



National Accreditation Program  
for Breast Centers  
American College of Surgeons

# Optimal Resources for Breast Care

**2024 Standards**

Revised December 2023

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**National Accreditation Program  
for Breast Centers**  
American College of Surgeons

# Optimal Resources for Breast Care

## **2024 Standards**

**Revised December 2023**

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## Important Information

These standards are intended solely as qualification criteria for National Accreditation Program for Breast Centers (NAPBC) accreditation. They do not constitute a standard of care and are not intended to replace the medical judgment of any physician or health care professional in individual or general circumstances.

“Standard” as used in *Optimal Resources for Breast Care* is defined as a “qualification for accreditation,” not standard of care.

In order for a program to be found compliant with the NAPBC Standards, the program must be able to demonstrate compliance with the entire standard as outlined in the **Definition and Requirements, Documentation, and Measure of Compliance** sections under each standard. The **Documentation** and **Measure of Compliance** sections under each standard are intended to provide summary guidance on how compliance must be demonstrated but are not intended to stand alone or supersede the **Definition and Requirements**.

In addition to verifying compliance with the standards as written and outlined in *Optimal Resources for Breast Care*, the NAPBC may also consider additional administrative factors when reviewing a program for accreditation. The NAPBC reserves the right to withhold accreditation based on such factors. Examples include, but are not limited to: non-payment of accreditation invoices and outstanding fees, failure to schedule or complete an accreditation site visit in a timely manner, failure to properly remit any or all contracts and contractual obligations related to NAPBC accreditation.

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## Confidentiality Requirements

The American College of Surgeons (ACoS) and the National Accreditation Program for Breast Centers (NAPBC) expect NAPBC-accredited programs to follow local, state, and federal requirements related to patient privacy, risk management, and peer review in complying with or providing information to demonstrate compliance with standards of accreditation. These requirements vary from state-to-state.

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## Acknowledgments

The National Accreditation Program for Breast Centers (NAPBC) is thankful to its Board, the representatives of the national professional organizations dedicated to breast health, and the members of the NAPBC Standards Revision Project who were vital to the completion of *Optimal Resources for Breast Care*. The NAPBC is further grateful to all those who provided thoughtful and essential comments during the public feedback period. The NAPBC acknowledges the extensive contributions of the following people who participated in the creation of *Optimal Resources for Breast Care*.

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## About the NAPBC

The National Accreditation Program for Breast Centers (NAPBC) is a quality program of the American College of Surgeons, assisted by representatives from other national professional organizations focused on breast health. The NAPBC is dedicated to the improvement of quality outcomes for patients with breast disease and breast cancer through the implementation of multidisciplinary care guided by evidence-based accreditation standards, and comprehensive professional and patient education.

### **The NAPBC: Background and the Value of Accreditation**

The evaluation and management of patients with diseases of the breast historically occurred in a fragmented and disorganized clinical setting. In a complex clinical environment involving a multitude of health care professionals and clinicians, patients are best served by utilizing multidisciplinary coordination. This team-based approach to patient care resulted in the birth of the “breast center” concept in the United States in the 1970s. In recent decades, there has been a proliferation of breast centers providing care to the thousands of patients diagnosed with breast cancer, as well as addressing the equally compelling needs of the many patients presenting with non-malignant breast diseases.

Evidence-based and consensus-developed standards have garnered widespread recognition and ever-increasing importance. The United States health care system is undergoing a dramatic transformation centered on data-driven quality improvement, and documentation of adherence to widely accepted standards of care for all diseases, including those of the breast.

In order to improve the quality of patient evaluation and management of patient care, NAPBC accreditation is granted to breast programs that demonstrate compliance with the standards established herein. NAPBC accreditation is awarded to hospitals, academic medical centers, teaching hospitals, freestanding cancer centers, and private medical practices that demonstrate compliance with the NAPBC standards.

NAPBC-accredited centers must provide the following services:

- A multidisciplinary team approach to coordinate the best possible patient care and available treatment options
- Access to breast-specific information, education, and support
- Ongoing monitoring and improvement of patient care
- Information about participation in clinical trials and new treatment options

### **Benefits of Becoming a NAPBC-Accredited Program**

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

NAPBC-accredited programs receive the following:

- A model for organizing and managing a breast program to ensure multidisciplinary, integrated, and comprehensive breast care services
- Internal and external assessment of breast program performance based on recognized standards, demonstrating a commitment to quality care
- Accreditation for having met performance measures for high-quality breast care
- National recognition as a NAPBC-accredited program

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## Standards Interpretation

NAPBC-accredited programs must understand, implement, and demonstrate compliance with the accreditation standards outlined in *Optimal Resources for Breast Care* as written and defined by the NAPBC. While a full glossary of terms is provided at the end of this manual, it is important to establish definitions for several of these key terms prior to reading the accreditation standards.

**Accredited Program(s):** A single or multiple-location medical institution providing diagnostic services, treatment services, and comprehensive multidisciplinary care for patients with breast disease or breast cancer, which has achieved accreditation by the National Accreditation Program for Breast Centers (NAPBC). This also refers to initial applicant programs that are actively pursuing accreditation with the NAPBC.

**Calendar year review:** Compliance criteria requiring annual review must be completed at least once for each full calendar year (January 1 – December 31).

**Triennial review:** Compliance criteria requiring triennial review must be completed at least once every three (3) years during the NAPBC-accredited program's triennial accreditation cycle.

**Individualized Shared Decision Making (ISDM):** A structured, collaborative approach to healthcare decision-making that moves beyond the traditional model of informed consent by engaging the patient, their family, and healthcare providers. ISDM frameworks help to ensure that all parties engage in the decision-making process, that the patient's circumstances, values, preferences, and culture are appropriately considered, and that decisions are based on the best available evidence.

The NAPBC acknowledges the inherent difficulties in defining what constitutes individualized shared decision making because, by design, an appropriately individualized care plan may vary dramatically from patient to patient. However, it is the NAPBC's belief that elevating the patient voice in the exam room is always laudable, and especially critical for marginalized or traditionally underserved communities.

Examples of individualized shared decision making include, but are not limited to: offering resources for patients that are written or provided in the language(s) spoken by the patient, using patient-friendly terms that are informed by patient preference, eliciting and making plans to address barriers to fully individualized care for the patient, documenting a patient's preferences relative to their care plan, or respectfully sharing these preferences with the rest of the care team. This list is not exhaustive, and NAPBC-accredited programs are encouraged to be both critical and creative in determining how best to meet the needs of their specific patient populations.

NAPBC Standards requiring the implementation of individualized shared decision making are evaluated for compliance through the required review and evaluation of a particular standard conducted by the BPLC. The BPLC evaluation must review and assess how individualized shared decision-making principles are utilized in the required delivery of patient care outlined in that particular standard. The BPLC review must include discussion of barriers to utilizing individualized shared decision making, and options for improving or expanding the utilization of individualized shared decision making for a particular standard. Documentation of the BPLC review is required in the BPLC meeting minutes, as outlined in each standard. **Please refer to the [Appendix](#) of *Optimal Resources for Breast Care* for additional resources and examples related to individualized shared decision making.**

**Protocol:** Previously referred to as “policies and procedures” in past versions of the NAPBC Standards, a protocol is a structured and consistent process crafted by the NAPBC-accredited program to help implement the required compliance criteria for specific NAPBC standards. Protocols must be written and documented in a manner that demonstrates compliance with whichever NAPBC standard the protocol is designed to address. Additionally, all protocols must be formally approved by the Breast Program Leadership Committee (BPLC). Identical protocols that apply to several affiliated NAPBC-accredited programs are acceptable. Such protocols must be specifically stylized for each affiliated program, and be formally approved by each BPLC, as applicable. Protocols do not need to be officially-recognized hospital or institutional policies. **Please refer to the NAPBC 2024 Standards FAQ for guidelines and recommendations related to the development of protocols.**

It is the responsibility of all NAPBC-accredited programs to read *Optimal Resources for Breast Care* in its entirety, and demonstrate compliance with all applicable requirements for all applicable standards.

In order for a program to be found compliant with the NAPBC Standards, the program must be able to demonstrate compliance with the entire standard as outlined in the **Definition and Requirements, Documentation, and Measure of Compliance** sections under each standard. The **Documentation** and **Measure of Compliance** sections under each standard are intended to provide summary guidance on how compliance must be demonstrated, but are not intended to stand alone or supersede the **Definition and Requirements**.

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## Breast Program Leadership Committee Evaluations

Specific NAPBC standards require the Breast Program Leadership Committee (BPLC) to review and assess various aspects of the NAPBC-accredited program, such as elements of care, adherence to required protocols, resource allocation, patient services, and barriers to care.

The following NAPBC standards require annual review, at least once **each calendar year**. These BPLC evaluations must be documented in the BPLC meeting minutes, and must take place within the same calendar year on which they are based, or no later than the first quarter of the following calendar year.

- Standard 2.4: Multidisciplinary Breast Care Conference
- Standard 5.4: Management of Patients at Increased Risk for Breast Cancer
- Standard 5.6: Evaluation and Treatment Planning for the Newly Diagnosed Cancer Patient
- Standard 5.7: Comprehensive Evaluation of Patient Factors Before Treatment
- Standard 5.9: Surgical Care
- Standard 5.10: Reconstructive Surgery
- Standard 5.11: Medical Oncology
- Standard 5.12: Radiation Oncology
- Standard 5.13: Surgical Pathology
- Standard 7.1: Quality Measures
- Standard 9.1: Clinical Research Accrual

The following NAPBC standards require triennial review, at least once **each accreditation cycle**. These BPLC evaluations must be documented in the BPLC meeting minutes, and must take place within the same accreditation cycle on which they are based.

- Standard 5.1: Screening for Breast Cancer
- Standard 5.2: Diagnostic Imaging of the Breast and Axilla
- Standard 5.3: Evaluation and Management of Benign Breast Disease
- Standard 5.5: Genetic Evaluation and Management
- Standard 5.8: Patient Navigation
- Standard 5.14: Breast Cancer Staging Using the AJCC System
- Standard 5.15: Survivorship
- Standard 5.16: Surveillance

The following NAPBC standards require reporting to the BPLC. These reports must be documented in the BPLC meeting minutes, and must take place within the same calendar year on which they are based.

- Standard 7.2: Quality Improvement Initiatives

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## Accreditation Process

Processes for accreditation are detailed and updated on the [NAPBC website](#) and within the [Quality Portal](#). The NAPBC reserves the right to revise accreditation processes as needed.

## Accreditation Awards

Compliance ratings for each standard are decided based on consensus by the assigned NAPBC Site Reviewer and the NAPBC staff. When required, the NAPBC Executive Reviewers will also contribute to the compliance rating decision as the final adjudicators.

Each standard is rated as “Compliant,” “Non-Compliant,” or “Not Applicable.”

Accreditation Status	Definition
<b>Accredited</b>	<p>Awarded when a program has completed the site visit process and demonstrated full compliance with all applicable standards.</p> <p><b>Accredited</b> outcomes:</p> <ul style="list-style-type: none"> <li>• Program appears on the <a href="#">“Find an Accredited Program”</a> website</li> <li>• Program has full access to the <a href="#">Quality Portal</a> and its related resources</li> <li>• Certificate of accreditation is awarded</li> </ul>
<b>Accredited – Corrective Action Required</b> <i>Renewal Programs Only</i>	<p>Awarded when a renewal program receives a non-compliant rating for at least one (1) applicable standard, but fewer than twenty percent (20%) of all applicable standards, rated during the site visit process.</p> <p><b>Corrective Action</b> outcomes:</p> <ul style="list-style-type: none"> <li>• Program has twelve (12) months from the date of the accreditation report to resolve all non-compliant standards ratings</li> <li>• Program appears on the <a href="#">“Find an Accredited Program”</a> website</li> <li>• Program has full access to the <a href="#">Quality Portal</a> and its related resources</li> <li>• Certificate of accreditation is awarded after all non-compliant standards ratings have been resolved and <b>Accredited</b> status has been achieved</li> </ul>
<b>Not Accredited – Corrective Action Required</b> <i>Initial Applicants Only</i>	<p>Awarded when an initial applicant receives a non-compliant rating for four (4) or fewer applicable standards rated during the site visit process.</p> <p><b>Not Accredited Corrective Action</b> outcomes:</p> <ul style="list-style-type: none"> <li>• Program has twelve (12) months from the date of the accreditation report to resolve all non-compliant standards ratings</li> <li>• Program does <b>not</b> appear on the <a href="#">“Find an Accredited Program”</a> website</li> <li>• Program has full access to the <a href="#">Quality Portal</a> and its related resources</li> <li>• Certificate of accreditation is awarded after all non-compliant standards ratings have been resolved and <b>Accredited</b> status has been achieved</li> </ul>
<b>Not Accredited</b>	<p>Awarded when a renewal program receives a non-compliant rating for twenty percent (20%) or more of the applicable standards rated during the site visit process.</p> <p>Awarded when an initial applicant receives a non-compliant rating for five (5) or more applicable standards rated during the site visit process.</p> <p>Awarded when any program does not resolve all non-compliant standards within the established timeframe for corrective action.</p> <p><b>Not Accredited</b> outcomes:</p> <ul style="list-style-type: none"> <li>• Program does <b>not</b> appear on the <a href="#">“Find an Accredited Program”</a> website</li> <li>• Program does <b>not</b> have access to the <a href="#">Quality Portal</a></li> <li>• Program may re-apply for accreditation as an initial applicant after documenting one (1) calendar year of compliance with all applicable standards</li> </ul>





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**NATIONAL ACCREDITATION PROGRAM FOR BREAST CENTERS**

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# 1 Institutional Administrative Commitment

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## **Rationale**

This chapter is designed to help NAPBC-accredited programs utilize their available resources, services, and administrative support to provide the best possible care to all patients with breast disease or breast cancer. Institutional administration must support the NAPBC-accredited program with aligned goals for patient experience, service, and high-quality care.

## 1.1 Administrative Commitment

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### Definition and Requirements

NAPBC-accredited programs must provide a letter of authority from facility leadership (CEO or equivalent) demonstrating commitment to the NAPBC-accredited program. The letter of authority must include, but is not limited to:

- A high-level description of the NAPBC-accredited program
- Any initiatives involving the NAPBC-accredited program during the accreditation cycle that were initiated for the purposes of ensuring quality of care and patient safety
- Facility leadership's involvement in the NAPBC-accredited program
- Examples of current and future financial investment in the NAPBC-accredited program
  - For example: plans for equipment purchases or expanded services

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### Documentation

#### Submitted with Pre-Review Questionnaire

- Letter of authority from facility leadership that includes all required elements

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### Measure of Compliance

Once each accreditation cycle, the NAPBC-accredited program fulfills all compliance criteria:

- NAPBC-accredited program authority is established and documented through a letter from facility leadership that addresses all required elements





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## 2 Program Scope and Governance

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## **Rationale**

The NAPBC Standards are designed to provide multidisciplinary care to all patients with breast disease or breast cancer. The leadership structure outlined in Chapter 2 promotes multidisciplinary oversight for the entire NAPBC-accredited program, and accountability for fulfilling the measures of compliance for each standard.

## 2.1 Breast Program Leadership Committee

### Definition and Requirements

The Breast Program Leadership Committee (BPLC) is the governing body of a NAPBC-accredited program and is chaired by the Breast Program Director (BPD). Each NAPBC-accredited program must have its own BPLC.

At minimum, the BPLC must consist of at least the following members:

- Three (3) physicians, representing three (3) different medical disciplines
  - One of the physician members must be the BPD

AND

- Two (2) healthcare professionals, representing different disciplines related to the management and/or care of patients with breast disease or breast cancer
  - The healthcare professional members cannot be physicians
  - The healthcare professional members may represent any different disciplines, including, but not limited to, the BPLC member disciplines outlined below

The BPLC is responsible for establishing the core group of health care providers who contribute to the various patient care protocols developed by the NAPBC-accredited program. The BPLC must plan, implement, evaluate, and improve all breast-related activities provided by the NAPBC-accredited program. The BPLC must maintain accurate meeting minutes, including documentation of meeting attendance for all appointed members, designated alternates, and any additional individuals in attendance.

Examples of BPLC member disciplines include, but are not limited to:

- Pathology
- Radiology
- Surgery
- Medical oncology
- Radiation oncology
- Reconstructive surgery
- Physical medicine
- Genetic professionals
- Nursing
- Oncology Data Specialists (ODSs)
- Research
- Radiology technologists
- Registered dietitian nutritionists
- Navigation professionals
- Social work
- Hospital administration

As the minimum membership requirement for the BPLC consists of three (3) physicians and two (2) healthcare professionals, it is not required for all of the disciplines outlined above to be represented on the BPLC.

It is recommended, but not required, that a community representative and/or patient representative be a full member of the BPLC.

Membership appointments to the BPLC must occur at the first meeting of a calendar year at least once during the accreditation cycle. All appointments must be documented in the BPLC meeting minutes. If an appointed member cannot continue to serve on the BPLC, a new member must be appointed at the next BPLC meeting, with documentation of the new appointment included in the BPLC meeting minutes.

For each appointed member of the BPLC, one (1) designated alternate member may be identified. Designating an alternate is optional. Only one (1) alternate may be designated for each appointed member of the BPLC.

