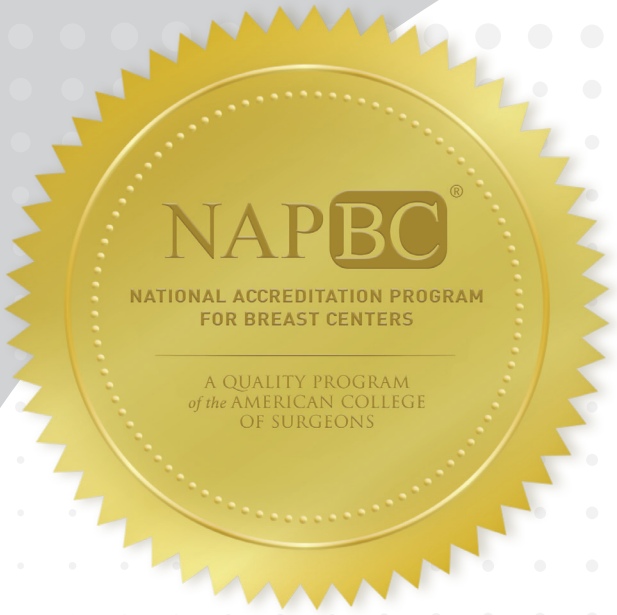

National Accreditation Program For Breast Centers

Standards Manual

2018 EDITION

ACCREDITATION *makes a difference*

American College of Surgeons
Inspiring Quality:
Highest Standards, Better Outcomes
100+years

Table of Contents

NAPBC®
NATIONAL ACCREDITATION PROGRAM FOR BREAST CENTERS

A QUALITY PROGRAM *of the* AMERICAN COLLEGE OF SURGEONS

Disclaimer

The *National Accreditation Program for Breast Centers Standards Manual* is intended as an instructive tool to assist health care providers and institutions in improving the care of patients with breast disease. It is not intended to replace the professional judgment of the physician, health care provider, or health care administrator in individual circumstances. The American College of Surgeons and the National Accreditation Program for Breast Centers cannot accept, and expressly disclaim, liability for claims arising from the use of this work.

Acknowledgments

ACKNOWLEDGMENT OF CONTRIBUTORS

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Specifically, the NAPBC acknowledges the many contributions of the members of the Standards and Accreditation Committee who were vital to the creation of the *2018 National Accreditation Program for Breast Centers Standards Manual*.

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The National Accreditation Program for Breast Centers (NAPBC)

NAPBC MISSION STATEMENT

The National Accreditation Program for Breast Centers (NAPBC) is a consortium of national, professional organizations focused on breast health and dedicated to the improvement of quality outcomes of patients with diseases of the breast through evidence-based standards and patient and professional education.

NAPBC BACKGROUND AND THE VALUE OF ACCREDITATION

The evaluation and management of patients with diseases of the breast historically occurred in a fragmented, disorganized setting. In this complex environment patients are best managed through multidisciplinary coordination. This team approach resulted in the birth of the breast center concept in the United States in the 1970s. In the past three to four decades there has been a proliferation of breast centers to accommodate the thousands of women diagnosed with breast cancer, as well as addressing the equally compelling needs of the many women presenting with non-malignant breast diseases.

Evidence-based and consensus-developed standards have gained increasing importance and recognition.

The United States health care system is undergoing a dramatic transformation centered on quality measurement and improvement and documentation of adherence to broadly accepted standards of care for all diseases including those of the breast. No other organization has established standards for the evaluation and management of patients with diseases of the breast or a survey process to monitor compliance. In order to improve the quality of evaluation and management of patients, the NAPBC accredits established breast centers. It recognizes that, in the United States, breast care is delivered in heterogeneous settings. The accreditation program is designed to be inclusive. Accreditation is awarded to academic medical centers, teaching hospitals, hospitals, freestanding centers, and private practices provided the NAPBC standards are met.

NAPBC-accredited centers demonstrate the following services:

- A multidisciplinary team approach to coordinate the best care and treatment options available
- Access to breast-specific information, education, and support
- Breast center data collection on quality indicators for subspecialties involved in breast cancer diagnosis and treatment
- Ongoing monitoring and improvement of care
- Information about participation in clinical trials and new treatment options

NAPBC BOARD MEMBER ORGANIZATIONS

- American Cancer Society
- American College of Radiology Commission on Breast Imaging
- American College of Radiology Imaging Network
- American College of Surgeons
- American Institute of Radiologic Pathology
- American Society of Breast Surgeons
- American Society of Clinical Oncology
- American Society of Plastic Surgeons
- American Society for Radiation Oncology
- Association of Cancer Executives
- Association of Oncology Social Work
- College of American Pathologists
- National Cancer Registrars Association
- National Consortium of Breast Centers
- National Society of Genetic Counselors
- Oncology Nursing Society
- Society of Breast Imaging
- Society of Surgical Oncology

BENEFITS OF BECOMING AN NAPBC-ACCREDITED CENTER

Accreditation by the NAPBC provides many notable benefits that will enhance a breast center and its quality of patient care.

NAPBC-accredited breast centers receive the following:

- A model for organizing and managing a breast center to ensure multidisciplinary, integrated, and comprehensive breast care services
- Internal and external assessment of breast center performance based on recognized standards to demonstrate a commitment to quality care
- Recognition as having met performance measures for high-quality breast care established by national health care organizations
- National recognition and public promotion
- Participation in a National Breast Disease Database to report patterns of care and effect quality improvement *(in development)*
- Access to breast center comparison benchmark reports containing national aggregate data and individual center data to assess patterns of care and outcomes relative to national norms *(in development)*

The Accreditation Process

ACCREDITATION CYCLE

The initial site visit date establishes the accreditation cycle. After initial accreditation, the re-accreditation site visit occurs once every three (3) years.

THE ANNUAL ACCREDITATION FEE

For centers seeking initial accreditation with the NAPBC, an invoice will be issued to the breast center for the annual accreditation fee, after approval of the initial accreditation application.

For re-accrediting centers, an invoice for the annual NAPBC accreditation fee is e-mailed to the breast center billing contact each year, approximately sixty (60) days prior to the center's accreditation due month.

Payment of the annual accreditation fee is due within thirty (30) days of the date of the invoice.

Failure to pay the annual accreditation fee may result in suspension of accreditation.

ACCREDITATION RESOURCES FOR CENTERS

A full list of accreditation resources is available on the NAPBC webpage, ***napbc-breast.org***.

INITIAL ACCREDITATION

All centers seeking accreditation for the first time must submit an application through the NAPBC Center Portal. Within thirty (30) days of submission of the application, or as soon as practical thereafter, the primary contact listed will be notified of approval or if additional information is required.

After approval of the application and completion of all required agreements, the breast center must complete the Center Profile in the NAPBC Center Portal.

One component of determining whether NAPBC accreditation will be awarded to a breast center is the site visit. The initial NAPBC site visit occurs after the applying center attests that the NAPBC standards have been in place and complied with in the center for twelve (12) months.

In preparation for accreditation, the center must:

1. Assess and demonstrate compliance with the requirements for all standards outlined in *National Accreditation Program for Breast Centers Standards Manual*
2. Submit payment for the annual accreditation fee
3. Confirm the site visit date with the assigned surveyor
4. Complete and upload required documentation to the Survey Application Record (SAR)

Centers are notified of their assigned NAPBC surveyors by e-mail.

Note: the site visit does not count as one of the required Breast Program Leadership Committee (BPLC) meetings.

REQUIRED DOCUMENTATION

All documentation demonstrating compliance with the NAPBC standards, excluding patient medical records, must be uploaded and completed in the SAR.

THE SITE VISIT

In preparation for the site visit, the SAR must be submitted no later than thirty (30) calendar days before the site visit.

The surveyor's role is to verify whether the breast center is in compliance with the NAPBC standards. On the day of the site visit, the surveyor will:

- Present information to key members of the center's leadership on the NAPBC
- Meet with the BPLC to discuss the activities and responsibilities of its members and to verify the accuracy of the data and documentation submitted
- Attend a Breast Conference to observe the center's multidisciplinary patient management and discussions
- Meet with the Breast Program Director to discuss the Director's roles and responsibilities
- Conduct a medical records review as outlined in the standards
- Tour the center
- Conduct a summation to provide initial impressions on the breast center's strengths, areas in need of improvement, and provide a chance for the Breast Care Team (BCT) and BPLC members to ask and respond to any additional questions

It is recommended that all members of the BPLC attend and participate in the site visit. At a minimum, the surveyor must meet with the following people:

- Administrators with fiduciary and administrative oversight of the center
- Key clinician leaders
- Breast Program Director

MEDICAL RECORDS REVIEW

Many NAPBC standards require a medical records review to ensure compliance with rating criteria. Compliance with these components of the rating criteria will be evaluated during the site visit, through the surveyor's medical records review of 20 patient medical records from the provided accession list. The percentage of medical records that meet the rating criteria will determine whether the breast center is in compliance with that aspect of the standard.

The breast center will provide the surveyor with an accession list of eligible cancer patients for the medical records review. No later than fourteen (14) calendar days before the site visit, the surveyor will inform the center of the selected, applicable medical records that will be reviewed.

In addition, the breast center will make available five (5) medical records, of their selection, of patients with non-malignant breast disorders, and five (5) additional medical records, of their selection, of patients with high risk lesions.

The medical records reviewed are not required to be deidentified. Review of the patient health information (PHI) is covered by the Business Associate Agreement (BAA) that the center signs at the time of application for accreditation.

THE POST-SURVEY EVALUATION

The Post-Survey Evaluation (PSE) is a required component of the NAPBC site visit. The PSE captures feedback from the breast center, which enables the NAPBC to evaluate and improve the site visit process. Feedback from the PSE also assists development of educational materials and training programs for both surveyors and participating centers.

All PSE responses are confidential and do not influence the NAPBC site visit results. Only one PSE is collected per center, therefore, responses on the evaluation form must represent a consensus opinion of the BPLC. The PSE must be completed within fourteen (14) calendars days of the site visit.

NOTIFICATION OF SITE VISIT RESULTS

A performance report, detailing the results of the breast center's site visit, will be available within forty-five (45) days of the site visit date, or as soon as practical thereafter. The Breast Program Director will receive an e-mail when the completed performance report is available.

The performance report provides the following:

- A summary of the site visit outcome and accreditation award
- The breast center's rating for each standard
- A narrative description for noncompliant standards
- Suggestions to improve or enhance the breast center

APPEALS

Centers may appeal a finding for any standard within forty-five (45) calendar days of the performance report notification. The appeals process is outlined in the Accreditation Decision Appeal Form on the NAPBC website.

DEFICIENCY RESOLUTION

A breast center that received one (1) to eight (8) deficiencies is required to complete the deficiency resolution process. The deficiency resolution process begins on the site visit date and ends twelve (12) months after the site visit date. A program that fails to resolve deficiencies within the allotted time are at risk of having accreditation withdrawn.

CERTIFICATES, MARKETING, AND VISIBILITY

Centers that are awarded Three Year Full accreditation and Three Year accreditation with deficiency, can order one (1) complimentary Certificate of Accreditation. Additional copies are available for purchase. Certificate information is on the marketing resources webpage. The link is provided in the performance report cover letter.

In addition to displaying the Certificate of Accreditation, the NAPBC encourages breast centers to use the marketing tools provided on the marketing resources webpage, to promote the value of NAPBC accreditation to patients, families, and the community. The marketing tools include an NAPBC-accredited center logo, patient brochures, event posters (for example, Breast Cancer Awareness), and more. A link to the marketing resources webpage will be provided to the breast center in the performance report cover letter, if the center achieves full accreditation.

Centers that are awarded full accreditation are listed on the NAPBC-accredited center locator. The locator is an online search engine for patients to find an accredited center. Listings on the locator include the center name, location, website, description, and an image of the breast center. Breast center profiles can be edited in the General Center Information section of the NAPBC Center Portal.

SITE VISIT POSTPONEMENT AND CANCELLATIONS

When extenuating circumstances affect center activity, a site visit postponement may be appropriate. Postponements are granted on a case-by-case basis, with a maximum postponement being six (6) months.

