with incomes above 250% of the Federal Poverty Level are charged for family planning services in accordance with a schedule of fees designed to recover the reasonable cost of providing services, including charges for clinical breast exams and cervical cancer screening.
- However, NC Women, Infant and Community Wellness Section funded clinics may not deny patients services or alter the quality of services if patients are unable to pay.

Sources:

1. Program Requirements for Title X Funded Family Planning Projects: https://opa.hhs.gov/grant-programs/title-x-service-grants/title-x-statutes-regulations-and-legislative-mandates
2. NC Women, Infant and Community Wellness Section, Family Planning Agreement Addenda: https://wicws.dph.ncdhhs.gov/provpart/
3. Federal Poverty Guidelines – For current federal poverty guidelines, https://bcccp.dph.ncdhhs.gov/Eligibility.asp#eligibility

TAB 9: Appendix C

APPENDIX C: NC Division of Health Benefits – Breast and Cervical Cancer Medicaid

North Carolina Medicaid

1. The Breast and Cervical Cancer Medicaid (BCCM) is a program of the NC Division of Health Benefits (DHB) that administers all other Medicaid programs in North Carolina.
2. BCCM is the way a patient applies for this full-coverage Medicaid. Patients must meet NC BCCCP eligibility criteria and be enrolled in NC BCCCP to apply.
3. Because the local BCCCP does the screening and provides the diagnostic workup that leads to cancer diagnosis or provides patient navigation only services to help a patient apply for BCCM, the local BCCCP navigator initiates the BCCM application instead of the local Department of Social Services (DSS).
4. Effective October 1, 2020, the DHB began to allow a broader definition of NC BCCCP providers. With this change, women diagnosed with breast and/or cervical cancer (and/or a breast or cervical precancerous lesion for which treatment is planned) outside of NC BCCCP may receive patient navigation-only services through NC BCCCP to apply for BCCM coverage for treatment. This allows women who have completed their screening and diagnostic work-up through an outside provider to receive NC BCCCP-funded patient navigation-only services by a local BCCCP provider to apply for BCCM.
5. DSS has the ability to make BCCM coverage retroactive for three months from the day a completed application is received by the local DSS. Coverage can only be made retroactive for three months prior to the date an application is received by the DSS. Women diagnosed not more than three months prior to the date of making BCCM application may be eligible to apply for BCCM coverage so long as they meet all other NC BCCCP eligibility criteria.
6. For more information and application, visit our website: https://bcccp.dph.ncdhhs.gov/BCCM.htm

NC Medicaid: Family Planning Services, Clinical Coverage Policy No: 1E-7; Medicaid and Health Choice, Amended Date: May 1, 2021; https://medicaid.ncdhhs.gov/obstetrics-and-gynecology-clinical-coverage-policies

North Carolina Breast and Cervical Cancer Control Program (NC BCCCP)

Breast and Cervical Cancer Medicaid (BCCM)

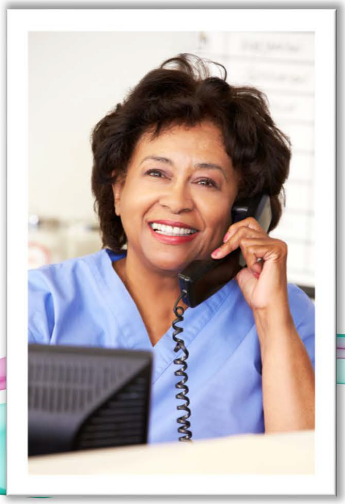
BCCM can pay for breast and/or cervical cancer treatment

Women must FIRST be eligible for NC BCCCP:

- Income below 250% of the Federal Poverty Level
- Uninsured or under-insured (not covered by Medicare Part B, Medicaid*, or major medical insurance)
- Patients must be enrolled in NC BCCCP to apply for BCCM
- Patient's diagnosis date must be within three months of BCCM application date

NC BCCCP services include:

- Screening for breast and/or cervical cancer
- Diagnostic work-up of abnormal breast or cervical cancer screening results or findings
- Assistance with application for BCCM



Physicians: It is preferable that a patient be referred and enrolled in BCCCP prior to being diagnosed with breast or cervical cancer in order to access all available services.

*Women with **Be Smart** Family Planning Medicaid may be eligible for services through NC BCCCP.

For more information, contact NC BCCCP at (919) 707-5300 or visit http://bcccp.dph.ncdhhs.gov/BCCM.htm

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES
Division of Public Health