Designated alternates must meet all the applicable requirements for BPLC membership outlined in this standard. Designated alternates for the three (3) physician members must also be physicians who are qualified to serve on the BPLC. Designated alternates for the two (2) healthcare professional members must also be healthcare professionals who are qualified to serve on the BPLC. Appointed BPLC members and their designated alternate are not required to represent the same medical discipline. An individual may only serve as an alternate for a single appointed member of the BPLC.

The identification of designated alternates must occur at the first meeting of the accreditation cycle. All designated alternates must be documented in the BPLC meeting minutes. If a designated alternate cannot continue to serve on the BPLC, a new alternate may be designated at the next BPLC meeting, with documentation of the new designated alternate included in the BPLC meeting minutes.

Requirements for BPLC membership:

- Physician BPLC members must be compliant with Standard 4.1
- Physician BPLC members must possess current medical licensure and active medical staff appointment
- Oncology nurse BPLC members must be compliant with Standard 4.2
- Physician assistant BPLC members must be compliant with Standard 4.3
- Genetic professional BPLC members must be compliant with Standard 4.4
- Navigation professional BPLC members must be compliant with Standard 4.5
- Healthcare professional BPLC members must have appropriate qualifications/certifications in their field

Each calendar year, the BPLC must:

- Meet a minimum of four (4) times per year
- Ensure each BPLC member or their designated alternate attends at least seventy-five percent (75%) of the BPLC meetings held each calendar year
- Plan, implement, evaluate, and improve all breast-related activities of the NAPBC-accredited program
- Ensure program compliance with all NAPBC Standards

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## Documentation

### Submitted with Pre-Review Questionnaire

- BPLC meeting minutes, including documentation of member attendance, and any additional individuals in attendance
- Breast Program Leadership Committee Template

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

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## Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- The BPLC must maintain multidisciplinary membership, including a minimum of three (3) physicians representing three (3) different medical disciplines, one of which must be the BPD, and two (2) healthcare professionals representing different disciplines related to the management and/or care of patients with breast disease or breast cancer
- BPLC membership, including any designated alternates, must be documented in the BPLC meeting minutes at the first meeting of the calendar year, at least once each accreditation cycle
- The BPLC must meet a minimum of four (4) times each calendar year
- All BPLC members or their designated alternate must attend at least seventy-five percent (75%) of BPLC meetings held each calendar year

## 2.2 Breast Program Director

### Definition and Requirements

A physician must be appointed as the Breast Program Director (BPD), who maintains the authority and accountability for the operations of the NAPBC-accredited program. Appointment of co-BPDs is permissible. If co-BPDs are appointed, at least one (1) must be a physician.

The appointment of the BPD must be documented in the Breast Program Leadership Committee (BPLC) meeting minutes during the first BPLC meeting of the calendar year, at least once during each accreditation cycle.

The responsibilities of the BPD include:

- Familiarity with the NAPBC Standards, and NAPBC site visit processes
- Ensuring the NAPBC-accredited program maintains compliance with the NAPBC Standards
- Designating an individual(s) to prepare and submit all information required and requested by the NAPBC, and confirming that the information submitted is accurate and complete. This information includes, but is not limited to:
  - Program application forms
  - Annual program updates
  - Updates/changes to the program name, ownership, and Federal Employer Identification Number (FEIN)
  - Change of the BPD(s)
  - Corrective action documentation
  - Appeals documentation
- Overseeing the selection of Breast Care Team (BCT) members
- Overseeing the development and maintenance of protocols for the BCT, and other NAPBC-accredited program personnel
- Overseeing the distribution of protocols to the BPLC and the BCT

### Documentation

#### Submitted with Pre-Review Questionnaire

- BPLC meeting minutes documenting the appointment of the BPD

### Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- A physician with authority and accountability for the operations of the NAPBC-accredited program is appointed as the Breast Program Director
- The Breast Program Director maintains compliance with all the responsibilities of the position

## 2.3 Breast Care Team

### Definition and Requirements

The NAPBC-accredited program must have a defined, multidisciplinary, Breast Care Team (BCT) with a minimum of one (1) physician member appointed by the Breast Program Leadership Committee (BPLC) and the Breast Program Director (BPD) to represent each of the following specialties:

- Surgery
- Pathology
- Radiology
- Medical oncology
- Radiation oncology

All new physicians (including surgeons, pathologists, radiologists, medical oncologists, radiation oncologists, and reconstructive surgeons) who are regularly involved in the evaluation and management of patients with breast disease or breast cancer in the NAPBC-accredited program after January 1, 2024, must be a member of the BCT, and maintain compliance with all NAPBC Standards.

Physicians involved in the evaluation and management of patients with breast disease or breast cancer at multiple NAPBC-accredited programs are only required to participate as a member of the BCT at a single NAPBC-accredited program where they provide care. Such physicians must provide a letter of attestation documenting BCT membership at the facility of participation. The letter of attestation must be issued by the Breast Program Leadership Committee (BPLC) and the Breast Program Director (BPD) at the facility of participation.

The BPD and the BPLC have discretion to appoint additional health care professionals as members of the BCT. These health care professionals include, but are not limited to: advanced practice providers, licensed/registered nurses, Oncology Data Specialists (ODSs), physical medicine providers, genetic professionals, researchers, supportive care team professionals, radiology technologists, navigation professionals, social workers, registered dietitian nutritionists (RDNs), exercise professionals, ordained clergy or religious leaders, financial advisors, certified lymphedema therapists, plastic or reconstructive surgeons, and clinical psychologists.

Requirements for BCT membership:

- Members must have appropriate qualifications/certifications/registrations in their field, as outlined in Chapter 4
- Collaboration and development of treatment plans, including transition of care, which will lead to the best possible outcomes for patients, as outlined in Chapter 5
- Members must provide patient care in compliance with the NAPBC Standards, and in accordance with institutional policies
- Surgery, pathology, radiology, medical oncology, and radiation oncology BCT members must participate in Multidisciplinary Breast Care Conferences (MBCC), as necessary to demonstrate compliance with Standard 2.4
  - At least one (1) surgeon, pathologist, radiologist, medical oncologist, and radiation oncologist must attend each MBCC
  - Other specialties are encouraged, but not required, to attend the MBCC
- Compliance with continuing education, as required by Standard 8.2

### Documentation

**Submitted with Pre-Review Questionnaire**

- Breast Care Team Template

### Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- The Breast Care Team is a defined, multidisciplinary team, with a minimum of one (1) appointed physician member from each of the following specialties: surgery, pathology, radiology, medical oncology, and radiation oncology, and additional appointed members at the discretion of the BPD and the BPLC
- All new surgeons, pathologists, radiologists, medical oncologists, radiation oncologists, and reconstructive surgeons who are regularly involved in the evaluation and management of patients with breast disease or breast cancer in the NAPBC-accredited program after January 1, 2024, are members of the Breast Care Team and maintain compliance with the NAPBC Standards
- Appointed members of the Breast Care Team meet all the membership requirements

## 2.4 Multidisciplinary Breast Care Conference

### Definition and Requirements

Multidisciplinary Breast Care Conferences (MBCC) are integral to improving the care of patients with breast disease or breast cancer by reviewing and contributing to patient management and patient outcomes, while providing education to physicians and other staff in attendance. Attendance and active participation are encouraged by all members of the Breast Care Team (BCT). All participants attending the MBCC must maintain complete confidentiality for all information disclosed during each conference.

The Breast Program Leadership Committee (BPLC) is responsible for monitoring individual and specialty attendance on an annual basis. **At least one (1) surgeon, radiologist, pathologist, radiation oncologist, and medical oncologist must attend each MBCC.** The BPLC must also set attendance requirements for all specialties attending the MBCC, which are applied at the individual level. For example, if the BPLC sets a seventy-five percent (75%) attendance requirement for surgeons, then each surgeon member of the BCT must attend seventy-five percent (75%) of MBCC meetings.

On-site supportive care team professionals, and reconstructive or plastic surgeons are strongly encouraged to attend each MBCC.

Treating physicians are strongly encouraged to attend the MBCC when their patients are being presented.

Attending the MBCC via videoconference is acceptable, but the virtual attendee(s) must have access to all meeting materials required for full participation and input, such as imaging studies, specimen photographs, and pathology reports and/or slides.

The MBCC discussion must address the following elements for each case presented:

- Clinical and/or pathological stage
- Treatment planning using evidence-based guidelines
- Options and eligibility for genetic testing (where applicable)
- Options and eligibility for clinical research studies (where applicable)
- Options and eligibility for supportive care services (where applicable)
- Visual display of clinically relevant pathology slides
- Visual display of clinically relevant imaging studies

If a MBCC is shared between NAPBC-accredited programs, each participating NAPBC-accredited program must maintain their own separate MBCC records, which document full compliance with this standard.

### Requirements for MBCC Frequency and Case Presentation

Analytic breast cancer cases must be presented and prospectively discussed by the NAPBC-accredited program during Multidisciplinary Breast Care Conferences (MBCC).

NAPBC-accredited programs with an annual analytic case load of **1-250 breast cancer cases** (excluding class of case 00) must meet the following requirements:

- MBCC meetings must be held twice a month, or more frequently at the discretion of the BPLC
  - MBCC meetings must be held at least twenty-four (24) times each calendar year
- A minimum of fifty percent (50%) of all analytic breast cancer cases must be presented and prospectively discussed each calendar year
- NAPBC-accredited programs with fewer than 100 annual analytic breast cancer cases have the option of including these cases as part of a general cancer conference

NAPBC-accredited programs with an annual analytic case load of **251+ breast cancer cases** (excluding class of case 00) must meet the following requirements:

- MBCC meetings must be held weekly, defined as an average of four meetings each month
  - MBCC meetings must be held at least forty-eight (48) times each calendar year
- The BPLC must develop and implement a protocol that defines a process to calculate the total number of analytic breast cancer cases that must be presented and prospectively discussed by the MBCC each calendar year
  - The protocol must include all relevant factors considered by the BPLC to calculate the number of analytic breast cancer cases that must be presented and discussed each calendar year
  - The BPLC must review and assess its compliance with the MBCC case presentation protocol
  - If the number of cases presented and prospectively discussed by the MBCC is below thirty percent (30%) of the total number of analytic breast cancer cases for the calendar year, the BPLC must provide written justification in the BPLC meeting minutes for presenting fewer than thirty percent (30%) of the total number of analytic breast cancer cases during that calendar year

Cases presented and prospectively discussed must include, but are not limited to:

- Newly-diagnosed cases with treatment not yet initiated, or treatment initiated, and discussion of additional treatment is required
- Cases previously diagnosed, initial treatment completed, and discussion of adjuvant treatment or treatment for recurrence or progression is needed
- Cases previously diagnosed, and discussion of supportive or palliative care is needed
- Cases in consideration for clinical trials/research

Each calendar year, the BPLC must discuss and evaluate the following:

- MBCC meeting frequency
- MBCC attendance by multidisciplinary physicians, and BCT members
- Number of cases presented, and the percentage of cases presented and prospectively discussed
- If applicable, assessment of compliance with the MBCC case presentation protocol
- If applicable, written justification for presenting fewer than thirty percent (30%) of the total number of analytic breast cancer cases for a calendar year
- Elements of discussion for each case, including, but not limited to, whether the following were discussed:
  - Clinical and/or pathological stage
  - Treatment planning using evidence-based guidelines
  - Appropriateness and availability for genetic testing, clinical research studies, and supportive care services, (where applicable)
  - Visual display of clinically relevant pathology slides
  - Visual display of clinically relevant imaging studies

The BPLC discussion and evaluation must be documented in the BPLC meeting minutes each calendar year.

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## Documentation

### Reviewed On-Site

- The site reviewer must attend a Multidisciplinary Breast Care Conference

### Submitted with Pre-Review Questionnaire

- Multidisciplinary Breast Care Conference Template
- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

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## Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- The Breast Program Leadership Committee (BPLC) must establish and oversee the following:
  - MBCC frequency requirements
  - MBCC attendance requirements
  - MBCC attendance records
  - Annual and prospective case presentations, including the required discussion elements
- The MBCC evaluation is completed by the BPLC, and documented in the BPLC meeting minutes







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## **3** Facilities and Equipment Resources

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## **Rationale**

Chapter 3 of the NAPBC Standards is designed to help NAPBC-accredited programs emphasize safety and continuity of care for patients with breast disease or breast cancer. While delivering the high-quality breast care associated with all NAPBC-accredited programs, maintaining the appropriate certifications and/or accreditations for the medical facility ensures high reliability and consistency across all service lines.

## 3.1 Facility Accreditation

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### Definition and Requirements

The NAPBC-accredited program must deliver breast care in an appropriate health care facility.

If required by state law, the facility must be licensed by the appropriate state licensing authority. If state licensure is not required, the facility must be accredited or licensed by a recognized federal, state, or local authority, appropriate to facility type.

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### Documentation

#### Submitted with Pre-Review Questionnaire

- Documentation of health care facility accreditation or licensure
- If applicable, a CoC Accreditation Report from the most recent CoC site visit demonstrating compliance with CoC Standard 3.1

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### Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- The facility is accredited or licensed by a recognized federal, state, or local authority, appropriate to the facility type

## 3.2 Radiation Oncology Quality Assurance

### Definition and Requirements

The NAPBC-accredited program must follow recognized quality assurance practices for the safe delivery of radiation oncology treatment. To demonstrate compliance with this standard, the facility must be accredited by any of the NAPBC-approved radiation oncology organizations outlined below, or the facility must implement a radiation oncology quality assurance (QA) program.

Accreditation from any of the following organizations is approved by the NAPBC to demonstrate compliance with this standard:

- The American College of Radiation Oncology (ACRO)
- The American Society for Radiation Oncology Accreditation Program for Excellence (ASTRO-APEX)
- The American College of Radiology Radiation Oncology Practice Accreditation (ACR- ROPA)

If the facility is not accredited by any of the organizations outlined above, a radiation oncology quality assurance (QA) program must be in place, and a Radiation Quality Assurance report must confirm adherence with the following quality assurance practices:

- Patient identity must be verified by two (2) independent methods before each encounter
- Daily, monthly, and annual quality assurance procedures must be completed on radiation treatment machines, following the guidelines of the American Association of Physicists in Medicine (AAPM)
- Dosage calculations must be independently verified for every new or changed treatment before starting treatment
- Patient-specific quality assurance must be completed prior to initiating Intensity-Modulated Radiation Therapy (IMRT)

If radiation oncology is referred to an outside facility, the NAPBC-accredited program must provide the required documentation as outlined above from the referred facility.

### Documentation

#### Submitted with Pre-Review Questionnaire

- Documentation of facility accreditation for radiation oncology, or the self-administered Radiation Quality Assurance report, which includes all the required elements

### Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- The facility is accredited by ACRO, ASTRO-APEX, or ACR-ROPA, or a self-administered quality assurance program is in place
- If the NAPBC-accredited program has a locally developed quality assurance program in place, a Radiation Quality Assurance report must confirm adherence to the required quality assurance practices

## 3.3 Image Guided Biopsy Quality Assurance

### Definition and Requirements

The NAPBC-accredited program must follow recognized quality assurance practices for the safe performance of image guided biopsy procedures, including accreditation from the American College of Radiology (ACR) as outlined below, and/or surgeon certification from the American Society of Breast Surgeons (ASBrS) for Stereotactic Breast Procedures and Breast Ultrasound.

#### Stereotactic Core Needle Biopsy

Stereotactic core needle biopsy must be performed at an ACR Stereotactic Breast Biopsy-accredited facility, or by an ASBrS Stereotactic Breast Procedures Certified Surgeon.

Surgeons performing stereotactic core needle biopsy at the NAPBC-accredited program must be certified to perform these procedures by the ASBrS Stereotactic Breast Procedures Certification Program. Surgeons performing stereotactic core needle biopsy must provide documentation of ASBrS Stereotactic Breast Procedures Certification at the time of the NAPBC site visit. Surgeons in the process of obtaining ASBrS Stereotactic Breast Procedures Certification must provide documentation of progress toward certification. Documentation of completion of the ASBrS Stereotactic Breast Procedures Certification Program for Surgical Fellows may also be utilized to meet the measure of compliance for this standard.

The ACR designation of Comprehensive Breast Imaging Center (CBIC) does meet the measure of compliance for radiology accreditation for ultrasound and MRI. However, ACR CBIC designation does not meet the measure of compliance for surgeons performing image guided biopsy.

#### Ultrasound-Guided Needle Biopsy

Diagnostic ultrasound and/or ultrasound-guided needle biopsy must be performed at an ACR Breast Ultrasound-accredited facility, or by an ASBrS Breast Ultrasound Certified Surgeon.

Surgeons who perform breast diagnostic ultrasound and/or ultrasound-guided breast biopsy at the NAPBC-accredited program must be certified to perform these procedures by the ASBrS Breast Ultrasound Certification Program. Surgeons performing breast diagnostic ultrasound and/or ultrasound-guided breast biopsy must provide documentation of ASBrS Breast Ultrasound Certification at the time of the NAPBC site visit. Surgeons in the process of obtaining ASBrS Breast Ultrasound Certification must provide documentation of progress toward certification. Documentation of completion

of the ASBrS Breast Ultrasound Certification Program for Surgical Fellows may also be utilized to meet the measure of compliance for this standard. The requirement for ASBrS Breast Ultrasound Certification does not apply to surgeons using ultrasound as an extension of the clinical diagnosis or for localization.

