MASSACHUSETTS

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Medical Policy

Radioactive Seed Localization of Nonpalpable Breast Lesions

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Policy Number: 469

BCBSA Reference Number: 6.01.57
NCD/LCD: N/A

Related Policies

None

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue[SM] and Medicare PPO Blue[SM] Members

Radioactive seed localization of nonpalpable breast lesions may be considered **MEDICALLY NECESSARY** for the purposes of locating lesions to guide excisional biopsy or breast-conserving surgery, because the clinical outcomes are likely to be equivalent to wire localization.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.
Medicare HMO Blue[SM]	Prior authorization is **not required**.
Medicare PPO Blue[SM]	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
19081	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including stereotactic guidance
19082	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; each additional lesion, including stereotactic guidance (List separately in addition to code for primary procedure)
19083	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including ultrasound guidance
19084	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; each additional lesion, including ultrasound guidance (List separately in addition to code for primary procedure)
19085	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including magnetic resonance guidance
19086	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; each additional lesion, including magnetic resonance guidance (List separately in addition to code for primary procedure)
19281	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including mammographic guidance
19282	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including mammographic guidance (List separately in addition to code for primary procedure)
19283	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including stereotactic guidance
19284	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including stereotactic guidance (List separately in addition to code for primary procedure)
19285	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including ultrasound guidance
19286	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including ultrasound guidance (List separately in addition to code for primary procedure)
19287	Placement of breast localization device(s) (eg clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including magnetic resonance guidance
19288	Placement of breast localization device(s) (eg clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including magnetic resonance guidance (List separately in addition to code for primary procedure)

76942	Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation

HCPCS Codes

HCPCS codes:	Code Description
A4648	Tissue marker, implantable, any type, each

DESCRIPTION

Nonpalpable Lesions

More nonpalpable lesions are currently detected (about 25% to 35% of breast cancers at diagnosis) due to the increased use of breast screening in asymptomatic women. These nonpalpable lesions require a localization technique to perform excisional biopsies or breast-conserving surgery (ie, lumpectomy).

Localization Methods

The traditional localization method for nonpalpable breast lesions is image-guided wire localization. This approach has limitations, including the following: the wire can bend or be displaced (because the wire protrudes from the breast); there may be scheduling issues given the wire should be placed on the same day as the surgery; and the radiologist may follow a different route to place the wire than the surgeon does to excise the lesion, which may complicate locating all of the lesion (in addition to potentially causing cosmetic concerns). The percentage of cases with positive margins after wire localization is 14% to 47%.

Radioactive seed localization of nonpalpable breast lesions uses radio-opaque titanium seed(s) containing radioactive iodine 125 (I-125). These seeds are inserted by a radiologist using ultrasound or stereotactic guidance to identify the location of a nonpalpable breast lesion. They may be placed several days or weeks before surgery. The surgeon then uses a gamma probe to locate the radioactive seed and remove it with surrounding tissue. The range of radioactive doses in 1 group of studies was 3.7 to 10.7 MBq (1 MBq=0.027 mCi).[1,2,] Seeds were 4.5x0.8 mm, which has been described as similar in size to a grain of rice. The half-life of I-125 is 60 days, and I-125 is a 27-keV source of gamma radiation.[3,] I-125 can be detected on a different signal than the 140-keV technetium 99 (Tc-99) that may be used for sentinel lymph node biopsy. Once the radioactive seed is removed, its presence in the tumor specimen is confirmed using the gamma probe. Lack of radioactivity in the tumor cavity is also assessed to ensure that the radioactive seed has not been left in the breast. A disadvantage of radioactive seed localization is that special procedures must be followed to safely handle and track the radioactive seed before placement and after excision.

Radioactive seed localization also may be used to guide excision after neoadjuvant chemotherapy, which is performed primarily in women with locally advanced cancer in an effort to shrink the tumor. A proportion of these women (25%-32%) are then able to have breast-conserving surgery rather than a mastectomy. The challenge is that if there is a complete clinical and radiologic response, it may be difficult to localize the original tumor bed. Pathologic confirmation of response is needed because there is residual microscopic cancer in about half of these patients. Radioactive seed localization can mark the tumor location before beginning neoadjuvant chemotherapy.

An alternative to wire localization or radioactive seed localization, developed in the late 1990s, is radio-guided occult lesion localization. First, a twist marker is placed in the breast to identify the tumor. Before surgery, a liquid radioactive radiotracer (Tc-99) is injected next to the twist marker using image guidance. The surgeon uses a gamma probe to locate the radiotracer and guide the incision. The main disadvantage of this approach is that the radiotracer has a short half-life (»6 hours). It also does not provide a point source of radiation. An advantage is that Tc-99 may be used for sentinel lymph node biopsy, so the same radiotracer is used for both purposes. Alternatively, a radioactive seed and Tc-99 for sentinel lymph node biopsy can be used concurrently. Another alternative is intraoperative ultrasound-guided resection, although the procedure is discussed less frequently in this literature. It can only be done when the lesion is detectable by ultrasound.

Summary

Description

Radioactive seed localization is used to detect nonpalpable breast lesions, which have become more common with the increasing use of breast cancer screening in asymptomatic women. This technique is used before breast-conserving surgery or excisional biopsies to identify the location of an original tumor after neoadjuvant chemotherapy. A radiologist places a titanium "seed" containing radioactive iodine 125 with an 18-gauge needle using ultrasound, mammography, or stereotactic guidance; then, using a gamma probe, the surgeon locates the seed and the breast tissue to be removed. Alternative methods to localize nonpalpable breast lesions include wire localization (the traditional approach) or radio-guided occult lesion localization.

Summary of Evidence

For individuals who have a nonpalpable breast lesion who are undergoing a procedure that requires lesion localization who receive RSL, the evidence includes systematic reviews and RCTs Relevant outcomes are other test performance measures, resource utilization, and treatment-related morbidity. Four RCTs have compared RSL with WL, and overall, they have reported similar outcomes (eg, rates of successful excision, the rate of positive margins) with both techniques. Systematic reviews have also found that outcomes with both localization methods are similar. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Policy History

Date	Action
11/2020	BCBSA National medical policy review. Description, summary, and references updated. Policy statements unchanged.
10/2019	BCBSA National medical policy review. Description, summary, and references updated. Policy statements unchanged.
10/2018	BCBSA National medical policy review. Description, summary, and references updated. Policy statement unchanged.
2/2017	BCBSA National medical policy review. Policy statement changed to medically necessary with information on least costly alternative moved to Policy Guidelines. Effective 2/1/2017.
3/2014	New medical policy describing medically necessary indications. Effective 3/1/2014.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

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6. Ahmed M, Douek M. Radioactive seed localisation (RSL) in the treatment of non-palpable breast cancers: systematic review and meta-analysis. Breast. Aug 2013; 22(4): 383-8. PMID 23673078
7. Langhans L, Tvedskov TF, Klausen TL, et al. Radioactive Seed Localization or Wire-guided Localization of Nonpalpable Invasive and In Situ Breast Cancer: A Randomized, Multicenter, Open-label Trial. Ann Surg. Jul 2017; 266(1): 29-35. PMID 28257326
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9. Preoperative seed placement for breast cancer surgery: clinical effectiveness, cost-effectiveness, and guidelines. Ottawa: CADTH; 2019 Apr. (CADTH rapid response report: summary of abstracts).
10. ACR Practice Parameter for the performance of stereotactic-guided breast interventional procedures.