5.3 Sentinel Node Biopsy for Breast Cancer

Definition and Requirements

All sentinel nodes for breast cancer must be identified, removed, and subjected to pathologic analysis to ensure that lymphatic mapping and sentinel lymphadenectomy provide accurate information for breast cancer staging.

Sentinel nodes are defined as (1) node(s) having uptake of a localization substrate (radioactive tracer and/or colored dye) that has been previously injected into the affected breast, (2) node(s) to which an afferent colored lymphatic travels, or (3) dominant lymph node(s) that are palpably suspicious as identified by the operating surgeon. Nodes with radioactive counts that are at least 10% that of the most radioactive node are considered sentinel nodes and should be removed.

This standard has been satisfied if (1) a diligent search has been made for sentinel nodes, and those nodes are removed when present, and (2) documentation of those specifics is complete and in synoptic format. Specifically, operative reports must indicate that all colored, radioactive, and/or suspicious nodes were removed, in addition to any noncolored nodes at the end of a colored lymphatic.

When performing a sentinel node biopsy in patients who have received neoadjuvant chemotherapy, removing a baseline biopsy-proven positive node (if applicable) and/or at least two to three sentinel nodes and/or using multiple substrates for sentinel node identification reduces the false negative rate.

Removal of nodes that do not correspond to a selected identification method does not meet compliance, unless the node is documented as being palpably suspicious.

Operative Report Requirements

Operative reports for patients undergoing sentinel node biopsy for breast cancer must include the following elements in synoptic format. The required elements and responses must be in the operative report of record, clearly identified, and the response options must be the same as in the CoC standard. A uniform synoptic reporting format should be used by all surgeons at the facility. To meet requirements for compliance, the synoptic elements/responses must be included in the operative report of record. If the brief op note is incorporated into the operative report, this is compliant. If the brief op note is a separate entry in the EMR, this is noncompliant.

Element	Response Options
Operation performed with curative intent.	Yes; No.
Methods used to identify sentinel and/or biopsy-proven lymph nodes *(select all that apply).*	Dye; Radioactive tracer; Superparamagnetic iron oxide; Clip; Other *(with explanation)*; N/A.
Sentinel lymph nodes removed *(select all that apply).*	Baseline biopsy-proven positive node; Blue nodes; Radioactive nodes; SPIO detected nodes; Palpably suspicious nodes; Other (*with explanation*).

Scope of Standard

This standard applies to all nodal staging operations performed with curative intent for patients with breast cancers of epithelial origin.

For current implementation information, visit *facs.org/ cocstandardsupdates*

Internal Audit of Compliance

Each calendar year, the cancer program must conduct an internal audit confirming at least eighty percent (80%) of eligible operative reports for sentinel node biopsy for breast cancer meet the technical requirements of the standard, are structured using synoptic format, and include all required data elements outlined in Standard 5.3.

The internal audit must evaluate a minimum of 30 total sentinel node biopsy cases. If the cancer program performs less than 30 cases meeting the scope of the standard, then all applicable cases must be reviewed. The audit must be completed using the CoC Operative Standards Audit Template for Sentinel Node Biopsy for Breast Cancer.

If the internal audit demonstrates less than eighty percent (80%) compliance with Standard 5.3, an action plan must be developed and implemented. An additional internal audit must be performed six months after the action plan is approved to determine the impact of the intervention(s).

The results of the internal audit and, if applicable, action plans must be presented and discussed by the cancer committee and documented in the cancer committee meeting minutes.

Documentation

Reviewed On-Site

- The site reviewer will review synoptic operative reports from applicable sentinel node biopsies for breast cancer.