The ACR CBIC designation does meet the measure of compliance for radiologists, but ACR CBIC designation does not meet the measure of compliance for surgeons performing diagnostic ultrasound and/or ultrasound-guided needle biopsy.

#### MRI Biopsies

The NAPBC-accredited program must have an ACR Breast MRI-accredited facility if MRI biopsies are performed by the NAPBC-accredited program.

### Documentation

#### Submitted with Pre-Review Questionnaire

- Documentation of all required accreditations and certifications, based on the procedures performed by the NAPBC-accredited program

### Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- Stereotactic core needle biopsy is performed by radiologists at a facility with ACR Stereotactic Breast Biopsy Accreditation
- Surgeons performing stereotactic core needle biopsy are certified by the ASBrS Stereotactic Breast Procedures Certification Program, or Surgical Fellows Program
- Diagnostic ultrasound and/or ultrasound-guided needle biopsy are performed by radiologists at a facility with ACR Breast Ultrasound Accreditation
- Surgeons performing diagnostic ultrasound and/or ultrasound-guided needle biopsy are certified by the ASBrS Breast Ultrasound Certification Program, or Surgical Fellows Program
- MRI biopsies are performed at a facility with ACR Breast MRI Accreditation

## 3.4 Breast Imaging Quality Assurance

### Definition and Requirements

The NAPBC-accredited program must follow recognized quality assurance practices for performing breast MRI. All mammography services must be provided in accordance with federal guidelines established by the Mammography Quality Standards Act (MQSA). To demonstrate compliance with this standard, the NAPBC-accredited program must meet any of the following criteria:

- American College of Radiology (ACR) Breast MRI Accreditation
- ACR Designated Comprehensive Breast Imaging Center (CBIC)
- Establish a referral relationship with a local facility to provide the breast MRI services outlined below

NAPBC-accredited programs performing breast MRI on-site must have the capacity to provide all of the following services:

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

If the NAPBC-accredited program does not have the capacity to perform all of the services outlined above, it must establish a referral relationship with a local facility with the capacity to provide all of the required services. The referred facility must meet either of the following criterion:

- American College of Radiology (ACR) Breast MRI Accreditation
- ACR Designated Comprehensive Breast Imaging Center (CBIC)

### Documentation

#### Reviewed On-Site

- If breast MRI services are referred to a local facility, the site reviewer will evaluate and confirm the referral relationship

#### Submitted with Pre-Review Questionnaire

- Documentation of ACR Breast MRI Accreditation or ACR CBIC designation

### Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- NAPBC-accredited programs performing breast MRI on-site must hold ACR Breast MRI Accreditation or ACR CBIC designation
- NAPBC-accredited programs not performing breast MRI on-site must have an established referral relationship with a local facility to provide these breast MRI services
  - The referred facility must hold ACR Breast MRI Accreditation or ACR CBIC designation
- NAPBC-accredited programs must provide all mammography services in accordance with federal guidelines established by the Mammography Quality Standards Act (MQSA)

## 3.5 Pathology Quality Assurance

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### Definition and Requirements

The NAPBC-accredited program must utilize recognized breast cancer surgical specimen pathology reporting templates, and those templates must contain the required core data elements outlined by the College of American Pathologists (CAP). The breast cancer surgical specimen pathology reports must utilize synoptic formatting.

To demonstrate compliance with this standard, the facility must document accreditation for anatomic pathology from any of the following organizations:

- College of American Pathologists (CAP)
- American Association for Laboratory Accreditation (A2LA)
- Accreditation Commission for Health Care (ACHC)
- The Joint Commission (TJC)
- COLA Laboratory Accreditation

NAPBC-accredited programs located in the state of New York (NY) or the state of Washington (WA) may provide documentation of clinical laboratory quality assurance for anatomic pathology from the New York State Department of Health or the Washington State Department of Health, respectively, in lieu of documentation of anatomic pathology accreditation from any of the organizations outlined above.

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### Documentation

#### Submitted with Pre-Review Questionnaire

- Documentation of approved anatomic pathology accreditation

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### Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- The facility is accredited for anatomic pathology by an approved laboratory accreditation organization or a qualifying state Department of Health





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## 4 Personnel and Services Resources

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## **Rationale**

Health care providers and staff take patients' lives in their hands every day. Each specialist must maintain appropriate credentials and complete continuing education in the treatment and/or management of breast disease and breast cancer to help ensure the delivery of high-quality care consistent with currently established best practices.

## 4.1 Physician Credentials

### Definition and Requirements

The management of patients with breast disease or breast cancer must be conducted by a multidisciplinary team, including surgeons, radiologists, pathologists, radiation oncologists, and medical oncologists. All physicians involved in the evaluation and management of patients with breast disease or breast cancer must meet either of the following requirements:

- Board certification from the American Board of Medical Specialties (ABMS), the American Osteopathic Association (AOA), or equivalent

OR

- Demonstrate ongoing cancer education by earning twelve (12) cancer-related Continuing Medical Education (CME) hours each calendar year, six (6) of which must be related to breast disease or breast cancer

### Scope of Standard

This standard applies to physician members of the Breast Care Team (BCT) who are involved in the evaluation and management of patients with breast disease or breast cancer at the accredited program for at least one (1) calendar year. This standard does not apply to physicians who are in fellowship, residency, or physicians within the five (5) years immediately following graduation from fellowship or residency.

### Documentation

#### Submitted with Pre-Review Questionnaire

- Physician Certification Credentials Template
- Documentation of CME credit hours for all BCT physicians who are not board certified and are involved in the evaluation and management of patients with breast disease or breast cancer
- If applicable, CoC Accreditation Report from the most recent CoC site visit documenting compliance with CoC Standard 4.1
- If applicable, CoC Physician Certification Credentials Template

### Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- All physicians on the Breast Care Team (BCT) involved in the evaluation and management of patients with breast disease or breast cancer must be board certified (or equivalent)
- Physicians who are not board certified must demonstrate ongoing cancer-related education by earning twelve (12) cancer-related CME credit hours each calendar year, six (6) of which must be related to breast disease or breast cancer

## 4.2 Oncology Nursing Credentials

### Definition and Requirements

Oncology nursing care must be provided by nurses with specialized knowledge and skill in breast disease or breast cancer as demonstrated by a cancer-specific certification, or continuing education in oncology nursing. Oncology nursing competency must be reviewed each calendar year, per hospital policy.

All registered nurse (RN) and advanced practice nurse (APRN) members of the Breast Care Team (BCT) who provide direct breast oncology care must demonstrate compliance with either of the following requirements:

- Current cancer-specific certification in the nurse's specialty from an accredited certification program
- OR
- Continuing education by completing thirty-six (36) cancer-related Nursing Continuing Professional Development (NCPD) hours each accreditation cycle
  - It is recommended, but not required, that NCPD hours applicable to patients with breast disease or breast cancer be prioritized over other cancer-related NCPD hours, whenever possible
  - A specific number of NCPD hours applicable to patients with breast disease or breast cancer is not required

Nurses in the process of obtaining a cancer-specific certification do not need to submit documentation of cancer-related continuing education, but must provide documentation of progress toward certification.

#### Oncology Nursing Certifications

- Oncology nursing certifications that qualify for this standard include, but are not limited to:
- Advanced Oncology Certified Nurse Practitioner (AOCNP®)
- Advanced Oncology Certified Clinical Nurse Specialist (AOCNS®)
- Advanced Oncology Certified Nurse (AOCN®)
- Certified Breast Care Nurse (CBCN®)
- Oncology Certified Nurse (OCN®)
- Oncology Nurse Navigator-Certified Generalist (ONN-CG™)

#### Continuing Education

Oncology nursing certification is strongly preferred. If a nurse providing direct breast oncology care is not certified, then the nurse must complete thirty-six (36) cancer-related NCPD hours each accreditation cycle, with a recommended emphasis on hours that are applicable to patients with breast disease or breast cancer.

#### Scope of Standard

This standard applies to registered nurses (RNs) and advanced practice nurses (APRNs) who are members of the BCT and provide direct breast care in the NAPBC-accredited program for at least one (1) calendar year. Specifically, the standard applies to BCT nurses in medical oncology who give chemotherapy, BCT nurses in radiation oncology, BCT nurse navigators, and BCT nurses in the cancer center or breast clinic(s) within the NAPBC-accredited program. This standard does not apply to nurses in the hospital who have occasional contact with cancer patients, it does not apply to operating room or recovery room nurses, and it does not apply to nurses who are not members of the BCT.

### Documentation

#### Submitted with Pre-Review Questionnaire

- Oncology Nursing Credentials Template
- Documentation of NCPD hours for all BCT nurses providing direct breast oncology care who do not hold a cancer-specific certification
- If applicable, CoC Accreditation Report from the most recent CoC site visit, documenting compliance with CoC Standard 4.2
- If applicable, CoC Oncology Nursing Credentials Template
- A protocol that states oncology nursing competency must be evaluated each calendar year, per hospital or facility policy

### Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- All BCT nurses providing direct breast oncology care hold a cancer-specific certification or demonstrate continuing education by completing thirty-six (36) cancer-related Nursing Continuing Professional Development (NCPD) hours each accreditation cycle, with a recommended emphasis on hours that are applicable to patients with breast disease or breast cancer
- Programs have in place a protocol that ensures oncology nursing competency is reviewed each calendar year, per hospital policy

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## 4.3 Physician Assistant Credentials

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### Definition and Requirements

Oncology care must be provided by physician assistants (PAs) with specialized knowledge and skill in breast disease or breast cancer as demonstrated by continuing education in oncology.

All PAs who provide direct breast oncology care must demonstrate ongoing education by earning thirty-six (36) cancer-related continuing education hours each accreditation cycle.

- It is recommended, but not required, that continuing education hours applicable to patients with breast disease or breast cancer be prioritized over other cancer-related continuing education hours, whenever possible
- A specific number of continuing education hours applicable to patients with breast disease or breast cancer is not required

#### Scope of Standard

This standard applies to PAs who provide direct breast care in the NAPBC-accredited program for at least one (1) calendar year. Specifically, the standard applies to PAs in medical oncology clinics, PAs in radiation oncology, PAs in infusion sites, and PAs in the breast center, cancer center, or breast clinics within the NAPBC-accredited program. This standard does not apply to PAs in the hospital who have occasional contact with cancer patients, and it does not apply to operating room or recovery room PAs. If the NAPBC-accredited program does not have PAs, this standard will be rated “not applicable.”

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### Documentation

#### Submitted with Pre-Review Questionnaire

- Physician Assistant Education Template

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### Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- All PAs providing direct breast oncology care earn thirty-six (36) cancer-related continuing education hours each accreditation cycle, with a recommended emphasis on hours that are applicable to patients with breast disease or breast cancer

## 4.4 Genetic Professional Credentials

### Definition and Requirements

Genetic counseling and testing for patients with breast disease or breast cancer must be performed by genetic professionals with an educational background in cancer genetics and hereditary cancer syndromes.

Genetic professionals must meet any of the following qualifications to demonstrate compliance with this standard, including, but not limited to:

- Board certification or board eligibility by the American Board of Genetic Counseling (ABGC)
- Board certification or board eligibility by the American Board of Medical Genetics and Genomics (ABMGG)
- Advanced Genetics Nursing Certification (AGNBC) from the American Nurses Credentialing Center (ANCC)
- Advanced Clinical Genomics Nurse (ACGN) credentials from the Nurse Portfolio Credentialing Commission (NPCC)
- Clinical Genomics Nurse (CGN) credentials from the Nurse Portfolio Credentialing Commission (NPCC)
- Completion of City of Hope Intensive Course in Genomic Cancer Risk Assessment
- Qualified, licensed, health care professional with Cancer Genetic Risk Assessment (CGRA) certification from the National Consortium of Breast Centers (NCBC)
- Qualified, licensed, health care professional with Advanced Oncology Certified Nurse Practitioner (AOCNP) credentials, or equivalent certification from the Oncology Nursing Certification Corporation (ONCC)
- Board certified or board eligible physician with experience in cancer genetics
  - This qualification requires providing cancer risk assessment to patients on a regular basis

The continuing education requirements for genetic professionals are outlined in Standard 8.2.

If genetic counseling is provided by a telegenetics company or a facility outside the NAPBC-accredited program, the outside company or facility must utilize genetic professionals who meet any of the qualifications outlined above.

NAPBC-accredited programs must consider conflict of interest when choosing professionals to provide cancer risk assessment and genetic counseling and testing.

Due to variability in access to genetic counseling and testing, it may be necessary for some NAPBC-accredited programs to utilize an alternative service delivery model to meet compliance with this standard. Please refer to the [Appendix of Optimal Resources for Breast Care](#) for more information on alternative service delivery models.

### Documentation

#### Submitted with Pre-Review Questionnaire

- Certification/credentialing documentation for all genetic professionals providing counseling and testing for patients with breast disease or breast cancer
- If applicable, documentation that qualified genetic professionals are utilized by the outside telegenetics company or facility

### Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- Genetic counseling and testing are performed by qualified genetic professionals

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## 4.5 Navigation Professional Credentials

### Definition and Requirements

Navigation services must be provided by qualified navigation professionals, including **Clinical Navigators** and **Patient Navigators**, who have documented training and education in providing individualized assistance to patients with breast disease or breast cancer, their families, and their caregivers.

**Clinical Navigators** hold healthcare licensure and/or certification required for their scope of practice by local and/or state laws. This includes Clinical Nurse Navigators, and Clinical Social Work Navigators. Clinical Navigators must meet compliance with this standard by holding a qualifying healthcare certification that includes patient navigation training, or documented completion of competency-based training and education in patient navigation for patients with breast disease or breast cancer from a qualifying training program.

**Patient Navigators** are navigation professionals who do not hold current healthcare licensure. Patient Navigators must meet compliance with this standard through documented completion of competency-based training and education in patient navigation for patients with breast disease or breast cancer from a qualifying training program.

**All individuals** providing patient navigation services at the NAPBC-accredited program must demonstrate compliance with this standard by holding a qualifying healthcare certification that includes patient navigation training, or documented completion of competency-based training and education in patient navigation for patients with breast disease or breast cancer from a qualifying training program. Patient navigation training provided locally by the NAPBC-accredited program does not meet the measure of compliance for this standard.

Qualifying healthcare certifications must include patient navigation within their exam to meet the measure of compliance for this standard. Examples of such qualifying certifications with documented patient navigation training and education include, but are not limited to:

- Oncology Certified Nurse (OCN®)
- Certified Breast Care Nurse (CBCN®)
- Oncology Nurse Navigator-Certified Generalist (ONN-CG™)
- Oncology Patient Navigator-Certified Generalist (OPN-CG™)
- Advanced Oncology Certified Nurse Practitioner (AOCNP®)

- Advanced Oncology Certified Clinical Nurse Specialist (AOCNS®)
- Advanced Oncology Certified Nurse (AOCN®)
- Breast Health Clinical Navigator (BHCN™)

Clinical Navigators in the process of obtaining a qualifying healthcare certification must provide documentation of progress toward certification.

Qualifying training programs must include competency-based training and education in patient navigation for patients with breast disease or breast cancer to meet the measure of compliance for this standard. Examples of such qualifying training programs include, but are not limited to:

- National Consortium of Breast Centers (NCBC): Certified Navigator Breast Advocate Program (CN-BA)
- George Washington University School of Medicine and Health Sciences Education Program: Oncology Patient Navigator Training
- Oncology Nursing Society: Equipping the Novice Oncology Nurse Navigator: An ONS Collaboration with AONN+
- American Cancer Society Leadership in Oncology Navigation (ACS LION™)

Navigation professionals in the process of obtaining qualifying training and education in patient navigation must provide documentation of progress toward completion.

The requirements for patient navigation services provided by the NAPBC-accredited program are outlined in Standard 5.8.

### Documentation

#### Submitted with Pre-Review Questionnaire

- Certification and/or training and education documentation for all navigation professionals providing patient navigation services

### Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- Patient navigation services are provided by qualified navigation professionals

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**National Accreditation Program  
for Breast Centers**  
American College of Surgeons



AMERICAN COLLEGE OF SURGEONS  
**NATIONAL ACCREDITATION PROGRAM FOR BREAST CENTERS**

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## **5** Patient Care: Expectations and Protocols

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## **Rationale**

The standards in Chapter 5 support care that focuses on the patient journey from the patient's perspective. Each standard is accompanied by rationale that describes the accreditation standard in the context of the patient journey.

## 5.1 Screening for Breast Cancer

### Rationale

Most people will never be diagnosed with breast cancer. But for those asymptomatic persons who are diagnosed, their journey begins with the screening process. The NAPBC-accredited program must view screening from that perspective.

### Definition and Requirements

The NAPBC-accredited program must utilize nationally recognized guidelines for breast cancer screening. Sources for nationally recognized guidelines include, but are not limited to:

- American College of Radiology
- American Cancer Society
- American Association for Cancer Research Cancer Progress Report
- Siteman Cancer Center: Your Disease Risk™

The NAPBC-accredited program must develop and implement a protocol addressing the following:

- Notification and education for patients with increased breast density
- Guidelines for the provision of supplemental screening to patients with increased breast density
- Appropriate use of available screening techniques, such as Digital Breast Tomosynthesis, breast ultrasound, Magnetic Resonance Imaging (MRI), Molecular Breast Imaging, and/or Contrast-Enhanced Mammography, for patients with increased density

The NAPBC-accredited program must utilize risk assessment screening strategies based on the needs of their patient population. The NAPBC-accredited program has full discretion regarding when this risk assessment occurs within their programmatic workflow. Patients who receive a screening mammogram at the NAPBC-accredited program must also be provided with evidence-based risk reduction strategies for breast cancer. The risk reduction strategies must either be discussed with the patient, or provided to them in a written or electronic format. It is not required that an individualized discussion occur with each patient, as long as the written or electronic resources for risk reduction are provided to the patient.

