

## CLARIFICATIONS, REMINDER AND FREQUENTLY ASKED QUESTIONS

**NOTE:** This document is not a substitute for reading the requirements detailed in the National Accreditation Program for Breast Centers Standards Manual (2018 Edition). Notably, there are a few areas where guidance in this document updates or clarifies requirements in the Manual. These areas are marked with this star: ★

### Preparing for the Site Visit

**How many months/years of data does a center provide for an initial site visit?**

Twelve months of materials/BPLC minutes.

**How many months/years of data does a center provide for a re-accreditation site visit?**

Three years of materials/BPLC minutes.

### Medical Record Review

**Can we submit Protected Health Information (PHI) to the Site Reviewer through the Pre-Review Questionnaire (PRQ) or by email?**

No. PHI cannot be provided electronically in any format. But medical records reviewed on-site do not need to be de-identified. Review of PHI on-site is covered by the Business Associate Agreement (BAA) that the center signs at the time of application for accreditation.

**Where can I find information on what must be included in the patient list provided to the Site Reviewer?**

Detailed instructions may be found in the *Virtual Site Visit Sample Agenda and Instructions* on preparing the patient list, selection of the cases by the Site Reviewer to be reviewed, and how to prepare the selected medical records. These instructions may be accessed in the Resources section of the [Quality Portal](#).

### Corrective Action

**How long does a center have to resolve deficiencies from a site visit if it receives an Accredited-Corrective Action Required or Not Accredited-Corrective Action Required status?**

★ A breast center that received one (1) to eight (8) deficiencies is required to complete the corrective action process. Documentation to resolve deficiencies must be submitted within 12 months of the date of the accreditation report. A center that fails to resolve deficiencies within the allotted time is at risk of having its accreditation withdrawn.

### Standard 1.1: Level of Responsibility and Accountability

**Does the Breast Program Leadership Committee (BPLC) have to review compliance with the standards on an annual basis?**

Yes. The review is to be documented in the BPLC minutes.

**Does the Breast Program Director (BPD) have to be a physician?**

No, but it is preferred.

**Can there be more than one BPD?**

Yes.

**What is the minimum number of members that have to be on the BPLC?**

There is to be a minimum of three physicians from different disciplines, plus the BPD. There is no upper limit, but centers are cautioned that the BPLC is a working group. Not every member of the Breast Care Team needs to be on the BPLC.

BPLC membership includes representation from multidisciplinary specialties. BPLC disciplines include, but are not limited to, pathology, radiology, surgery, medical oncology, radiation oncology, reconstruction, research, nursing, social work, hospital administration, and other members as deemed necessary by the BPLC.

**How often is the BPLC to meet each year?**

The BPLC is expected to meet at least four times each calendar year.

**If we refer out for plastic surgery, does a plastic surgeon still need to be a BPLC member?**

It is preferable to have a plastic surgeon on the BPLC, but not required. If you refer out for reconstructions, the plastic surgeon is not required to be on the BPLC.

**We have a couple of surgeons who elect to not participate in the NAPBC accreditation. Do we exclude their data and cases for the reporting of NAPBC data?**

The number of cases used to determine compliance with standards would be limited to the patients seen by physicians who are part of the breast care team (BCT). This impacts the selection of cases for CAP compliance, the number of cases needing survivorship care plans expected by the standard, the cancer conference requirement, etc. A physician who is not a member of the BCT could present a case at the MBCC, but this patient would not be counted in the breast center caseload or when determining compliance with the standards. It is the hope that the BPLC can convince non-participating surgeons to become part of the BCT. [Addition December 2020].

### Standard 1.2: Multidisciplinary Breast Care Conference

#### What are the attendance requirements for the BCT at the Multidisciplinary Breast Care Conference (MBCC)?

The 50% required attendance for individual surgeons, medical oncologists, and radiation oncologists detailed in Standard 1.2: Multidisciplinary Breast Care Conference has been retired, effective January 1, 2020. Attendance, however, is strongly encouraged to promote multidisciplinary decision making. [Addition December 2020].



The Breast Program Leadership Committee (BPLC) is expected to set attendance requirements for all specialties attending the Multidisciplinary Breast Care Conference (MBCC). It is still expected that there be at least one surgeon, radiologist, pathologist, radiation oncologist, and medical oncologist at each MBCC meeting. It is also strongly encouraged that treating physicians attend the MBCC when their patients are being presented. The BPLC is responsible for monitoring individual and specialty attendance on an annual basis. [Added October 2019]

#### Some of our patients are seen at two hospitals for diagnosis and/or surgery. Can we share the MBCC since we share these patients?