Submitted with Pre-Review Questionnaire

- CoC Operative Standards Audit Template for Sentinel Node Biopsy for Breast Cancer
- Cancer committee meeting minutes documenting the required audit of operative reports each calendar year, including any required action plans

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

Each calendar year, the cancer program fulfills the compliance criteria:

1. All sentinel nodes for breast cancer are identified using one or more of the following methods: tracer(s), clips, and/or palpation.
2. All nodes identified as being sentinel nodes are removed at the time of surgery.
3. All removed sentinel nodes are subjected to pathologic analysis.
4. Compliance with sentinel node removal is achieved if at least one of the following conditions is met:
    a. Removal of the baseline biopsy-proven positive node or at least one palpably suspicious node, regardless of the method of detection selected.
    b. Removal of nodes that correspond to the identification method(s) selected, as follows:
        i. Blue-stained nodes and/or nodes at the end of a blue lymphatic channel are compliant only if dye is selected as an identification method.
        ii. Radioactive nodes are compliant only if radioactive tracer is selected.
        iii. Superparamagnetic iron oxide (SPIO)-detected nodes are compliant only if SPIO is selected.
5. Operative reports for sentinel node biopsies for breast cancer document the required elements in synoptic format.
6. Each calendar year, the cancer program conducts an internal audit confirming at least eighty percent (80%) of eligible operative reports for sentinel node biopsy for breast cancer meet the technical requirements of the standard, are structured using synoptic format, and include all required data elements.
7. The results of the internal audit and any action plans are presented to the cancer committee and documented in the cancer committee meeting minutes. The cancer committee report meets the requirements outlined on page vii, "Standards Requiring Annual Review."

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5.4 Axillary Lymph Node Dissection for Breast Cancer

Definition and Requirements

Axillary lymph node dissection (ALND) for breast cancer involves removal of level I and II lymph nodes within an anatomic triangle defined by the axillary vein, chest wall, and latissimus dorsi, with preservation of key neurovascular structures.

For appropriately selected patients, ALND serves two purposes: (1) to provide important staging and prognostic information that can inform treatment decisions, and (2) to improve locoregional disease control.

When ALND is performed, the standard has been satisfied if (1) dissection to established axillary anatomic boundaries is complete, and (2) documentation of operative specifics is complete and in synoptic format. The contents of an ALND for breast cancer should include the level I and II axillary lymph node basins. Complete removal of the nodes within these basins constitutes complete dissection within the following boundaries: the axillary vein, the latissimus dorsi muscle, and the chest wall (serratus anterior muscle). In the course of the dissection, the long thoracic nerve and the thoracodorsal nerve should be preserved unless visibly involved with cancer. The intercostobrachial nerves should be spared when possible. Although the numbers of lymph nodes retrieved in an ALND performed after neoadjuvant chemotherapy is often lower than when ALND is performed in the upfront surgery setting, the surgical techniques that guide ALND are identical in these two settings.

Axillary dissection of levels I and II should be complete, with resection of all soft tissue within the boundaries specified above. Level III nodes also may be removed if clinically involved or suspicious at surgery, although the benefit of their removal is isolated to improvement of local-regional control, and limited data support their removal.

Operative Report Requirements

Operative reports for patients undergoing axillary lymph node dissection must include the following elements in synoptic format. The required elements and responses must be in the operative report of record, clearly identified, and the response options must be the same as in the CoC standard. A uniform synoptic reporting format should be used by all surgeons at the facility. To meet requirements for compliance, the synoptic elements/responses must be included in the operative report of record. If the brief op note is incorporated into the operative report, this is compliant. If the brief op note is a separate entry in the EMR, this is noncompliant.

Element	Response Options
Operation performed with curative intent.	Yes; No.
Axillary nodal tissue within the boundaries of the axillary vein, chest wall and latissimus dorsi muscle was resected.	Yes; No *(with explanation)*.
Nerves identified and preserved during dissection *(select all that apply)*.	Long thoracic nerve; Thoracodorsal nerve; Branches of the intercostobrachial nerves; Other *(with explanation)*.
Level III nodes removed.	No. Yes (*with explanation)*

Scope of Standard

This standard applies to all axillary lymph node dissections performed with curative intent for patients with breast cancers of epithelial origin.

For current implementation information, visit *facs.org/ cocstandardsupdates*

Internal Audit of Compliance

Each calendar year, the cancer program must conduct an internal audit confirming at least eighty percent (80%) of eligible operative reports for axillary lymph node dissection for breast cancer meet the technical requirements of the standard, are structured using synoptic format, and include all required data elements outlined in Standard 5.4.

