

**Contractor Name**

Wisconsin Physicians Service (WPS)

**Contractor Number**

00951, 00952, 00953, 00954  
5101, 5201, 5301, 5401  
05102, 05202, 05302, 05402,  
52280

**Contractor Type**

Carrier  
Fiscal Intermediary (FI)  
MAC A  
MAC B

**LCD Database ID Number****LCD Version Number****LCD Title**

Sentinel Lymph Node Biopsy

**Contractor's Determination Number**

GSURG-036

**AMA CPT/ ADA CDT Copyright Statement**

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**CMS National Coverage Policy**

Title XVIII of the Social Security Act section 1862 (a)(1)(A). This section allows coverage and payment of those services that are considered to be medically reasonable and necessary.

Title XVIII of the Social Security Act section 1862 (a)(7). This section excludes routine physical examinations and services

Title XVIII of the Social Security Act section 1833 (e). This section prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

Pub. 100-4 Medicare Claims Processing Manual- Chapter 12 - Physicians/Nonphysician Practitioners 20.4.4 - Supplies B3-15900.2. This section prohibits Medicare payment for a radiopharmaceutical agent when the provider has not performed the diagnostic radiologic procedures.

**Primary Geographic Jurisdiction**

**Carrier:** Wisconsin, Illinois, Michigan, Minnesota

**MAC A/B:** Iowa, Missouri, Nebraska, Kansas

**Fiscal Intermediary A:** Alaska, Alabama, Arizona, Arkansas, California - Entire State, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Maine, Michigan, Minnesota, Missouri - Entire State, Mississippi, Montana, North Carolina, North Dakota, Nebraska, New Hampshire, New Jersey, New Mexico, Nevada, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Vermont, Washington, Wisconsin, West Virginia, Wyoming, American Samoa, Guam, Northern Mariana Islands, Puerto Rico, U.S. Virgin Islands

## **Oversight Region**

## **CMS Consortium**

## **Original Determination Effective Date**

## **Revision Effective Date**

### **Indications and Limitations of Coverage and/or Medical Necessity**

Sentinel lymph node biopsy involves the identification, removal, and evaluation of lymph nodes that drain the area of a malignant tumor. This is for prognostic, not therapeutic purposes. When one or more tumor cells from a primary tumor migrates into lymphatic fluid, they usually lodge in the first node in the lymphatic channel that drains the tumor. This first node is referred to as the sentinel node. If the malignant cells from the tumor have spread to the lymph system, they are most likely to be found in the sentinel node when evaluated by a pathologist.

One or more multiple lymphatic channels or basins, each of which has its own sentinel node, may drain any primary tumor site. When a sentinel node in a given chain is free of tumor cells, it may be assumed that the remainder of the lymph nodes in that lymphatic channel is also free of cancer. When tumor cells are identified in a sentinel node, it suggests that cancer has spread to other nodes, indicating that a regional lymph node dissection may be necessary to assess the extent of metastasis.

Methods used to identify sentinel node include use of lymphoscintigraphy and/or direct visualization during surgery following an injection of vital dye (e.g., isosulfan blue). Lymphoscintigraphy is a nuclear medicine procedure performed prior to the surgical procedure to locate and mark the sentinel node (s) for the surgeon. It is performed by injecting a radioactive tracer under the skin, which flows toward and into the sentinel node and its lymphatic channel, and is imaged by a gamma camera that produces a map of the path of the radioactive tracer and its first appearance in the sentinel node. **This is injected several hours before surgery.** The vital dye is used during surgery to visualize the lymphatic channels, allowing more effective use of the gamma probe. Thus these techniques are complimentary.