north carolina bcccp breast & cervical cancer control program

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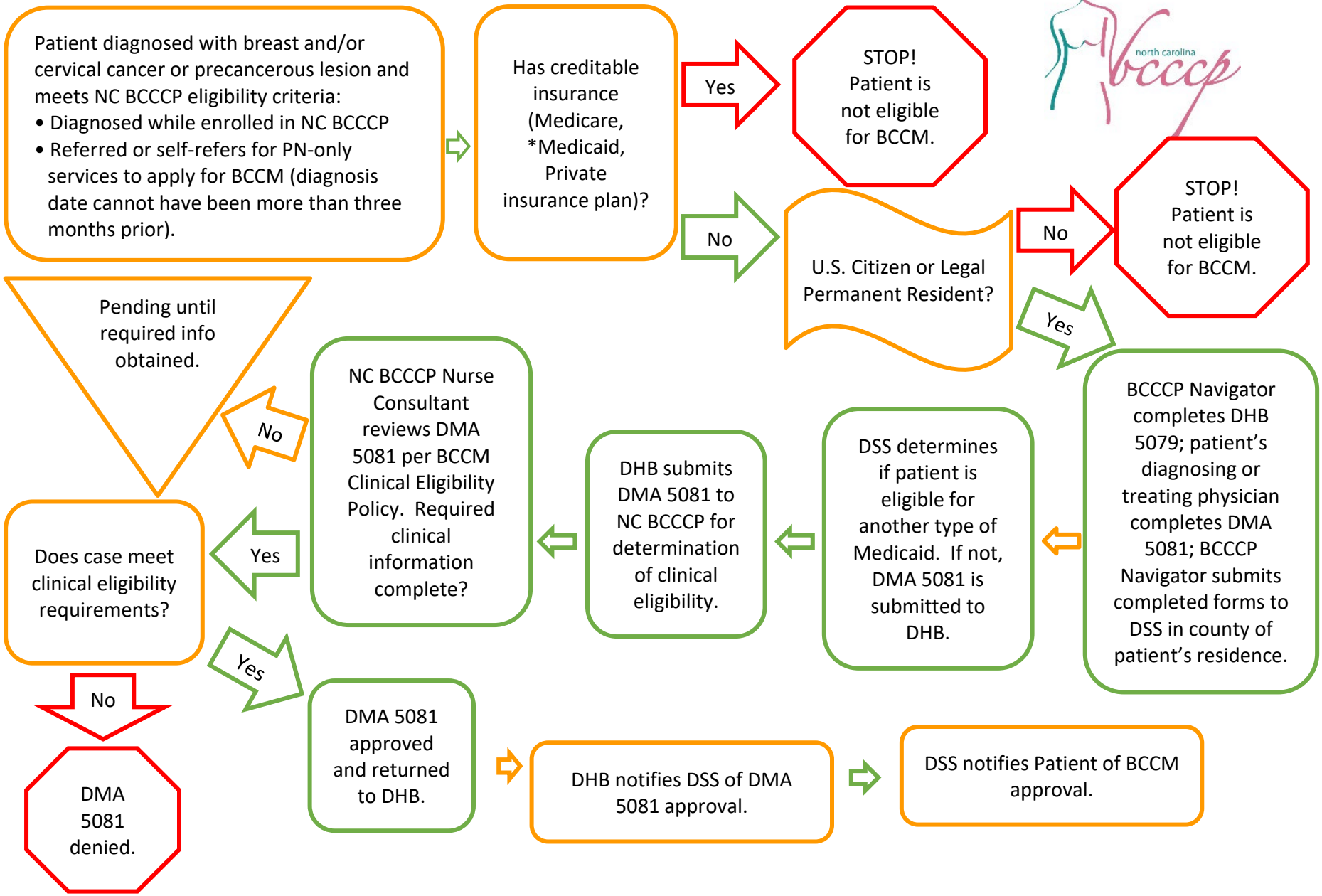
NC BCCCP BCCM Process Flow



TAB 10: Appendix D

APPENDIX D: NC BCCCP and NC WISEWOMAN Program Policies

1. NC BCCCP & NC WISEWOMAN Policy for Patients Insured Under the Patient Protection and Affordable Care Act (ACA)
2. NC BCCCP & NC WISEWOMAN Patient Navigation Policy
3. NC BCCCP Eligibility for Family Planning Patients

NC BCCCP and NC WISEWOMAN Program Policy for Patients Insured Under the Patient Protection and Affordable Care Act (ACA)

NC BCCCP & NC WISEWOMAN Program Policy for Patients Insured Under the Patient Protection and Affordable Care Act (ACA)	**Category/Number: N/A**
Approved By: _____ **NC BCCCP Medical Advisor** _____ **NC BCCCP Program Director**	**Section: NC BCCCP Training Manual-Overview** **Program: NC BCCCP & NC WISEWOMAN Program**
Effective Date: 06/29/2015 **Current Revision Effective Date:** 4/1/2021 **Revision History Date/s:** 3/27/2018	**Review Date/s:** _____ _____ _____

Purpose:

The North Carolina Breast and Cervical Cancer Control Program is required by law to be the payer of last resort for women enrolled in the program. (Public Law 101-354, 42 U.S.C. § 300n (d)). Therefore, insurance must be billed for patients who have insurance, including those who have policies through the Patient Protection and Affordable Care Act (ACA), the health reform bill passed in 2010.

Policy:

Impact on local agencies: Payer of Last Resort

All women seeking to be enrolled in NC BCCCP must be assessed at each visit for insurance status. If they are uninsured, they must be referred to the Health Insurance Marketplace. Referral may be directly to www.healthcare.gov, or may be to a local entity that helps apply for Affordable Care Act (ACA) insurance, such as a navigator. NC BCCCP providers must document all referrals to the Health Insurance Marketplace.

Definitions:

***Women who are uninsured*:** If the patient does **NOT** have insurance or her healthcare coverage is **NOT** yet effective, the woman may be enrolled in NC BCCCP if she meets age and income eligibility criteria. If NC BCCCP paid for a screening or diagnostic service, the woman will count toward service targets, and you may be reimbursed by NC BCCCP at the per-capita rate.

Women who are <u>underinsured</u> for screening: If the woman has insurance, she may still be enrolled in NC BCCCP if she meets age and income eligibility criteria, and her insurance does not cover all screening services at 100%. However, the insurance must be billed as the primary insurance. Once the insurance has paid the portion it covers and an Explanation of Benefits (EOB) has been received, NC BCCCP may pay the difference between what insurance covers and the amount allowed on the NC BCCCP Fee Schedule.

<u>For example:</u>

Procedure is billed at	$150.00
Maximum fee allowed by BCCCP is	$ 75.00
Insurance pays	$ 50.00
BCCCP may pay	$ 25.00
Amount service provider must write off	$ 75.00

These women count toward service targets, since NC BCCCP paid for a portion of the screening and/or diagnostic costs. You may be reimbursed by NC BCCCP at the per-capita rate.

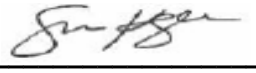
Women who are insured for screening but underinsured for diagnostic work-up: If the patient's insurance covers the screening services at 100%, NC BCCCP cannot pay for any portion of the screening. However, if the patient needs diagnostic work-up which is not covered at 100%, NC BCCCP may pay the difference between what insurance pays and the amount allowed by the NC BCCCP Fee Schedule. This patient will count toward service targets, and you may be reimbursed by NC BCCCP at the per-capita rate.

Responsibilities: BCCCP provider

Procedure:
Local BCCCP staff will assess at each visit for insurance status, if uninsured refer to the Health Insurance Marketplace and document in the medical record.

Legal Authority:
(Public Law 101-354, 42 U.S.C. § 300n (d)).

