6.01.57	Radioactive Seed Localization of Nonpalpable Breast Lesions		
Original Policy Date:	February 27, 2015	**Effective Date:**	December 1, 2019
Section:	6.0 Radiology	**Page:**	Page 1 of 11

Policy Statement

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 (see Policy Guidelines and Benefit Application sections).

Policy Guidelines

Based on the currently available evidence, radioactive seed localization of nonpalpable breast lesions is likely to produce outcomes equivalent to wire localization. Therefore, the "least costly alternative" provision of the medically necessary definition may apply (see Benefit Application section).

When breast localization device(s) such as radioactive seeds are placed without biopsy, the procedure would be reported with one of the following codes, depending on the type of imaging guidance used and whether the lesion is an initial or subsequent lesion:

- **19281**: Placement of breast localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including mammographic guidance
- **19282**: Placement of breast localization device(s) (e.g., 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) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including stereotactic guidance
- **19284**: Placement of breast localization device(s) (e.g., 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) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including ultrasound guidance
- **19286**: Placement of breast localization device(s) (e.g., 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) (e.g. clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including magnetic resonance guidance
- **19288**: Placement of breast localization device(s) (e.g. clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including magnetic resonance guidance (List separately in addition to code for primary procedure)

If the breast localization device(s) is placed at the time of image-guided biopsy, it would be reported with one of the following codes depending on the type of imaging guidance used and whether the lesion is an initial or subsequent lesion:

- **19081**: Biopsy, breast, with placement of breast localization device(s) (e.g., 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) (e.g., 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) (e.g., 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) (e.g., 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) (e.g., 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) (e.g., 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)

The seeds might be reported with the tissue marker HCPCS code:

- **A4648**: Tissue marker, implantable, any type, each

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.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

In 2011, the BrachySciences Radioactive Seed Localization Needle with AnchorSeed™ (Biocompatibles) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process (K111979). This device is indicated for the localization of suspicious tissues (nonpalpable lesions) for excision with the use of radioactive seeds.

In 2012, the Best® Localization Needle with I-125 Seed (Best Medical International) was cleared for marketing by the FDA through the 510(k) process (K122704). This device is indicated for breast localization under the direct supervision of a qualified physician. It comprises an I-125 seed and an 18-gauge 5- to 20-cm needle.

These devices are not always used for radioactive seed localization. Radioactive seeds approved for another indication (i.e., off-label) may also be implanted with an 18-gauge needle. These seeds were initially approved for permanent implantation (i.e., brachytherapy) in select localized tumors such as prostate cancer. These seeds use I-125 beads (activity from 0.1 to 1.0 mCi) encapsulated in a titanium tube. An example is the International Isotopes I3RAD I-125 Seed, which, in 1999, was cleared for marketing by the FDA through the 510(k) process (K992963). FDA product code: KXK.

Rationale

Background

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 (i.e., 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. One study mentioned that the radiation dose associated with I-125 seeds (0.29 mCi) was less than that for a mammogram or chest radiograph. 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.

Literature Review
Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Radioactive Seed Localization
Clinical Context and Test Purpose
The purpose of implanting localized radioactive seeds in patients who have a nonpalpable breast lesion and are undergoing a procedure that requires lesion localization is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does implantation of localized radioactive seeds improve the net health outcomes of individuals with a nonpalpable breast lesion that requires lesion localization prior to surgical excision?

The following PICOs were used to select literature to inform this review.

Patients
The relevant population of interest are individuals with a nonpalpable breast lesion that requires lesion localization prior to surgery.

Interventions
The therapy being considered is implantation of localized radioactive seeds.

Comparators
The following therapies are currently being used to make decisions about identifying nonpalpable breast lesions: wire localization and radio-guided occult lesion localization. Implantation of radioactive seeds is performed in a radiology outpatient setting.

Outcomes
The general outcomes of interest are the accuracy of breast lesion localization, surgical margins, and reoperation rates.

Short-term follow-up is necessary to ensure positive surgical margins.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews
Several systematic reviews have compared radioactive seed localization (RSL) with other localization methods. A Cochrane review by Chan et al (2015) evaluated RCTs comparing localization techniques to guide surgical excision of nonpalpable breast lesions.[4] Eleven RCTs were identified; two compared RSL with wire localization (WL), six compared radio-guided occult lesion localization with WL, and three used less common techniques. The primary outcomes were the successful localization of the lesion, successful excision of the lesion, positive excision margins, and the need for further excision. Meta-analyses were conducted for several of these outcomes for RSL and WL. There were no significant differences in the rates of successful excision with RSL or WL (relative risk, 1.00; 95% CI [confidence interval], 0.99 to 1.01) or rates of positive margins (relative risk, 0.67; 95% CI, 0.43 to 1.06). Reviewers concluded that the published evidence did not clearly support one localization method over another.