The internal audit must evaluate a minimum of 30 total axillary lymph node dissection cases. If the cancer program performs less than 30 cases meeting the scope of the standard, then all applicable cases must be reviewed. The audit must be completed using the CoC Operative Standards Audit Template for Axillary Lymph Node Dissection for Breast Cancer.

If the internal audit demonstrates less than eighty percent (80%) compliance with Standard 5.4, an action plan must be developed and implemented. An additional internal audit must be performed six months after the action plan is approved to determine the impact of the intervention(s).

The results of the internal audit and, if applicable, action plans must be presented and discussed by the cancer committee and documented in the cancer committee meeting minutes.

Documentation

Reviewed On-Site

- The site reviewer will review synoptic operative reports from applicable axillary lymph node dissections for breast cancer.

Submitted with Pre-Review Questionnaire

- CoC Operative Standards Audit Template for Axillary Lymph Node Dissection for Breast Cancer
- Cancer committee meeting minutes documenting the required audit of operative reports each calendar year, including any required action plans

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

Each calendar year, the cancer program fulfills the compliance criteria:

1. Axillary lymph node dissections for breast cancer include removal of level I and II lymph nodes within an anatomic triangle comprised of the axillary vein, chest wall (serratus anterior), and latissimus dorsi, with preservation of the main nerves in the axilla.
2. Operative reports for axillary lymph node dissections for breast cancer document the required elements in synoptic format.
3. Each calendar year, the cancer program conducts an internal audit confirming at least eighty percent (80%) of eligible operative reports for axillary lymph node dissection for breast cancer meet the technical requirements of the standard, are structured using synoptic format, and include all required data elements.
4. The results of the internal audit and any action plans must be presented to the cancer committee and documented in the cancer committee meeting minutes. The cancer committee report meets the requirements outlined on page vii, "Standards Requiring Annual Review."

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5.6 Colon Resection

Definition and Requirements

Tumor Location

Preoperative and intraoperative tumor location of colon cancer may both be recorded, but in cases of discrepancy, the intraoperative tumor location should be considered the definitive tumor location. In some cases, tumor location may be determined intraoperatively to be different from preoperative assessment. Colon and Rectum, NOS can be used sparingly for rare tumors where more than one segment of colon is involved, and origin cannot be determined.

Extent of Colon and Vascular Resection

For patients with colon cancer, resection of the tumor-bearing bowel segment and complete lymphadenectomy must be performed en bloc with proximal vascular ligation at the origin of the primary feeding arteries and veins* as follows:

- Right hemicolectomy - ileocolic and right colic (if present).
- Extended right hemicolectomy - ileocolic, right colic (if present), and middle colic.
- Transverse colectomy - middle colic.
- Splenic flexure – middle colic and ascending left colic.
- Left hemicolectomy - inferior mesenteric.
- Sigmoid resection - inferior mesenteric.
- Total abdominal colectomy - ileocolic, right colic (if present), middle colic, and inferior mesenteric.
  - If performed with proctectomy - superior and middle rectal.

- Other – Describe segments and vasculature resected anomalous to standard practice and explain the reason(s).

**Operative Standards for Cancer Surgery*, Volume 1, page 288.

Operative Report Requirements

Operative reports for patients undergoing resection for colon cancer must include the following elements in synoptic format. The required elements and responses must be in the operative report of record, clearly identified, and the response options must be the same as in the CoC standard. If the operation involves more than one primary tumor/resection, a distinct synoptic section is required for each tumor/resection. A uniform synoptic reporting format should be used by all surgeons at the facility. To meet requirements for compliance, the synoptic elements/responses must be included in the operative report of record. If the brief op note is incorporated into the operative report, this is compliant. If the brief op note is a separate entry in the EMR, this is noncompliant.

Element	Response Options
Operation performed with curative intent	Yes; No.
Tumor location *(select all that apply)*	Cecum; Ascending colon; Hepatic flexure; Transverse colon; Splenic flexure; Descending colon; Sigmoid colon; Rectosigmoid junction; Rectum NOS; Colon, NOS.
Procedure (*select all that apply*)	Right hemicolectomy; Extended right hemicolectomy; Transverse colectomy; Splenic flexure resection; Left hemicolectomy; Sigmoid colon resection; Total abdominal colectomy; Total abdominal colectomy, with proctectomy;

	Other *(with explanation)*.
En bloc lymphadenectomy with proximal vascular ligation was performed (*select all that apply)*	Ileocolic artery and vein; Right colic artery and vein; Middle colic artery and vein; Ascending left colic artery and vein; Inferior mesenteric artery and vein; Superior and middle rectal; Other *(with explanation)*.