Valid extenuating circumstances that may warrant a site visit postponement include, but are not limited to:

- Natural disasters (for example, hurricane, earthquake, tornado, flood) that directly affect the center
- Anthropogenic hazards (for example, fire, industrial accidents) that directly affect the center

Examples of circumstances that do not warrant a site visit postponement include, but are not limited to:

- Software conversion or IT issues
- Staff absences, turnovers, or resignations
- Delayed abstracting or missing data
- Standard deficiencies

The Breast Program Director must submit a formal request for a postponement via e-mail to NAPBC@facs.org. The request must include specifics regarding the rationale for the request, a proposed plan, and a timeline to resolve the issues necessitating the postponement request. The center will be notified of the postponement request decision as soon as practical, following receipt of the written request.

Centers are discouraged from canceling the scheduled site visit. However, if site visit cancellation becomes necessary after the site visit date is confirmed, the breast center must submit a written notification to NAPBC@facs.org. The center will be invoiced for a cancellation fee and any non-refundable travel expenses incurred by the surveyor.

Accreditation Information

Ratings for each standard are assigned based on a consensus by the NAPBC Surveyor and an NAPBC Technical Reviewer. When required, the applicable review subcommittee will also contribute to the standard rating decision, as a final adjudicator.

CRITICAL STANDARDS

Three (3) standards are considered critical standards. The breast center must be in compliance with the following standards at the time of the site visit in order to receive NAPBC Accreditation:

- Standard 1.1: Level of Responsibility and Accountability
- Standard 1.2: Multidisciplinary Breast Cancer Conference
- Standard 2.1: Multidisciplinary Patient Management

ACCREDITATION AWARDS AND RATING SYSTEM

Based on the rating criteria specified for each standard a "Compliant," or "Noncompliant," rating is assigned. Any standard with a "Noncompliant" rating is a "deficiency."

Accreditation awards are determined by the number of noncompliant ratings the breast center receives. Following the site visit, a center receives one of the three Accreditation Awards.

Three Year Accreditation is conferred to a center that receives a "Compliant" rating for all standards at the time of the site visit. A certificate of accreditation is issued.

Three Year Accreditation with Deficiency is conferred to a center when one (1) to three (3) of the standards are rated "Noncompliant" at the time of the site visit. Deficiency resolution documentation must be submitted within 12 months of the date of the site visit. A certificate of accreditation is issued.

Three Year Contingency Accreditation is conferred to a center when four (4) to eight (8) standards are rated "Noncompliant" at the time of the site visit. Deficiency resolution documentation must be submitted within twelve (12) months of the date of the site visit. A center that does not resolve its deficiencies within the allotted timeframe is at risk of having its accreditation status discontinued. A certificate of accreditation is only issued after resolution of all deficiencies.

Accreditation Deferred is conferred to a center when one (1) or more of the critical standards is rated "Noncompliant." Accreditation Deferred is also conferred to a center that receives a "Noncompliant" rating for nine (9) or more standards. When applicable, NAPBC staff will work directly with the center to assist with deficiency resolution, so accreditation may be reinstated. The deferred status is resolved by submission of documentation for compliance and/or an additional site visit within twelve (12) months. Centers can also choose to withdraw, improve their performance, and then reapply for accreditation as a new center. Note, new center application fees will apply when reapplying for accreditation.

Chapter One:
Center Leadership

Level of Responsibility and Accountability

STANDARD 1.1 The organizational structure of the breast center gives the Breast Program Director (BPD) and Breast Program Leadership Committee (BPLC) responsibility and accountability for provided services.

DEFINITION AND REQUIREMENTS

Breast Program Director
There must be a single Breast Program Director with authority and accountability for the operation of the breast center.

Breast Program Leadership Committee
The Breast Program Leadership Committee (BPLC) is the governing body of the breast center and is chaired by the BPD. There must be a core group of health care professionals from different disciplines who contribute to the policies and procedures of the center. BPLC member disciplines include, but are not limited to, pathology, radiology, surgery, medical oncology, radiation oncology, reconstruction, research, nursing, social work, hospital administration, and other members when probable and as deemed necessary by the BPD.
To ensure all decisions of the BPLC include the voice of the patients we serve, it is recommended that a community representative and/or patient representative be a full member of the BPLC.

Requirements for BPLC membership:

- The physician committee members have current specialty board certification in their area of specialty or be in the process of obtaining board certification as applicable
- The physician committee members possess current medical licensure and appropriate active medical staff appointment
- The non-physician committee members have appropriate qualifications/certifications in their field and hold appropriate breast program relationships and accountability as outlined in the applicable standards
- The committee members establish and maintain an environment of professional development and scholarship
- The committee members regularly participate in organized clinical discussions, journal clubs, and conferences

The BPD and the BPLC are responsible for goal setting, as well as planning, initiating, implementing, evaluating, and improving all breast-related activities in the center.

Breast Care Team
The breast center must have a designated Breast Care Team (BCT). The BCT includes health care professionals who contribute to the active assessment, treatment, and/or dissemination of information to a breast center patient, including pathologists, radiologists, surgeons, medical oncologists, radiation oncologists, cancer registrars, physician assistants, radiology technologists, registered nurses, licensed practical nurses, nurse practitioners, genetic counselors, patient navigators, social workers, and other members deemed necessary by the BPLC.

Requirements for BCT membership:

- Have appropriate qualifications/certifications/registrations in their field
- Collaborate and develop a treatment plan that will lead to the best possible quality outcome for the breast disease patient
- Provide patient care in accordance with institutional policies and in compliance with National Accreditation Program for Breast Centers (NAPBC) Standards
- Attend the multidisciplinary conference as appropriate
- Participate in annual continuing education sessions in compliance with NAPBC requirements

All professionally credentialed members of the BCT must have appropriate certification.

All physician team members are required to be board certified or in the process of obtaining board certification.

Other Program Personnel
The program must ensure the availability of all necessary administrative personnel for the effective administration of the program. Some examples include, but are not limited to:

- Chief executive office/dean
- Center/hospital administration
- Marketing director
- Administrative assistants
- Data analysts

PROCESS REQUIREMENTS

Breast center or medical staff office process requirements:
The breast center or medical staff formally establishes the responsibility, accountability, and multidisciplinary membership required for the BPLC to fulfill its role.

The center documents the BPD's and the BPLC's responsibility and accountability using a method appropriate to the center's organizational structure.

Examples include, but are not limited to:

- The center bylaws designate the BPLC as a subcommittee of the cancer committee within a larger institution with authority defined
- The medical staff bylaws designate the BPLC to be a standing committee with authority defined
- Policies and procedures for the center define authority of the BPD and the BPLC
- Policies and procedures for the medical staff define the authority of the BPD and the BPLC

The breast center must have a defined multidisciplinary Breast Care Team with a minimum of one appointed physician member from each of the following specialties: surgery, pathology, radiology, medical oncology, and radiation oncology.

BPD process requirements:

- Be familiar with and comply with NAPBC site visit policies and procedures as outlined in the NAPBC Standards Manual
- Designate an individual to prepare and submit all information required and requested by the NAPBC (including program changes/requests), and ensure that the information submitted is accurate and complete. This information includes, but is not limited to:
    - Program application forms
    - Annual program updates
    - Center name updates/changes
    - Satellite site information
    - Change of Breast Program Director
    - Voluntary withdrawal
    - Deficiency resolution
    - Appeals
- Oversee and monitor compliance with the NAPBC Standards, including all participating satellite centers
- Ensure the medical staff bylaws, policies, and regulations designate and define the BPLC authority and reporting accountability
- Approve the selection of BCT members as appropriate, and confirm that all professionally credentialed members of the BCT have specialty certification
- Define the policies and procedures for the BCT and other breast program personnel
- Distribute policies and procedures to the BPLC and BCT

BPLC process requirements:

- Meet a minimum of four times per year
- In conjunction with the BPD, plan, develop, implement, and evaluate all activities of the breast center
- Oversee and monitor compliance with the NAPBC Standards, including all participating satellite centers
- Review all center data annually

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

Upload/describe the organizational structure of the breast center.

Complete and upload the Breast Care Team Worksheet.

Upload BPLC meeting minutes for the last three years.

Upload bylaws or policy and procedures, or other center-approved methods, used to document the level of responsibility and accountability designated to the BPD.

Complete and upload the BPLC annual audit template.

EVALUATION

The surveyor will discuss the organizational structure of the center and review and discuss all required documentation during the site visit

RATING COMPLIANCE

Compliance:

1. The organizational structure of the breast center gives the BPD and BPLC responsibility and accountability for provided breast center services.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

RESOURCES

NAPBC Accreditation Resources, *facs.org/quality-programs/napbc/accreditation/resources*

Multidisciplinary Breast Care Conference

STANDARD 1.2 The Breast Program Leadership Committee (BPLC) establishes, monitors, and evaluates the multidisciplinary breast care conference (MBCC) frequency, Breast Care Team (BCT) attendance, prospective and total annual case presentation, including American Joint Committee on Cancer (AJCC) staging, and discussion of nationally accepted guidelines.

DEFINITION AND REQUIREMENTS

Breast care conferences are integral to improving the care of breast disease patients by contributing to patient management and outcomes while providing education to physicians and other staff in attendance. Input should be encouraged from all BCT members.

The breast center must ensure the multidisciplinary breast care conferences are scheduled to permit attendance on a regular basis. Conferences must include prospective multidisciplinary case evaluation by the BCT.

This comprehensive approach allows the BCT to:

1. Promote inclusion of a broad range of physician and other specialists to address early diagnosis, quality of life, ethics, or other relevant topics
2. Improve patient care, promote effective management of resources, and make decisions which reflect the patient's goals for treatment
3. Discuss treatment options, including investigational therapy, for breast cancer patients to offer a collaborative recommendation

Monitoring of breast cancer conference activity by the BPLC, including multidisciplinary representation and individual attendance, ensures that conferences provide consultative services for patients as well as offer education to physicians and allied health professionals. The confidentiality of all information disclosed at these conferences is to be maintained by all participants.

The BPLC establishes and monitors individual BCT member attendance from surgery, medical oncology, and radiation oncology. Attendance by those individuals is no less than 50 percent (50%) of MBCCs held each calendar year. The BPLC may set higher rates.

A representative from both Pathology and Radiology must be present at all MBCCs. Individual attendance rates for radiologists and pathologists are set by the BPLC.

BCT Member	Attendance Rate
Surgeon **Medical Oncologist** **Radiation Oncologist**	Individuals attend no less than 50%* of MBCCs each calendar year (12 months). **BPLC can set higher rate*
Pathologist **Radiologist**	Each speciality is represented at all MBCCs. BPLC sets the individual attendance rate for each calendar year (12 months).

The MBCC is focused on treatment planning for newly diagnosed patients, patients who have treatment decisions to be made, and patients with recurrent breast cancer. Representation from surgery, medical oncology, radiation oncology, pathology, and radiology is required.

The MBCC includes:

1. A presentation of relevant history and physical elements, including family history
2. A discussion of stage, risk profile, surgical options/pre-surgical options
3. Visual display of pathology slides and radiology imaging and a discussion regarding radiology-pathology correlation
4. Discussion regarding clinical trials, genetics risk, and reconstructive options
5. Consideration of nationally recognized guidelines at the conference (for example, the National Comprehensive Cancer Network); these guidelines must be available for reference during the conference
6. An open discussion by all conference participants

Definition of Prospective case review:

- Newly diagnosed breast cancer and treatment not yet initiated
- Newly diagnosed breast cancer and treatment initiated, but discussion and additional treatment is needed
- Previously diagnosed, initial treatment completed, but discussion of adjuvant treatment or treatment recurrence or progression is needed
- Consideration for clinical trials
- Previously diagnosed and discussion of supportive or palliative care is needed

Analytic Case Load	Required MBCC Frequency	Case Presentation
100 cases or less	Every two weeks or twice monthly, or more frequently at the discretion of the BPLC. • Centers with fewer than 100 analytic breast cancer cases per year have the option of including these cases as part of a general cancer conference.	Eighty-five percent (85%) of cases reviewed must be prospective
101 – 250 cases	Every two weeks or twice monthly, or more frequently at the discretion of the BPLC.	Case presentation thresholds are determined by the BPLC.
251 + cases	Weekly	Case presentation thresholds are determined by the BPLC.