For patients identified as high-risk for the development of breast cancer, the NAPBC-accredited program must also provide referral(s) to the appropriate health care providers. The requirements for the management of patients at increased risk for breast cancer are outlined in Standard 5.4.

### Evaluation by the BPLC

Each accreditation cycle, the BPLC must review and assess:

- The protocol for notifying and educating patients about increased density
- The appropriate use of available screening techniques, such as Digital Breast Tomosynthesis, breast ultrasound, MRI, Molecular Breast Imaging, and/or Contrast-Enhanced Mammography, for patients with increased density
- The risk reduction strategies provided to patients

As barriers to compliance with this standard are identified, they must be addressed by the NAPBC-accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

### Documentation

#### Reviewed On-Site

- The site reviewer will evaluate preselected medical records for patients who do not have cancer to confirm compliance with this standard, including:
  - Appropriate use of available screening techniques
  - Risk assessment, with referral to appropriate health care providers for patients at increased risk of breast cancer, as outlined in Standard 5.4

#### Submitted with Pre-Review Questionnaire

- Required protocol
- Example of education on additional screening provided to patients with increased density
- Examples of risk reduction materials
- Example resources/referrals provided to patients addressing risk reduction
- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

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## Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- Adoption of nationally recognized guidelines for screening
- A protocol is developed and implemented for:
  - Notifying, educating, and providing additional screening for patients with increased density
  - Risk assessment and provision of appropriate referrals
  - Appropriate use of available screening techniques, including which patients must receive supplemental screening
- Patients who receive a screening mammogram also receive evidence-based risk reduction strategies for breast cancer
- The BPLC evaluation is completed and documented in the BPLC meeting minutes once each accreditation cycle

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## 5.2 Diagnostic Imaging of the Breast and Axilla

### Rationale

Abnormal imaging or clinical findings trigger a cascade of events that may be enormously stressful for the patient and the patient's support system. There are a variety of clinical and non-clinical issues that must be considered. Steps to minimize anxiety, avoid confusion, and facilitate a timely approach to the imaging abnormality must be considered.

### Definition and Requirements

This standard evaluates patients with a clinical finding or an abnormal mammogram. Requirements for patients without an abnormal finding are outlined in Standard 5.1.

A protocol must be developed and implemented to address the following:

- Confirmation that during the diagnostic process the patient has been evaluated to determine their risk for the development of breast cancer
  - When the risk evaluation occurs is left to the discretion of the NAPBC-accredited program, as long as it occurs during the diagnostic process
- Access to biopsy services for patients that have an abnormal mammogram or MRI
- Performance of a recommended biopsy, or the notification of a recommended biopsy to the patient

### Imaging and Pathology Concordance

A process must be developed and implemented for radiology and pathology to evaluate the concordance between imaging and biopsy pathology. For example: the radiologist comments on concordance in the biopsy report; or through a radiology/pathology conference. Imaging and biopsy pathology slides or biopsy reports must be reviewed. A process must be in place addressing the management of any discordant reviews.

The results of the concordance decision must be documented in the medical record with a recommended action.

For example, clinical follow-up, surgical consultation recommendation, excision recommendation, or imaging follow-up. The NAPBC-accredited program must have a process in place for follow-up on any recommended actions.

### Communication of Results

Biopsy pathology results and any follow-up recommendations must be communicated directly to the patient, or the referring physician. A written or electronic copy of the biopsy pathology results must be provided to the patient.

### Evaluation by the BPLC

Each accreditation cycle, the BPLC must review and assess:

- The barriers to efficient diagnosis for abnormal imaging
  - For example: turnaround time for core biopsy results
- The process for discordant biopsies is reviewed and any barriers are assessed
- The processes for patient follow-up, biopsy recommendations, and biopsy results are reviewed, and any barriers assessed

As barriers to compliance with this standard are identified, they must be addressed by the NAPBC-accredited program.

The BPLC evaluations and discussions must be documented in the BPLC meeting minutes.

### Documentation

#### Submitted with Pre-Review Questionnaire

- Required protocol
- Documentation of the process for evaluating, documenting, and follow-up on radiology and pathology concordance
- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

### Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- A protocol is developed and implemented for:
  - Risk evaluation at the time of diagnostic breast imaging if not performed during screening
  - Referral and access to biopsy for patients with abnormal mammogram or MRI
  - Performance of a recommended biopsy or communication to the patient regarding the recommendation for biopsy
- A process is in place for:
  - Evaluating, communicating, and documenting concordance between imaging and biopsy pathology
  - Management of discordant reviews
  - Follow-up of recommended action
- Biopsy pathology results are communicated to the patient or the referring physician
- The BPLC evaluation is completed and documented in the BPLC meeting minutes once each accreditation cycle

## 5.3 Evaluation and Management of Benign Breast Disease

### Rationale

Anxiety, concern, and worry often accompany the evaluation, testing, and treatment recommendation processes for patients with non-malignant abnormalities. These patients must receive advice about the meaning of the abnormality and treatment or non-treatment options available to them.

### Definition and Requirements

This standard evaluates patients with benign breast disease. For example: nipple discharge, cysts, infections of the breast, and benign lesions (such as radial scar, fibroadenoma, and papilloma).

A protocol must be developed and implemented to manage and follow patients with benign breast disease according to nationally recognized guidelines. For example:

- Appropriate additional imaging for patients without cancer (density and MRI use)
- Concordance between physical exam, imaging, and pathology
- Establishment of a follow-up plan

### Communication of Results

Patients with a benign biopsy or surgery must have their pathology reviewed with them, either by the NAPBC-accredited program or the referring physician. This review must be documented in the patient medical record.

If the NAPBC-accredited program is not the provider communicating the results, a documented protocol must be in place to contact the patient and confirm they have received the results. The method of contact is at the discretion of the NAPBC-accredited program. The patient must also be provided with a contact number in case they wish to further discuss the biopsy results.

### Evaluation by the BPLC

Each accreditation cycle, the BPLC must review and assess:

- The barriers to efficient evaluation and diagnosis of patients with benign breast disease
  - If the BPLC identifies non-compliance or barriers to compliance, an intervention or new protocol must be proposed and documented in the BPLC meeting minutes with plans for interval monitoring
- The protocol for assessing and documenting concordance and any related barriers
- The protocol for the follow-up plan and any related barriers

As barriers to compliance with this standard are identified, they must be addressed by the NAPBC-accredited program.

The BPLC evaluations and discussions must be documented in the BPLC meeting minutes.

### Documentation

#### Reviewed On-Site

- The site reviewer will evaluate preselected medical records to confirm compliance with this standard, if not confirmed during the review of Standard 5.1, including:
  - Medical records for patients who do not have cancer are evaluated for appropriate additional imaging (density and MRI use)
  - Documentation of the process for evaluation, documentation, and follow-up of radiology and pathology concordance
  - Documentation of communication of follow-up plans and pathology results

#### Submitted with Pre-Review Questionnaire

- The required protocol to manage and follow patients with benign breast disease
- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

### Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- A protocol is in place for managing and following patients with benign breast disease according to nationally recognized guidelines
- Patients with a benign biopsy or surgery must have their pathology reviewed with them, with documentation in the medical record
- The BPLC evaluation is completed and documented in the BPLC meeting minutes once each accreditation cycle

## 5.4 Management of Patients at Increased Risk for Breast Cancer

### Rationale

People at increased risk for the development of an index breast cancer or a recurrence may suffer considerable anxiety about their own future and the implications for their loved ones. Decisions regarding employment, insurability, prophylactic options, and future family-related choices can be overwhelming. Patients benefit from comprehensive, accurate, risk assessment, which facilitates an appropriate understanding of their cancer risks, and making informed decisions with their health care providers.

### Definition and Requirements

The NAPBC-accredited program must develop and implement a protocol for the management of patients who are at an increased risk for breast cancer. Examples of patients at increased risk for breast cancer include patients with dense breast tissue, lifestyle risk factors, family history of cancer, and a history of high-risk lesions.

The established protocol must address the following requirements:

- Consideration for risk reduction strategies, including lifestyle modification, as outlined in Standard 5.1
  - When appropriate, high-risk patients must be offered pharmacologic or surgical intervention
- Imaging surveillance following evidence-based guidelines
- Referral to appropriate health care providers for patients with high-risk lesions discovered on a breast biopsy, with appropriate management according to nationally recognized guidelines
  - Examples of high-risk lesions: atypical ductal hyperplasia (ADH), atypical lobular hyperplasia (ALH), and lobular carcinoma in situ (LCIS)
- Referral to genetic professionals for patients with possible genetic risk based on family history, or other factors for genetic evaluation and testing as outlined in Standard 5.5
- Consideration for referral to genetic professionals for patients with abnormal test results (such as pathogenic, likely pathogenic, or variant of uncertain significance) performed by non-genetic professionals, or with test results performed at outside institutions

Risk reduction strategies must be discussed with the patient and documented in the medical record.

### Evaluation by the BPLC

Each calendar year, the BPLC must review and assess:

- The protocol for managing patients at increased risk for breast cancer not due to a hereditary cancer syndrome

As barriers to compliance with this standard are identified, they must be addressed by the accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

### Documentation

#### Reviewed On-Site

- The site reviewer will evaluate preselected medical records for patients at increased risk for breast cancer to confirm compliance with this standard, including:
  - Discussion of risk reduction strategies and pertinent family history, with documentation in the patient medical record
  - Consideration for genetic counseling and testing in accordance with nationally recognized guidelines for high-risk patients with breast disease or breast cancer

#### Submitted with Pre-Review Questionnaire

- Required protocol
- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

### Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- The protocol is developed and implemented for the management of patients at increased risk for breast cancer
- The BPLC evaluation is completed and documented in the BPLC meeting minutes once each calendar year

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## 5.5 Genetic Evaluation and Management

### Rationale

Accurate genetic evaluation and testing has a major impact on all aspects of cancer care, from primary cancer screenings to guiding management and treatment decisions, and ongoing cancer surveillance. Genetic evaluation and management must consider the impact that the identification of pathogenic and likely pathogenic genetic variants have, or may have, on the patient and family unit.

### Definition and Requirements

The NAPBC-accredited program must, at a minimum, **consider** genetic counseling and testing for the following patients:

- All newly diagnosed patients with breast disease or breast cancer
- Patients determined to be at high risk for genetic cancer predisposition
  - These patients are determined based on screening as outlined in Standards 5.1 and 5.4

This consideration for genetic counseling and testing must be in accordance with nationally recognized guidelines, and documented in the patient medical record.

The NAPBC-accredited program must develop and implement a protocol addressing the following requirements for managing patients for genetic evaluation:

- Evidence-based process for genetic evaluation, counseling, and testing
- Provision of a written/electronic copy of the genetic evaluation and testing discussed with the patient, reported to the treatment team, and documented in the medical record
- Documentation of effort to help patients inform at-risk family members and/or provide cascade testing
- Consideration for referral to genetic professionals for patients with abnormal test results (such as pathogenic, likely pathogenic, or variant of uncertain significance) performed by non-genetic professionals, or with test results performed at outside institutions

Qualified genetic professionals approved to provide genetic counseling and testing are outlined in Standard 4.4.

Any genetics services not provided on-site by the NAPBC-accredited program must be provided through a referral relationship with other facilities and/or local agencies, or via telegenetics services. Alternative service delivery models may be utilized by NAPBC-accredited programs to maximize delivery of optimal genetics services to all eligible patients. Please refer to the [Appendix](#) of *Optimal Resources for Breast Care* for alternative service delivery models approved by the NAPBC for genetic counseling and testing.

### Evaluation by the BPLC

Each accreditation cycle, the BPLC must review and assess:

- Considerations for genetic evaluation and management, as outlined above

As barriers to compliance with this standard are identified, they must be addressed by the NAPBC-accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

### Documentation

#### Reviewed On-Site

- The site reviewer will evaluate preselected medical records for patients who have had a genetic evaluation. Specifically, the site reviewer will evaluate at least one (1) positive case (pathogenic/likely pathogenic (P/LP) variant in a breast cancer predisposition gene) and one (1) negative case (no P/LP variant identified, but the patient may be identified and managed as high risk based on family/personal history and/or breast cancer risk calculations). These medical records will be assessed for:
  - Consideration of patients for genetic counseling and testing
  - Documentation of personalized genetic risk assessment and evaluation
  - Documentation of pertinent family history
  - Genetic evaluation and testing results are provided to and discussed with the patient
  - Appropriate management for individuals with both pathogenic or likely pathogenic genetic variants and variants of uncertain significance (VUS) or negative results with residual high risk based on family history
  - Discussion of family members appropriate for cascade testing

### Submitted with Pre-Review Questionnaire

- Required protocol
- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

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## Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- Newly diagnosed and high-risk patients with breast disease or breast cancer are considered for genetic counseling and testing according to nationally recognized guidelines, with documentation in the patient medical record
- A protocol is developed and implemented for managing patients for genetic evaluation
- Genetic testing and counseling are offered to appropriate patients, and testing results are provided to and discussed with the patient
- The BPLC evaluation is completed and documented in the BPLC meeting minutes once each accreditation cycle

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## 5.6 Evaluation and Treatment Planning for the Newly Diagnosed Cancer Patient

### Rationale

The diagnosis of breast cancer starts a cascade of events for which the patient is unprepared. Few people are familiar with the set of risks and decisions that must be made. This is naturally a time of great fear and apprehension. Timely and compassionate care will help mitigate the tremendous emotional swings that are associated with this new phase of the patient's life, and the lives of their support system.

### Definition and Requirements

The NAPBC-accredited program must complete the following workups for all newly diagnosed patients with breast cancer:

- Staging
- Biopsy
- Imaging
- Metastatic workup
- Laboratory workup
- Evaluation of barriers to care

#### Staging

In this context, staging requires assignment of the proper cancer stage using the American Joint Committee on Cancer (AJCC) system. The core biopsy, imaging, and physical exam determine the clinical prognostic stage, which must be reported according to the most recent AJCC system. The clinical prognostic stage must be determined based on the information available at the time of staging. The clinical prognostic stage must be discussed with the patient prior to treatment, and the stage must be documented in the patient medical record.

Over the course of ongoing patient evaluation and treatment, the stage assignment must be appropriately determined and documented in the patient medical record. The later stage assignments must be discussed with the patient, and used during any Multidisciplinary Breast Care Conference (MBCC). Recurrence, and post-neoadjuvant stage, are examples of later stage assignment.

#### Biopsy

The NAPBC-accredited program must review clinically relevant outside biopsy/surgical pathology slides before providing treatment. This includes patients who are newly diagnosed, and patients with recurrence or previous treatment. This review may be conducted as an official consultation, or at the Multidisciplinary Breast Care Conference (MBCC).

If the outside slides cannot be obtained for review, this must be discussed with the patient and documented in the patient medical record. In the absence of the outside slides, the outside pathology report must be reviewed. This review may be conducted as an official consultation, or at the Multidisciplinary Breast Care Conference (MBCC).

#### Imaging

The NAPBC-accredited program must review all clinically relevant outside breast imaging studies that may affect locoregional management decisions before providing treatment. This review may be conducted as an official consultation, or at the Multidisciplinary Breast Care Conference (MBCC). If the review is conducted at the MBCC, the images must be shown.

If the outside breast imaging cannot be obtained for review, the NAPBC-accredited program must complete any necessary imaging studies before providing treatment.

#### Metastatic Workup

The NAPBC-accredited program must complete a metastatic workup, as indicated by evidence-based national guidelines. The workup must be documented in the patient medical record.

#### Laboratory Workup

The NAPBC-accredited program must complete a laboratory workup, as indicated by evidence-based national guidelines. The workup must be documented in the patient medical record.

#### Barriers to Care

The NAPBC-accredited program must evaluate and address any barriers to effective and efficient care.

Examples of such barriers include, but are not limited to:

- Timely acquisition of outside imaging and pathology
- Insurance pre-approvals
- Financial impact on the patient and family
- Limited resources such as PET scanner, CT etc.

## Evaluation by the BPLC

Each calendar year, the BPLC must review and assess:

- Implementation of individualized shared decision making
  - For resources and information related to the implementation of individualized shared decision making, please refer to the [Appendix of Optimal Resources for Breast Care](#)
- The process of, and obstacles between, diagnosis and treatment time
  - For example: turnaround time for core biomarkers and genomic ancillary testing results, additional imaging, access and availability of specialists, and pre-authorizations
- Whether or not clinically relevant outside biopsy/surgical pathology slides and clinically relevant outside breast imaging studies are being obtained and reviewed before treatment at the NAPBC-accredited program

As barriers to compliance with this standard are identified, they must be addressed by the accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

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## Documentation

### Reviewed On-Site

- The site reviewer will evaluate preselected medical records to confirm compliance with this standard, including:
  - Staging
  - Review of clinically relevant outside biopsy/surgical pathology slides
  - Review of clinically relevant outside imaging studies
  - Appropriate metastatic and laboratory workup
  - Evaluating and addressing barriers to effective and efficient care

### Submitted with Pre-Review Questionnaire

- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

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## Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- Clinical staging is documented in the patient medical record and discussed with the patient before treatment at the NAPBC-accredited program
- Clinically relevant biopsy/surgery pathology slides from outside facilities are reviewed by the NAPBC-accredited program before providing treatment
- Clinically relevant breast imaging studies from outside facilities are reviewed at the NAPBC-accredited program before providing treatment
- Appropriate workups (metastatic workup, laboratory) are documented in the patient medical record
- Barriers to effective and efficient care are evaluated and addressed
- The BPLC evaluation is completed and documented in the BPLC meeting minutes once each calendar year

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## Bibliography

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Gradishar WJ, Moran MS, Abraham J, et al. Breast cancer, version 3.2022, NCCN clinical practice guidelines in oncology. *J Natl Compr Canc Netw*. 2022;20(6):691–722. doi: 10.6004/jnccn.2022.0030.