The isosulfan blue dye is selectively taken up by the lymphatic vessels that drain the tumor site and stains them blue. Multiple injections are usually made at equidistant points around the primary lesion shortly before surgery. If a gamma probe is not used, the dissection will begin along the blue-stained vessels that are closest to the primary dye injection site. The surgeon may use a portable, hand-held gamma-ray detection instrument to aid in identification and confirmation of a sentinel node previously identified by nuclear medicine lymphoscintigraphy. When held to the sentinel node, the level of radioactivity registers at very high levels. (This process called intraoperative lymphoscintigraphy, is included in the biopsy procedure and is not reported separately). Once located, the sentinel node is removed and sent to the pathology department for appropriate microscopic evaluation.

Sentinel node biopsy can provide accurate staging information that can be used to determine and refine treatment options. It may also identify the presence of metastasis. An additional advantage of sentinel

node biopsy is that if the sentinel node(s) is negative for tumor, a complete lymphadenectomy, with its increased morbidity, may be avoided.

For sentinel biopsy in breast cancer to be adequately predictive of the state of the complete axilla, surgeons sufficiently accomplished in the technique must do the procedure. The literature in this subject indicates that there is a significant learning curve in gaining adequate proficiency in this technique. It is preferable for the procedure to be done using a combination of injection of vital dye and radiopharmaceutical tracer to allow both visual and radioscintigraphic identification of the sentinel node(s). The surgeon, during the operative procedure, typically performs the vital dye injection. The radiopharmaceutical procedure requires the participation of a nuclear medicine physician, or radiologist, or a physician who is licensed in the handling of nuclear materials, and who is trained and experienced in this technique. The radiopharmaceutical injection procedure and the surgical excision of the sentinel node for biopsy are separately reportable services.

Sentinel Lymph node biopsy is generally covered by Medicare for the following:

1. Clinical Stage I Breast carcinoma stage I or II with no palpable lymph nodes in the axilla)
2. Clinical Stage I or II malignant melanoma of the skin.

Contraindication for sentinel node biopsy in patients with breast carcinoma:

Stage III or IV breast carcinoma or Stage I or II with palpable axillary lymphadenopathy on the ipsilateral side of the breast cancer.

Contraindication for sentinel lymph node biopsy in patients with malignant melanoma:

1. Previous wide excision that disrupts lymphatic flow.
2. Not being a candidate for adjuvant therapy.
3. Melanoma of the head and/or neck.

### **Benefit Category**

Inpatient Hospital Services

Physician Services

### **CPT/HCPCS Section & Benefit Category**

Surgery, Cardiovascular System/Lymph Nodes and Lymphatic Channels, Radiology, Nuclear Medicine/Diagnostic

### **CPT/HCPCS Codes**

38500	Biopsy or excision of lymph node(s); open, superficial
38505	by needle, superficial (e.g., cervical, inguinal, axillary)
38510	open, deep cervical node(s)
38520	open, deep cervical node(s) with excision scalene fat pad
38525	open, deep axillary node(s)
38530	open, internal mammary node(s)
38542	Dissection, deep jugular node(s)
38792	Injection procedure; for identification of sentinel node
78195	Lymphatics and lymph nodes imaging

### **Does the CPT 30% Rule Apply**

No

### **ICD-9 Codes that Support Medical Necessity**

Note: ICD-9 codes must be coded to the highest level of specificity.

172.0	Malignant neoplasm of skin; lip
172.1	Eyelid, including canthus
172.2	ear and external auditory canal
172.3	other and unspecified parts of face
172.4	scalp and neck
172.5	Trunk, except scrotum
172.6	Upper limb, including shoulder
172.7	Lower limb, including hip
172.8	Other specified sites of skin
172.9	Melanoma of skin, site unspecified
174.0	Malignant neoplasm of female breast; nipple and areola
174.1	Central portion
174.2	Upper-inner quadrant
174.3	Lower-inner quadrant
174.4	Upper-outer quadrant
174.5	Lower-outer quadrant
174.6	Axillary tail
174.8	Other specified sites of female breast
174.9	Breast (female), unspecified
175.0	Malignant neoplasm of male breast, nipple and areola
175.9	Other and unspecified sites of male breast
217	Benign neoplasm of breast
229.0	Benign neoplasm of other; lymph nodes
233.0	Carcinoma in situ of breast and genitourinary system
611.71	Signs and symptoms in breast; Mastodynia
611.72	Signs and symptoms in breast; Lump or mass in Breast
784.2	Swelling, mass, or lump, in head and neck
785.6	Enlargement of lymph nodes

The correct use of an ICD-9-CM code listed above does not assure coverage of a service. The service must be reasonable and necessary in the specific case and must meet the criteria specified in this policy.