NC BCCCP and NC WISEWOMAN Program Patient Navigation Policy

NC BCCCP & NC WISEWOMAN Program Patient Navigation Policy	**Category/Number: N/A**
Approved By:  **NC BCCCP Medical Advisor**  **NC BCCCP Program Director**	**Section: NC BCCCP Training Manual -Overview** **Program: NC BCCCP/NC WISEWOMAN Program**
Effective Date: 05/04/15 **Current Revision Effective Date:** 04/01/21 **Revision History Date/s:**	**Review Date/s:** 5/30/17; 3/29/18; 03/11/2019

Purpose:

- To ensure that women enrolled in the NC BCCCP or NC WISEWOMAN receive timely and appropriate diagnostic and treatment services.
- To identify non-medical patient barriers, such as transportation, scheduling, and lack of understanding about the need for or nature of follow-up procedures.
- To overcome these barriers so that the patient can keep follow-up appointments and take action on recommendations.

Policy:

It is the policy of the NC BCCCP and NC WISEWOMAN Program to follow the recommendations of the CDC's NBCCEDP and WISEWOMAN programs, including recommendations based on the Screening and Diagnostic Services Chapter of the *NBCCEDP Program Guidance Manual* and the *WISEWOMAN Technical Assistance and Guidance Document*.

All NC BCCCP or NC WISEWOMAN Program enrolled women with an abnormal screening result must be assessed for their need of patient navigation services and provided with such services accordingly. Screening results which require a patient navigation assessment are:

- Clinical breast exam results of discrete palpable mass, serous or bloody nipple discharge, nipple or areolar scaliness, or skin dimpling or retraction.

- Mammogram results of BIRADS 3, 4, or 5.
- Pap test results of ASC-US if HPV is positive, LSIL, or high-grade lesions.
- WISEWOMAN alert values of systolic BP >180 mmHg, diastolic BP >120 mmHg, or fasting blood glucose values of <50 or >250 mg/dL.

Patient navigation services conclude when a client initiates treatment, refuses treatment, or is no longer eligible for NC BCCCP or NC WISEWOMAN services. When a woman concludes her cancer treatment or is receiving medical care for her NC WISEWOMAN alert values, has been released by her treating physician to return to a schedule of routine screening, and continues to meet NC BCCCP and/or NC WISEWOMAN eligibility requirements, she may return to the program and receive all its services.
Patient navigation is defined as assisting NC BCCCP or NC WISEWOMAN eligible women to identify and overcome barriers to screening, diagnosis, and/or treatment.

Responsibilities: Local BCCCP Providers

Procedure:
The NC BCCCP & NC WISEWOMAN patient navigation policy outlines the key elements of patient navigation. These are assessing, planning, coordinating, monitoring, developing resources, and evaluating. The elements represent a cooperative process including the BCCCP or WISEWOMAN provider, the patient, and medical providers to ensure timely and appropriate diagnostic and treatment services.

Assessing:
This element involves a cooperative effort between the BCCCP or WISEWOMAN provider and patient to determine the patient's need for essential support to complete the recommended screening or follow-up. To comply with patient privacy protection policy, BCCCP and WISEWOMAN providers must document consent to services and ensure confidentiality. Providers should use the top half of the DHHS Form 4091 or another approved method to document Patient Navigation Needs Assessment.

Planning:
This element includes the development of a written plan for an individual patient. The plan should meet the immediate, short-term, and long-term needs identified in the assessment. BCCCP and WISEWOMAN providers should collaborate with the patient to set goals and related activities with timeframes and delineate who is responsible for meeting the goals. Providers should use the bottom half of the DHHS Form 4091 or another approved method to document the Patient Navigation Care Plan when a need has been identified by the assessment. Patient navigation needs assessment and/or care plan will be documented in the patient's medical record to assure continuity of care.

Coordinating:
This element is the brokering of referral to needed services. Local BCCCP and WISEWOMAN providers should document the steps taken in the patient plan. Maintaining close communication between local BCCCP and WISEWOMAN providers, the patient, and the patient's medical providers will ensure that services – both medical and supportive – are coordinated for optimal outcomes.

Monitoring:
This element involves the ongoing reassessment of the patient's needs through regular communication. Local BCCCP and WISEWOMAN providers should update patient plans on the basis of routine re-assessments. Documentation of who, what, and when in the patient's written plan for patient navigation will determine when it might be necessary to update the plan. Plans should be simple and relate to assisting the woman to keep her screening or follow-up appointments. In most cases, BCCCP and WISEWOMAN providers should use notation stating that the patient kept her appointment and that she understood what her next action should be and when.

Developing Resources:
This element includes the establishment of formal and informal agreements to maximize the availability of and access to essential screening support services and diagnostic and treatment resources. It also includes the promotion of self-sufficiency and self-determination among patients by ensuring that women gain the knowledge, skills, and support needed to obtain necessary services. Patient education regarding the purpose and expected outcomes of diagnostic testing should be promoted and tailored for each individual woman. The ultimate goal of the program is not just to ensure that the woman receives the needed services, but also that she gains knowledge and skills for follow-up that are independent of patient navigation support (e.g., self-efficacy).

Evaluating:
This element involves assessing patient satisfaction, access, and timeliness of referral services, as well as the quality of individual patient navigation plans. Local BCCCP and WISEWOMAN providers should ask and answer questions such as "Were barriers to diagnosis and treatment overcome in a timely fashion?"

References:
NBCCEDP Program Guidance Manual and the WISEWOMAN Technical Assistance and Guidance Document.

NC BCCCP Eligibility for Family Planning Patients

Title: NC BCCCP Eligibility for Family Planning Patients	**Category/Number: N/A**
Approved By: _____ **NC BCCCP Medical Advisor** _____ **NC BCCCP Program Director**	**Section: NC BCCCP Training Manual-Overview** **Program: NC BCCCP**
Effective Date: 04/08/15 **Current Revision Effective Date:** 04/01/21 **Revision History Date/s:** 02/17/21	**Review Date/s:** _____ _____ _____

Purpose:

Because Family Planning provides a clinical breast exam and Pap test for eligible women, NC BCCCP funds should not be used to pay for these services if the woman is eligible for or enrolled in family planning.