Scope of Standard
This standard applies to all resections performed with curative intent for patients with colon adenocarcinoma, including emergent cancer operations when the cancer is biopsy-proven or suspected, and applies to all operative approaches.

For current implementation information, visit *facs.org/ cocstandardsupdates*

Internal Audit of Compliance
Each calendar year, the cancer program must conduct an internal audit confirming at least eighty percent (80%) of eligible operative reports for colon resection meet the technical requirements of the standard, are structured using synoptic format, and include all required data elements outlined in Standard 5.6.

The internal audit must evaluate a minimum of 30 total colon resection cases. If the cancer program performs less than 30 cases meeting the scope of standard, then all applicable cases must be reviewed. The audit must be completed using the CoC Operative Standards Audit Template for Colon Resection.

If the internal audit demonstrates less than eighty percent (80%) compliance with Standard 5.6, an action plan must be developed and implemented. An additional internal audit must be performed six months after the action plan is approved to determine the impact of the intervention(s).

The results of the internal audit and, if applicable, action plans must be presented and discussed by the cancer committee and documented in the cancer committee meeting minutes.

Documentation

Reviewed On-Site
- The site reviewer will review synoptic operative reports from applicable resections for colon cancer.

Submitted with Pre-Review Questionnaire
- CoC Operative Standards Audit Template for Colon Resection
- Cancer committee meeting minutes documenting the required audit of operative reports each calendar year, including any required action plans

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

Each calendar year, the cancer program fulfills the compliance criteria:

1. Resection of the tumor-bearing bowel segment and complete lymphadenectomy is performed en bloc with proximal vascular ligation at the origin of the primary feeding vessel(s). The resection is compliant if the corresponding vessels below are ligated or if an explanation is included with "other":
    a Right hemicolectomy – ileocolic, right colic (if present)
    b Extended right hemicolectomy –ileocolic, right colic (if present), middle colic
    c Transverse colectomy – middle colic
    d Splenic flexure resection – middle and ascending left colic
    e Left hemicolectomy – inferior mesenteric
    f Sigmoid resection – inferior mesenteric
    g Total abdominal colectomy –ileocolic, right colic (if present), middle colic, inferior mesenteric
    h Total abdominal colectomy, with proctectomy – ileocolic, right colic (if present), middle colic, inferior mesenteric, superior and middle rectal
2. Operative reports for resections for colon cancer document the required elements in synoptic format.
3. Each calendar year, the cancer program conducts an internal audit confirming at least eighty percent (80%) of eligible operative reports for colon resection meet the technical requirements of the standard, are structured using synoptic format, and include all required data elements.
4. The results of the internal audit and any action plans must be presented to the cancer committee and documented in the cancer committee meeting minutes. The cancer committee report meets the requirements outlined on page vii, "Standards Requiring Annual Review."

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5.7 Total Mesorectal Excision

Definition and Requirements

Total mesorectal excision (TME) is performed for patients undergoing radical surgical resection of mid and low rectal cancers.

"Total mesorectal excision (TME) of rectal cancer leverages existing tissue planes to perform a complete resection of the tumor and the associated draining lymph nodes. … As shown in several studies, a complete mesorectum resulting from performing a TME in the proper tissue plane results in lower rates of local and distant recurrence than resection with an incomplete mesorectum." *Operative Standards for Cancer Surgery*, Volume 2, page 194.

By maintaining the intact fascia propria of the rectum and operating in the space between the mesorectum and the endopelvic fascia, the surgeon can achieve a resection with a negative margin, while simultaneously preserving neurovascular structures.

Per the College of American Pathologists (CAP) cancer protocol template for rectal cancer resections, the quality of TME resection (complete, near complete, or incomplete) must be documented in curative resection of rectal adenocarcinoma pathology reports in synoptic format.