No, each center needs to have its own MBCC. [Updated December 2020]

#### Do physicians need to be physically present at the MBCC?

If in-person attendance is not possible, video-conferencing is acceptable as that would allow participants to review materials presented at the conference, including mammography films, breast ultrasound images, and pathology slides.

#### Who provides the staging information at the MBCC?

The managing physician has the responsibility of assigning clinical stage. The MBCC provides an opportunity for all clinicians to actively discuss the clinical or working stage as well as the recommended treatment options for each patient presented. It is suggested that the stage assigned be recorded so the center can easily document that staging was used to guide treatment decisions.

### Standard 1.3: Evaluation and Management Guidelines

#### What is the intent of this standard?

The purpose of this standard is to ensure that patients receive multidisciplinary care at accredited breast centers that is consistent with national guidelines. The BPLC reviews and approves the multidisciplinary patient evaluation and management guidelines once a year and includes that in the BPLC minutes.

### Standard 2.1: Multidisciplinary Patient Management

#### How is this standard reviewed during the medical record review?

The medical record review substantiates that all appropriate BCT members have seen the patients and delivered care. It should also support that BCT members are aware of the care being delivered by other members of the team.

## Standard 2.2: Patient Navigation

### What type of training must the navigator have?

If patient navigation is provided by a lay navigator, the lay navigator is required to have documented patient navigation training with appropriate documentation of that training. To meet the standard, the training must result in a certificate.

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

- National Consortium of Breast Center (NCBC) Breast Program Navigator Certification,
- Oncology Nursing Society (ONS) Oncology Nurse Navigator Core Competencies,
- Academy of Oncology Nurse & Patient Navigators (AONN),
- Educare [previous certification currently accepted],
- Harold P. Freeman Patient Navigation Institute, and
- George Washington Institute Oncology Patient Navigator Training.

[Updated October 2019]

## Standard 2.3: Breast Conservation

### What will the Site Reviewer evaluate during the medical record review for Standard 2.3?

The Site Reviewer will look for documentation of shared decision making and risks and benefits for those patients undergoing mastectomy who are eligible for breast conservation. For patients who are eligible for breast conservation, the medical record should reflect the shared decision making leading to a decision of mastectomy to include but not limited to the risks and benefits as well as decision making factors such as gene mutation carrier, previous mantle radiation, or complication preventing radiation.

### Which type of stage is used to evaluate Standard 2.3?

The clinician should use the staging information that is available at the time the treatment decision is made. Clinical stage and the clinical prognostic stage tables should be used. For example, the clinical stage will be used prior to the definitive operation or for the decision for neo-adjuvant chemotherapy. The pathological stage and the pathological prognostic stage tables would be used after all the T,N,M, grade, receptors, Her-2 and possibly genomic information becomes available after definitive surgery.

## Standard 2.4: Sentinel Node Biopsy

### Which type of stage is used to evaluate Standard 2.4?

Clinical stage is used to evaluate this standard.

### ★ The following supersedes the list of patients considered candidates for axillary sentinel lymph node biopsy:

- American Joint Committee on Cancer (AJCC) Stage I, IIA, and IIB invasive breast cancer with no clinically suspicious axillary lymph nodes
- Previously pathologic nodes that after neoadjuvant chemotherapy are clinically negative

- Extensive ductal carcinoma in situ (DCIS) requiring total mastectomy, no suspicious axillary nodes, if not using Superparamagnetic Iron Oxide tracer for potential delayed sentinel lymph node biopsy
- DCIS requiring wide excision in an anatomic location interfering with future, accurate sentinel lymph node mapping, no suspicious axillary nodes, if not using Superparamagnetic Iron Oxide tracer for potential delayed sentinel lymph node biopsy [Added May 2022]

### Standard 2.5: Breast Cancer Surveillance

#### What is the intent of Standard 2.5?

This standard focuses on centers creating a general plan for surveillance (not patient-specific) of patients who have completed initial treatment, for metastases and recurrence or the development of a new breast primary. Multidisciplinary input into the surveillance plan is necessary to optimize coordinating care. The plan includes a method for communicating the plan to the patient. The plan is reflected in the BPLC minutes.

#### How do you define ‘surveillance by specialty’?

The requirement for the specialty-specific surveillance plan simply means that all specialties contribute to the plan. For example, the medical oncologist should provide input on the frequency of follow-up lab tests/PET scans for patients that undergo chemotherapy; the surgical oncologist should provide input on follow-up exams and imaging. The BPLC ought to decide as a group on the final plan based on input from all specialties.

### Standard 2.6: Breast Cancer Staging

#### What must a program show for compliance with Standard 2.6?

Physician members of the Breast Care Team (BCT) use the most current AJCC clinical T,N,M, grade, HER2, ER, PR and assign the applicable clinical, and either pathological or post neoadjuvant therapy stage when making treatment decisions. Staging should be included in all medical records related to treatment decisions.