However, Family Planning may not be able to cover all expenses related to a screening cycle. In those cases, NC BCCCP funds may be able to help.

Policy:

The North Carolina Breast and Cervical Cancer Control Program is legally required to be the payer of last resort for women enrolled in the program. (Public Law 101-354, 42 U.S.C. § 300n [d]). As a result, NC BCCCP is unable to provide screening services that may be provided by the Family Planning (Title X) program.

Local BCCCP agencies should develop a policy and standing orders regarding situations in which they will accept a Family Planning patient for diagnostic work up to balance service to women in need with the goal of protecting NC BCCCP funds for the NC BCCCP priority population. Policies must be approved by the agencies' BCCCP Nurse Navigators.

Responsibilities: Local BCCCP Providers

Procedure:

Situations in which NC BCCCP may be used to help:

Breast circumstances

- Women ages 50 – 64 may have a screening mammogram and/or diagnostic workup provided through NC BCCCP, using Federal BCCCP funds. These women will count toward Federal service targets. The local agency is eligible to be reimbursed $325 of Federal funds for these patients.
- Women ages 40 - 49 may have a screening mammogram and/or diagnostic workup provided through NC BCCCP, using State BCCCP funds. These women will count toward State service targets. The local agency is eligible to be reimbursed $325 of State funds for these patients.
- Women ages 30 – 39 are not eligible for screening through NC BCCCP; however, if women in this age range present with an abnormal clinical breast examination, or if they are found to be at high risk for developing breast cancer (see NC BCCCP Risk Assessment Policy), they may qualify for a mammogram and/or diagnostic workup through NC BCCCP. These women will count toward NC BCCCP service targets. The local agency is eligible to be reimbursed $325 for these patients.
- If women ages 21 – 29 present with an abnormal clinical breast examination, they may qualify for an NC BCCCP-funded ultrasound and/or diagnostic workup. These women will count toward NC BCCCP service targets. The local agency is eligible to be reimbursed $325 for these patients.

Cervical circumstances

- Women ages 21 – 64 who have a Family Planning Pap result of ASC-H, HSIL or worse may have a diagnostic workup provided through NC BCCCP. These women will count toward Federal service targets. The local agency is eligible to be reimbursed $325 of Federal funds for these patients. Serving these patients through NC BCCCP may enable them to qualify for Breast and Cervical Cancer Medicaid to pay for treatment if they meet other eligibility requirements and have a diagnosis of CIN 2 or worse.
- Women ages 25 - 64 who have a Family Planning Pap result of persistent ASC-US or LSIL may have a diagnostic workup provided through NC BCCCP. These women will count toward NC BCCCP service targets. The local agency is eligible to be reimbursed $325 of NC BCCCP funds for these patients. Serving these patients through NC BCCCP may enable them to qualify for Breast and Cervical Cancer Medicaid to pay for treatment if they meet other eligibility requirements and have a diagnosis of CIN 2 or worse; however, the likelihood of CIN disease in these patients is relatively low and follow-up for women under the priority age of 40 – 64 may be more appropriately done with funding other than NC BCCCP.

- Women ages 21 - 24 who have a Family Planning Pap result of ASC-US or LSIL that progresses to ASC-H, HSIL, or AGC may have a diagnostic workup provided through NC BCCCP. These women will count toward NC BCCCP service targets. The local agency is eligible to be reimbursed $325 of NC BCCCP funds for these patients. Serving these patients through NC BCCCP may enable them to qualify for Breast and Cervical Cancer Medicaid to pay for treatment if they meet other eligibility requirements and have a diagnosis of CIN 2 or worse. Immediate colposcopy is not appropriate for this youngest population with an ASC-US or LSIL result and no prior history of abnormal Pap results.

Legal Authority: (Public Law 101-354, 42 U.S.C. § 300n (d)).

References:

- *The Breast Screening Manual: A Guide for Health Departments and Providers* (DHHS, December 2016 updated June 2018)

- *The Cervical Screening Manual: A Guide for Health Departments and Providers* (DHHS, December 2020)

- Shiffman, Mark et.al., (2020). *An Introduction to the 2019 ASCCP Risk-Based Management Consensus Guidelines. Journal of Lower Genital Tract Disease* Vol. 24, Number 2, April 2020.

TAB 11: Appendix E

APPENDIX E: Other Resources for Information and Treatment

1. CancerCare Financial Assistance
2. CancerCare Co-Payment Assistance Foundation
3. Patient Advocate Foundation
4. Additional Resources Outside of NC BCCCP

This fact sheet is provided as an example of financial resources that might be available for those seeking assistance with the expense of care and treatment of cancer. References to products, services, companies, private individuals, or trademarks does not constitute endorsement, recommendation, or guarantee by the NC Department of Health and Human Services. Other resources may be available, and it is up to the individual to discover and use resources they deem appropriate for their particular circumstances.

CancerCare Financial Assistance

Financial Assistance

CancerCare®offer limited financial assistance for cancer-related costs and our professional oncology social workers can help you find resources

CancerCare® provides limited financial assistance to people affected by cancer. As a nonprofit organization, funding depends on the sources of support we receive at any given time. If we do not currently have funding to assist you, our professional oncology social workers will always work to refer you to other financial assistance resources. Please check our website (www.cancercare.org) periodically for funding updates.

Funding is currently available for:

- Transportation, Home Care and Child Care
- Women with all diagnoses.
- Children with all diagnoses.
- Men and women with pancreatic cancer.
- Men and women with multiple myeloma (transportation only).
- Men and women with all diagnoses residing in San Diego and Imperial counties, CA.
- Men, women and children with all diagnoses in certain counties in New York State, New Jersey and Connecticut.
- Pain and anti-nausea medication, oral hormonal medication, lymphedema supplies and durable medical equipment
- Women and men with breast cancer.