A meta-analysis by Pouw et al (2015) included studies evaluating RSL, with or without a comparator intervention.[5] Sixteen studies were identified; the number of patients in individual studies ranged from 13 to 2222. Among the included studies, six compared RSL with WL, one compared RSL with radio-guided occult lesion localization, and the remaining studies were uncontrolled. However, this systematic review only reported outcomes for RSL cases. The primary outcomes were irradicality (i.e. , positive margins) and for re-excision. In the 16 studies, the average proportion of patients with irradicality was 10.3% (range, 3%-30.3%) and the average re-excision rate was 14.2% (range, 4%-42%).

Ahmed et al (2013) published a systematic review and meta-analysis of RCTs and nonrandomized controlled studies of RSL and WL.[6] Positive margins for wide local incision were significantly less likely for RSL vs WL (odds ratio, 0.51; 95% CI, 0.36 to 0.72; p<0.001) for 5 studies. Reoperations were less likely for RSL (odds ratio, 0.47; 95% CI, 0.33 to 0.69; p<0.001) for the 4 trials included. Shorter surgery was significantly more likely using RSL than WL (mean difference, -1.32 minutes; 95% CI, -2.32 to -0.32 minutes; p=0.01) for the 2 trials included. Based on 2 trials, there was no statistically significant difference in the volume of breast tissue excised during surgery (mean difference, 1.46 cm^3; 95% CI, -22.35 to 25.26 cm^3; p=0.90).

Randomized Controlled Trials
Four RCTs (two included in the Cochrane reviews, two newer RCTs) are described below and summarized in Tables 1 (characteristics) and two (results).

Langhans et al (2017) published an RCT comparing RSL (n=207) with WL (n=206).[7] Patients with nonpalpable invasive breast cancer or ductal carcinoma in situ (DCIS) visible on ultrasound were included. The primary outcome was margin status after breast-conserving surgery (BCS); secondary outcomes were the duration of the surgical procedure, the weight of the surgical specimen, and the patient's pain perception. Resection margins were positive in 11.8% of cases in the RSL group compared with 13.3% of the WGL group (p=0.65). There was no difference in margin status based on per-protocol analysis (p=0.62). The was no significant difference in the duration of surgical procedure (p=0.12), the weight of the surgical specimen (p=0.54), or the patients' pain perception (p=0.28)

Bloomquist et al (2016) published an RCT comparing RSL (n=70) with WL (n=55).[8] The trial included adult women with nonpalpable invasive carcinoma or DCIS who were eligible for BCS. Multifocal disease and extensive disease requiring bracketing were not exclusion criteria. The primary outcomes were the patient-reported assessment of procedure-related pain and overall convenience of the procedure. Patients in the RSL group completed a questionnaire immediately after the procedure and patients in the WL group completed a questionnaire at the first postoperative visit. The difference in timing could have biased outcomes (e.g., patients may remember pain during the procedure differently by the time they had a postoperative visit). The pain was measured on a 1- (no pain) to 5- (severe pain) point Likert-type scale. Convenience was also rated from one (poor convenience) to five (excellent convenience). Median pain scores during the procedure did not differ significantly between groups. However, the convenience of RSL was rated significantly higher than WL. The median convenience score was five in the RSL group and three in the WL group (p<0.001).

Surgical outcomes were also reported. There was no significant difference in the rate of positive margins (RSL=19.4% vs WL=15.3%; p=0.053). There were also no significant differences in the volume of extracted tissue: the mean volume was 77.0 cm^2 in the RSL group and 67.4 cm^2 in the WL group (p=0.67). All targeted lesions were successfully excised, and there were no lost seeds or transected wires.

Lovrics et al (2011) published the findings of an RCT assessing 205 patients.[9] Participants had nonpalpable early-stage breast cancer and were undergoing BCS. Randomization to RSL or WL was centralized, concealed, and stratified (by the surgeon for seven surgeons). The two groups were similar except that multifocal disease was more common in the RSL patients. Mean age was about 60.9 years for both arms. Exclusion criteria included male patients, pregnancy or lactation, multicentric or locally advanced disease, lobular carcinoma in situ only, and contraindications for BCS. Localization was performed using mammography or ultrasound on the day of surgery. Tumor location was confirmed using 2-view mammography. An intention-to-treat analysis was performed, and the power calculation was reported: A sample size of 333 patients could detect a 15% difference in positive margins across arms with 80% power at a 5% significance level.