PROCESS REQUIREMENTS

The BPLC establishes and monitors the MBCC frequency.

The BPLC establishes and monitors specialty and individual member attendance requirements for the BCT.

The BPLC establishes and monitors a case presentation threshold for the MBCC.

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

Upload the breast center MBCC policy.

Upload a copy of the MBCC schedule/calendar from the last complete year, prior to the site visit date.

Complete and upload the NAPBC Multidisciplinary Breast Cancer Conference Attendance Tracking form.

EVALUATION

The surveyor will attend a breast cancer conference during the site visit, to observe the multidisciplinary involvement in case presentations.

RATING COMPLIANCE

Compliance:

1. The BPLC establishes, monitors, and evaluates the MBCC frequency, BCT attendance, prospective and total annual case presentation, including AJCC staging, and discussion of nationally accepted guidelines.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

Evaluation and Management Guidelines

STANDARD 1.3 The Breast Program Leadership Committee (BPLC) adopts evidence-based breast disease patient management and treatment guidelines. The guidelines are referenced by the Breast Care Team (BCT) during the multidisciplinary breast cancer conference (MBCC). These guidelines are used in patient care.

DEFINITION AND REQUIREMENTS

Patient management and treatment guidelines promote an organized approach to providing care. National organizations that have developed breast care guidelines include, but are not limited to:

- American Society of Clinical Oncology (ASCO)
- American Society for Radiation Oncology (ASTRO)
- National Comprehensive Cancer Network (NCCN)

Programs can also develop individual breast cancer guidelines.

Examples of referencing the guidelines include having web access, a PowerPoint presentation, or handouts available during the MBCC.

PROCESS REQUIREMENTS

The BPLC will implement breast disease management and treatment guidelines developed by national organizations appropriate to the patients who are diagnosed and treated by the center. Guidelines adopted by the BPLC are reviewed and documented in the BPLC meeting minutes annually.

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

EVALUATION

The surveyor will review patient medical records during the medical records review portion of the site visit to evaluate compliance with the patient management and treatment guidelines that have been identified by the BPLC, and ensure that these guidelines are referenced during the MBCC at the site visit.

RATING COMPLIANCE

Compliance:

1. The BPLC adopts evidence-based breast disease patient management and treatment guidelines.
2. The guidelines are referenced by the BCT during the MBCC.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

Chapter Two:
Clinical Services

Multidisciplinary Patient Management

STANDARD 2.1 Management of patients with breast disease is conducted by a multidisciplinary team.

DEFINITION AND REQUIREMENTS

The National Accreditation Program for Breast Centers (NAPBC) has identified 17 Breast Center Components, required for accreditation, in the spectrum of breast disease diagnosis, treatment, surveillance, and rehabilitation/support.

PROCESS REQUIREMENTS

The center must provide the 17 NAPBC Breast Center Components either at the center (on-site) or by referral.

The Breast Program Leadership Committee (BPLC) defines and implements the standard of practice (SOP)/policy and procedure for multidisciplinary patient evaluation and management.

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

Complete the Breast Center Components section of the NAPBC center portal indicating which services are provided on-site or by referral.

Upload the SOP/policy and procedure for multidisciplinary patient evaluation and management at your center.

EVALUATION

The surveyor will discuss the process for multidisciplinary patient management during the site visit. Multidisciplinary care will be confirmed during the medical records review.

RATING COMPLIANCE

Compliance:

1. The center provides all of the NAPBC breast center components at the center (on-site) or by referral.
2. Patient evaluation and management is conducted by a multidisciplinary team according to the BPLC SOP/policy and procedure.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

Patient Navigation

STANDARD 2.2 A patient navigation process is in place to guide the patient with a breast abnormality through provided and referred services.

DEFINITION AND REQUIREMENTS

Patient navigation refers to individualized assistance offered to patients, families, and caregivers to help overcome health care system barriers and facilitate timely access to quality health and psychosocial care throughout the continuum of care.

Breast disease patient navigation can and should take on different forms in different communities as dictated by the needs of the patient, his or her family, and the community.

The patient navigation process includes consistent care coordination throughout the continuum of care and an assessment of the physical, psychological, and social needs of the patient. The anticipated results are enhanced patient outcomes, increased satisfaction, and reduced costs of care. This process may involve different individuals at each point of care.

Examples of patient navigation include, but are not limited to:

- Providing education, support, and coordination to assist patients in securing appointments
- Providing educational resources on breast health, breast cancer, and breast care
- Connecting patients and families to resources and support services
- Promoting communication between the patient and health care providers
- Coordinating services throughout the continuum of care

Benefits of patient navigation include:

- Enhancing the patient's quality of life, sense of autonomy, and self-determination for managing his/her own health
- Reinforcing the physician-patient relationship
- Expediting care

PROCESS REQUIREMENTS

Patient navigation is provided by a professional (for example, nurse, social worker) who has documented training to provide individualized assistance to breast disease patients, families, and caregivers at risk.

If patient navigation is provided by a lay navigator, then he or she is required to have documented patient navigation training.

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

Upload documentation of training of patient navigator(s) into the SAR.

Identify the individual(s) who provide patient navigation in the center along with their qualifications and role.

EVALUATION

The surveyor will discuss the patient navigation process and will review the credential(s) and/or documentation of the individual(s) providing patient navigation during the site visit.

RATING COMPLIANCE

Compliance:

1. The breast center has a patient navigation process to guide patients with a breast abnormality from pre-diagnosis through provided and referred services.
2. Patient navigators are trained professionals or trained lay navigators.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

Breast Conservation

STANDARD 2.3 Breast-conserving surgery is offered to appropriate patients with breast cancer. A target rate of at least 50 percent of all eligible patients diagnosed with early-stage breast cancer (Stage 0, I, II) is treated with breast conserving surgery.

DEFINITION AND REQUIREMENTS

Breast-conserving surgery for patients with early-stage breast cancer is a nationally accepted standard of care in appropriately selected patients.

Patients are generally considered eligible for breast-conserving surgery if the tumor is localized and can be completely removed with negative margins, leaving a cosmetic result that is acceptable to the patient, and if they are candidates for radiation treatment.

Performance Measure
The NAPBC requires the Breast Program Leadership Committee (BPLC) to review the quality of patient care using the NAPBC-identified performance measures appropriate to the patients who are treated by the center each year.

Performance Measure
Breast-conservation surgery rate for women with American Joint Committee on Cancer (AJCC) Stage 0, I, or II breast cancer.

PROCESS REQUIREMENTS

Accession List and Data Review Requirements for the Site Visit
The center is required to provide a de-identified accession (case) list of breast cancer cases diagnosed and/or treated at the center (class of case 10–22) prior to the site visit date. Class of case is defined in the *Facility Oncology Registry Data Standards (FORDS)* manual.

Despite strong evidence supporting the safety of breast-conserving surgery for the treatment of early-stage breast cancer, an increasing number of women are opting for mastectomy. There appear to be regional differences in the patient's preference of operation, making a target rate for breast-conserving surgery difficult to apply across the country.

The BPLC evaluates the breast-conservation surgery rate for women with AJCC Stage 0, I, or II breast cancer, treated at the breast center, annually, and comments on whether the rate is appropriate and expected in their community. The BPLC should consider the influences that are driving the decision making and discuss approaches to understanding the driving forces.

Evidence of this monitoring activity will be documented in the BPLC meeting minutes, including action(s) taken to correct any identifiable performance issues.

Compliance is reviewed annually by the BPLC.

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

Document the annual audit by the BPLC in the meeting minutes. Include the calculation and discussion of the breast-conservation surgery rate for women with AJCC Stage 0, I, or II breast cancer.

EVALUATION

The surveyor will review patient medical records during the medical records review portion of the site visit to evaluate compliance with performance measure(s) and the use of breast-conserving surgery. If the breast-conserving surgery rate is below fifty percent (50%), the surveyor will review and determine if it is justified.

RATING COMPLIANCE

Compliance:

1. Breast-conserving surgery is offered to appropriate patients with breast cancer as evidenced by the medical records review.
2. A target rate of at least 50 percent of all eligible patients diagnosed with early-stage breast cancer (Stage 0, I, II) is treated with breast-conserving surgery.
3. The breast-conserving surgery rate is evaluated during the annual audit by the BPLC and documented in the meeting minutes.
4. Annual performance rates are reported for the breast-conservation surgery rate for women with AJCC Stage 0, I, or II breast cancer, and performance rates and action(s) taken to correct any identifiable performance issues are documented in the BPLC meeting minutes.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

RESOURCES

Society of Surgical Oncology (SSO)-American Society for Radiation Oncology (ASTRO) and SSO-ASTRO-American Society of Clinical Oncology (ASCO) Consensus Guidelines on Breast-Conserving Surgery, *https://www.astro.org/Clinical-Practice-Statements.aspx*

Sentinel Node Biopsy

STANDARD 2.4 Axillary sentinel lymph node biopsy is considered or performed for patients with early-stage breast cancer (Clinical Stage I, II).

DEFINITION AND REQUIREMENTS

Patients currently considered candidates for axillary sentinel lymph node biopsy include those with:

- American Joint Committee on Cancer (AJCC) Stage I, IIA, and IIB invasive breast cancer with no suspicious axillary lymph nodes
- Resectable, locally advanced, invasive breast cancer, either before or after neoadjuvant systemic therapy
- Extensive ductal carcinoma in situ (DCIS) requiring total mastectomy, no suspicious axillary nodes
- DCIS requiring wide excision in an anatomic location interfering with future, accurate sentinel lymph node mapping, no suspicious axillary nodes
- Unilateral or bilateral prophylactic mastectomy

Some patients who meet the criteria above may be deemed inappropriate for sentinel node biopsy. An example of such a patient might be an elderly, debilitated patient with a clinically negative axilla.

A patient can decline a sentinel node biopsy. If the patient declines, it should be documented in the patient medical record.

The accuracy of sentinel lymph node biopsy may be compromised in patients who have had previous ipsilateral breast-conserving surgery, axillary surgery, or breast radiation therapy.

PROCESS REQUIREMENTS

Accession List and Data Review Requirements for the Site Visit
The center is required to provide a de-identified accession (case) list of breast cancer cases diagnosed and/or treated at the center (class of case 10–14) prior to the site visit date. Class of case is defined in the *Facility Oncology Registry Data Standards (FORDS)* manual.

When sentinel node biopsy is not offered, the medical record should indicate the reason.

Patients can decline sentinel node biopsy. The medical record should indicate that this procedure has been offered.

Compliance is reviewed annually by the Breast Program Leadership Committee (BPLC).

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

Document the annual audit by the BPLC in the meeting minutes.

EVALUATION

The surveyor will review patient medical records during the medical records review portion of the site visit to evaluate compliance with sentinel lymph node biopsy utilization.

RATING COMPLIANCE

Compliance:

1. Axillary sentinel lymph node biopsy is considered or performed for patients with early-stage breast cancer (Clinical Stage I, II).
2. Compliance is reviewed annually by the BPLC and documented in the meeting minutes.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

RESOURCES

Choosing Wisely, *choosingwisely.org*

Breast Cancer Surveillance

STANDARD 2.5 A plan is in place for ensuring evidence-based guidelines are followed for surveillance of breast cancer patients.

DEFINITION AND REQUIREMENTS

A plan is in place to ensure that patients are returning for follow-up evaluation.

PROCESS REQUIREMENTS

The Breast Program Leadership Committee (BPLC) designs a surveillance plan using evidence-based guidelines for follow-up surveillance, including imaging, other testing as appropriate and clinical evaluation, which can be used for most patients.

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

Upload/describe the plan designed by the BPLC that defines surveillance by specialty involved in the patient's care.

Documentation reflecting follow-up outlined in the center's surveillance plan is included in patient medical records.

EVALUATION

The surveyor will review and discuss the surveillance documentation during the site visit.