Eligibility

In order to be eligible for financial assistance you must:

- have a diagnosis of cancer confirmed by an oncology health care provider.
- be in active treatment for your cancer.
- live in the U.S. or Puerto Rico.
- meet our eligibility guidelines of 250% of the Federal Poverty.

Additional Resources:

- Cancer Financial Assistance Coalition (CFAC) (cancerfac.org)
  CFAC is a group of organizations that help cancer patients, and their loved ones manage the financial challenges of cancer. CFAC maintains an up-to-date database of organizations that provide financial help.

- Cancer.net's Patient Guide, "Managing the Cost of Living with Cancer"
  This guide from the American Society of Clinical Oncology (ASCO) provides helpful tips for talking with your health care team about the costs of cancer care. The guide includes resources to assist you in financial planning before, during and after treatment.

For additional information:

- www.cancercare.org
- info@cancercare.org
- 1-800-813-HOPE (4673)

Note: Information is subject to change. Please refer to the website for the most recent updates. Created 5/19/2015; Updated 6/23/21

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CancerCare Co-Payment Assistance Foundation

Need help with chemotherapy or targeted treatment co-payments?

Visit the CancerCare® Co-Payment Assistance Foundation's website: (http://cancercare.org/copayfoundation)

CancerCare® Co-Payment Assistance Foundation (CCAF) offers a seamless, same-day approval process through a proven, state-of-the-art platform.

CancerCare® Co-Payment Assistance Foundation provides easy and immediate access to the full array of CancerCare® support services, including:

- Telephone, online and in-person counseling (http://www.cancercare.org/counseling),
- Support groups (http://www.cancercare.org/support_groups),
- Information and resource referrals, publications (http://www.cancercare.org/publications),
- Education (http://www.cancercare.org/connect_workshops), and
- Financial assistance (http://www.cancercare.org/financial) with treatment-related expenses such as transportation and childcare.

How to Apply:

You can apply on behalf of your patient online through our PORTAL site (http://portal.cancercarecopay.org/). To apply by phone, call 866-55-COPAY (866-552-6729) to speak with a co-payment specialist. They will determine if your patient is eligible for assistance. Office hours are 9 a.m. – 7 p.m. (EST) Monday through Thursday, and 9 a.m. to 5 p.m. (EST) on Friday. You'll need to have the following patient information available when you call or apply online:

- Name,
- Date of birth,
- Phone number,
- Primary mailing address,
- Social Security number,
- Number of dependents,
- Household income,
- Primary health insurance provider, and
- Diagnosis and product or medication.

CancerCare® Co-Payment Assistance Foundation
275 Seventh Avenue, 22nd Floor
New York, NY 10001
866-55-COPAY (866-552-6729)
Fax: 212-601-9762

Note: Information is subject to change. Please refer to the website for the most recent updates. Created 5/19/2015; Updated 6/23/21

This fact sheet is provided as an example of financial resources that might be available for those seeking assistance with the expense of care and treatment of cancer. References to products, services, companies, private individuals, or trademarks does not constitute endorsement, recommendation, or guarantee by the NC Department of Health and Human Services. Other resources may be available, and it is up to the individual to discover and use resources they deem appropriate for their particular circumstances.