### **Diagnoses that Support Medical Necessity**

ICD-9 codes listed above

### **ICD-9 Codes that DO NOT Support Medical Necessity**

Those that are not listed in this policy

### **Diagnoses that DO NOT Support Medical Necessity**

Those that are not listed in this policy

### **Documentation Requirements**

Documentation supporting the medical necessity for sentinel lymph node biopsy such as ICD-9 codes must be submitted with each claim. Claims submitted without such evidence will be denied as not medically necessary. The patient's medical records must contain documentation that fully supports the medical necessity for sentinel lymph node biopsy. This documentation includes, but not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures. This documentation must be available to the carrier upon request.

Sentinel lymph node biopsy performed prior to but during the same operative session of an axillary node dissection may not be reported separately unless the results change the planned procedure.

Documentation showing that the sentinel lymph node biopsy was a diagnostic procedure must be available to support the medical necessity of additional procedures performed during the same operative session.

### Utilization Guidelines

NA

### Sources of Information and Basis for Decision

1. National Cancer Institute. Breast cancer (PDQ®): Treatment-health professionals. [Last modified November 1999]. Retrieved November 22, 1999 from the World Wide Web: [http://cancernet.nci.nih.gov/search/results.aspx?DBID=pdq&TYPE=search&SFMT=pdq\\_statement/1/0/0&8=208\\_00013H](http://cancernet.nci.nih.gov/search/results.aspx?DBID=pdq&TYPE=search&SFMT=pdq_statement/1/0/0&8=208_00013H) Orr RK, Hoehn JL, Col NF. The learning curve for sentinel node biopsy in breast cancer. *Arch Surg* 1999; 134:764-767.
2. National Cancer Institute. Melanoma (PDQ®): Treatment-Health professionals. [Last modified 07/99]. Retrieved November 22, 1999 from the World Wide Web [http://cancernet.nci.nih.gov/cgi-bin/srchcgi.exe?DBID=pdq&TYPE=search&SFMT=pdq\\_statement/1/0/0&8=208\\_01302H](http://cancernet.nci.nih.gov/cgi-bin/srchcgi.exe?DBID=pdq&TYPE=search&SFMT=pdq_statement/1/0/0&8=208_01302H)
3. DeAngelis GA, Gizienski T, Moore MM. Axillary sentinel lymph node biopsy in breast cancer staging. *Appl Rad* 1999; June: 8-11
4. Reynolds C, Mick R, et al. Sentinel lymph node biopsy with metastasis: Can axillary dissection be avoided in patients with breast cancer? *J Clin Oncology* 1999; 17:20-1726.
5. Gadd MA, Cosimi AB, et al. Outcome of patients with melanoma and histologically negative sentinel lymph nodes. *Arch Surg* 1999; 134: 381-387.
6. Gershenwald JE, Thompson W, et al. Multi-institutional melanoma lymphatic mapping experience: The prognostic value of sentinel lymph node status in 612 stage I or stage II melanoma patients. *J Clin Oncol* 1999; 17(3): 976-983.
7. Krag D. Current status of sentinel lymph node surgery for breast cancer. *J Natl Cancer Inst* 1999; 91(4):302-303.
8. Veronesi U, Paganelli G, et al. Sentinel lymph node biopsy and axillary dissection in breast cancer: Results in a large series. *J Natl Cancer Inst* 1999; 91(4): 368-373.
9. Bostick P, Essner R, et al. Comparison of blue dye and probe-assisted intraoperative lymphatic mapping in melanoma to identify sentinel nodes in 100 lymphatic basins. *Arch Surg* 1999; 134: 43-49.
10. Dunnwald LK, Mankoff DA, et al. Technical aspects of sentinel node lymphoscintigraphy for breast cancer. *J Nucl Med Technol* 1999; 37: 106-111.
11. Krag D, Weaver D, et al. The sentinel node in breast cancer. A multicenter validation study. *N Engl J Med* 1998; 339(14): 941-946.
12. McMasters KM, Giuliana AE, et al. Sentinel-lymph-node-biopsy for breast cancer: Not yet the standard of care. *N Engl J Med* 1998; 339(14): 990-995.
13. McIntosh SA, Purushotham AD. Lymphatic mapping and sentinel node biopsy in breast cancer. *Br J. Surg* 1998; 85(10): 1347-1356.
14. Sandrucci S, Mussa A. Sentinel lymph node biopsy and axillary staging of T1-T2 No breast cancer. A multicenter study. *Semin Surg Oncol* 1998; 15(4): 278-283.
15. Foster RS, Wood WC. Alternative strategies in the management of primary breast cancer. *Arch Surg* 1998; 133: 1182-1186.
16. Albertini, John J., MD, et al. Lymphatic mapping and sentinel node biopsy in the patient with breast cancer. *JAMA* 1996; 276(22): 1818-1822.