Mahul B. Amin, Stephen B. Edge, Frederick L. Greene, David R. Byrd, Robert K. Brookland, Mary Kay Washington, Laura R. Meyer. *AJCC Cancer Staging Manual*, 8th ed. Chicago, IL: Springer Cham; 2018.

Sprague BL, Ahern TP, Herschorn SD, et al. Identifying key barriers to effective breast cancer control in rural settings. *Prev Med* 2021;152(Pt 2):106741. doi.org/10.1016/j.ypmed.2021.106741.

Teberian I, Kaufman T, Shames J, et al. Trends in the use of percutaneous versus open surgical breast biopsy: An update. *J Am Coll Radiol* 2020;17(8):1004–1010. doi: 10.1016/j.jacr.2020.02.015

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Waks AG, Winer EP. Breast cancer treatment: A review. *JAMA*. 2018;321(3):288–300. doi: 10.1001/jama.2018.19323

## 5.7 Comprehensive Evaluation of Patient Factors Before Treatment

### Rationale

Patients must be viewed in the context of their entire personhood. Decisions made purely based on clinical care guidelines run the risk of failure if they do not consider all of the factors that affect the patient. Unless these factors are considered during the evaluation period, there is a risk that treatments will either not be accepted or will not produce the results that are expected.

### Definition and Requirements

#### Evaluation by the BPLC

Each calendar year, the BPLC must review and assess one (1) of the following categories of patient pre-treatment evaluation:

- Patient assessments
  - For example: frailty, range of motion, surgical risk factor, baseline lymphedema
- Evaluation for referrals to oncofertility, cardiooncology, exercise program, nutrition counseling, genetics, or physical therapy
- Social well-being assessments
  - For example: psychosocial distress, social and behavioral determinants of health
    - › Patient living arrangements (living alone, married, cohabitation)
    - › Patient work status (employed, unemployed, multiple jobs)
    - › Patient income (stable/unstable income; financially independent/dependent)

As barriers to compliance with this standard are identified, they must be addressed by the accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

### Documentation

#### Submitted with Pre-Review Questionnaire

- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

### Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- The BPLC evaluation is completed and documented in the BPLC meeting minutes once each calendar year

### Bibliography

Coughlin S.S. Social determinants of breast cancer risk, stage, and survival. *Breast Cancer Res Treat* 2019;177:537–548.

Gilchrist SC, Barac A, Ades PA, et al. Cardio-oncology rehabilitation to manage cardiovascular outcomes in cancer patients and survivors: A scientific statement from the American Heart Association. *Circulation* 2019;139(21):e997–e1012. doi: 10.1161/CIR.0000000000000679.

Stout NL, Binkley B, Schmitz KH, et al. A prospective surveillance model for rehabilitation for women with breast cancer. *Cancer*. 2012;118(SUPPL.8):2191–2200. PMID: 22488693.

## 5.8 Patient Navigation

### Rationale

Individuals undergoing treatment for breast disease or breast cancer are generally unfamiliar with the numerous phases of care, and the associated decision-making related to each that must be made as they traverse the patient journey. Navigation professionals serve as a resource and ally in this stressful time.

### Definition and Requirements

Patient navigation begins at the time of patient presentation to the NAPBC-accredited program and continues beyond treatment. Patient navigation plays an integral role in the patient journey as it assists with transitions of care, continuity, and communication between the treatment team members.

A protocol must be developed and implemented to address patient navigation throughout the patient journey. For example:

- The patient has a point of contact (the navigation professional(s)) from the moment of diagnosis onward
- Facilitation of timely transitions between surgery and medical oncology treatment
- Assistance with addressing survivorship and surveillance throughout treatment
- Alerting the radiation oncology team if a patient cannot complete chemotherapy, and finishes treatment early

### Evaluation by the BPLC

Each accreditation cycle, the BPLC must review and assess:

- The protocol for patient navigation

As barriers to compliance with this standard are identified, they must be addressed by the accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

### Documentation

#### Submitted with Pre-Review Questionnaire

- Required protocol
- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

### Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- A protocol is developed and implemented to address patient navigation throughout the patient journey
- The BPLC evaluation is completed and documented in the BPLC meeting minutes once each accreditation cycle

### Bibliography

Force T. Oncology Navigation Standards of Professional Practice. *Clinical Journal of Oncology Nursing*. 2022;26(3):E14-E25. doi:<https://doi.org/10.1188/22.cjon.e14-e25>

Valverde PA, Burhansstipanov L, Patierno S, et al. Findings from the National Navigation Roundtable: A call for competency-based patient navigation training. *Cancer*. 2019;125(24):4350-4359. doi:10.1002/cncr.32470) and shows the skills and knowledge comprehension for entry, intermediate and advanced navigators.

Kline RM, Rocque GB, Rohan EA, et al. Patient Navigation in Cancer: The Business Case to Support Clinical Needs. *Journal of Oncology Practice*. 2019;15(11):585-590. doi:<https://doi.org/10.1200/jop.19.00230>

National Academies of Sciences, Engineering, and Medicine. Integrating social care into the delivery of health care: Moving upstream to improve the nation's health. Washington, DC: National Academies Press; 2019. Available at: <https://doi.org/10.17226/25467>. Accessed on November 7, 2022.

## 5.9 Surgical Care

### Rationale

Many patients will require surgical treatment for their cancer. The concept of undergoing anesthesia and having part of their body altered or removed is extraordinarily stressful. While this is something the breast care team is familiar with, getting the patient to a level of comfort requires thoughtful consideration, education, and inclusion of the patient in the decision-making process.

### Definition and Requirements

Patients with breast cancer must receive education and management as outlined in this standard when undergoing surgery for breast cancer:

- Guideline/evidence-based care, with documentation in the patient medical record
  - Examples of guideline/evidence-based care include, but are not limited to:
    - › The NAPBC-accredited program follows national guidelines provided by ASCO for the management of locally advanced inflammatory and T2 triple negative and HER2 positive breast cancer, and patients are referred for neoadjuvant systemic therapy
    - › The NAPBC-accredited program establishes a process for axillary management, including up front sentinel node biopsy, up front axillary dissection, and completion axillary dissection based on current literature
- Preoperative and postoperative patient education, addressing preparation for surgery and postoperative recovery, with documentation in the patient medical record
- Utilization of Enhanced Recovery after Surgery (ERAS) protocols and/or opioid-sparing multimodal pain management strategies to facilitate same-day discharge, with documentation in the patient medical record
  - The NAPBC-accredited program must develop and implement a protocol for utilizing ERAS and/or opioid-sparing multimodal pain management strategies for patients undergoing surgery for breast cancer

Patients undergoing surgery for breast cancer at the NAPBC-accredited program must be considered for a preoperative functional assessment. The NAPBC-accredited program must develop and implement a protocol for preoperative functional assessment and appropriate referrals to exercise, physical therapy, and/or lymphedema management for patients undergoing surgery for breast cancer.

- For resources and information related to the functional assessment protocol, please refer to the [Appendix](#) of *Optimal Resources for Breast Care*
- A single functional assessment protocol may be utilized to meet compliance with Standards 5.9, 5.10, 5.11, and 5.12

The patient must receive a copy of the definitive surgery pathology report. Providing the patient with either a written or electronic copy of the report in any format meets the measure of compliance for this standard. The report must be discussed with the patient.

#### CoC Operative Standards

NAPBC-accredited programs must demonstrate compliance with Commission on Cancer (CoC) Standard 5.3 Sentinel Node Biopsy for Breast Cancer, and Standard 5.4 Axillary Lymph Node Dissection for Breast Cancer. If the NAPBC-accredited program is part of a hospital that is Commission on Cancer accredited, demonstration of a compliant rating for Standards 5.3 and 5.4 in the CoC Accreditation Report meets the measure of compliance for this requirement of this standard.

#### Evaluation by the BPLC

Each calendar year, the BPLC must review and assess:

- Implementation of individualized shared decision making
  - For resources and information related to the implementation of individualized shared decision making, please refer to the [Appendix](#) of *Optimal Resources for Breast Care*
- Surgical outcomes and processes and ways to improve outcomes and processes. For example, re-excision rate, infection rate, and/or patient satisfaction

As barriers to compliance with this standard are identified, they must be addressed by the accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

## Documentation

### Reviewed On-Site

- The site reviewer will evaluate preselected medical records to confirm compliance with this standard, including:
  - Care provided according to evidence-based guidelines
  - Preoperative and postoperative patient education
  - Utilization of ERAS protocols and/or multimodal pain management
  - Compliance with Commission on Cancer Standards 5.3 and 5.4

### Submitted with Pre-Review Questionnaire

- Examples of preoperative and postoperative patient education
- Required protocol for preoperative functional assessment and appropriate referrals
- Required protocol for Enhanced Recovery after Surgery (ERAS) and/or multimodal pain management
- If applicable, CoC Accreditation Report documenting a compliant rating for Standards 5.3 and 5.4
- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

## Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- Patients undergoing surgery for breast cancer receive the following education and management with documentation in the patient medical record:
  - Care provided according to evidence-based guidelines
  - Preoperative and postoperative patient education
  - Utilization of ERAS protocols and/or multimodal pain management
  - Compliance with Commission on Cancer Standards 5.3 and 5.4
- A protocol is developed and implemented for preoperative functional assessment and appropriate referrals

- A protocol is developed and implemented for Enhanced Recovery after Surgery (ERAS) and/or multimodal pain management
- A copy of the definitive surgery pathology report is provided to and discussed with the patient
- The BPLC evaluation is completed and documented in the BPLC meeting minutes once each calendar year

## Bibliography

American Society of Clinical Oncology. Breast Cancer. Available at: <https://www.asco.org/practice-patients/guidelines/breast-cancer>. Accessed November 7, 2022.

Golshan M, Loibl S, Wong SM, et al. Breast conservation after neoadjuvant chemotherapy for triple-negative breast cancer: Surgical results from the brightNess randomized clinical trial. *JAMA Surg*. 2020;155(3):e195410. Doi:10.1001/jamasurg.2019.5410

Gradishar WJ, Moran MS, Abraham J, et al. Breast cancer, version 3.2022, NCCN clinical practice guidelines in oncology. *J Natl Compr Canc Netw* 2022;20(6):691–722. Doi: 10.6004/jnccn.2022.0030.

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Rockson S. Lymphedema after breast cancer treatment. *N Engl J Med*. 2018;379:1937–1944. Doi: 10.1056/NEJMcp1803290

Sella T, Weiss A, Mittendorf EA, et al. Neoadjuvant endocrine therapy in clinical practice: A review. *JAMA Oncol*. 2021;7(11):1700–1708. Doi: 10.1001/jamaoncol.2021.2132

Waks AG, Winer EP. Breast cancer treatment: A review. *JAMA*. 2019;321(3):288–300. Doi: 10.1001/jama.2018.19323

## 5.10 Reconstructive Surgery

### Rationale

Patients who require surgical treatment for their cancer may not be focused on postoperative cosmetic outcomes due to fears of cancer recurrence, while others are too focused on potential disfigurement to make sound oncologic decisions. The surgical team must collaborate with the patient to understand and address concerns, and consider physical, social, cultural, and emotional factors that may impact treatment decisions while striving to restore the patient's sense of well-being safely and efficiently.

### Definition and Requirements

Patients with breast cancer must receive education and management as outlined in this standard when undergoing surgery for breast cancer:

- Appropriate patients undergoing mastectomy are offered a preoperative referral to a reconstructive/plastic surgeon, with documentation in the patient medical record
  - Breast reconstruction referrals must be 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
  - Reconstruction may also include assistance with oncoplastic reconstructions/reductions, symmetry procedures, and other related procedures/assistance
- Education about the risks and benefits of reconstructive surgery, with documentation in the patient medical record
  - For example: postoperative appearance, the use of a prosthesis, delayed reconstruction, timing of reconstruction relative to radiation and systemic therapy
- Multidisciplinary input on the impact of reconstruction on other treatment modalities is obtained preoperatively, with documentation in the patient medical record

Patients undergoing reconstructive surgery at the NAPBC-accredited program must be considered for a preoperative functional assessment. The NAPBC-accredited program must develop and implement a protocol for preoperative functional assessment and appropriate referrals to exercise, physical therapy, and/or lymphedema management for patients undergoing reconstructive surgery.

- For resources and information related to the functional assessment protocol, please refer to the [Appendix of Optimal Resources for Breast Care](#)
- A single functional assessment protocol may be utilized to meet compliance with Standards 5.9, 5.10, 5.11, and 5.12

Surgeons must seek to maximize satisfaction of cosmesis within the limits of cancer care and patient factors.

### Evaluation by the BPLC

Each calendar year, the BPLC must review and assess:

- Implementation of individualized shared decision making
  - For resources and information related to the implementation of individualized shared decision making, please refer to the [Appendix of Optimal Resources for Breast Care](#)
- How the program evaluates outcomes of reconstructive surgery. For example: cosmesis/quality of life/function
  - The BPLC evaluates patient satisfaction, and documents an action plan based on identified opportunities for improvement. For example, oncoplastic Continuing Medical Education for surgeons, or increased referral for oncoplastic cases with plastic surgeon

Each accreditation cycle, the BPLC must review and assess:

- The availability of reconstructive options available to all patients and the impact on multidisciplinary care on the patient

As barriers to compliance with this standard are identified, they are addressed by the accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

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## Documentation

### Reviewed On-Site

- The site reviewer will evaluate preselected medical records to confirm compliance with this standard, including:
  - Preoperative referral to a reconstructive/plastic surgeon or documentation of discussion
  - Education about the risks and benefits of reconstructive surgery
  - Multidisciplinary input on the impact of reconstruction on other treatment modalities

### Submitted with Pre-Review Questionnaire

- Required protocol for preoperative functional assessment and appropriate referrals
- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

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## Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- Patients with breast cancer receive the following education and management with documentation in the patient medical record:
  - Appropriate patients undergoing mastectomy are offered a preoperative referral to a reconstructive/plastic surgeon
  - Education about the risks and benefits of reconstructive surgery
  - Multidisciplinary input on the impact of reconstruction on other treatment modalities
- A protocol is developed and implemented for preoperative functional assessment and appropriate referrals

- The BPLC evaluation of the implementation of individualized shared decision making, and evaluation of outcomes of reconstructive surgery are completed and documented in the BPLC meeting minutes once each calendar year
- The BPLC evaluation of the availability of reconstructive options to all patients and its impact on multidisciplinary care of the patient is completed and documented in the BPLC meeting minutes once each accreditation cycle

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## Bibliography

Buter PD, Morris MB, Momoh AO. Persistent disparities in postmastectomy breast reconstruction and strategies for mitigation. *Ann Surg Oncol.* 2021;28(11):6099–6108. Doi: 10.1245/s10434-021-10487-z

Offodile AC 2<sup>nd</sup>, Gu C, Boukavalas S, et al. Enhanced recovery after surgery (ERAS) pathways in breast reconstruction: Systematic review and meta-analysis of the literature. *Breast Cancer Res Treat.* 2019; 173(1):65–77. Doi: 10.1007/s10549-018-4991-8

Panchal H, Matros E. Current trends in post-mastectomy breast reconstruction. *Plast Reconstr Surg.* 2017;140(5):7S–13S. doi: 10.1097/PRS.00000000000003941

Santosa KB, Qi J, Kim HM et al. Long-term patient-reported outcomes in postmastectomy breast reconstruction. *JAMA Surg.* 2018;153(10):891–899. Doi: 10.1001/jamasurg.2018.1677

Temple-Oberle C, Shea-Budgell MA, Tan M, et al. Consensus review of optimal perioperative care in breast reconstruction: Enhanced recovery after breast surgery (ERAS) society recommendations. *Plast Reconstr Surg.* 2017;139(5):1056e–1071e. doi: 10.1097/PRS.00000000000003242

## 5.11 Medical Oncology

### Rationale

Patients with breast cancer are often prescribed oral or intravenous medications that are costly and can cause significant short- or long-term side effects. At times, these toxicities are tolerated for only modest improvements in survival. Programs should discuss treatment side effects and toxicities with patients and their support system while elaborating on the benefits of such treatments. Care must be taken to prevent or alleviate the side effects of treatment medications.