RATING COMPLIANCE

Compliance:

1. The BPLC designs and implements a surveillance plan using evidence-based guidelines for follow-up surveillance.
2. Surveillance documentation reflecting follow-up outlined in the center's surveillance plan is included in patient medical records.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

RESOURCES

American Society of Clinical Oncology (ASCO) breast cancer follow-up guidelines
asco.org/practice-guidelines/quality-guidelines/guidelines/breast-cancer

National Comprehensive Cancer Network (NCCN) guidelines
nccn.org/professionals/physician_gls/f_guidelines.asp

Breast Cancer Staging

STANDARD 2.6 The Breast Program Leadership Committee (BPLC) develops a process to monitor physician use of American Joint Committee on Cancer (AJCC) staging in treatment planning for breast cancer patients.

DEFINITION AND REQUIREMENTS

Accurate clinical and pathologic staging of breast cancer patients enables the physician to determine appropriate treatment. Staging facilitates the reliable evaluation of treatment results and outcomes reported to various institutions on a local, regional, and national basis. AJCC staging is assigned using the criteria outlined in the current edition of the AJCC Cancer Staging Manual.

All staging classifications—and, most importantly, clinical and pathological classifications—are documented in the medical record.

All physician members of the Breast Care Team (BCT) use clinical TNM and identify the stage grouping prior to making treatment decisions.

The BPLC develops a process for use of AJCC staging in defining treatment for breast cancer patients.

PROCESS REQUIREMENTS

Accession List and Data Review Requirements for the Site Visit
The center is required to provide a de-identified accession (case) list of breast cancer cases diagnosed and/or treated at the center (class of case 10–22) prior to the site visit date. Class of case is defined in the *Facility Oncology Registry Data Standards (FORDS)* manual.

The BPLC develops and reviews the use of the AJCC staging process and discusses the results of the review with the BCT.

Compliance is reviewed annually by the BPLC.

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

Describe or upload the AJCC staging process for breast cancer patient treatment.

Document the BCT discussion of the staging process review, and the annual audit by the BPLC, in the meeting minutes.

EVALUATION

The surveyor will review the staging process, and patient medical records during the medical records review portion of the site visit, to confirm the use of AJCC staging in treatment planning for breast cancer patients.

RATING COMPLIANCE

Compliance:

1. The BPLC develops a process to monitor physician use of AJCC staging in treatment planning for breast cancer patients.
2. The BPLC reviews the use of the AJCC staging process and discusses the results of the review with the BCT.
3. Compliance is reviewed annually by the BPLC and documented in the meeting minutes.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

RESOURCES

American Joint Committee on Cancer, *cancerstaging.org*

Pathology

STANDARD 2.7 The College of American Pathologists (CAP) guidelines are followed for all breast cancers, including estrogen and progesterone receptors and Her2 status for all invasive breast cancers. Estrogen receptor status is recommended for ductal carcinoma in situ (DCIS) but not required by CAP. Pathology slides from an outside/referring institution are reviewed prior to first course of treatment.

DEFINITION AND REQUIREMENTS

The National Accreditation Program for Breast Centers (NAPBC) requires that all breast cancer pathology reports contain the required (core) data elements outlined on the **CAP cancer protocol template** and are reported in synoptic format for primary excisions or mastectomy after fine needle aspiration (FNA) or core biopsy.

Estrogen and progesterone receptors and Her2 studies need to only be performed on one specimen (such as the core biopsy or excision specimen), but must be included in the synoptic report (even if performed on the core biopsy or at an outside/referring institution).

Imaging studies are correlated with pathology when feasible.

If the biopsy is performed at an outside/referring institution, the biopsy pathology slides must be reviewed at the breast center or the affiliated pathology department prior to first course of treatment. The review may be done as an official consultation report, or verbally reported at the multidisciplinary conference.

PROCESS REQUIREMENTS

Accession List and Data Review Requirements for the Site Visit
The center is required to provide a de-identified accession (case) list of breast cancer cases diagnosed and/or treated at the center (class of case 10–22) prior to the site visit date. Class of case is defined in the *Facility Oncology Registry Data Standards (FORDS)* manual.

Report all breast cancer pathology in accordance with the CAP guidelines.

Report all breast cancer pathology from primary excision or mastectomy after FNA or core biopsy in synoptic format.

Review all pathology slides from outside/referring institutions prior to first course of treatment at the center. If extenuating circumstances exist that preclude the review, this is documented in the medical record.

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

EVALUATION

The surveyor will review patient medical records during the medical records review portion of the site visit to evaluate compliance with pathology reporting.

RATING COMPLIANCE

Compliance:

1. The CAP guidelines are followed for all breast cancers, including estrogen and progesterone receptors and Her2 status for all invasive breast cancers.
2. All breast cancer pathology from the primary surgical treatment is reported in synoptic format.
3. Pathology slides from an outside/referring institution are reviewed prior to first course of treatment.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

RESOURCES

College of American Pathologists, *cap.org*

Breast Imaging

STANDARD 2.8 The Breast Program Leadership Committee (BPLC) is required to adopt nationally recognized mammography screening guidelines and advise and educate the medical community affiliated with the breast center on the selected guidelines.

DEFINITION AND REQUIREMENTS

Federal law mandates that mammography must be performed at Mammography Quality Standards Act (MQSA)-certified facilities.

Screening mammography is an exam performed on an asymptomatic woman to detect early, clinically unsuspected breast cancer.

Diagnostic imaging/Ultrasound and/or MRI is used to evaluate a patient with abnormal clinical findings that have been found by the patient or their doctor. Diagnostic imaging can also be done after an abnormal screening mammogram in order to evaluate the area of concern on the screening exam.

Medical community, for the purposes of this standard, is defined as all providers who regularly refer to the breast center.

PROCESS REQUIREMENTS

Mammographic Screening
There are several guidelines published suggesting when to start and stop screening mammography and how frequently it should be performed. The BPLC is required to adopt nationally recognized screening mammography guidelines that include:

1. Women of average risk should begin routine, annual screening as early as age 40 but no later than age 45.
2. Screening under age 40 may occur for women who are at increased risk for breast cancer.
3. The screening schedule should continue as long as the woman is in good health.

The BPLC will advise and educate the medical community who refer patients to the breast center on the selected guidelines annually.

Diagnostic Imaging
Centers performing breast magnetic resonance imaging (MRI) must have the capacity to perform all of the following:

- Mammographic correlation
- Directed breast ultrasound
- MRI-guided intervention

If the center does not have the capacity to perform all of the above services, the center must have an established referral relationship with a local facility that can provide these services. The National Accreditation Program for Breast Centers (NAPBC) strongly recommends that the referred facility is accredited by the American College of Radiology (ACR) for breast MRI.

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

Mammographic Screening
The BPLC adopts nationally recognized screening mammography guidelines as outlined above.

In the BPLC meeting minutes, document when and how the medical community affiliated with the breast center was advised and educated regarding the selected guidelines. Mechanisms include, but are not limited to, letters, lectures, small group sessions, and newsletters.

Diagnostic Imaging
For breast MRI, provide documentation of Breast Imaging Center of Excellence (BICOE) accreditation or ACR accreditation. If the center refers breast MRI services to a local facility, the surveyor will review the referral relationship.

EVALUATION

The surveyor will review and discuss the required documentation during the site visit.

RATING COMPLIANCE

Compliance:

1. The BPLC adopts nationally recognized mammography screening guidelines.
2. The BPLC has advised and educated the medical community who refer patients to the breast center on the adopted mammography screening guidelines annually.
3. Centers performing breast MRI meet one of the following criteria:
    a. BICOE accreditation
    b. ACR accreditation for breast MRI
    c. Has a referral relationship with a local facility to provide all breast MRI services

Noncompliance: The center does not fulfill one or more of the compliance criteria.

RESOURCES

American College of Radiology (ACR) guidelines for mammographic screening, diagnostic imaging, and breast MRI

American Cancer Society (ACS) guidelines for mammographic screening

National Comprehensive Cancer Network (NCCN) guidelines for mammographic screening

Needle Biopsy

STANDARD 2.9 Palpation-guided or image-guided needle biopsy is the initial diagnostic approach rather than open biopsy.

DEFINITION AND REQUIREMENTS

Either fine-needle aspiration for cytologic evaluation or core needle biopsy constitutes the initial diagnostic approach for palpable or occult lesions. Open surgical biopsy as an initial approach should be avoided, as it does not allow for treatment planning and is associated with a high reexcision rate. In those instances when open surgical biopsy is used, the reason for its use is documented in the medical record.

Performance Measure
The NAPBC requires the Breast Program Leadership Committee (BPLC) to review the quality of patient care using the NAPBC-identified performance measures appropriate to the patients who are treated by the center each year.

Performance Measure
Needle/core biopsy is performed prior to surgical treatment of breast cancer.

PROCESS REQUIREMENTS

Accession List and Data Review Requirements for the Site Visit
The center is required to provide a de-identified accession (case) list of breast cancer cases diagnosed and/or treated at the center (class of case 10–22) prior to the site visit date. Class of case is defined in the *Facility Oncology Registry Data Standards (FORDS)* manual.

The BPLC evaluates the overall needle biopsy rate annually for cancer patients. When open surgical biopsy is used, the reason for its use is documented in the medical record.

Compliance is reviewed annually by the BPLC.

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

Calculate and record the overall needle biopsy rate annually for eligible breast cancer patients (overall needle biopsy rate is calculated by the number of needle biopsies performed/total number of biopsies of breast cancer patients).

Document the annual audit by the BPLC in the meeting minutes.

EVALUATION

The surveyor will review patient medical records during the medical records review portion of the site visit to evaluate the utilization of palpation-guided or image-guided needle biopsy and open surgical biopsy.

RATING COMPLIANCE

Compliance:

1. Palpation-guided or image-guided needle biopsy is the initial diagnostic approach rather than open biopsy.
2. When open surgical biopsy is used, the reason for its use is documented in the medical record.
3. Compliance is reviewed annually by the BPLC and documented in the meeting minutes.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

Ultrasonography

STANDARD 2.10 Diagnostic ultrasound and/or ultrasound-guided needle biopsy are performed at an American College of Radiology (ACR) ultrasound-accredited facility or by an American Society of Breast Surgeons (ASBrS) breast ultrasound-certified surgeon.

DEFINITION AND REQUIREMENTS

The National Accreditation Program for Breast Centers (NAPBC) requires radiologists who perform breast ultrasound and/or ultrasound-guided breast biopsy in a hospital setting or breast center setting to provide confirmation that their facility is accredited through the ACR Breast Ultrasound Accreditation Program.

Radiologists in facilities performing breast ultrasound and/or ultrasound-guided breast biopsy need to provide documentation of ACR accreditation or verification of application at the time of the site visit.

The NAPBC requires surgeons who perform breast diagnostic ultrasound and/or ultrasound-guided breast biopsy in a hospital setting, breast center setting, or private practice office to be certified in these procedures through the ASBrS Breast Ultrasound Certification Program. Surgeons performing breast diagnostic ultrasound and/or ultrasound-guided breast biopsy will need to provide documentation of ASBrS certification or verification of application at the time of the site visit.

An ACR Breast Imaging Centers of Excellence (BICOE) designation will meet requirements for radiology, but not surgeons.

PROCESS REQUIREMENTS

The facility where breast ultrasound and/or ultrasound-guided breast biopsy is performed, and the radiologists performing the breast ultrasound and/or ultrasound-guided breast biopsy, are accredited through the ACR Breast Ultrasound Accreditation Program.

Surgeons performing breast diagnostic ultrasound and/or ultrasound-guided breast biopsy in a hospital, breast center, or private practice office are certified through the ASBrS Breast Ultrasound Certification Program.

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

Provide documentation of ACR breast ultrasound accreditation for the facility where breast ultrasound and/or ultrasound-guided breast biopsy is performed and the radiologists performing the breast ultrasound and/or ultrasound-guided breast biopsy.

Provide documentation of ASBrS Breast Ultrasound Certification for surgeons performing breast diagnostic ultrasound and/or ultrasound-guided breast biopsy in a hospital, breast center, or private practice office.

EVALUATION

The surveyor will review documentation confirming accreditation/certification during the site visit.