Patient Advocate Foundation

PAF Patient Advocate Foundation

Solving Insurance and Healthcare Access Problems | since 1996

421 Butler Farm Road | Hampton, VA 23666
800.532.5274 | patientadvocate.org
Se Habla Español

Patient Advocate Foundation CO-PAY RELIEF

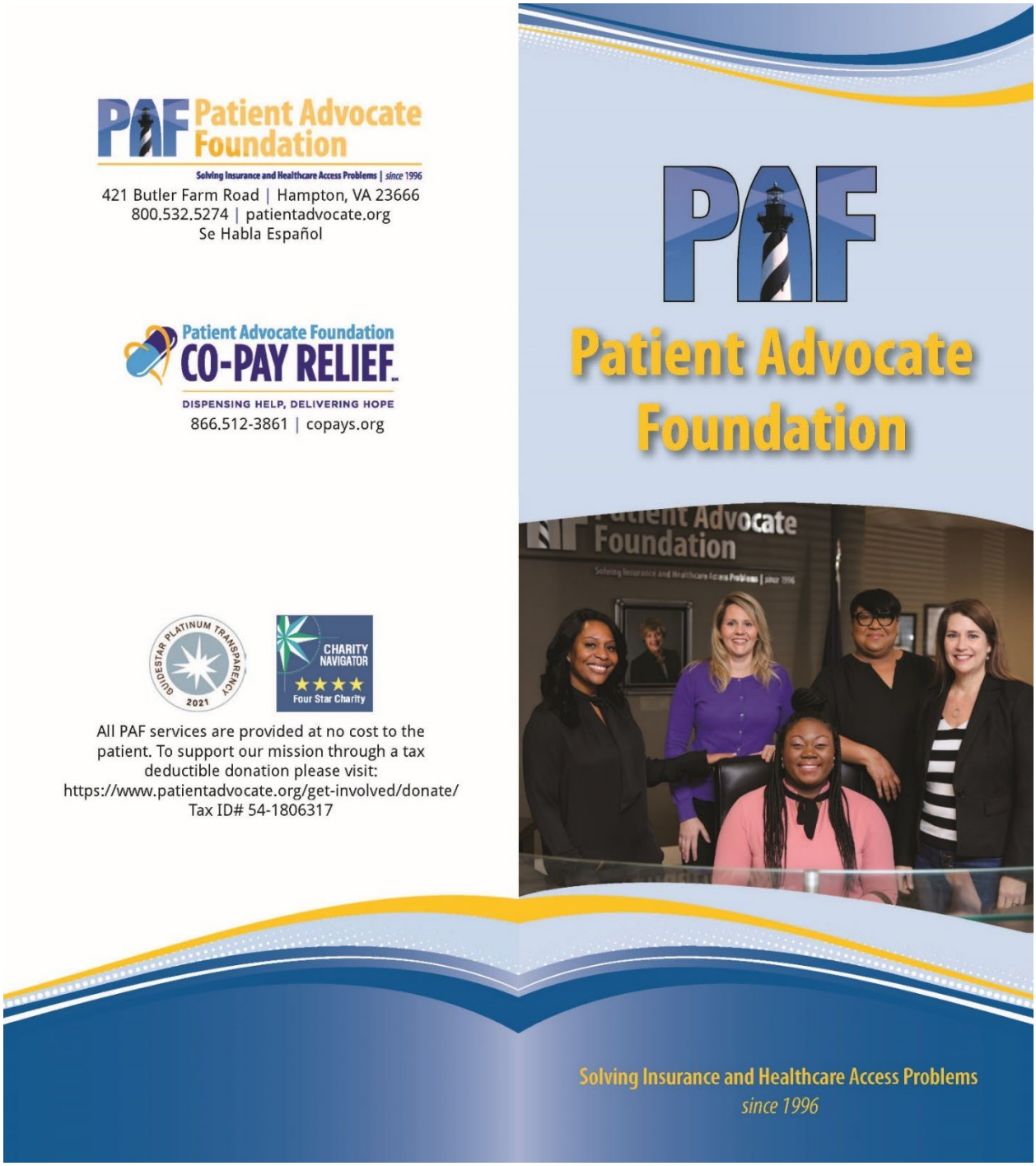
DISPENSING HELP, DELIVERING HOPE

866.512-3861 | copays.org

GUIDESTAR PLATINUM TRANSPARENCY 2021

CHARITY NAVIGATOR ★★★★ Four Star Charity

All PAF services are provided at no cost to the patient. To support our mission through a tax deductible donation please visit:
https://www.patientadvocate.org/get-involved/donate/
Tax ID# 54-1806317



Our Commitment to Assist

Patient Advocate Foundation (PAF) is a national 501(c)3 non-profit organization which provides case management services and financial aid to Americans with chronic, life-threatening and debilitating illnesses.

How We Help...

Delivering effective, compassionate **Case Management** assistance to patients is at the heart of our mission. Our dedicated case managers can help you get the care you need, connect you to community support, and even help you get financial assistance. We can help with:

- Insurance navigation, education, appeals and prior authorizations
- Debt crisis issues related to out-of-pocket medical or cost-of-living expenses
- Screening and enrollment in available safety net programs.

"Because of my case manager's persistence, we were able to get to the bottom of things and get a [large] discount on the cost of rehabilitation. This was no small feat and required her expertise in several areas. She was polite and reasonable but asked the appropriate questions. I could not have done this without her help. Thank you."

Tony, stroke

PAF's **Co-Pay Relief (CPR)** program provides direct financial assistance to qualified patients with co-payments, co-insurance and deductibles required by the patient's insurer for any medications prescribed to treat and/or manage their disease, and for medical insurance premiums in some disease funds. CPR offers:

- Immediate eligibility decision
- Multiple payment methods including virtual pharmacy cards
- Best in class service and compliance

"Without the support of the Co-Pay Relief program I would not have been able to get the medication I needed. My life would have ended 1½ years ago. "Thank you" cannot express my gratefulness."

David, Multiple Myeloma

Our **Financial Aid Funds** provide small grants to low-income patients for a broad range of support needs. We also partner with other non-profit organizations to manage the administration of their financial aid programs. These programs help with non-medical expenses, including transportation, housing, short-term lodging, utilities and nutritional needs.

PAF's **Education and Interactive Training Initiatives** deliver actionable guidance and expert advice on healthcare topics in a variety of formats, with content that is relevant to all audiences, including patients, caregivers, healthcare professionals and those that are currently healthy. Tools include:

- National Financial Resource Directory
- Interactive training modules
- Educational Resource Library
- COVID Care Resource Center

Health Services Research focuses on understanding the patient experience and priorities of care, evaluating the impacts that cost, social determinants and health policy have on access, treatment choices and outcomes.

Call 1-800-532-5274 to connect with our services.

Additional Resources Outside of NC BCCCP

1. American Cancer Society – www.cancer.org or call 1-800-227-2345
2. Another Brown Face – psychological and emotional support – call 919-884-6388
3. The AstraZeneca Foundation Patient Assistance Program provides therapies free of charge to those who could not otherwise afford them. Contact the AstraZeneca Cancer Support Network at 1-866-99 AZ CSN or 1-866-992-9276 or – https://www.rxhope.com/PAP/info/PAPList.aspx?programid=1662&fieldType=programid
4. Breast Cancer Research Foundation – www.bcrfcure.org or call 1-866-FIND-A-CURE (1-866-346-3228)
5. BreastCancerTrials.org – www.breastcancertrials.org or call 1-888-282-7099
6. Partners in Care (239) 936-3756 – Partners in Care (yourpartnersincare.org)
7. Hadassah – www.hadassah.org
8. Helene Foundation (919) 280-7800 – https://www.helenefoundation.org/referrals
9. Hope Abounds (910) 799-7178 – https://www.hopeabounds.org/get-help
10. Living Beyond Beast Cancer – www.lbbc.org or call 1-855-807-6386
11. Lump to Laughter – https://lumptolaughter.org/
12. The Male with Breast Cancer Coalition – https://malebreastcancercoalition.org
13. Merck & Co., Inc. has a drug assistance program. Visit www.merckhelps.com or call 1-800-727-5400 for more information about the program and enrollment forms.
14. Metastatic Breast Cancer Network – www.mbcn.org or call 1-888-500-3070
15. Novartis has a drug assistance program. Call 1-888-669-6682 or visit https://www.patientassistancenow.com/index.jsp.
16. One Up on Cancer – https://www.1uponcancer.org/help/
17. Contact the NC Women's and Children's Health Section to find out if the patient qualifies for the medically needy program at 1-919-707-5510.
18. To find out if patients qualify for assistance, contact Disability Determination Services – www.ncdhhs.gov/assistance/disability-services/disability-determination-services.
19. Pretty in Pink Foundation – www.prettyinpinkfoundation.org or call 1-919-532-0532
20. Redes en Accion – The National Latino Cancer Research Network – call 1-210-562-6500 or https://redesenaccion.com/.
21. SHARE – www.sharecancersupport.org or call 1-844-ASK-SHARE (1-844-275-7427)