Although the surgeon should always strive to perform a complete TME, near-complete TME yields similar rates of local recurrence and survival and is considered to meet the expectations of this standard. Conversely, incomplete TME is associated with a significantly higher risk of local recurrence and cancer related death than either complete or nearcomplete TME.

Scope of Standard

This standard applies to all radical, anatomic operations for rectal adenocarcinoma performed with curative intent and excludes in-situ lesions ~~and primary resection specimens with no residual cancer (e.g. following neoadjuvant therapy)~~. CoC programs accredited by the National Accreditation Program for Rectal Cancer (NAPRC) are exempt from demonstrating compliance with CoC Standard 5.7.

For current implementation information, visit *facs.org/cocstandardsupdates*

Tumor Location

The table below provides guidance on tumor location.

	NAPRC Synoptic Report	CAP Pathology Report
Data Element Name	Location of tumor within rectum	Rectal tumor location
"High" rectal tumor response	High	Entirely above anterior peritoneal reflection
"Mid" rectal tumor response	Middle	Straddles anterior peritoneal reflection
"Low" rectal tumor response	Low	Entirely below anterior peritoneal reflection

Documentation

Reviewed On-Site

• The site reviewer will review synoptic pathology reports from applicable radical resections for middle and low rectal cancers.

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

Each calendar year, the cancer program fulfills the compliance criteria:

1. Total mesorectal excision is performed for patients undergoing radical surgical resections of mid and low rectal cancers, resulting in complete or near-complete total mesorectal excision.

2. Pathology reports for resections of rectal adenocarcinoma document the quality of TME resection (complete, near complete, or incomplete) in synoptic format.

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5.8 Pulmonary Resection

Definition and Requirements

The surgical pathology report associated with any curative intent pulmonary resection for primary lung malignancy must report the oncologic status of lymph nodes from at least one (named and/or numbered) hilar station and at least three distinct (named and/or numbered) mediastinal stations.

"The hilum and mediastinum should be thoroughly staged at the time of lung resection, even in patients who are undergoing nonanatomic parenchymal-sparing resections such as… [a] wedge resection." *Operative Standards for Cancer Surgery*, Volume 1, page 93.

For reference, single digit stations are mediastinal (2-9) and double digit stations are hilar (10 or higher).

Per the College of American Pathologists (CAP) cancer protocol template for pulmonary resections, the nodal stations examined by the pathologist must be documented in curative pulmonary resection pathology reports in synoptic format. Surgeons are expected to designate the lymph node station from which each node/group of nodes was/were taken on the histology requisition form.

Scope of Standard

This standard applies to all primary pulmonary resections performed with curative intent for non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC), and carcinoid tumors of the lung~~, and excludes primary resection specimens with no residual cancer (e.g. following neoadjuvant therapy)~~. This standard applies to all operative approaches. This standard applies to all lung cancer subtypes regardless of their propensity for nodal metastasis. At present, the AJCC Version 9 Lung does not distinguish radiographic ground glass opacities from other lung tumors.

Mediastinoscopy specimens are surgical and therefore may be included in the final pathology synoptic report to count towards the Standard 5.8 nodal requirements. While transbronchial FNA/EBUS sampling is a critical component of the pre-operative clinical staging process, it is not considered completely equivalent to surgical lymph node sampling when a curative operation is performed. Transbronchial FNA nodal samples, therefore, do not count towards the Standard 5.8 surgical nodal requirements.

This standard applies to all operative approaches for curative lung cancer resection and outlines a minimum systematic sampling paradigm for early-stage lung cancer treatment. Further, patients with more advanced disease may benefit from a more thorough nodal dissection.

For current implementation information, visit *facs.org/~~-~~cocstandardsupdates*

Documentation

Reviewed On-Site

- The site reviewer will review synoptic pathology reports from applicable pulmonary resections for NSCLC, SCLC, or carcinoid tumors of the lung.

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

Each calendar year, the cancer program fulfills the compliance criteria:

1. Pulmonary resections for primary lung malignancy include lymph nodes from at least one (named and/ or numbered) hilar station and at least three distinct (named and/or numbered) mediastinal stations.
2. Pathology reports for curative pulmonary resection document the nodal stations examined by the pathologist documented in synoptic format.

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