RATING COMPLIANCE

Compliance:

1. Diagnostic ultrasound and/or ultrasound-guided needle biopsy are performed at an ACR ultrasound-accredited facility by accredited radiologists.
2. Surgeons performing diagnostic ultrasound and/or ultrasound-guided needle biopsy in hospitals, breast centers, and private practice offices are certified through the ASBrS Breast Ultrasound Certification Program.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

RESOURCES

American College of Radiology, *acr.org*

American Society of Breast Surgeons, *breastsurgeons.org*

Stereotactic Core Needle Biopsy

STANDARD 2.11 Stereotactic core needle biopsy is performed at an American College of Radiology (ACR)-accredited facility or by surgeons under the standards and requirements developed by the ACR and the American College of Surgeons (ACoS), or by an American Society of Breast Surgeons (ASBrS) Breast Procedure Program-certified surgeon.

DEFINITION AND REQUIREMENTS

Stereotactic core needle biopsy is most commonly used to diagnose suspicious microcalcifications and is performed with dedicated equipment. It is also used to biopsy masses and/or architectural distortions not visible on ultrasonography.

The physician performing the biopsy communicates a description of the lesion(s) to the pathologist.

The National Accreditation Program for Breast Centers (NAPBC) requires accreditation/certification by the ACR, ACR and ACoS, or ASBrS for the performance of stereotactic core needle biopsy.

The ACR designation of Breast Imaging Center of Excellence (BICOE) will meet requirements for radiology, but not surgeons.

PROCESS REQUIREMENTS

Radiology facilities and physicians performing stereotactic core needle biopsy procedures in centers applying for NAPBC accreditation will be required to demonstrate that they are currently accredited/certified by one of the organizations mentioned above.

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

Provide documentation of accreditation/certification for radiology facilities and physicians performing stereotactic core needle biopsy.

EVALUATION

The surveyor will review documentation confirming stereotactic breast biopsy accreditation/certification during the site visit.

RATING COMPLIANCE

Compliance:

1. Radiology facilities and physicians performing stereotactic core needle biopsy are accredited/certified by the ACR, ACR and ACoS, or ASBrS.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

RESOURCES

American College of Radiology, *acr.org*

American College of Radiology and American College of Surgeons, *facs.org/quality-programs/cancer/breast-biopsy*

American Society of Breast Surgeons, *breastsurgeons.org*

Radiation Oncology

STANDARD 2.12 Radiation oncology treatment services are provided by or referred to radiation oncologists who are board certified or in the process of board certification by the American Board of Radiology (ABR). The center can be accredited by the American College of Radiology Radiation Oncology Practice Accreditation (ACR-ROPA), the American Society for Radiation Oncology Accreditation Program for Excellence (ASTRO-APEx), the American College of Radiation Oncology (ACRO), or has a self-administered quality assurance program in place.

DEFINITION AND REQUIREMENTS

Radiation therapy is a primary component of multimodality treatment, and it is administered by board-certified physicians or physicians in the process of board certification in radiation oncology from the ABR. Board certification from the ABR should be in therapeutic radiology or radiation oncology.

Quality assurance practices with respect to radiation treatment are followed, as demonstrated by one of the following:

- Accreditation by one of the following is preferred:
  - ACR-ROPA
  - ASTRO-APEx
  - ACRO
- A quality assurance program is in place, and a Radiation Quality Assurance report confirms adherence to the following minimal quality assurance practices:
  - Patient identity is verified by two independent methods prior to each encounter
  - Daily, monthly, and annual radiation treatment machine quality assurance (QA) procedures are performed that comply with the American Association of Physicist in Medicine (AAPM) guidelines (machine-specific QA)
  - There is an independent check of dose calculation for every new or changed treatment prior to starting treatment
  - Patient-specific QA is done prior to initiation of Intensity-Modulated Radiation Therapy (IMRT)

Performance Measures

The NAPBC requires the Breast Program Leadership Committee (BPLC) to review the quality of patient care using the NAPBC-identified performance measures appropriate to the patients who are treated by the center each year.

Performance Measure
Radiation therapy is administered within one year (365 days) of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer.
Radiation therapy is considered or administered within one year (365 days) of diagnosis for women undergoing mastectomy for breast cancer with four or more positive regional lymph nodes.

PROCESS REQUIREMENTS

Accession List and Data Review Requirements for the Site Visit
The center is required to provide a de-identified accession (case) list of breast cancer cases diagnosed and/or treated at the center (class of case 10–22) prior to the site visit date. Class of case is defined in the *Facility Oncology Registry Data Standards (FORDS)* manual.

If radiation oncologists are in the process of board certification by the ABR at the time of the site visit, certification should be obtained as applicable. The center must send documentation confirming board certification to the NAPBC administrative office.

If the center has a locally developed quality assurance program in place, a Radiation Quality Assurance report must be submitted no later than thirty (30) days prior to the site visit, confirming adherence to the minimal quality assurance practices listed above.

Radiation therapy is administered within one year (365 days) of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer.

Radiation therapy is considered or administered within one year (365 days) of diagnosis for women undergoing mastectomy for breast cancer with four or more positive regional lymph nodes.

Compliance is reviewed annually by the BPLC.

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

Provide documentation of board certification for all radiation oncologists on the Breast Care Team (BCT).

Provide documentation of radiation oncology department/facility accreditation by one of the organizations/programs listed above, or the Radiation Quality Assurance report for a locally developed quality assurance program.

Document the annual audit by the BPLC, including the review of the performance measures listed above, in the meeting minutes.

EVALUATION

The surveyor will confirm board certification and accreditation by one of the organizations/programs listed above, or will review the Radiation Quality Assurance report, during the site visit.

The surveyor will review patient medical records during the medical records review portion of the site visit, to evaluate compliance with the performance measures listed above.

RATING COMPLIANCE

Compliance:

1. Radiation oncology treatment services are provided by or referred to board-certified radiation oncologists.
2. The radiation oncology department/facility has been accredited by ACR-ROPA, ASTRO-APEx, or ACRO, or a self-administered quality assurance program is in place and the breast cancer quality measure is endorsed by the NQF for radiation.
    a. If the center has a locally developed quality assurance program in place, a Radiation Quality Assurance report is submitted no later than thirty (30) days prior to the site visit, confirming adherence to the minimal quality assurance practices listed above.
3. Radiation therapy is administered within one year (365 days) of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer.
4. Radiation therapy is considered or administered within one year (365 days) of diagnosis for women undergoing mastectomy for breast cancer with four or more positive regional lymph nodes.
5. Compliance is reviewed annually by the BPLC and documented in the meeting minutes.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

RESOURCES

American Board of Radiology, *theabr.org*

American College of Radiology Radiation Oncology Practice Accreditation, *acr.org*

American Society for Radiation Oncology Accreditation Program for Excellence, *astro.org*

American College of Radiation Oncology, *acro.org*

National Quality Forum, *qualityforum.org*

Medical Oncology

STANDARD 2.13 Medical oncology treatment services are provided by or referred to medical oncologists who are board certified or in the process of board certification.

DEFINITION AND REQUIREMENTS

Medical oncology (systemic therapy) is a primary component of multimodality treatment, and it is administered by board-certified physicians or physicians in the process of board certification in medical oncology by the American Board of Medical Specialists (ABMS) or the American Board of Internal Medicine (ABIM). Board certification for medical oncologists took effect in 1970 and is provided by the ABIM. Medical oncologists demonstrating competence and privileged by their facility prior to 1970 will also be recognized as board certified in medical oncology.

Performance Measures
The NAPBC requires the Breast Program Leadership Committee (BPLC) to review the quality of patient care using the NAPBC-identified performance measures appropriate to the patients who are treated by the center each year.

Performance Measure
Combination chemotherapy is considered or administered within four months (120 days) of diagnosis for women under the age of 70 with AJCC T1c, Stage II, or Stage III hormone-receptor-negative breast cancer.
Tamoxifen or third-generation aromatase inhibitor is considered or administered within one year (365 days) of diagnosis for women with AJCC T1c, Stage II, or Stage III hormone-receptor-positive breast cancer.

PROCESS REQUIREMENTS

Accession List and Data Review Requirements for the Site Visit
The center is required to provide a de-identified accession (case) list of breast cancer cases diagnosed and/or treated at the center (class of case 10–22) prior to the site visit date. Class of case is defined in the *Facility Oncology Registry Data Standards (FORDS)* manual.

For those medical oncologists in the process of obtaining board certification from the ABMS or the ABIM, certification should be obtained as applicable.

Combination chemotherapy is considered or administered within four months (120 days) of diagnosis for women under the age of 70 with AJCC T1c, Stage II, or Stage III hormone-receptor-negative breast cancer.

Tamoxifen or third-generation aromatase inhibitor is considered or administered within one year (365 days) of diagnosis for women with AJCC T1c, Stage II, or Stage III hormone-receptor-positive breast cancer.

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

Provide documentation of board certification by the ABMS or the ABIM for all medical oncologists on the breast care team.

EVALUATION

The surveyor will confirm board certification and review patient medical records to evaluate compliance with the medical oncology performance measures listed above during the site visit.

RATING COMPLIANCE

Compliance:

1. Medical oncology treatment services are provided by or referred to medical oncologists who are board certified or in the process of board certification.
2. Combination chemotherapy is considered or administered within four months (120 days) of diagnosis for women under the age of 70 with AJCC T1c, Stage II, or Stage III hormone-receptor-negative breast cancer.
3. Tamoxifen or third-generation aromatase inhibitor is considered or administered within one year (365 days) of diagnosis for women with AJCC T1c, Stage II, or Stage III hormone-receptor-positive breast cancer.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

RESOURCES

American Board of Medical Specialists, *abms.org*

American Board of Internal Medicine, *abim.org*

National Quality Forum, *qualityforum.org/Home.aspx*

Nursing

STANDARD 2.14 Nursing care is provided by nurses with specialized knowledge and skills in diseases of the breast.

DEFINITION AND REQUIREMENTS

The complex needs of cancer patients and their families require specialized oncology nursing knowledge and skills to achieve optimal patient care outcomes. The oncology nurse is an integral member of the multidisciplinary Breast Care Team (BCT).

Qualifications of a nurse with specialized knowledge and skills include:

- Holding one of the following certifications from the Oncology Nursing Certification Corporation (ONCC):
  - Certified Breast Care Nurse (CBCN®)
  - Advanced Oncology Certified Nurse Practitioner (AOCNP®)
  - Advanced Oncology Certified Clinical Nurse Specialist (AOCNS®)
  - Oncology Certified Nurse (OCN®)
  - Advanced Oncology Certified Nurse (AOCN®)
- A nurse with documented knowledge and skills from previous education and experience in the care of women with breast disease

PROCESS REQUIREMENTS

Nursing care is provided by nurses certified in oncology nursing and/or with documented qualifications of specialized knowledge and skills in diseases of the breast.

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

EVALUATION

The surveyor will review and discuss the required documentation during the site visit.

RATING COMPLIANCE

Compliance:

1. Nursing care is provided by nurses with specialized knowledge and skills in diseases of the breast.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

RESOURCES

Oncology Nursing Society (ONS), *ons.org*

Oncology Nursing Certification Corporation, *oncc.org*

Support and Rehabilitation

STANDARD 2.15 Support and rehabilitation services are provided or referred.

DEFINITION AND REQUIREMENTS

Comprehensive breast cancer care is multidisciplinary and includes medical health professionals addressing patient needs identified along the breast cancer continuum from diagnosis through survivorship. Supportive services help patients and their families cope with the day-to-day details of a breast cancer diagnosis. These resources address emotional, physical, financial, and other needs of the breast cancer patient. Supportive services address the needs of the majority of patients, as well as provide for special populations or needs.

The supportive services offered on-site will vary depending upon the scope of the facility, local staff expertise, and patient population.

Oncology Social Work Certification (OSW-C)-certified oncology social workers are preferred.

Supportive services not provided on-site are provided through referral to other facilities and/or local agencies.

Supportive services may include:

- Lymphedema management and risk reduction practices
- Integrative medicine (for example, yoga, tai chi, exercise)
- Psychosocial distress screening and support
- Nutritional counseling
- Palliative care
- Support groups
- Transportation services
- Financial services
- Other complementary services, such as music/art therapy, relaxation, and massage, used in conjunction with rehabilitation disciplines

PROCESS REQUIREMENTS

An annual report of supportive services is presented to the Breast Program Leadership Committee (BPLC).