22. Sharsheret: Your Jewish Community Facing Breast Cancer – www.sharsheret.org or 1-866-474-2774
23. The Sister Study (Estudio de Hermanas) – www.sisterstudy.niehs.nih.gov or call 1-877-4SISTER (1-877-474-7837)
24. Susan G. Komen® Breast Cancer Foundation. Visit https://www.komen.org **Error! Hyperlink reference not valid.**or call 1-877 GO KOMEN (1-877-465-6636)
25. Tigerlily Foundation – www.tigerlilyfoundation.org or call 1-888-580-6253
26. Triple Negative Breast Cancer Foundation® – www.tnbcfoundation.org/helpline/ or call 1-877-880-TNBC (1-877-880-8622)
27. Young Survival Coalition – www.youngsurvival.org or call 1-877-972-1011 or 1-866-474-2774

TAB 12: Appendix F

APPENDIX F: Breast Cancer Staging

Women who are diagnosed with breast cancer will be assigned a stage of disease by the specialist who makes the diagnosis. Although it will not be necessary for providers in local health departments to assign a stage to a patient's cancer, understanding the staging system might be helpful in interpreting correspondence from oncologists or breast surgeons.

The TNM Classification for Breast Cancer
Based on the AJCC Cancer Staging Manual 8th edition

Staging is a way of describing where the cancer is located, how much the cancer has grown, and if or where it has spread. Doctors use diagnostic tests to find out the cancer's stage, so staging may not be complete until all the tests are finished. Knowing the stage helps the doctor to decide what kind of treatment is best and can help predict a patient's prognosis, which is the chance of recovery.

The eighth edition of the American Joint Committee on Cancer (AJCC) staging manual, effective January 1, 2018, outlines a new prognostic staging system that relies not only on the anatomic extent of disease, but also on prognostic biomarkers. A clinical prognostic stage table for use in all patients has been developed, based on history, physical examination, imaging studies if performed, and relevant biopsies. It incorporates T, N, M, and tumor grade; and human epidermal growth factor receptor 2 (HER2), estrogen receptor (ER), and progesterone receptor (PR) status. For those who undergo surgical resection as their initial treatment (before receipt of any systemic or radiation therapy), a pathologic prognostic table has been developed and assigns stage based on all clinical information, biomarker data, and findings from surgery and resected tissue.
In areas in which biomarker testing is performed, prognostic stage groups should be utilized. Although the prognostic staging system provides refined information regarding outcomes, the anatomic staging was retained to allow a common lexicon for patients treated worldwide who may not have access to biomarker testing. Additionally, the anatomic staging system provides a link to cases treated historically, staged using previous editions of the TNM system. Adding information about tumor grade, hormone-receptor status, HER2 status, and possibly Oncotype DX test results has made determining the stage of a breast cancer more complex, but also more accurate.

AJCC Cancer Staging Manual 8th ed. 2017, Corr. 3rd printing 2018 Edition
By Mahul B. Amin (Editor), Stephen B. Edge (Editor), Frederick L. Greene (Editor), David R. Byrd (Editor), Robert K. Brookland (Editor), Mary Kay Washington (Editor), Jeffrey E. Gershenwald (Editor), Carolyn C. Compton (Editor), Kenneth R. Hess (Editor), Daniel C. Sullivan (Editor), J. Milburn Jessup (Editor), James D. Brierley (Editor), Lauri E. Gaspar (Editor), Richard L. Schilsky (Editor), Charles M. Balch (Editor), David P. Winchester (Editor), Elliot A. Asare (Editor), Martin Madera (Editor), Donna M. Gress (Editor), Laura R. Meyer (Editor)

Additional Resources

1. https://www.uptodate.com/contents/tumor-node-metastasis-tnm-staging-classification-for-breast-cancer
2. https://pubs.rsna.org/doi/full/10.1148/rg.2018180056
3. https://www.cancer.org/content/dam/CRC/PDF/Public/8580.00.pdf

TAB 13: Appendix G

APPENDIX G: Breast Density

North Carolina requires all health care facilities that perform mammography examinations to include information about the patient's individual breast density in the summary of the report.

The American College of Radiology's BI-RADS® reporting of breast composition describes the proportion of fatty tissue to fibroglandular tissue as one of four categories:

1. The breast is almost entirely fat.
2. There are scattered fibroglandular densities.
3. The breast tissue is heterogeneously dense, which could obscure detection of small masses.
4. The breast tissue is extremely dense. This may lower the sensitivity of mammography.

Categories 3 (heterogeneously dense) and 4 (extremely dense) are considered "dense breasts."

Breast density describes the amount of normal fibrous and glandular tissue in proportion to normal fatty tissue. Breasts are considered mammographically dense if a patient has a more fibrous or glandular tissue than breast fat.

As many as 50% of women in the U.S. have dense breast tissue and the other half have non-dense tissue (more fatty tissue). Of those women with dense breast tissue, 10% have extremely dense breast tissue.

Dense breast tissue may make it more difficult for radiologists to detect cancer on mammograms. Normal dense tissue, cancer, and benign masses may all appear white on the mammogram. This accounts for the phenomenon called masking. The cancer/benign lesion is obscured by the normal surrounding breast tissue. Hence, the sensitivity of mammography is reduced by 10-20%, making screening mammograms less precise in women with dense breasts.

The recommendations for mammography are the same for women with dense breasts as non-dense breast women. Many cancers are still detected on mammograms even if the patient has dense breast tissue.

A mammogram is the only screening test that has demonstrated a reduction in breast cancer deaths. There is no recommendation that it be replaced with another screening test at the current time.

If a patient has dense breast tissue and is interested in additional screening options, a breast cancer risk assessment may be useful. This will allow a discussion of whether supplemental tests will be helpful, and if so, what tests to order.

Screening breast MRI (magnetic resonance imaging) in HIGH-RISK patients (>20% lifetime risk of developing breast cancer) has been shown to increase the cancer detection rate. It is recommended by the American Cancer Society for high-risk patients in addition to a yearly screening mammogram.