### Definition and Requirements

Patients with breast cancer must receive education and management as outlined in this standard when receiving medical oncology treatment for breast cancer:

- Guideline/evidence-based care (such as NCCN, ASCO, QOPI), with documentation in the patient medical record
  - Examples of guideline/evidence-based care include, but are not limited to:
    - › Genomic testing is considered in patients with endocrine responsive disease with 0-3 positive nodes
    - › Appropriate patients with endocrine responsive disease are considered for endocrine therapy
    - › Consideration of HER2 targeted therapy if HER2 positive. If this is not administered, then documentation why it was not administered
    - › Patients with triple negative disease are considered for chemotherapy (neoadjuvant, when appropriate)
  - Patients falling outside of evidence-based guidelines are discussed at the Multidisciplinary Breast Care Conference (MCBB), or with multidisciplinary input
- Exercise therapy recommendations for pain control, fatigue, anxiety, depression, sleep, loss of function and improved survival, with documentation in the patient medical record

Patients receiving medical oncology care at the NAPBC-accredited program must be considered for a pre-treatment functional assessment. The NAPBC-accredited program must develop and implement a protocol for pre-treatment functional assessment and appropriate referrals to exercise, physical therapy, and/or lymphedema management for patients receiving medical oncology care.

- For resources and information related to the functional assessment protocol, please refer to the [Appendix of \*Optimal Resources for Breast Care\*](#)
- A single functional assessment protocol may be utilized to meet compliance with Standards 5.9, 5.10, 5.11, and 5.12

The NAPBC-accredited program must develop and implement a protocol for the assessment of side effects of systemic therapy, and appropriate referrals and interventions.

Examples include, but are not limited to:

- Nutrition support is offered for patients to maintain a healthy diet while experiencing the side effects of chemotherapy
- Acupuncture is offered for control of chemotherapy induced neuropathy
- Pharmacological interventions are available to address symptoms. For example: pain, nausea, hot flashes, vaginal dryness, sexual dysfunction
- Cold caps are offered to avoid chemotherapy induced alopecia

### Evaluation by the BPLC

Each calendar year, the BPLC must review and assess:

- Implementation of individualized shared decision making
  - For resources and information related to the implementation of individualized shared decision making, please refer to the [Appendix of \*Optimal Resources for Breast Care\*](#)
- Medical oncology outcomes and processes, and ways to improve outcomes and processes. For example, hospitalizations, febrile neutropenia, dose reduction

As barriers to compliance with this standard are identified, they must be addressed by the accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

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## Documentation

### Reviewed On-Site

- The site reviewer will evaluate preselected medical records to confirm compliance with this standard, including:
  - Care provided according to evidence-based guidelines
  - Exercise therapy recommendations

### Submitted with Pre-Review Questionnaire

- Required protocols
- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

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## Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- Patients with breast cancer receive the following education and management with documentation in the patient medical record:
  - Care provided according to evidence-based guidelines
  - Exercise therapy recommendations
- A protocol is developed and implemented for pre-treatment functional assessment and appropriate referrals
- A protocol is developed and implemented for the assessment of side effects of systemic therapy, and appropriate referrals and interventions
- The BPLC evaluation is completed and documented in the BPLC meeting minutes once each calendar year

## 5.12 Radiation Oncology

### Rationale

Radiation therapy added to local surgical therapy can decrease cancer recurrence and sometimes alleviate symptoms. NAPBC-accredited programs should discuss the risk of treatment-related complications and side effects with the potential benefits and provide the safest, most effective treatment with the lowest number of fractions considering all patient factors.

### Definition and Requirements

Patients with breast cancer must receive education and management as outlined in this standard when receiving radiation oncology treatment for breast cancer:

- Guideline/evidence-based care (such as NCCN, ASTRO), with documentation in the patient medical record
  - Examples of guideline/evidence-based care include, but are not limited to:
    - › All lymph node positive patients with breast cancer are evaluated by radiation oncology or discussed at the MBCC
    - › Patients who are candidates for breast conservation and postoperative radiation are discussed at MBCC or referred to a radiation oncologist
    - › The majority of early-stage patients with breast cancer having breast conservation surgery are treated with a form of hypo-fractionation
    - › Offering observation when appropriate
    - › Offering regional nodal radiation when appropriate
  - Patients falling outside of evidence-based guidelines are discussed at the Multidisciplinary Breast Care Conference (MBCC), or with multidisciplinary input

Patients receiving radiation oncology care at the NAPBC-accredited program must be considered for a pre-treatment functional assessment. The NAPBC-accredited program must develop and implement a protocol for pre-treatment functional assessment and appropriate referrals to exercise, physical therapy, and/or lymphedema management for patients receiving radiation oncology care.

- For resources and information related to the functional assessment protocol, please refer to the [Appendix of \*Optimal Resources for Breast Care\*](#)
- A single functional assessment protocol may be utilized to meet compliance with Standards 5.9, 5.10, 5.11, and 5.12

The NAPBC-accredited program must develop and implement a protocol for the assessment of side effects of radiation therapy, and appropriate referrals and interventions. Examples include, but are not limited to:

- Evaluation and referral for lymphedema or mobility complications
- Evaluation and treatment of radiation related dermatitis
- Post-treatment instructions are provided to each patient at the conclusion of treatment, addressing appropriate expectations and management of post-treatment side effects

### Evaluation by the BPLC

Each calendar year, the BPLC must review and assess:

- Implementation of individualized shared decision making
  - For resources and information related to the implementation of individualized shared decision making, please refer to the [Appendix of \*Optimal Resources for Breast Care\*](#)
- Radiation oncology outcomes and processes, and ways to improve outcomes and processes

As barriers to compliance with this standard are identified, they must be addressed by the accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

### Documentation

#### Reviewed On-Site

- The site reviewer will evaluate preselected medical records to confirm compliance with this standard, including:
  - Care provided according to evidence-based guidelines

#### Submitted with Pre-Review Questionnaire

- Required protocols
- The BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

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## Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- Patients with breast cancer receive the following education and management with documentation in the patient medical record:
- Care provided according to evidence-based guidelines
- A protocol is developed and implemented for pre-treatment functional assessment and appropriate referrals
- A protocol is developed and implemented for the assessment of side effects of radiation therapy, and appropriate referrals and interventions
- The BPLC evaluation is completed and documented in the BPLC meeting minutes once each calendar year

## 5.13 Surgical Pathology

### Rationale

Surgical pathology can provide prognostic information, particularly in cases of neoadjuvant therapy. Pathology reports must be timely, accurate, self-standing documents containing the necessary data to guide treating clinicians, including information on initial receptors, margins, and complete nodal evaluation.

### Definition and Requirements

The NAPBC-accredited program must review clinically relevant outside biopsy/surgical pathology slides before providing treatment to the patient (see Standard 5.6).

Estrogen and progesterone receptors, and HER2 studies only need to be performed on one (1) specimen (for example: the core biopsy), but the results must be included in the synoptic report for the definitive surgery, even if performed on the core biopsy or at an outside facility. Referring to prior pathology reports does not meet the measure of compliance for this standard.

#### Evaluation by the BPLC

Each calendar year, the BPLC must review and assess:

- Pathology outcomes and processes, and ways to improve outcomes and processes. For example, the time between the definitive surgery and definitive surgery pathology results

As barriers to compliance with this standard are identified, they must be addressed by the accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

### Documentation

#### Reviewed On-Site

- The site reviewer will evaluate preselected medical records to confirm compliance with this standard, including:
  - The pathology report for the definitive surgery

#### Submitted with Pre-Review Questionnaire

- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

### Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- Estrogen and progesterone receptors and HER2 studies are included in the definitive surgery pathology report
- The BPLC evaluation is completed and documented in the BPLC meeting minutes once each calendar year

## 5.14 Breast Cancer Staging Using the AJCC System

### Rationale

Once a Stage grouping is assigned, patients carry that for the rest of their treatment and for all future visits. Staging is also critical for gathering data that allows researchers to conduct studies to help improve care. It is therefore critical that Stage grouping using both anatomic and non-anatomic features is gathered. Documentation of pathological (postoperative) staging or posttherapy pathological (post-neoadjuvant and surgery) staging using genomic and pathologic data helps guide oncologists to make appropriate choices for systemic therapies, and help eliminate over- and under-treatment.

### Definition and Requirements

Pathological staging (after surgical treatment) or posttherapy pathological staging (after neoadjuvant therapy followed by surgical resection) must be reported by the managing physician according to the most recent American Joint Committee on Cancer (AJCC) system, which includes appropriate genomic testing to determine prognostic stage. AJCC staging must be documented in the medical record, and discussed with the patient.

#### Evaluation by the BPLC

Each accreditation cycle, the BPLC must review and assess:

- Documentation of clinical, pathological, and, if available, prognostic staging

As barriers to compliance with this standard are identified, they must be addressed by the NAPBC-accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

### Documentation

#### Reviewed On-Site

- The site reviewer will evaluate preselected medical records to confirm compliance with this standard, including:
  - Documentation of pathological or posttherapy pathological stage and related discussion

#### Submitted with Pre-Review Questionnaire

- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

### Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- Pathological or posttherapy pathological staging must be reported by the managing physician and discussed with the patient, with documentation of both in the medical record
- The BPLC evaluation is completed and documented in the BPLC meeting minutes once each accreditation cycle

### Bibliography

Mahul B. Amin, Stephen B. Edge, Frederick L. Greene, David R. Byrd, Robert K. Brookland, Mary Kay Washington, Laura R. Meyer. *AJCC Cancer Staging Manual*, 8<sup>th</sup> ed. Chicago, IL: Springer Cham; 2018.

Survivorship and surveillance begin at the point of diagnosis, and warrant consideration throughout the patient journey.

## 5.15 Survivorship

### Rationale

Patients with breast disease or breast cancer are at risk for complications and symptoms that can delay other treatments and interfere with recovery. Identification and control of these symptoms is essential to promote compliance with continued therapies and restore the patient's sense of normalcy. After treatment, some patients need assistance and guidance to help them return to their “new normal.” Other patients may see their diagnosis as a “wake up call” to improve their overall health. NAPBC-accredited programs promoting a healthy lifestyle will not only decrease patient risk for disease recurrence, but will also improve the patient's post-cancer well-being.

### Definition and Requirements

The NAPBC-accredited program must use evidence-based guidelines to develop and implement a protocol addressing persistent symptoms, functional issues, and social and behavioral determinants of health for maximizing symptom management, physical function, and social well-being among patients with breast disease or breast cancer. Evidence-based guidelines include those provided by the ACSM, APTA, ONS, ACS, NCCN, and ASCO.

Examples of evidence-based guidelines include, but are not limited to, the following:

- Referral to local or online exercise programs
- Referral to a social worker if psychosocial distress remains elevated post-treatment
- Referral to outpatient rehabilitation if specific functional complaints arise
- Referral to outpatient rehabilitation for evaluation and treatment for lymphedema, as needed

The protocol must also address how patients with breast disease or breast cancer are connected to evidence-based elements of breast cancer recovery.

- For example, ensuring that breast cancer survivors receive referrals to exercise programming at follow-up appointments
- For services that are not available on-site, the treatment team must help facilitate patient access to needed resources

It is recommended, but not required, that a written summary of treatment and associated survivorship recommendations is provided to the patient and the patient's primary care provider.

Patients must be encouraged to maintain a relationship with their primary care provider, who is informed about the care the patient received, and potential side effects the patient may encounter.

### Evaluation by the BPLC

Each accreditation cycle, the BPLC must review and assess:

- The protocol for following evidence-based guidelines to address persistent symptoms, functional issues, and social and behavioral determinants of health, for maximizing symptom management, physical function, and social well-being among patients with breast disease or breast cancer
- Barriers to maximizing wellness of patients with breast disease or breast cancer after treatment

As barriers to compliance with this standard are identified, they must be addressed by the NAPBC-accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

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## Documentation

### Reviewed On-Site

- The site reviewer will evaluate preselected medical records to confirm compliance with this standard, including:
  - Persistent symptoms are queried and addressed according to evidence-based guidelines
  - Social and behavioral health is assessed regularly and addressed according to evidence-based guidelines

### Submitted with Pre-Review Questionnaire

- Required protocol
- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

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## Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- A protocol is developed and implemented for following evidence-based guidelines for addressing persistent symptoms and maximizing physical function and social and behavioral health
- Symptom status, functional status, and social well-being are tracked in the patient medical record
- The BPLC evaluation is completed and documented in the BPLC meeting minutes once each accreditation cycle

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## Bibliography

Ligibel JA, Bohlke K, May AM, et al. Exercise, diet, and weight management during cancer treatment: ASCO guideline. *J Clin Oncol*. 2022;40(22):2951–2507. JCO2200687

Michelle B Riba, Kristine A Donovan, Barbara Andersen, et al. Distress Management, Version 3.2019, NCCN clinical practice guidelines in oncology. *J Natl Compr Canc Netw*. 2019;17(10):1229–1249.

National Lymphedema Network Position paper. Screening and measurement for early detection of breast cancer related lymphedema (2011). [www.lymphnet.org/position-papers](http://www.lymphnet.org/position-papers)

Stout NL, Brown JC, Schwartz AL, et al. An exercise oncology clinical pathway: Screening and referral for personalized interventions. *Cancer*. 2020; 126(12):2750–2758. PMID: 32212338

## 5.16 Surveillance

### Rationale

As patients finish treatment, they may require education regarding the potential for long-term effects and disease recurrence. Communicating the post-treatment plan for surveillance of long-term effects and disease recurrence helps minimize patient anxiety and increase the likelihood of their full participation in surveillance plans.

### Definition and Requirements

The NAPBC-accredited program must use evidence-based guidelines to develop and implement a protocol addressing the following:

- Appropriate clinical and imaging surveillance for disease progression or recurrence
- Surveillance for long-term and late effects of disease and treatment
  - For example: Assessing patients for depression, cardiotoxicity, lymphedema, sexual well-being, and sleep disturbance
- Surveillance for disease, surveillance for long-term and late effects, and requirements for documenting in the patient medical record
  - For example: Patients who receive axillary dissections are automatically referred to rehabilitation for ongoing assessments and, if necessary, lymphedema treatment

For services that are not available on-site, the NAPBC-accredited program must facilitate access to the necessary resources and services.

#### Evaluation by the BPLC

Each accreditation cycle, the BPLC must review and assess:

- The protocol for following evidence-based guidelines for disease surveillance and long-term and late effects of disease and treatment

As barriers to compliance with this standard are identified, they must be addressed by the NAPBC-accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

### Documentation

#### Reviewed On-Site

- The site reviewer will evaluate preselected medical records to confirm compliance with this standard, including:
  - Disease surveillance is addressed according to evidence-based guidelines
  - Treatment of long-term and late effects is addressed according to evidence-based guidelines and/or disease site team recommendations

#### Submitted with Pre-Review Questionnaire

- Required protocol
- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

### Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- A protocol is developed and implemented for following evidence-based guidelines for disease surveillance and long-term and late effects of treatment
- Surveillance for disease and long-term and late effects is documented in the patient medical record
- The BPLC evaluation is completed and documented in the BPLC meeting minutes once each accreditation cycle

### Bibliography

Gilchrist SC, Barac A, Ades PA, et al. Cardio-oncology rehabilitation to manage cardiovascular outcomes in cancer patients and survivors: A scientific statement from the American Heart Association. *Circulation* 2019;139(21):e997–e1012. Doi: 10.1161/CIR.0000000000000679.

Stout NL, Binkley B, Schmitz KH, et al. A prospective surveillance model for rehabilitation for women with breast cancer. *Cancer*. 2012;118(SUPPL.8):2191–2200. PMID: 22488693

Swinnen J, Keupers M., Soens J. et al. Breast imaging surveillance after curative treatment for primary non-metastasized breast cancer in non-high-risk women: A systematic review. *Insights Imaging*. 2018;9(6):961–970.





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## 6 Data Surveillance and Systems

Submission to a NAPBC-specific database is not required by *Optimal Resources for Breast Care*, therefore, there are no Chapter 6 standards.







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## 7 Quality Improvement

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## Rationale

The Institute of Medicine outlines the following factors as contributory to high-quality care: safe, timely, effective, efficient, equitable, and patient-centric. NAPBC-accredited programs must embark on quality improvement initiatives that address these factors in order to continuously improve the quality of the care they deliver to patients with breast disease or breast cancer.

## In Development

## 7.1 Quality Measures

### Definition and Requirements

The National Accreditation Program for Breast Centers (NAPBC) requires accredited programs to treat patients with breast disease or breast cancer in accordance with all nationally accepted quality measures. The NAPBC approves such nationally accepted quality measures based on a determination of need for quality or accountability regarding a specific aspect of breast care. All approved quality measures must be reviewed and implemented by the NAPBC-accredited program. The timeline for implementation and the expected compliance rate for all new quality measures is determined by the NAPBC. The Breast Program Leadership Committee (BPLC) must monitor the accredited program's adherence with all required quality measures.

If adherence to any required quality measure falls below its expected rate of compliance, a corrective action plan must be developed and implemented to improve performance. The corrective action plan must document how the NAPBC-accredited program will investigate and resolve all barriers affecting a required quality measure which falls below its expected rate of compliance.

Programs with no cases eligible for assessment in an approved quality measure are exempt from demonstrating compliance with the requirements for that individual quality measure.