Compliance is reviewed annually by the BPLC.

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

Document the presentation of the annual supportive services report and annual audit by the BPLC in the meeting minutes.

EVALUATION

The surveyor will discuss the support and rehabilitation services available and the annual report of supportive services presented to the BPLC during the site visit.

RATING COMPLIANCE

Compliance:

1. Support and rehabilitation services are provided or referred.
2. An annual report of supportive services is presented to the BPLC.
3. Compliance is reviewed annually by the BPLC and documented in the meeting minutes.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

RESOURCES

National Accreditation Program for Breast Centers (NAPBC) Accreditation Resources, *facs.org/quality-programs/napbc/accreditation/resources*

Breast Cancer Advocacy Organizations, *facs.org/quality-programs/napbc/accreditation/resources/patient-resources/organizations*

Genetic Evaluation and Management

STANDARD 2.16 Cancer risk assessment, genetic counseling, and genetic testing services are provided or referred.

DEFINITION AND REQUIREMENTS

Cancer risk assessment and genetic counseling is the process of identifying and counseling individuals at risk for familial or hereditary breast cancer syndromes. As an important part of normal patient care an initial cancer risk assessment is generally conducted by treating clinicians in the form of a basic family history. The purpose of genetic counseling is to further educate patients about their risk of developing breast cancers, help them obtain personal meaning from cancer genetic information, and to empower them to make educated and informed decisions about genetic testing, cancer screening, and cancer prevention. Identifying patients at increased risk of developing breast and other cancers due to a family history of breast and other cancers or a known hereditary cancer syndrome can have dramatic effects on early detection and cancer outcomes. For this reason, cancer risk assessment and genetic counseling has become the standard of care for patients with a personal and/or family history of breast cancer.

Breast cancer patients are referred to a cancer genetics professional based on national guidelines (for example, the National Comprehensive Cancer Network [NCCN], the American Society of Clinical Oncology [ASCO], or the American Society of Breast Surgeons [ASBrS]).

Genetic counseling is performed by a cancer genetics professional who has an educational background in genetics and cancer genetics, counseling, and hereditary cancer syndromes and can provide accurate risk assessment and empathetic genetic counseling to cancer patients and their families.

Pretest Counseling:

- Collect relevant information needed to assess a patient's personal and family medical history: A three- to four-generation pedigree, including detailed medical information about the patient's first-, second-, and third-degree relatives should be obtained. Gathering information about both paternal and maternal family history, ancestry/ethnicity, and consanguinity is necessary.
- Evaluate the patient's cancer risk: One aspect of risk assessment is discussing the absolute risk that the patient will develop a specific type of cancer or cancers based on the family history. The second aspect is the risk that the patient carries a heritable or germline mutation in a cancer susceptibility gene.
- Perform a psychosocial assessment.
- Educate the patient about the suspected hereditary cancer syndrome, if appropriate: The provider should review cancer risks associated with gene mutations, including basic concepts such as genes and inheritance patterns and more advanced concepts of penetrance and variability expressivity and the possibility of genetic heterogeneity.
- Obtain informed consent for genetic testing, when recommended: The informed consent should include the purpose of the test and who the ideal person is to test, possible test results, likelihood of positive results, technical aspects and accuracy of the test, the possibility of inconclusive test results and how these results affect medical management, economics and insurance considerations, laws protecting against genetic discrimination, utilization of test results, alternatives to genetic testing, and the storage and potential reuse of genetic material.

Posttest Counseling:

- Disclosure of the results and posttest counseling should include a discussion of the results, significance and impact of the test results, medical management options, informing other relatives, future contact, and available resources.

PROCESS REQUIREMENTS

Genetic counseling is provided by:

- An American Board of Genetic Counseling (ABGC) board-certified/board-eligible genetic counselor or (in some states) a licensed genetic counselor.
- An American College of Medical Genetics (ACMG) physician board certified in medical genetics.
- A genetics clinical nurse (GCN), an advanced practice nurse in genetics (APNG), or a nurse who is Advanced Genetics Nursing-Board Certified (AGN-BC) credentialed through the American Nurses Credential Center (ANCC). Credentialing is obtained through successful completion of a professional portfolio review process.
- An advanced practice oncology nurse (APON) who is prepared at the graduate level (master's or doctorate) with specialized education in cancer genetics and hereditary cancer predisposition syndromes; certification by the Oncology Nursing Certification Corporation (ONCC) as AOCNP or AOCNS is preferred.
- A board-certified/board-eligible physician or other trained health care professional with expertise and experience in cancer genetics (defined as providing cancer risk assessment on a regular basis) employing a model that includes both pretest and posttest counseling.

Patients identified to have a variant of uncertain significance (VUS) on a hereditary cancer panel and tested by one of the above providers need to be referred to a genetics professional for assistance with interpretation for the patient and the patient's family.

Centers that are geographically challenged or do not have access to a board-certified or licensed genetic counselor may utilize the services of a nationwide network of genetic experts available by telephone to provide consultation and guidance.

Continuing Education Requirement
Specialized training in cancer genetics is ongoing and documented with Continuing Medical Education (CME) Credit/Continuing Education Units (CEU) in the field of breast cancer genetics. Two (2) CME Credits/CEUs are obtained annually, ideally with one related to breast cancer susceptibility gene (BRCA)1/2 and one related to genes other than BRCA1/2 that cause hereditary breast cancer.

Educational seminars should include the spectrum of services for breast cancer genetics, including genetic risk assessment, genetic counseling, indications and decision-making regarding genetic testing, and appropriate posttest counseling.

Education limited to learning how to order a genetic test is not considered adequate training for risk assessment and genetic counseling.

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

Describe the process by which patients get genetic assessment and counseling.

Provide certification/credentialing for the cancer genetics professional(s) performing genetic counseling.

Provide documentation on annual CME Credits/CEUs obtained by cancer genetics professional(s) performing genetic counseling.

EVALUATION

The surveyor will confirm that cancer risk assessment, genetic counseling, and genetic testing services are provided or referred based on national guidelines during the site visit.

The surveyor will confirm the certification/credentialing of the cancer genetics professional(s) during the site visit.

The surveyor will review the annual CME Credits/CEUs obtained by cancer genetics professional(s) during the site visit.

RATING COMPLIANCE

Compliance:

1. Cancer risk assessment, genetic counseling, and genetic testing services are provided or referred.
2. Breast cancer patients are referred to a cancer genetics professional based on national guidelines (for example, NCCN, ASCO, ASBrS).
3. Genetic counseling is performed by certified/credentialed cancer genetics professional(s) or a board-certified/board-eligible physician or other trained health care professional with expertise and experience in cancer genetics.
4. Cancer genetics professional(s) obtain two (2) breast-related CME Credits/CEUs (ideally with one related to BRCA1/2 and one related to genes other than BRCA1/2 that cause hereditary breast cancer) annually.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

RESOURCES

American Board of Genetic Counseling, *abgc.net*

American Board of Medical Genetics, *abmg.org*

American College of Medical Genetics, *acmg.net*

American Nurses Credentialing Center, *nursecredentialing.org*

American Society of Human Genetics, *ashg.org*

City of Hope Cancer Genetics Career Development Program, *cityofhope.org*

International Society of Nurses in Genetics, *isong.org*

National Society of Genetic Counselors, *nsgc.org*

Oncology Nursing Certification Corporation, *oncc.org*

Oncology Nursing Society, *ons.org*

Guidelines and recommendations for cancer risk assessment and genetic counseling for hereditary breast cancer syndromes:

Agency for Healthcare Research and Quality, *ahrq.gov*

American Society of Breast Surgeons' Consensus Statement, *breastsurgeons.org*

American Society of Clinical Oncology-Cancer Genetics Practice Guidelines, *asco.com*

National Comprehensive Cancer Network, *nccn.org*

Educational Resources

STANDARD 2.17 Culturally appropriate educational resources are available for patients along with a process to provide them. The materials provided are reviewed on an annual basis and adjusted for the patient population.

DEFINITION AND REQUIREMENTS

Centers provide patients with educational information covering evaluation and management of breast diseases.

Centers with culturally diverse populations must provide educational resources in languages commonly spoken in the community.

Centers are required to provide information and resources to women who are diagnosed with Stage IV breast cancer.

Centers are required to provide information about fertility options for women of childbearing age who are diagnosed with breast cancer.

PROCESS REQUIREMENTS

Educational resources are reviewed and revised on an annual basis and adjusted based on the patient population.

Educational materials can be provided in print, online, or as audiovisual aides and can be given directly to the patient or made available in a patient education library at the center.

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

Describe the processes for providing educational resources to patients.

Provide samples of required educational materials.

EVALUATION

The surveyor will review samples of educational resources and the process to provide the resources to patients during the site visit.

RATING COMPLIANCE

Compliance:

1. Culturally appropriate educational resources are available for patients along with a process to provide them.
2. Educational resources/materials are provided to women diagnosed with Stage IV breast cancer.
3. Educational resources/materials on fertility options are provided to women of childbearing age who are diagnosed with breast cancer.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

RESOURCES

National Accreditation Program for Breast Centers (NAPBC) Accreditation Resources, *facs.org/quality-programs/napbc/accreditation/resources*

Reconstructive Surgery

STANDARD 2.18 All appropriate patients undergoing mastectomy are offered a preoperative referral to a reconstructive/plastic surgeon. Reconstructive surgery is provided by or referred to reconstructive/plastic surgeons who are board certified or in the process of board certification.

DEFINITION AND REQUIREMENTS

As part of an informed decision-making process, every effort should be made to ensure patients undergoing mastectomy are offered a preoperative discussion with a reconstructive/plastic surgeon who is board certified or in the process of board certification by the American Board of Plastic Surgery (ABPS). Board certification should be obtained as applicable.

The Breast Program Leadership Committee (BPLC) is required to evaluate and report the referral offer compliance rate annually for all appropriate referral candidates.

The type of breast reconstructive surgery is dependent on the nature of the defect and the overall health of the patient. While there is an increasing trend in immediate breast reconstruction utilizing tissue expanders, implants, or autologous tissue transfer, patients should be made aware of all of their options, including delayed reconstruction. Patients need to be aware that breast reconstruction does not interfere with surveillance or detection of local recurrence. Consideration needs to be given to the timing of reconstruction with respect to systemic adjuvant chemotherapy or radiation therapy.

The American Society of Plastic Surgeons (ASPS) developed a quality improvement program, Tracking Operations and Outcomes for Plastic Surgeons (TOPS). This program is designed to provide plastic surgeons with a mechanism to submit clinical and demographic information into multiple, confidential databases, minimize redundant data entry, and provide clinical/practice information to plastic surgeons and their specialty to measure outcomes.

PROCESS REQUIREMENTS

Accession List and Data Review Requirements for the Site Visit
The center is required to provide a de-identified accession (case) list of breast cancer cases diagnosed and/or treated at the center (class of case 10–22) prior to the site visit date. Class of case is defined in the F*acility Oncology Registry Data Standards (FORDS)* manual.

Breast reconstruction referrals are documented in the patient medical record. If the patient is deemed inappropriate and/or the patient declines the referral offer, it must be documented in the patient medical record.

Reconstructive surgery is provided by or referred to reconstructive/plastic surgeons who are board certified or in the process of board certification.

The BPLC evaluates and reports the referral offer compliance rate annually for all appropriate referral candidates.

Compliance is reviewed annually by the BPLC.

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

Provide documentation of board certification for all reconstructive/plastic surgeons on the Breast Care Team (BCT).

Document the annual referral offer compliance rate and annual audit by the BPLC in the meeting minutes.

EVALUATION

The surveyor will review board certification, annual compliance audit, and patient medical records during the medical records review portion of the site visit, to evaluate compliance.