For patients at INTERMEDIATE RISK (15-20% lifetime risk), such as those with a personal history of breast cancer or a prior biopsy with a diagnosis of atypia, the American Cancer Society reports that there is not enough data at the current time to recommend an MRI in these patients. However, a patient-centered shared decision-making approach is recommended, and it should be discussed with the patient that the additional test may detect other findings (non-cancers/false positives) that may lead to follow-up testing or biopsy.

The data on screening ultrasound is limited; therefore, there is no formal approval from the radiology community at the current time. Screening breast ultrasound is now offered at many centers. The patient must be made aware that if she chooses to have ultrasound screening for dense breasts with no other abnormal finding, she will be charged additional out of pocket expenses.

Breast tomosynthesis (3D mammography) expands the technology of conventional mammography. Some centers are currently using it in addition to screening mammography since preliminary results on its performance are positive. However, we do not know how well tomosynthesis performs in women with extremely dense breasts. At the current time, your patient must be made aware that if she chooses to have breast tomosynthesis screening for dense breasts with no other abnormal finding, she will be charged additional out of pocket expenses.

Insurance coverage for any supplemental breast cancer screening tests is not mandated in North Carolina. Screening breast MRI may be covered by insurance for HIGH-RISK women, but not for the average risk patient. Consequently, women who want other types of screening may be asked to pay out of pocket.

Please visit this website for more information:

> **Error! Hyperlink reference not valid.**https://www.ncacr.org/index.php/advocacy/public-awareness/breast-health

Please visit the website link to assist in utilizing the AJCC Cancer Staging Manual, 8th edition:

> https://slideplayer.com/slide/12705983/

NOTE: NC BCCCP does **not** pay for screening with ultrasound or MRI as adjunct screening solely for the finding of dense breasts. Under certain rare circumstances, an MRI may be performed and paid for through NC BCCCP **only if preauthorized**.

TAB 14: Appendix H

APPENDIX H: UNDERSTANDING GENETIC RISK FOR BREAST CANCER

How genes affect cancer risk.

Cancer is a disease of abnormal gene function. Genes contain the instructions on how to make proteins the body needs to function, when to destroy damaged cells, and how to keep the cells in balance. Genes control things such as hair color, eye color, and height. They can also affect a person's chance of getting certain diseases, such as breast cancer.

Every cell in the body has all the genes a person was born with, but different types of cells may use different genes. For example, muscle cells use a different set of genes than skin cells. The genes that the cell is using are activated or turned on, while the genes that the cell doesn't need are turned off and not used.

An abnormal change in a gene is called a mutation. The 2 types of mutations are inherited and acquired (somatic).

- An inherited gene mutation is present in the egg or sperm that formed the child. After the egg is fertilized by the sperm, it created one cell called a zygote that divided to create a fetus (which became a baby). Since all the cells in the body came from this first cell, these kinds of mutations are in every cell in the body (including eggs or sperm) and so can be passed on to the next generation.
- An acquired (somatic) mutation is not present in the zygote, but is acquired some time later. It occurs in one cell, and then is passed on to any new cells that are the offspring of that cell. This kind of mutation is not present in the egg or sperm and cannot be passed on to the next generation. Somatic mutations are much more common than inherited mutations. Most cancers are caused by acquired mutations.

All people have 2 copies of most genes – one from each parent. When someone has inherited an abnormal copy of a gene, their cells already start out with one mutation. If the other copy of the gene stops working (because of an acquired mutation, for example), the gene can stop functioning altogether. When the gene that stops working is a cancer susceptibility gene, cancer can develop. Some cancer susceptibility genes function as tumor suppressor genes. Tumor suppressor genes are normal genes that slow down cell division, repair DNA mistakes, or tell cells when to die (a process known as apoptosis or programmed cell death). When tumor suppressor genes do not work properly, cells can grow out of control, which can lead to cancer. Many family cancer syndromes are caused by inherited defects of tumor suppressor genes.

- **Genes and Cancer** – https://www.cancer.org/cancer/cancer-causes/genetics/genes-and-cancer.html

- **Family Cancer Syndromes** – http://www.cancer.org/cancer/cancercauses/geneticsandcancer/heredity-and-cancer.
- **Understanding Genetic Testing for Cancer** – https://www.cancer.org/cancer/cancer-causes/genetics/genetic-testing-for-cancer-risk/understanding-genetic-testing-for-cancer.html
- **What Happens During Genetic Testing for Cancer Risk?** – https://www.cancer.org/cancer/cancer-causes/genetics/what-happens-during-genetic-testing-for-cancer.html
- **Understanding Genetic Testing for Cancer** – https://www.cancer.org/cancer/cancer-causes/genetics/genetic-testing-for-cancer-risk/understanding-genetic-testing-for-cancer.html
- **Should I Get Genetic Testing for Cancer Risk?** – https://www.cancer.org/cancer/cancer-causes/genetics/genetic-testing-for-cancer-risk/should-i-get-genetic-testing-for-cancer-risk.html

NOTE: NC BCCCP does **not** currently pay for Genetic Testing. Please contact your NC BCCCP Nurse Consultant if you have questions.

TAB 15: Appendix I

APPENDIX I: STAFF DIRECTORIES

NC Department of Health and Human Services / Division of Public Health
Chronic Disease and Injury Section
NC Cancer Prevention and Control Branch
Physical Location: 5505 Six Forks Rd, 1st Floor, Raleigh, NC 27609
Mailing Address: 1922 Mail Service Center, Raleigh, NC 27699-1922
Fax Number: (919) 870-4812
Main Number: (919) 707-5300

STAFF	Position	Phone and email
Breast and Cervical Cancer Control Program		
Debi Nelson, MAEd,	Branch Manager Cancer Prevention	O: 919-707-5155 C: 919-218-2585 debi.nelson@dhhs.nc.gov
Vacant	Operations Supervisor	
Cushanta Horton, MPH	Epidemiologist	O: 919-707-5312 cushanta.horton@dhhs.nc.gov
Vacant	Evaluator, BCCCP & Comp. Cancer	O: 919-707-5339
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TAB 16: Appendix J

Appendix J: REFERENCES

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