17. Giuliano, AE, et al. Lymphatic mapping and sentinel lymphadenectomy for breast cancer. *AM Sug* 1994; 220(3): 391-401.
18. American Medical Association. *CPT Assistant* 9(7): 6-7, 10 (July 1999).
19. Symposium: Lymphatic mapping and sentinel node biopsy – part 2. *Contemp Surg* 1998; 53(5): 356-361.
20. Powsner R. Sentinel node lymphoscintigraphy in staging cutaneous melanoma. *Ann Radiol* 1998; 27: 13-18.
21. Morton DL, Thompson JF, Cochran AJ, et al. Sentinel-node biopsy or nadal observation in melanoma. *N Engl J Med* 2006; 355:1307-17

**Advisory Committee Meeting Notes**

Meeting Date:

Illinois	09/16/2009
Michigan	09/09/2009
Minnesota	09/24/2009
Wisconsin	09/25/2009
J5 MAC	10/08/2009
Jurisdictional Open Meeting	08/19/2009

**Start Date of Comment Period**

10/08/2009

**End Date of Comment Period**

11/23/2009

**Start Date of Notice Period**

(Published)

**Revision History**

**Last Reviewed On**

**Related Document**

See Article: [Coding Guidelines for GSURG-036 Sentinel Node Biopsy](#)

**Does this LCD contain a "Least Costly Alternative" Provision?**

No

## Companion Article

### Article Title

#### Billing and Coding Guidelines for GSURG-036 Sentinel Node Biopsy

### Effective Date

### Coding Information

Sentinel lymph node identification and biopsy typically involves a multidisciplinary approach. A nuclear medicine procedure called **lymphoscintigraphy** may be performed in advance of the surgical procedure to locate and mark the sentinel node(s) for the surgeon. Briefly, a radioactive tracer is injected under the skin, flows toward and into the sentinel node and its lymphatic chain, and is imaged by a gamma camera that produces a map of the path of the radioactive tracer and its first appearance in the sentinel node. When performed, the injection and lymphoscintigraphy procedures are coded and reported separately by the radiologist.

The procedure may be performed under general or monitored anesthesia care (MAC). The patient is positioned on the operating table so that the planned injection site and the previously marked sentinel node site are accessible to the surgeon. The injection site is generally located around the periphery of the primary tumor or, in some cases, the primary tumor excision site (excised at a previous operative session).

To facilitate visualization of the sentinel node, the surgeon may inject a vital dye-isosulfan blue-which is selectively taken up by the lymphatic vessels that drain the tumor site and stains them blue. Absorption usually requires rarely more than 15 minutes. Four injections are usually made at equidistant points around the primary lesion.