The BPLC, following the AJCC guidelines, has a process for use of AJCC staging (for example, who is responsible for completing the clinical, and either pathological staging or post neoadjuvant therapy staging and where the staging is documented).The BPLC reviews the use of the AJCC staging process and discusses the results of the review with the BCT.

The medical record review will identify the use of AJCC Stage designation in essentially all clinical notes with emphasis on those clinical visits that result in treatment decisions.

### Standard 2.7: Pathology

#### ★ Does the CAP protocol portion of the standard apply to Fine Needle Aspirations or core biopsies?

No. [Updated December 2020]

**What are the requirements for performing estrogen and progesterone receptors and HER2 studies?**

Estrogen and progesterone receptors and HER2 studies need only be performed on one specimen (such as the core biopsy or excision specimen), but must be included in the synoptic report of the definitive surgery (even if performed on the core biopsy or at an outside/referring institution). This helps the BCT members easily confirm the non-anatomic factors in one location.

**What is required for the review of pathology at the NAPBC Center if the patient was diagnosed elsewhere?**

There is an expectation that the pathology slides be reviewed prior to treatment. Pathology must still be reviewed if they are part of the same system (but not the same pathologists or pathology group). Slides can be reviewed at the multidisciplinary conference. [Added October 2019]

**Does the standard require a review of slides at my center if a second opinion from another facility has already confirmed breast cancer?**

Yes, the intent of the standard is that the slides are reviewed at the center where the patient is being treated. Accordingly, the slides need to be reviewed at the center treating the patient, despite previous reviews at other centers. An official report is not required per NAPBC requirements.

**Standard 2.9: Needle Biopsy**

**What is the preferred method of diagnosis for breast cancer or breast disease?**

Needle biopsy is the preferred method for all patients, including non-malignant cases. However, for purposes of filling out the Standard 2.9 section of the Pre-Review Questionnaire (PRQ), numbers should be provided for just breast cancer patients. The reason only cancer patients are requested is that the NAPBC recognizes the difficulty in ascertaining the total number of non-malignant breast biopsies since they are not in the cancer registry.

Please note: Compliance with the expectations of Standard 2.9 will also be assessed during the medical record review of non-malignant breast disease patients. The Site Reviewer will look at the non-malignant charts to ensure that needle biopsy is the preferred approach to patients with a palpable mass or an abnormal screening examination.

**Standard 2.11: Stereotactic Core Needle Biopsy**

**Can the American College of Surgeons and American College of Radiology’s Stereotactic Breast Biopsy Accreditation Program be used to comply with Standard 2.11?**



No, it has been retired and is no longer an option for compliance with this standard. Stereotactic core needle biopsy is performed by a radiologist at an American College of Radiology (ACR)-accredited facility or by an American Society of Breast Surgeons (ASBrS) Breast Procedure Program-certified surgeon.

### Standard 2.14: Nursing

#### Which nurses does Standard 2.14 apply to?

This standard applies to nurses in medical oncology who give chemotherapy, nurses in radiation oncology, nurse navigators, and nurses who are full-time in the breast center. It does not apply to nurses in the hospital who might have occasional contact with cancer patients and it does not apply to OR or Recovery Room nurses.

### Standard 2.18: Reconstructive Surgery

#### What will the Site Reviewer evaluate during the medical record review for Standard 2.18?

Centers will be requested to provide documentation of reconstructive surgery referral or discussion for mastectomy patients from the accession list chosen by the Site Reviewer. Referral will be evaluated by the Site Reviewer during chart review.

### Standard 2.19: Evaluation and Management of Non-Malignant Breast Diseases

#### What medical records must be provided for the Site Reviewer to evaluate Standard 2.19?

★ For the medical record review, the center makes available on the day of the site visit ten (10) medical records of its selection: five (5) for patients with benign breast conditions (for example, fibroadenoma, mastitis, or nipple discharge) and five (5) for patients with high-risk lesions (for example, atypical ductal hyperplasia, atypical lobular hyperplasia or lobular carcinoma in situ).

### Standard 2.20: Breast Cancer Survivorship Care

#### What is the required compliance percentage for Standard 2.20?

★ For 2019, the center must deliver care plans to at least 50% of eligible patients each year. However, the continued impact of the COVID-19 pandemic has placed a great deal of stress on patients and breast centers. For this reason, the NAPBC has decided to temporarily suspend the requirement to deliver a survivorship care plan (SCP) to 50% of eligible patients for Standard 2.20.