RATING COMPLIANCE

Compliance:

1. All appropriate patients undergoing mastectomy are offered a preoperative referral to a reconstructive/plastic surgeon, and the referral is documented in the patient medical record.
2. Reconstructive surgery is provided by or referred to reconstructive surgeons who are board certified or in the process of board certification.
3. Compliance is reviewed annually by the BPLC and documented in the meeting minutes.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

RESOURCES

American Board of Plastic Surgery, *abplsurg.org*

American Society of Plastic Surgeons, *plasticsurgery.org*

Tracking Operations and Outcomes for Plastic Surgeons, *plasticsurgery.org*

Evaluation and Management of Non-Malignant Breast Diseases

STANDARD 2.19 Evaluation and management of non-malignant breast disease follows nationally recognized guidelines.

DEFINITION AND REQUIREMENTS

Non-malignant breast disease is a spectrum of breast physiologic, physical and imaging abnormalities that can cause the patient or treating physician concern but do not result in a diagnosis of breast cancer. Non-malignant breast conditions range from inconsequential imaging abnormalities (such as a resolved density) or minor clinical finding (lipoma of the breast) to severe atypia.

A process is in place to ensure evaluation with the intent to rule out a malignancy, determine the patient's risk status and subsequently initiate appropriate surveillance and management.

Non-malignant breast conditions include, but are not limited to the following clinical presentations:

- Mastodynia/pain
- Skin changes such as thickening, rashes, indentations, and other lesions
- Masses
- Nipple discharge
- Inflammatory changes
- Imaging abnormalities
- Skin thickening
- Densities: BIRADS category 3, 4, or 5

PROCESS REQUIREMENTS

The Breast Program Leadership Committee (BPLC) determines the nationally recognized guidelines that will be used to evaluate and manage patients with non-malignant breast disease at the center.

Appropriate evaluation and management of non-malignant breast disease is documented in the medical record.

The center will select five (5) high-risk patient (atypical hyperplasia, lobular carcinoma in situ) medical records for the medical record review portion of the site visit.

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

Upload/describe your center's process for management of patients with high-risk lesions.

Documentation of good clinical practice in the care of these patients will be determined by the chart review.

EVALUATION

The surveyor will review the high-risk patient charts during the medical records review portion of the site visit to evaluate adherence to national guidelines for the evaluation and management of non-malignant breast disease.

RATING COMPLIANCE

Compliance:

1. Evaluation and management of non-malignant breast disease follows nationally recognized guidelines.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

RESOURCES

National Comprehensive Cancer Network (NCCN), *nccn.org*

Breast Cancer Survivorship Care

STANDARD 2.20 A comprehensive process to prepare and disseminate a breast cancer survivorship care plan, with accompanying treatment summary, to all eligible patients within six (6) months of completing active treatment and no later than one year (365 days) from date of diagnosis is developed and implemented.

DEFINITION AND REQUIREMENTS

The Institute of Medicine (IOM) report *From Cancer Patient to Cancer Survivor* outlines the importance of providing cancer survivors with a comprehensive treatment summary and follow-up plan (in other words, a survivorship care plan) that addresses follow-up care to improve health and quality of life. This document serves as a communication and education tool that survivors can provide to all of their health care providers in various disciplines.

The **Survivorship Care Plan (SCP)** is the record of a patient's breast cancer history, what transpired during active treatment, current continued long-term treatment (in other words, hormonal and targeted therapy), recommendations for follow-up care and surveillance testing/examination, referrals for support services the patient may need going forward, and other information pertinent to the survivor's short- and long-term survivorship care. It is to stipulate specifically what surveillance is to be performed, at what frequency, by whom, and when.

The American Society of Clinical Oncology (ASCO) has defined the minimum data elements to be included in a treatment summary and SCP. The center is not required to use the ASCO template, however, the SCP template selected for use by the center must, at a minimum, include ASCO's recommended minimum data elements to meet compliance for this standard. The minimum set of data elements and ASCO's template are available on the ASCO website.

An eligible patient, for the purposes of this standard, is defined as a patient who:

- Was diagnosed with Stage 0 (ductal carcinoma in situ), I, II, or III breast cancer,
- Was treated with curative intent for an initial breast cancer occurrence,
- Is an analytic case, and
- Has completed active therapy (chemotherapy and radiation), though may still be receiving hormonal or targeted therapy

Ineligible Patients and Timeline Extension

- Patients diagnosed with Stage IV breast cancer are not required to have a SCP, as they are assumed to be under continuous treatment. However, consideration should be given to providing these patients with ongoing treatment summaries for their use and to be shared with their primary care physician (PCP), including a listing of common potential late effects and their possible timing.
- The one-year-from-diagnosis requirement to provide a SCP is extended to 18 months for patients receiving hormonal and targeted therapy.

PROCESS REQUIREMENTS

Breast centers must develop and implement processes to monitor the preparation and dissemination of a SCP for all eligible patients.

- A SCP is manually or electronically prepared by the health care provider(s) who coordinate the oncology treatment for the patient with input from the patient's other care providers. Providers who are part of the patient's care team and appropriate under this standard to deliver the SCP:
  - Physicians
  - Registered nurses
  - Advanced practitioner nurses
  - Nurse practitioners
  - Physician assistants
  - Credentialed clinical navigators (does not include lay navigators)

If two different facilities are providing treatment, both facilities should work together to collaborate on providing a completed SCP. The facility providing follow-up and monitoring of the patient (medical oncology) should provide the SCP. In all cases, facilities should work together to provide the information necessary for completion of a SCP containing all required elements.

- The SCP is given to and discussed with the patient within six (6) months of completing active treatment and no longer than one year (365 days) from date of diagnosis. Survivors are to be provided with multiple copies of their SCP to allow them to share it with additional care providers and retain a master copy of this living document for their records. Providing the SCP without discussion with the patient does not meet the standard.
- This SCP is given to all providers involved in the survivor's care, including the PCP and/or gynecologist and other cancer-related and non-cancer-related practitioners. The SCP includes a list of providers with whom the SCP has been shared.

Implementation of the standard and required percentage of SCPs provided must follow the schedule as outlined:

- End of 2016: Provide SCPs to ≥ 25 percent of eligible patients who have completed treatment
- End of 2017 and on: Provide SCPs to ≥ 50 percent of eligible patients who have completed treatment

To calculate the percentage of eligible patients, it is recommended that you begin with your number of analytic cases as the denominator and then subtract ineligible patients.

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

Provide the standard of practice (SOP)/policy and procedure for preparation and dissemination of a comprehensive breast cancer treatment summary and SCP. The documented process must include at minimum:

- Defined patient eligibility
- Identify appropriate mechanism(s) for generating the SCP
- Identify appropriate individual(s) for delivering the SCP
- The method and timing of delivery of the SCP
- Tracking and reporting the number of SCP's provided to eligible patients

Provide a sample treatment summary and SCP.

Document the annual audit by the Breast Program Leadership Committee (BPLC) in the meeting minutes.

EVALUATION

The surveyor will review the number of SCPs provided during the medical records review portion of the site visit. The surveyor will also review and discuss the SCP and the implemented survivorship care process, as well as confirm the annual audit by the BPLC.

RATING COMPLIANCE

Compliance:

1. A comprehensive process to prepare and disseminate a breast cancer survivorship care plan, with accompanying treatment summary, to all eligible patients within six (6) months of completing active treatment and no later than one year (365 days) from date of diagnosis is developed and implemented.
2. Compliance is reviewed annually by the BPLC and documented in the meeting minutes.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

RESOURCES

Patient Eligibility: The decision matrix below displays eligibility by treatment scenario and is intended to be a companion tool for use with National Accreditation Program for Breast Centers (NAPBC) Standard 2.20. The scenarios listed are not intended to be an exhaustive or definitive list.

PATIENTS DIAGNOSED	FIRST COURSE OF TREATMENT – CURATIVE INTENT			
with DCIS / Stage 0 Stage I–III	**SURGERY**	**CHEMO**	**RADIATION**	**SCP**
Your Center	Your Center	Elsewhere	Elsewhere	Yes
Your Center	Your Center	None	None	Yes
Your Center	Elsewhere	Your Center	Your Center	Yes
Your Center	Elsewhere	Your Center	None	Yes
Your Center	Elsewhere	Your Center	Elsewhere	Yes
Your Center	Elsewhere	None	Your Center	Yes
Your Center	Elsewhere	Elsewhere	Your Center	Yes
Your Center	Elsewhere	None	None	Yes
Elsewhere	Your Center	Your Center	Your Center	Yes
Elsewhere	Your Center	Elsewhere	Your Center	Yes
Elsewhere	Your Center	Your Center	Elsewhere	Yes
Elsewhere	Elsewhere	Your Center	Your Center	Yes
Stage IV **Recurrence** **LCIS**				No No No

American Cancer Society (ACS) SCP,
cancer.org/treatment/survivorship-during-and-after-treatment/survivorship-care-plans.html

American Society of Clinical Oncology Cancer Treatment and SCP,
cancer.net/survivorship/follow-care-after-cancer-treatment/asco-cancer-treatment-and-survivorship-care-plans

Chapter Three:
Research

Clinical Trial Information

STANDARD 3.1 Information about the availability of breast cancer-related clinical trials is provided to patients through a formal mechanism.

DEFINITION AND REQUIREMENTS

By providing information about the availability of breast cancer-related clinical trials, the facility offers patients the opportunity to participate in the advancement of evidence-based medicine.

PROCESS REQUIREMENTS

A formal process is in place for providing information about breast cancer-related clinical trials and other clinical research.

Methods of providing information include, but are not limited to:

- Access to the Internet or Intranet search services through the patient library
- Articles in facility newsletters
- Pamphlets or brochures in patient waiting rooms or patient packets
- Physician/nurse-led patient education

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

Upload/describe the process and formal mechanism in place to provide information to patients about breast cancer-related clinical trials and other clinical research.

EVALUATION

The surveyor will review the breast cancer-related clinical trial information provided to patients and discuss the process to provide the information during the site visit.

RATING COMPLIANCE

Compliance:

1. A process and formal mechanism is in place to provide information to patients about breast cancer-related clinical trials.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

RESOURCES

Coalition of Cancer Cooperative Groups, *cancertrialshelp.org*

National Cancer Institute, *cancer.gov/clinicaltrials*

Clinical Trial Accrual

STANDARD 3.2 Two percent (2%) or more of all eligible breast cancer patients are accrued to treatment-related breast cancer clinical trials and/or research protocols annually.

DEFINITION AND REQUIREMENTS

Clinical research advances science and patient care. The center must demonstrate that efforts to enroll eligible patients in clinical trials are being made and that the center meets or exceeds the two percent annual accrual rate. The National Accreditation Program for Breast Centers (NAPBC) recommends inviting the clinical trials nurse and/or other research leaders to the multidisciplinary breast cancer conference (MBCC).

Eligible patients are those patients:

- Seen at the center for diagnosis and/or treatment and placed on a clinical trial through the facility
- Seen at the center for diagnosis and/or treatment and placed on a trial through the office of a staff physician
- Seen at the center for diagnosis and/or treatment and placed on a trial through another facility
- Seen at the center for any reason and placed on a prevention or breast cancer control trial

Treatment-related clinical trial groups include, but are not limited to:

- NCI-sponsored programs such as the Community Clinical Oncology Program (CCOP)
- Cooperative trial groups such as the Alliance for Clinical Trials in Oncology
- University-related research
- Pharmaceutical company-sponsored research
- Locally developed, investigator initiated trials

In addition to well-established clinical trials, research conducted at the local level offers patients the opportunity to contribute to treatment, prevention, diagnostic, screening, and quality-of-life trials.

Local breast cancer research studies include, but are not limited to:

- Primary prevention
- Early detection
- Quality-of-life evaluation and recommendations
- Symptom management
- Economics of care
- Diagnostic and screening trials
- Psychosocial interventions
- Prospective cohort studies (registry)

PROCESS REQUIREMENTS

Centers must accrue eligible patients to breast cancer-related clinical research at the minimum percentage rate of two percent (2%) annually. Accrual is tracked by the following research study categories:

- Interventional trials
- Screening
- Tissue collection
- Behavioral
- Registry
- Investigator initiated

Centers participating in clinical research show that an independent review mechanism consistent with national standards is in place and used. Research projects involving participation by human subjects must be approved by an internal or external institutional review board (IRB). Patients participating in clinical trials must give their informed consent.