#### Evaluation by the BPLC

Each calendar year, the BPLC must review and assess:

- Compliance with all required quality measures
- Development and implementation of corrective action plans for all quality measures that fall below the expected rate of compliance

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

### Documentation

#### Submitted with Pre-Review Questionnaire

- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

### Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- The BPLC monitors the program's compliance with quality measures approved by the NAPBC
- The BPLC develops and implements a corrective action plan for any quality measure that falls below its expected rate of compliance
- The BPLC evaluation is completed and documented in the BPLC meeting minutes once each calendar year

## 7.2 Quality Improvement Initiatives

### Definition and Requirements

Under the guidance of the Breast Program Director (BPD) and the Breast Program Leadership Committee (BPLC), the NAPBC-accredited program must measure, evaluate, and improve its performance through at least one (1) breast cancer-specific quality improvement (QI) initiative each calendar year.

This QI initiative requires the NAPBC-accredited program to identify a problem, understand the root cause of the identified problem through use of a recognized performance improvement methodology, and implement a planned solution to the problem. Reports on the status of the QI initiative must be given to the BPLC at least twice each calendar year, and documented in the BPLC meeting minutes.

### Required Components for Quality Improvement Initiatives

#### 1. Review Data to Identify the Problem

The QI initiative must be focused on an already-identified, quality-related problem specific to the NAPBC-accredited program.

The following may be used to identify the focus of the QI initiative:

- Barriers, supported by data, identified during the BPLC evaluations required by Chapter 5 of *Optimal Resources for Breast Care*
- Data-focused quality programs identified through a chart review of a specific cohort of patients in order to assess an area of specific concern, or to assess an area of care specified in nationally recognized guidelines
- Data-focused quality programs identified through a physician, specialty-specific quality improvement program; examples include, but are not limited to, the American Society of Breast Surgeons' Mastery of Surgery program, the American Society for Radiation Oncology's Radiation Oncology Incident Learning System (RO-ILS), or the American Society of Plastic Surgeons' Tracking Operations and Outcomes for Plastic Surgeons (TOPS) program
- Data-focused quality program identified through a specialty-based facility-specific quality improvement program; examples include, but are not limited to, the American College of Radiology's National Mammography Database (NMD), or the National Consortium of Breast Centers' National Quality Measures for Breast Centers program (NQMBC)

- Data-focused quality programs identified through an internal institution-specific or health-system-specific database, which may include the entire cancer registry or a smaller established clinical database
- Data-focused problems identified in a Standard 7.1 quality measure
- Problems identified through review of National Cancer Database data, including Cancer Quality Improvement Program (CQIP) or Rapid Cancer Reporting System (RCRS) data
- Any other data-focused breast cancer-specific, quality-related problem determined by the BPLC

#### 2. Write the Problem Statement

The QI initiative must have a problem statement. The problem statement must outline:

- A specific, already identified, quality-related problem that is specific to the NAPBC-accredited program to solve through the QI initiative
- The baseline and goal metrics (must be numerical)
- The anticipated timeline for completing the QI initiative, and achieving the expected outcome

The problem statement for the QI initiative cannot state that a study is being done to see if a problem exists. The problem must already be known to exist.

#### 3. Choose and Implement Performance Improvement Methodology and Metrics

The BPD and BPLC must identify the subject matter experts needed to execute the QI initiative. For example, if the QI initiative is focused on the time between pre-surgery chemotherapy and surgery, then at least one (1) breast surgeon and one (1) medical oncologist must be included on the QI initiative team.

A recognized, standardized performance improvement methodology must be selected and implemented to conduct the QI initiative (for example, Lean, DMAIC, or PDCA/PDSA).

In line with the quality improvement methodology selected, the team must conduct analysis to identify all factors contributing to the problem. This may involve literature review and/or root-cause analyses. Based on the results of this analysis, an intervention is developed that aims to fix the cause of the problem being studied.

It is recommended to establish a project calendar, which includes the launch date of the QI initiative, when status updates will be given at BPLC meetings, and a project end date.

QI initiatives are expected to last approximately one (1) year. If additional time is required, the initiative may be extended for a second year, for a total of two (2) years. However, a new QI initiative must be started at the beginning of each calendar year, even if a previous QI initiative is still in progress. The last BPLC meeting of the calendar year must include a status update for any ongoing QI initiative that will be extended into a second calendar year.

#### 4. Implement Intervention and Monitor Data

The intervention chosen in step three must be implemented. If oversight of the implementation suggests the intervention is not working, then the intervention must be modified.

#### 5. Present Quality Improvement Initiative Summary

Once the QI initiative has been completed, a document summarizing the initiative and the results must be presented and discussed with the BPLC and the BCT, and documented in the BPLC meeting minutes. The results of the QI initiative must be quantifiable, using outcomes data compared to the baseline data and the numerical goal metrics established in step two. The results of the QI initiative must also be compared with national benchmark data, whenever possible.

The summary presentation must include:

- Summary of the data reviewed to identify the problem
- The problem statement
- The QI initiative team members
- Performance improvement methodology utilized
- The implemented intervention
- If applicable, any adjustments made to the intervention
- Results of the implemented intervention

#### BPLC Reports

Updates to the BPLC on the QI initiative's status at least twice each calendar year must be provided. Status updates, at a minimum, indicate the current status of the QI initiative and the planned next steps. The final summary and results report may qualify as one (1) of the required reports.

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## Documentation

### Reviewed On-Site

- Documentation of QI initiative team's work from throughout the initiative (for example, meeting minutes, literature review, etc.)

### Submitted with Pre-Review Questionnaire

- Quality Improvement Initiative Template
- BPLC meeting minutes documenting required status updates and presentation of the QI initiative summary

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that NAPBC-accredited programs follow local, state, and federal requirements related to patient privacy, risk management

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## Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- One (1) quality improvement initiative based on an identified quality-related problem is initiated each calendar year. The QI initiative documentation includes how it measured, evaluated, and improved performance through implementation of a recognized, standardized performance improvement methodology
- Status updates are provided to the BPLC twice each calendar year. Reports are documented in the BPLC meeting minutes
- A final presentation of a summary of the quality improvement initiative is presented after the QI initiative is complete. The summary presentation includes all required elements





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## 8 Education: Professional and Community Outreach

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## Rationale

NAPBC-accredited programs must strive to focus efforts on education about breast cancer prevention, healthy lifestyles, and screening awareness. Such education helps lessen the physical, emotional, and financial burdens of a potential cancer diagnosis by improving the odds of faster detection, and faster treatment. Lifestyle modifications, such as achieving and maintaining a healthy body mass index, and reducing alcohol intake can reduce the risk for breast cancer. Continuing education for health care professionals providing care to patients with breast disease or breast cancer ensures that providers remain current on new options for neoadjuvant, primary, and adjuvant treatment to help deliver the best possible outcomes for their patients.

## 8.1 Education, Prevention, and Early Detection Programs

### Definition and Requirements

Each calendar year, the NAPBC-accredited program must provide or coordinate a minimum of two (2) education programs targeted to the local community. These programs must focus on breast disease or breast cancer education, prevention, and/or early detection. Coordinating these programs with other facilities or local agencies does meet the measure of compliance for this standard.

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. For early detection programs, the NAPBC-accredited program must have a follow-up process in place for patients with positive findings.

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 for high-risk populations
- Screening mammography and clinical examination

An education or prevention program may address multiple cancer sites, but at least one (1) component of the program must be dedicated to breast disease or breast cancer.

Education and prevention programs may be held virtually, but there must be real-time interaction with participants. Pre-recorded programs and resources with no option for participant interaction or participation **do not** meet the measure of compliance for this standard.

### Documentation

#### Submitted with Pre-Review Questionnaire

- Education, Prevention, and Early Detection Program Template
- The process used to follow up with patients found to have positive findings as a result of participation in early detection programs

### Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- Each calendar year, two (2) or more breast disease or breast cancer education, prevention, and/or early detection programs are provided
- For early detection programs, follow-up must be provided to patients with positive findings

## 8.2 Continuing Education

### Definition and Requirements

#### The Breast Care Team (BCT)

Physicians and advanced practice providers (including advanced practice registered nurses, nurse practitioners, and physician assistants) who are members of the BCT must complete a minimum of **two (2) total hours of breast-specific** Continuing Medical Education (CME) or Nursing Continuing Professional Development (NCPD), each calendar year. Documentation must be available for each breast-specific educational activity contributing toward the two (2) credit hours. Local, state, regional, and national educational activities are all acceptable. Any combination of credits (0.25, 0.5, 1.0, 2.0) earned from breast-specific educational activities is acceptable. For example: eight 0.25 CME credits; two 1.0 NCPD credits; two 0.5 and one 1.0 CME credits.

- Industry-sponsored educational activities that promote specific products or therapies **do not** count toward meeting the measure of compliance for this standard
- CME and NCPD credits earned for attending a Multidisciplinary Breast Care Conference (MBCC) **do not** count toward meeting the measure of compliance for this standard

CME and NCPD credits earned for compliance with Standards 4.1, 4.2, or 4.3 (excluding credits earned from MBCC attendance) may be utilized to meet the measure of compliance for this standard, as long as those credits are breast-specific.

The requirements outlined above only apply to physician and advanced practice provider members of the BCT.

Other members of the BCT are encouraged to complete annual, breast-specific, continuing education; however, that is not a requirement to meet the measure of compliance for this standard.

#### Genetic Professionals

Genetic professionals (as defined in Standard 4.4) at the NAPBC-accredited program who provide care to patients with breast disease or breast cancer must complete a minimum of **two (2) total hours** of genetics-related Continuing Medical Education (CME) or Nursing Continuing Professional Development (NCPD) each calendar year. The two (2) credit hours must focus on cancer genetics and hereditary cancer predisposition syndromes. Documentation must be available for each cancer-specific genetic educational activity contributing toward the two (2) credit hours. Local, state, regional, and national educational activities are all acceptable. Any combination of credits (0.25, 0.5, 1.0, 2.0) earned from cancer-specific educational activities is acceptable. For example: eight 0.25 CME credits; two 1.0 NCPD credits; two 0.5 and one 1.0 CME credits.

- Educational activities provided by commercial genetic testing laboratories regarding how to perform genetic testing **do not** count toward meeting the measure of compliance for this standard
- CME and NCPD credits earned for attending a Multidisciplinary Breast Care Conference (MBCC) **do not** count toward meeting the measure of compliance for this standard

CME and NCPD credits earned for compliance with Standards 4.1 or 4.2 (excluding credits earned from MBCC attendance) may be utilized to meet the measure of compliance for this standard, as long as those credits focus on cancer genetics and hereditary cancer predisposition syndromes.

If genetic counseling is provided by a telegenetics company or an outside facility, the NAPBC-accredited program must obtain a letter of attestation from the outside company or facility documenting that all qualified genetic professionals meet the measure of compliance for this standard by completing a minimum of two (2) total hours of genetics-related Continuing Medical Education (CME) or Nursing Continuing Professional Development (NCPD) each calendar year. The two (2) credit hours must focus on cancer genetics and hereditary cancer predisposition syndromes.

#### Continuing Education Units

Continuing Education Units (CEUs) are acceptable to demonstrate compliance with this standard for appropriate genetic professionals. Documentation of **0.2 CEUs** must be available to demonstrate compliance with this standard. All requirements and restrictions outlined above also apply to personnel documenting CEUs instead of CME or NCPD.

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## Documentation

### Submitted with Pre-Review Questionnaire

- Continuing Education Template
- If applicable, a letter of attestation from the outside telegenetics company or facility, documenting compliance with this standard

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## Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- Physician and advanced practice provider members of the BCT must complete a minimum of two (2) hours of breast-specific CME or NCPD each calendar year
- Genetic professionals at the NAPBC-accredited program who provide care to patients with breast disease or breast cancer must complete a minimum of two (2) hours of CME, NCPD, or 0.2 CEUs each calendar year, focusing on cancer genetics and hereditary cancer predisposition syndromes
- If applicable, a letter of attestation is obtained from the outside telegenetics company or facility, documenting compliance with this standard





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## 9 Research

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## **Rationale**

In order to advance medical science in service to patient care in every sense, it is important to learn as much as possible from patients who receive treatment. Accordingly, NAPBC-accredited programs must endeavor to enroll patients into scientific studies that may broaden the overall understanding of breast diseases.

## 9.1 Clinical Research Accrual

### Definition and Requirements

The NAPBC-accredited program must enroll a **minimum** of two percent (2%) of its analytic breast cancer cases in clinical research studies. The clinical research studies must be related to breast disease or breast cancer. This requirement must be met each calendar year.

#### Cancer-Related Research Studies Eligible for Accrual

Clinical research studies eligible to count for accrual must meet the following requirements:

1. Related to breast disease or breast cancer
2. Approved by an internal or external Institutional Review Board (IRB) that is responsible for the review and oversight of the research study
3. Have informed, written, subject consent (unless consent is waived by the IRB)

Categories of breast disease or breast cancer-related clinical research studies eligible for accrual:

- Basic Science
- Device Feasibility
- Diagnostic
- Health Services Research
- Prevention
- Screening
- Supportive Care
- Treatment

Definitions for these categories may be found on the National Cancer Institute Clinical Trial Reporting Program User Guide (see Primary Purpose Value Definitions).

Additional categories of breast disease or breast cancer-related clinical research studies for accrual:

- Cancer-specific biorepositories or tissue banks
  - Such biobanks must collect samples for use in clinical trials and/or clinical research
- Economics of cancer care
  - Studies that assess the costs and effectiveness of cancer interventions and/or analyze the financial impact of cancer care on patients
- Genetic studies
  - Studies that examine contributing genes or how different exposures modify the effect of a gene mutation that may be at risk for cancer development
  - Studies that examine genetic polymorphisms and mutations for early risk assessment

- Patient registries with an underlying breast disease or breast cancer research focus
  - Such registries must be used in clinical trials and/or clinical research
- Epidemiological studies with an underlying breast disease or breast cancer research focus

Humanitarian Use Devices studies cannot be counted as an accrual under this standard.

#### Calculating Compliance

Compliance with this standard is calculated using the number of subjects with breast disease or breast cancer enrolled in eligible clinical research studies (numerator), and the total number of annual analytic breast cancer cases (denominator).

To count for accrual, subjects enrolled in eligible clinical research studies must fall into at least one (1) of the following categories:

- Diagnosed and/or treated at your program and enrolled in a breast disease or breast cancer-related clinical research study within your program
- Diagnosed and/or treated at your program and enrolled in a breast disease or breast cancer-related clinical research study within a staff physician's office of your program
- Diagnosed and/or treated at the program, then referred by your program for enrollment onto a breast disease or breast cancer-related clinical research study through another program or facility
- Referred to your program for enrollment onto a breast disease or breast cancer-related clinical research study through another program or facility

Researchers and clinical trial investigators who accept referral of subjects from other programs for the purpose of participation in a breast disease or breast cancer-related clinical research study must cooperate with the data management team of the cancer program from which the patient was referred.

If one (1) subject is enrolled in two (2) different trials or studies, that subject may be counted twice for accrual. However, if one (1) subject is enrolled in two (2) arms of a protocol, or enrolled in a sub-study of a protocol, that subject only counts once for accrual.

If the clinical research is cancer-related, but it is not specific to breast disease or breast cancer, subject accruals are allowed to count provided the study relates to breast disease or breast cancer. The subjects enrolled must still be patients with breast disease or breast cancer.

### **Evaluation by the BPLC**

Each calendar year, the BPLC must review and assess:

- The yearly accrual to breast disease or breast cancer-related clinical research studies
- If the required accrual percentage is not met, the BPLC identifies contributing factors and identifies an action plan to address those factors

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

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## **Documentation**

### **Reviewed On-Site**

- Tracking documents that detail the number of subjects accrued to specific clinical research studies

### **Submitted with Pre-Review Questionnaire**

- Clinical Research Template
- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that NAPBC-accredited programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

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## **Measure of Compliance**

The NAPBC-accredited program fulfills all compliance criteria:

- The annual number of breast disease or breast cancer subjects accrued to breast disease or breast cancer-related clinical research studies meets or exceeds two percent (2%)
- The BPLC evaluation is completed and documented in the BPLC meeting minutes



## Appendix

### Alternative Service Delivery Models for Genetic Counseling

Quality genetic counseling is dependent on services provided by healthcare professionals with genetic training and continuing education, such as a NAPBC-approved qualified genetic professionals (see Standard 4.4). It is therefore vital to utilize collaborative alternative service delivery models within NAPBC-accredited programs that promote the delivery of high-value genetics services by all clinicians. Alternative service delivery models provided by qualified genetic professionals may include any of the following:

Alternative Service Delivery Models	
<b>Telegenetics</b>	Genetic counseling may be provided remotely by live videoconferencing. This approach may involve the genetic professional to be present at a healthcare facility with access to the required telegenetics equipment. Increasingly, telegenetics may be facilitated through various software or applications that allow either or both the patient and/or provider to participate in telegenetics appointments outside of a healthcare facility setting. Telegenetics services are also increasingly provided by commercial companies that provide support for all aspects of genetic counseling and testing, while working in conjunction with referring physicians.
<b>Group Genetic Counseling</b>	In this model, different patients have pre-test counseling together provided by the genetic professional, typically for the same clinical indication (such as a family history of breast cancer). This model may allow for break-out sessions for individual discussions between patients and genetic professional after the group session.
<b>Mainstreaming</b>	Several different forms of this delivery model currently exist: <ul style="list-style-type: none"> <li>• Genetic professionals assisting and partnering with non-genetic clinicians for risk assessment and/or pre-test or post-test counseling</li> <li>• Genetic professionals educating a community of clinicians (such as providing in-services or educational presentations) to facilitate management of routine cases with post-test referral to genetic professionals</li> </ul>
<b>Tumor-First Testing Models</b>	In this model, genetic screening is first performed on tumor tissue, often as part of the pathology workflow, with genetic counseling by the genetic professional offered based on the tumor results. Considerable care must be taken when using this model to ensure proper informed consent. Clinicians must also be aware that, depending on the type of tumor testing employed, the chance of missing a germline genetic variant is high, and the clinicians must also be sure to perform proper risk assessment and genetic testing based on other personal and family risk factors present in the patient.
<b>Direct Genetic Testing</b>	In the direct model, patients are offered genetic testing with little to no pre-test discussion. Written documents, recorded videos, or other resources may be provided instead of genetic counseling. Considerable care must be taken to ensure appropriate informed consent is completed with each patient. Clinicians must also be wary to avoid the potential negative outcomes of this model, including unnecessary prophylactic surgeries, unnecessary testing, psychosocial distress, and false reassurance from results leading to inappropriate medical management. Post-test genetic counseling by a genetic professional is crucial in this model to ensure proper understanding of the test results, and optimal medical management of the patient.
<b>Direct Access/ Direct-to-Consumer-Testing*</b>	This model is not currently appropriate for all patients and may only be most suitable for curious patients, and those without access to counseling due to financial limitations. This testing is prone to false-negatives and false-positives as it is not designed as a clinical test. Any variants found on a direct-to-consumer test must be confirmed in a CLIA-certified laboratory. Direct-to-consumer testing results should be reviewed by a healthcare provider experienced in genomics, and interpreting such test results.* <b>*This delivery model does not currently meet the measure of compliance for genetic services as required by Standard 5.5.</b>

It is important to note that these models all have numerous benefits and limitations, and that NAPBC-accredited programs may need to utilize several different models to accommodate the unique needs of their different clinics and patient populations. Regardless of the service delivery model used, the genetic professional must meet the defined requirements specified in the measures of compliance for Standard 4.4, and all aspects of appropriate genetic risk assessment and testing that must be complete as described in the measures of compliance for Standard 5.5.