Site visits that evaluate compliance for years 2020, 2021, and 2022 will still review all aspects of Standard 2.20, such as development of a survivorship care plan, and it is expected that the standard will be met as much as feasible. However, a non-compliant rating will not be given if SCPs are delivered to less than 50% of eligible patients seen during those years. Centers should endeavor to provide cancer patients access to resources and information either online or virtually even if they are unable to provide a SCP.

Centers that have current deficiencies in Standard 2.20 should submit documentation on what they were able to do for their patients during the pandemic period and resolution will be considered on a case-by-case basis.

Centers are encouraged to utilize the COVID-19 Accreditation Tracker to document the impact of COVID-19 on all standard compliance. The tracker is available in the resources section of the Quality Portal. [Added December 16, 2020; Updated March 2022]

### Standard 3.1: Clinical Trial Information

#### What information must center provide patients under Standard 3.1?

Patients are to be educated on the availability of breast cancer-related clinical trials. Patients should also be educated as to what it means to be included in a clinical trial.

### Standard 3.2: Clinical Trial Accrual

#### Which patients can be counted as “accrued” (i.e. who is the numerator)?

Accrued patients are defined as patients:

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

Note: Community Clinical Oncology Program (CCOP) is now the Community Oncology Research Program (NCORP)

#### ★ What is the denominator for calculating compliance with Standard 3.2?

The denominator is the number of the accredited center’s breast cancer patients.

### Standard 4.1: Education, Prevention, and Early Detection Programs

#### What must be documented for Standard 4.1?

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

In the documentation, the community event is described, including the process for selecting it. The center completes the Education, Prevention, and Early Detection Program template.

A display table at a larger vent does not meet the intent of this standard, although, it is acknowledged there is value in this activity as well. [Addition December 2020].

Note: Additional topic/content suggestions for education, prevention, and/or early detection programs are metastatic breast cancer and inflammatory breast cancer.

### Standard 5.1: Breast Care Team Education

#### Which type of providers/BCT members must centers provide documentation for?

This standard applies to physician members of the BCT. It also applies to advanced practice registered nurses and physician assistants (and other comparable roles) who are members of the BCT. While it is encouraged that all BCT members undergo ongoing, breast-specific continuing education, it is not necessary to provide documentation regarding education for other specialties of the BCT (e.g. radiology technologists or certified tumor registrars).

For physician members of the BCT who are also providing genetic counseling in accordance with Standard 2.16, the education requirement in Standard 5.1 is in addition to the education requirement in Standard 2.16 Genetic Evaluation and Management.

#### How long must each of the two required CME credit be?

The two required CMEs must come from separate lectures and must be breast related. Each of the two required CME credits should be approximately one hour in length. One two-hour CME does not meet the standard. [Added December 2020]

### Standard 6.1: Quality and Outcomes

#### How many Quality Studies are required for Standard 6.1?

★ Effective January 1, 2020, the number of quality studies required each year in Standard 6.1: Quality and Outcomes has been lowered. Programs are only required to complete two quality studies for Standard 6.1, one of which must be a center-specific study. [Updated December 2020]

#### Can a study for Standard 6.1 relate to another NAPBC standard?

A study cannot be conducted solely for purposes of meeting a NAPBC standard. For example, a study cannot be done to make sure that required multidisciplinary attendance is met for the Multidisciplinary Breast Care Conference. But a study could aim to enhance upon how a program meets the requirements of a standard.

#### Does a study need to be completed within one year?

No. As necessary, a study may extend into a second year. However, the center still needs to start at least one new center-specific quality study and one physician, specialty-specific quality improvement program OR two center-specific quality studies each year even if the study from the previous year is still ongoing. [Updated October 2019]

#### Can studies be almost the same (same year)?

No, studies need to be on different topics.

#### Can the same study be used for both NAPBC and the Commission on Cancer (CoC)?

Yes, but programs need to make sure that the study meets the requirements of both the CoC and the NAPBC. In some cases, the CoC requirements are more rigorous than those of the NAPBC.

**Can the Breast Module QOPI be used for a study?**

Yes, QOPI can be used as physician participation in a specialty-specific quality improvement program. A summary of the data over the past year or time of study must be presented to the BPLC.

**Can RO-ILS be used for a study?**

Yes, the ASTRO Radiation Oncology Incident Learning System (RO-ILS) can be used as a physician participation in a specialty-specific quality improvement program. A summary of the data over the past year or time of study must be presented to the BPLC. It must be breast specific. [Added October 2019]

**What type of documentation should be submitted in the Pre-Review Questionnaire (PRQ) to show we participated in the CALLER study?**

In addition to a letter that documents participation, you will need to document that the surgeon presented the results/feedback to the BPLC at least once during the year. If preferred, it can be written up like a program- centered study and documented in the minutes. This counts as a physician specialty-specific quality improvement program/study.