A study coordinator, data manager, or other clinical research professional is available to assist in enrolling patients, monitoring patient accrual, and identifying and providing information/education about new trials.

Patient accrual and compliance is reviewed annually by the Breast Program Leadership Committee (BPLC).

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

Track accrual by research study category.

Document the center's accrual rate and annual audit by the BPLC in the meeting minutes.

EVALUATION

The surveyor will review and discuss the clinical trials program and accrual rate during the site visit.

RATING COMPLIANCE

Compliance:

1. Two percent (2%) or more of all eligible breast cancer patients are accrued to treatment-related breast cancer clinical trials and/or research protocols annually.
2. Compliance is reviewed annually by the BPLC and documented in the meeting minutes.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

RESOURCES

ClinicalTrials.gov, *clinicaltrials.gov*

National Cancer Institute, *cancer.gov/clinicaltrials*

Chapter Four:
Community Outreach

Education, Prevention, and Early Detection Programs

STANDARD 4.1 Each year, two or more breast disease education, prevention, and/or early detection programs are provided or coordinated with other facilities or local agencies targeted to the community. For early detection programs, follow-up is provided to patients with positive findings.

DEFINITION AND REQUIREMENTS

Prevention programs identify risk factors and use strategies to modify attitudes and behaviors to reduce the chance of developing breast cancer. Early detection programs apply screening guidelines to detect cancers at an early stage, which improves the likelihood of increased survival and decreased morbidity.

Education, prevention, and early detection programs are provided or coordinated with other facilities and/or local agencies (for example, the American Cancer Society).

Education, prevention, and/or early detection programs include, but are not limited to:

- Risk reduction through lifestyle modification or chemoprevention
- Breast cancer awareness
- Breast care education
- Genetic counseling to high-risk population
- Screening mammography and clinical examination

PROCESS REQUIREMENTS

Each year, the center offers two or more education, prevention, and/or early detection programs, on-site or coordinated with other facilities and/or local agencies (for example, the American Cancer Society), at scheduled intervals as defined by the BPLC.

The BPLC defines and implements a process for follow-up with patients with positive findings from early detection programs.

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

Complete and upload the Education, Prevention, and Early Detection Program template.

Upload/describe the process used to follow up with patients found to have positive findings as a result of participation in early detection programs.

EVALUATION

The surveyor will review and discuss the annual breast disease education, prevention, and/or early detection programs, and the process for follow-up, during the site visit.

RATING COMPLIANCE

Compliance:

1. Each year, two or more breast disease education, prevention, and/or early detection programs are provided or coordinated with other facilities or local agencies targeted to the community.
2. For early detection programs, follow-up is provided to patients with positive findings.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

Chapter Five:
Professional Education

Breast Care Team Education

STANDARD 5.1 Members of the Breast Care Team (BCT) participate in a minimum of two local, state, regional, or national breast-specific Continuing Medical Education (CME) (or equivalent) educational activities annually.

DEFINITION AND REQUIREMENTS

Educational activities ensure that members of the breast care team possess current knowledge of breast cancer prevention, early detection, diagnosis, treatment, and follow-up care. Members of the BCT participate in a minimum of two local, state, regional, or national breast-specific CME or equivalent educational activities annually.

Breast disease-related CME (or equivalent) educational activities include, but are not limited to:

- A lecture
- A local, state, regional, or national meeting/conference/workshop (attendance at two independent breast disease-related educational sessions, each supported by CME or equivalent, during one convened conference will meet compliance with this standard)
- A web conference
- Journal CME or equivalent
- Online education

Industry-sponsored educational programs that promote specific products or therapy are not acceptable for meeting this standard.

CME credit offered for attendance at the multidisciplinary breast cancer conference (Standard 1.2) does not count toward meeting this standard.

PROCESS REQUIREMENTS

Physician members of the BCT participate in a minimum of two breast-specific CME activities annually. Documentation of CME credits is required.*

Non-physician members of the BCT, directly seeing patients in preoperative or postoperative settings, participate in a minimum of two breast-specific Continuing Education (CE) (or equivalent) activities, appropriate to the discipline, annually. Documentation of CE (or equivalent) units/credits is required.

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

Upload the BCT educational activity tracking template.

EVALUATION

The surveyor will review and discuss the BCT educational activities during the site visit.

RATING COMPLIANCE

Compliance:

1. Members of the BCT participate in a minimum of two local, state, regional, or national breast-specific CME (or equivalent) educational activities annually.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

RESOURCES

Continuing Medical Education for physicians is regulated by the Accreditation Council for Continuing Medical Education (ACCME) and the American Osteopathic Association (AOA).

* For physician members of the BCT who are also providing genetic counseling in accordance with Standard 2.16, the education requirement in this standard is in addition to the education requirement in Standard 2.16 Genetic Evaluation and Management.

Chapter Six:
Quality Improvement

Quality and Outcomes

STANDARD 6.1 Each year the breast center conducts or participates in three (3) or more center-specific studies that measure quality and/or outcomes, or two (2) or more center-specific studies and one (1) or more of the physician members participate in their specialty-specific quality improvement program. The findings are communicated and discussed with the members of the multidisciplinary Breast Care Team (BCT) and other breast center staff.

DEFINITION AND REQUIREMENTS

The annual evaluation of services and care provide specific information to measure quality and an opportunity to correct deficiencies and enhance patient outcomes. These studies of quality may include structure, process, and patient outcome variables, and are selected by the Breast Program Leadership Committee (BPLC).

Study topics must be selected based on a problematic quality-related issue relevant to the breast center and local patient population, and used as a means to identify a potential issue or understand why a problem is occurring. Quality studies can evaluate various spectrums of patient care, including diagnosis, treatment access, and supportive care; within that spectrum they can be issues related to structure, process, and outcomes.

Each quality study is required, at a minimum, to have the following components:

- Must indicate the study topic that identifies a problematic quality-related issue within the breast center
- Define study methodology and the criteria for evaluation, including data needed to evaluate the study topic or answer the quality-related question
- Conduct the study according to the identified measures and methodology
- Prepare a summary of the study findings
- Design a corrective action plan based on evaluation of the data (if needed)
- Establish follow-up steps to monitor the actions implemented (if needed)

PROCESS REQUIREMENTS

Each year the breast center conducts or participates in three (3) or more center-specific studies that measure quality and/or outcomes, or two (2) or more center-specific studies and one (1) or more of the physician members participate in their specialty-specific quality improvement program.

For physician specialty-specific quality improvement programs, a summary of the data over the past year or time of study is presented to the BPLC.

A summary of the analysis of data and outcome of each study is discussed with the members of the BCT and other breast center staff.

The BPLC sets specific quality improvement goals for the center based on the quality studies. The goals and processes to implement changes in program activities are documented and discussed with the BCT.

Compliance is reviewed annually by the BPLC and documented in the meeting minutes.

Note the following standard specifications:

- The BPLC is required to conduct the annual audit within the 12 month date range. It is not required that studies be completed within the 12 month period, but they must be reviewed.
- Quality studies that duplicate topics or studies from year-to-year do not fulfill this standard.
- Quality improvement study designs and research cannot be counted/allocated to subsequent triennial accreditation cycles.
- Review of data presented in the NCDB data reports or tools (including measure compliance) do not fulfill the requirement for this standard.

DOCUMENTATION

Complete all required standard fields in the Survey Application Record (SAR).

Complete the template documenting the types of studies conducted and the methods utilized to communicate the study results, goals, and processes to implement changes in program activities with the BCT.

Provide documentation of physician and/or center participation in a national quality improvement initiative related to breast care, and the methods utilized to communicate the study results, goals, and processes to implement changes in program activities, with the BPLC and the BCT.

Document the annual audit by the BPLC in the meeting minutes.

EVALUATION

The surveyor will review and discuss the quality studies and required documentation during the site visit.

RATING COMPLIANCE

Compliance:

1. Each year the breast center conducts or participates in three (3) or more center-specific studies that measure quality and/or outcomes, or two (2) or more center-specific studies and one (1) or more of your physician members participate in their specialty-specific quality improvement program.
2. For physician specialty-specific quality improvement programs, a summary of the data over the past year or time of study is presented to the BPLC.
3. A summary of the analysis of data and outcome of each study is discussed with the members of the BCT and other breast center staff.
4. The BPLC sets specific quality improvement goals for the center based on the quality studies. The goals and processes to implement changes in program activities are documented and discussed with the BCT.

Noncompliance: The center does not fulfill one or more of the compliance criteria.

RESOURCES

Specialty-specific quality improvement programs:

- The American Society of Breast Surgeons Mastery of Breast Surgery℠ Program
- ASCO's Quality Oncology Practice Initiative (QOPI®)
- ASPS Tracking Operations and Outcomes for Plastic Surgeons (TOPS)
- The American College of Surgeons Surgeon Specific Registry (SSR)

Glossary, Key Terms, and Acronyms

Glossary, Key Terms, and Acronyms

Accession number: A unique patient identifier assigned when the patient is abstracted in the cancer registry. The accession number consists of the year in which the patient was first seen at the reporting facility and the consecutive order in which the patient was abstracted.

Adjuvant therapy: Additional treatment given after primary treatment (typically surgery) to reduce the risk of recurrence, e.g., systemic therapy or radiation therapy.

Annually: Once each calendar year.

ACR: American College of Radiology

Breast Center: The Breast Center is a singular or multiple locations providing diagnostic services, treatment services, and comprehensive care for patients with breast disease.

Breast Program Director (BPD): See definition and requirements in Standard 1.1.

Breast Program Leadership Committee (BPLC): See definition and requirements in Standard 1.1.

Breast Care Team (BCT): See definition and requirements in Standard 1.1.

Calendar year: January 1-December 31.

Calendar month: The first of the month through the last day of the month. For example, March 1 to March 31 or April 1 to April 30.

CAP: College of American Pathologists

Class of Case: Class of Case divides cases into two groups that reflects the program's primary responsibility in managing the cancer, analytic and non-analytic cases. More information Class of Case is available in the Facility Oncology Registry Data Standards.

Community representative: An individual who resides within the breast center's service area.

Compliance: The Breast Center meets all rating criteria as stated in each standard.

Definitive treatment: Neoadjuvant therapy, surgical resection, initiation of non-operative care, or initiation of palliative care.

Eligible Breast Cancer Patients: Breast cancer patients who are treated by a physician member of the Breast Care Team (BCT) at the Breast Center.

Elsewhere: A hospital, facility, or health care organization that is not owned, co-owned, or part of the licensure of the Breast Center.

Medical Records Review: The evaluation of patient medical records to determine compliance with specific standards.

Monitor: Closely and consistently observe and evaluate a function or process.

NAPBC: National Accreditation Program for Breast Centers

Neoadjuvant therapy: Treatment given to initiative treatment and/or reduce the size of the primary breast cancer before the primary surgical treatment.

Newly diagnosed: Patients who have received a breast cancer diagnosis at the Breast Center.

Noncompliance: The Breast Center does not meet one or more of the rating criteria as stated in each standard.

Patient representative: A current or former breast center patient.

Performance Report: Document notifying the Breast Center of the accreditation award.

Previously Undiagnosed: Breast cancer patients who receive the first diagnosis of breast cancer at the Breast Center.

Provided Services: Diagnostic services, treatment services, and comprehensive care are provided at the Breast Center.

Rating Criteria: The required elements for each standard that are evaluated during the site visit to determine compliance.

Referred Services: Diagnostic services, treatment services, and comprehensive care are provided elsewhere.

Satellite: A satellite must meet all of the following criteria:

1. Shared leadership with main center
2. Shared interdisciplinary breast cancer conference
3. Shared medical records (electronic or paper)
4. Must see patients at this center

Site Visit: An on-site review of the breast center by an NAPBC surveyor to determine compliance with NAPBC standards.

Surveyor: NAPBC-trained physician or other health care professional who conducts site visits and reviews breast center program activity documentation.

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A QUALITY PROGRAM *of the* AMERICAN COLLEGE OF SURGEONS

AMERICAN COLLEGE OF SURGEONS
Inspiring Quality:
Highest Standards, Better Outcomes

100+*years*