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## Resources and Examples for Individualized Shared Decision Making (ISDM)

### Agency for Healthcare Research and Quality (AHRQ)

#### [SHARE Curriculum Tools](#)

- Resources for starting a shared decision-making dialogue with patients
- Communication tools for shared decision making
- Implementation resources for shared decision making
- Webinars on implementation and overcoming barriers to shared decision making

### Association of Community Cancer Centers (ACCC)

#### [Shared Decision Making: Practical Implementation for the Oncology Team](#)

- Featured publication regarding methods for establishing patient engagement, with an emphasis on shared decision making

### National Cancer Institute (NCI)

#### [Communication in Cancer Care – Models of Communication](#)

- Models of communication
- Demographic and cultural considerations in cancer communication
- Education and training in cancer communication

### Examples of Individualized Shared Decision Making

Each calendar year, the NAPBC-accredited program must provide BPLC meeting minutes documenting the implementation and/or utilization of ISDM in the treatment of patients with breast disease or breast cancer. Examples included, but are not limited to, the following:

- Diversity training on cultural sensitivity
- Diversity training on gender identity and gender expression
- Identifying patient values, goals, preferences, and priorities
- Incorporating patient values, goals, preferences, and priorities into treatment decision-making
- How to run a family meeting
- The role of families and caregivers in supporting treatment decision-making
- Coaching on communication of treatment risks and benefits to patients, families, and caregivers
- Conducting difficult conversations (discussing prognosis, bad news, and end of life)
- Use of evidence-based decision aids to guide conversations with providers and patients
- Basic training about shared decision making and how it differs from informed consent

### Examples of Individualized Shared Decision Making in Clinical Scenarios

- A 72-year-old patient with triple negative breast cancer, atrial fibrillation, and hypertension. The decision is made to provide a NeoPACT regimen (docetaxel/carboplatin + pembrolizumab), instead of neoadjuvant anthracycline.
- A postmenopausal patient with early-stage ER+ breast cancer, genomic testing showing low risk, a strong family and personal history of osteoporosis, and concerns for bone fracture, chooses to start tamoxifen instead of an aromatase inhibitor.
- A young patient with four children, and a member of an Orthodox community with traditionally larger families, receives a referral to reproductive endocrinology to discuss fertility preservation before deciding whether or not to proceed with neoadjuvant chemotherapy.
- A patient who has avoided any systemic therapy due to fears associated with chemotherapy, chooses to start HP+ endocrine therapy for a fungating triple positive breast mass.

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## Resources and Examples for Functional Assessment

Standard 5.9 – Surgical Care, Standard 5.10 – Reconstructive Surgery, Standard 5.11 – Medical Oncology, and Standard 5.12 – Radiation Oncology all require the NAPBC-accredited program to develop and implement a protocol for preoperative/pre-treatment functional assessment with appropriate referrals to exercise, physical therapy, and/or lymphedema management. The specifications of “preoperative” and “pre-treatment” are included to clarify that, when indicated, the functional assessment is intended to be performed prior to surgical resection, reconstructive surgery, the initiation of medical oncology treatment, and/or the initiation of radiation oncology treatment.

A single protocol may be implemented to meet the functional assessment requirements for Standards 5.9 – 5.12. If a single protocol is implemented, the final protocol must specify each of these standards it is intended to meet. The NAPBC-accredited program may also choose to implement different functional assessment protocols for each of these standards. The NAPBC-accredited program has full discretion to develop their own functional assessment, utilize an existing functional assessment tool, or use the functional assessment described below.

An example of a functional assessment that meets the requirements for these standards may include the following:

1. Shoulder abduction test
  - a. Patient raises affected arm(s) from lateral to 180 degrees overhead, one at a time
2. Timed “Up and Go” test
  - a. Patient gets up from a seated position, walks ten (10) feet in a straight line and back to a seated position in under twelve (12) seconds

This assessment is intended to be quickly and easily administered by any qualified health care professional in a clinical setting. If the patient is unable to complete these tests, consider referral for further evaluation by rehabilitation services.

### Centers for Disease Control and Prevention

#### STEADI Initiative

- “Up and Go” test
- STEADI algorithm
- Evaluation Plan
- Resources for inpatient and outpatient care

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## Glossary, Acronyms, and Key Terms

**A2LA:** American Association for Laboratory Accreditation

**AAPM:** American Association of Physicists in Medicine

**ABGC:** American Board of Genetic Counseling

**ABMGG:** American Board of Medical Genetics and Genomics

**ABMS:** American Board of Medical Specialties

**ACCC:** Association of Community Cancer Centers

**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.

**Accreditation Report:** Document released to NAPBC programs at the conclusion of their initial or reaccreditation site visit. The accreditation report includes compliance ratings for each applicable standard and may include specific comments regarding the program's performance. The accreditation report also states the assigned accreditation award and, if applicable, the corrective action due date.

**Accredited Program(s):** A single or multiple-location medical institution providing diagnostic services, treatment services, and comprehensive multidisciplinary care for patients with breast disease or breast cancer, which has achieved accreditation by the National Accreditation Program for Breast Centers (NAPBC). This also refers to initial applicant programs that are actively pursuing accreditation with the NAPBC.

**ACHC:** Accreditation Commission for Health Care

**ACoS:** The American College of Surgeons

**ACoS Cancer Programs:** American College of Surgeons' programs focused on improving care and treatment for patients with cancer, including Commission on Cancer, National Accreditation Program for Breast Centers, National Accreditation Program for Rectal Cancer, the National Cancer Database, American Joint Committee on Cancer, and the Clinical Research Program.

**ACR:** American College of Radiology

**ACRO:** American College of Radiation Oncology

**ACR-ROPA:** American College of Radiology Radiation Oncology Practice Accreditation

**ACS:** The American Cancer Society

**ACGN:** Advanced Clinical Genomics Nurse

**ACSM:** American College of Sports Medicine; ACSM Guidelines for Exercise and Cancer.

**ADH:** Atypical Ductal Hyperplasia; a type of high-risk breast lesion.

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

**AGN-BC:** Advanced Genetics Nursing Certification

**AHRQ:** Agency for Healthcare Research and Quality

**AJCC:** American Joint Committee on Cancer

**ALH:** Atypical Lobular Hyperplasia; a type of high-risk breast lesion.

**Analytic breast cancer case:** Cases for which the hospital provided the initial diagnosis of cancer and/or for which the hospital contributed to first course treatment.

**ANCC:** American Nurses Credentialing Center

**Annually:** Once each calendar year.

**AOA:** American Osteopathic Association

**AOCN:** Advanced Oncology Certified Nurse

**AOCNP:** Advanced Oncology Certified Nurse Practitioner

**AOCNS:** Advanced Oncology Certified Clinical Nurse Specialist

**Appeal:** A part of the site visit process where the applicant program contests one (1) or more of the findings of the site visit.

**APRN:** Advanced Practice Registered Nurses

**APTA:** American Physical Therapy Association

**ASBrS:** American Society of Breast Surgeons

**ASCO:** American Society of Clinical Oncology

**ASTRO:** American Society for Radiation Oncology

**ASTRO-APEX:** The American Society for Radiation Oncology Accreditation Program for Excellence

**BICOE:** Breast Imaging Center of Excellence. Retired terminology. See “CBIC”

**Breast Care Team (BCT):** See definition and requirements in Standard 2.3.

**Breast Program Director (BPD):** See definition and requirements in Standard 2.2.

**Breast Program Leadership Committee (BPLC):** See definition and requirements in Standard 2.1.

**Calendar year:** January 1 – December 31.

**Calendar year review:** Compliance criteria requiring annual review must be completed at least once for each full calendar year (January 1 – December 31).

**CAP:** College of American Pathologists

**CBCN:** Certified Breast Care Nurse

**CBIC:** Comprehensive Breast Imaging Center designation from the American College of Radiology

**CE:** Continuing Education

**CEU:** Continuing Education Unit

**CEO or equivalent:** A high-ranking member of hospital/institutional administration with the authority for high level decision making and resource allocation.

**CGN:** Clinical Genomics Nurse

**CGRA:** Cancer Genetic Risk Assessment certification

**Class of Case:** Class of Case divides cases into two (2) 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.

**CME:** Continuing Medical Education

**CoC:** The Commission on Cancer

**Community representative:** An individual who resides within the accredited program's service area.

**Compliance:** The accredited program meets all the compliance criteria required for a specific standard.

**CQIP:** Cancer Quality Improvement Program, a report provided to accredited programs by the National Cancer Database that includes short-term quality and outcome data and long-term data, including five-year survival rates for commonly treated malignancies.

**Corrective action:** The process by which a cancer program shows they have met a standard(s) that was noncompliant at the time of the site visit.

**CTR(s):** Certified Tumor Registrar. Retired terminology see "ODS"

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

**DMAIC:** Acronym for Define, Measure, Analyze, Improve, and Control; DMAIC is a structured quality improvement methodology.

**ER(+/-):** Estrogen receptor (positive/negative)

**ERAS:** Enhanced Recovery After Surgery

**Evaluation of barriers:** "As barriers to compliance with this standard are identified, they must be addressed by the NAPBC-accredited program." This is a common requirement for standards in Chapter 5 of *Optimal Resources for Breast Care*. Any conflict or obstacle which deters, limits, or prevents compliance with a particular standard must be specifically discussed and managed by the NAPBC-accredited program to prevent non-compliance with the NAPBC standards.

**Genetic Professional:** The NAPBC defines genetic professionals as health care professionals who hold any of the qualifications outlined in Standard 4.4.

**HER2:** Human epidermal growth factor receptor 2

**HR(+/-):** Hormone receptor (positive/negative)

**IMRT:** Intensity-Modulated Radiation Therapy

**Individualized Shared Decision Making (ISDM):** ISDM is a structured, collaborative approach to healthcare decision-making that moves beyond the traditional model of informed consent by engaging the patient, their family, and healthcare providers. ISDM frameworks help to ensure that all parties engage in the decision-making process, that the patient's circumstances, values, preferences, and culture are appropriately considered, and that decisions are based on the best available evidence. Please refer to the [Appendix](#) of *Optimal Resources for Breast Care* for additional resources and examples related to individualized shared decision making.

**IRB:** Internal Review Board

**LCIS:** Lobular Carcinoma in situ

**LGBTQ:** Lesbian, gay, bisexual, transgender, questioning/queer

**MBCC:** Multidisciplinary Breast Care Conference

**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.

**MQSA:** Mammography Quality Standards Act

**MRI:** Magnetic Resonance Imaging

**NAPBC:** National Accreditation Program for Breast Centers

**NAPBC-accredited program(s):** A single or multiple-location medical institution providing diagnostic services, treatment services, and comprehensive multidisciplinary care for patients with breast disease or breast cancer, which has achieved accreditation by the National Accreditation Program for Breast Centers (NAPBC).

**NAPRC:** National Accreditation Program for Rectal Cancer

**NCCN:** National Comprehensive Cancer Network

**NCDB:** National Cancer Database

**NCI:** National Cancer Institute

**NCPD:** Nursing Continuing Professional Development (formerly CNE- Continuing Nursing Education)

**Neoadjuvant therapy:** Treatment provided to initiate further treatment and/or reduce the size of the primary breast cancer before definitive treatment.

**Newly diagnosed:** Patients who have received a breast cancer diagnosis at the NAPBC-accredited program, or have received a diagnosis elsewhere and present for evaluation and/or treatment at the NAPBC-accredited program before receiving any treatment elsewhere.

**NMD:** National Mammography Database

**Non-compliance:** The NAPBC-accredited program does not meet one (1) or more of the compliance criteria required for a specific standard.

**NQBC:** National Consortium of Breast Centers' National Quality Measures for Breast Centers Program

**OCN:** Oncology Certified Nurse

**ODS:** Oncology Data Specialist

**ONCC:** Oncology Nursing Certification Corporation

**ONN-CG:** Oncology Nurse Navigator-Certified Generalist

**ONS:** Oncology Nursing Society

**Outside provider/outside facility:** Any individual or entity that is not part of the NAPBC-accredited program at a specific medical institution. These outside providers/facilities may, or may not, be involved in the treatment, testing, or evaluation of patients receiving care at the NAPBC-accredited program.

**PA:** Physician Assistant

**Patient representative:** A current or former patient of a NAPBC-accredited program.

**PCP:** Primary Care Physician

**PDCA:** Plan, Do, Check, Act; PDCA is a structured quality improvement methodology.

**PDSA:** Plan, Do, Study, Act; PDSA is a structured quality improvement methodology.

**Policy and procedure:** Retired terminology. See “Protocol”

**PR(+/-):** Progesterone receptor (positive/negative)

**Pre-Review Questionnaire (PRQ):** An online reporting tool that is utilized to demonstrate compliance with NAPBC standards. Formerly known as “Survey Application Record (SAR)”.

**PRO:** Patient Reported Outcomes

**Protocol:** Previously referred to as “policies and procedures” in past versions of the NAPBC Standards, a protocol is a structured and consistent process crafted by the NAPBC-accredited program to help implement the required compliance criteria for specific NAPBC standards. Protocols must be written and documented in a manner that demonstrates compliance with whichever NAPBC standard the protocol is designed to address. Additionally, all protocols must be formally approved by the Breast Program Leadership Committee (BPLC). Identical protocols that apply to several affiliated NAPBC-accredited programs are acceptable. Such protocols must be specifically stylized for each affiliated program, and be formally approved by each BPLC, as applicable. Protocols do not need to be officially-recognized hospital or institutional policies. **Please refer to the NAPBC 2024 Standards FAQ for guidelines and recommendations related to the development of protocols.**

**PRQ:** See “Pre-Review Questionnaire”

**QOPI:** Quality Oncology Practice Initiative

**RCRS:** Rapid Cancer Reporting System

**RDN:** Registered Dietitian Nutritionist

**Referred Services:** Diagnostic services, treatment services, and comprehensive care that are provided at another facility.

**RO-ILS:** American Society for Radiation Oncology’s Radiation Oncology Incident Learning System

**Site Reviewer:** NAPBC-trained health care professional who conducts site visits, and reviews the compliance documentation of a NAPBC-accredited program. The site reviewer assists in verifying whether the accredited program meets compliance with the NAPBC Standards.

**Site Visit:** A virtual or in-person review of the NAPBC-accredited program by a NAPBC site reviewer to verify compliance with the NAPBC standards, and recommend an accreditation award. After initial accreditation, site visits occur once every three (3) years.

**Standard:** Qualification criteria for NAPBC accreditation (not standard of care).

**Survey/Surveyor:** Retired terminology. See “Site Visit” and “Site Reviewer”.

**Synoptic format:** A structured format that includes all of the following:

- All core elements must be reported (whether applicable or not)
- All core elements must be reported in a “diagnostic parameter pair” format, in other words, data element followed by its response (answer)
- Each diagnostic parameter pair must be listed on a separate line or in a tabular format to achieve visual separation
- All core elements must be listed together in a single location in the pathology or operative report

**TJC:** The Joint Commission

**TOPS:** American Society of Plastic Surgeons’ Tracking Operations and Outcomes for Plastic Surgeons (TOPS) Program

**Triennial review:** Compliance criteria requiring triennial review must be completed at least once every three years (3) during the NAPBC-accredited program’s triennial accreditation cycle.

**VUS:** Variants of uncertain significance



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