The skin is then prepped and draped and an incision is made carefully to allow access to the now-dyed lymphatic chain. If a gamma probe is not used, the dissection will begin along the blue-stained vessels that are closest to the primary dye injection site, and proceed toward the regional lymphatic basin along these vessels until the blue-stained sentinel node is identified. The surgeon may use a portable, hand-held gamma-ray detection instrument to aid in identification and confirmation of a sentinel node previously identified by nuclear medicine lymphoscintigraphy. The highly sensitive instrument detects radioactivity. When held to the sentinel node, the level of radioactivity registers at very high levels compared to surrounding tissue or background radiation in the operating room. (**Note:** Both the injection of the dye and the intraoperative lympho-scintigraphy are included in the biopsy procedure and are not reported separately.) Once located, the sentinel node is removed and may be sent for frozen section. If a second sentinel node has been identified, it is removed as well. If each sentinel node is negative for tumor, the procedure is terminated and the lymphatic vessels are ligated. The wound is closed in layers.

### Coding Guidelines

1. To report this service, use the appropriate CPT code.
2. All of the coverage criteria must be met before the service can be reimbursed by Medicare.
3. Diagnosis (es) must be present on any claim submitted, and must be coded to the highest level of specificity;
4. The diagnosis code(s) must be representative of the patient's condition.
5. When the ICD-9-CM diagnosis codes 172.0-172.9 are used to identify malignant melanoma of the skin. The patient records must document that the tumor is Clinical Stage I.
6. When ICD-9-CM codes 174.0-174.9, 175.0, or 175.9 are used to identify breast cancer, the patient records must document that the tumor is Clinical Stage I or II.

7. Sentinel node excision should be report by the using the appropriate CPT code (38500-38542). If a second sentinel node is excised from a different lymphatic chain through a separate incision at the same operative session, report the appropriate CPT code for the second incision and append the -59 modifier.
8. Sentinel lymph node biopsy performed prior to but during the same operative session of an axillary node dissection may not be reported separately unless the results change the planned procedure. However, if the decision to perform a more comprehensive procedure is based on the biopsy result, the biopsy is diagnostic and the biopsy service may be reported separately using a 59 modifier.
9. Injection of vital dye (Isosulfan Blue Dye or similar agents) to visualize the sentinel node may not be reported separately.
10. The radiopharmaceutical is payable only when billed with the imaging code (CPT code 78195).
11. CMS Pub. 100-4 Medicare Claims Processing Manual- Chapter 12 - 20.4.4 - Supplies states that Carriers make a separate payment for supplies/radiopharmaceutical when furnished in connection with a diagnostic radiologic procedure (78195) or therapeutic procedure.  
<http://www.cms.hhs.gov/Manuals/IOM/list.asp>
12. If the radiopharmaceutical is not payable; the injection of the radiopharmaceutical is not payable. Services related to non covered services are also not covered. This reference may be found in Section 180 of Chapter 16 of the Medicare Benefit Policy Manual and at the following website:  
<http://www.cms.hhs.gov/manuals/Downloads/bp102c16.pdf>
13. Lymphatic and lymph glands imaging (code 78195), if performed by a radiologist or nuclear medicine physician, may be coded separately and a claim submitted only if a “film” (hard copy) is created for the surgeon’s review (an electronic “soft copy if done by a radiology/nuclear medicine department that normally uses filmless roentgenograms is also acceptable). This may be subject to postpayment review. Documentation in the form of a report/film must be available to the carrier upon request.

#### **CPT/HCPCS Codes**

38500	Biopsy or excision of lymph node(s); open, superficial
38505	by needle, superficial (e.g., cervical, inguinal, axillary)
38510	open, deep cervical node(s)
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38530	open, internal mammary node(s)
38542	Dissection, deep jugular node(s)
38792	Injection procedure; for identification of sentinel node
78195	Lymphatic and lymph nodes imaging

#### **Note:**

#### **Published/Website**

#### **Revision History**

An asterisk (\*) indicates a revision to that section.