In the RSL arm, 18 patients had WL; 6 because the seed was not available at surgery; 3 because the seed would not deploy; and 2 because the seed was displaced. For seven patients, no explanation was provided. In three cases, the wire was added to seed localization to bracket larger lesions. One seed and two wires migrated, and one wire fell out during surgery.

All index lesions were removed. There were no between-group differences, except the following: the mean surgical time was shorter for RSL (19.4 minutes vs 22.2 minutes, respectively; p<0.001); surgeons found excision after RSL easier (p=0.008); and patients found RSL less painful (p=0.038). However, there was no statistically significant difference in patients' anxiety level. There were no between-group differences in the proportion of positive margins (10.5% for RSL vs11.8% for WL) or reoperation rates. Results for positive margins were similar when the analysis was rerun based on the treatment patients received (per-protocol analysis). Also, the percentage of positive margins was higher for DCIS (20.4%) than for invasive cancer (9.2%; p=0.020). A related study by Reedijk et al (2012) analyzed factors associated with positive margins, including localization under stereotactic guidance, in situ disease, large tumor size, and multifocal disease.[10]

Gray et al (2001) randomized 97 women with nonpalpable breast lesions to RSL (n=51) or WL (n=47).[1] The method of randomization was not reported. Fifty-six patients underwent excisional biopsies for suspicious lesions judged inappropriate for percutaneous biopsy techniques, and 41 patients with a confirmed diagnosis of breast cancer by core needle biopsy had BCS (47% of RSL patients, 37% of WL patients). Both WL and RSL were performed using ultrasound or mammography guidance. Surgery was performed up to five days later.

Fifty-two patients had invasive carcinoma; 9 had DCIS, and 36 had benign lesions. There were no statistically significant differences in the number of patients with RSL or WL within each category. Outcomes for both localization techniques were similar for migration of the localization device (i.e., seed or wire); ability to locate the lesion during surgery; time for radiographic localization and for surgical excision; subjective ease of the procedure for radiologists, patients, or surgeons; and volume of tissue removed. Specimen radiographs were used with WL but not with RSL. There were fewer positive margins with RSL (26%) than with WL (57%; p=0.02).

Table 1. Summary of Key Randomized Controlled Trial Characteristics for RSL and WL

Study	Countries	Sites	Dates	Participants	Interventions	
					RSL	***WL***
Langhans et al (2017)[7,]	Denmark	2	2014-2016	444 women with nonpalpable breast invasive breast cancer	207	206
Bloomquist et al (2016)[8,]	U.S.	1	2011-2014	125 women with nonpalpable breast lesions	70	55
Lovrics et al (2011)[9,]	Canada	3	2004-2010	305 women with invasive or ductal carcinoma in situ	152	153
Gray et al (2001)[1,]	U.S.	1	1999-2001	97 women with nonpalpable breast lesions	51	47

RSL radioactive seed localization; WL: wire localization.

Table 2. Summary of Randomized Controlled Trial Results for RSL and WL

Outcome	Langhans et al (2017)[7,]	Bloomquist et al (2016)[8,]	Lovrics et al (2011)[9,]	Gray et al (2001)[1,]
Localization device migration				
RSL	NR	6 seeds	1 seed	No substantial migration
WL	NR	7 wires	2 wires; 1 wire fell out	No substantial migration
Removal of suspicious lesion	100% for both	100% for both	100% for both	100% for both
Positive margin rate, n (%)				
RSL	23 (11.8)	14 (19.4)	16 (10.5)	26%
WL	26 (13.3)	9 (15.3)	18 (11.8)	57%
p	0.65	0.53	0.990	0.02
Re-excision rate, n (%)				
RSL	NR	NR	17 (11.2)	NR
WL	NR	NR	20 (13.1)	NR
p	NR	NR	0.786	NR
Patient rating	• Pain (NS)	• Pain (*NS*) • Convenience: Significantly higher for RSL than WL (p<0.001)	• Pain with RSL less than with WL (p=0.038 • Anxiety (*NS*)	*NS*

NR: not reported; NS: not significant; RSL: radioactive seed localization; WL: wire 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 RCTs and systematic reviews. The 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 (e.g., 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.

Supplemental Information

Practice Guidelines and Position Statements

The American College of Radiology (2013; amended 2014) issued practice guidelines for imaging management of ductal carcinoma in situ and invasive breast carcinoma.[11] Both wire localization (using mammographic, sonographic, or magnetic resonance imaging guidance) and radioactive seed localization (using mammographic or sonographic guidance) as techniques for preoperative image-guided localization of nonpalpable breast lesions are discussed as techniques to guide surgeons.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02800317	Primary Radioactive Iodine Seed Localisation in the Axilla in Axillary Node PositiveBreast Cancer Combined With Sentinel Node Procedure (RISAS) Following Neoadjuvant Chemotherapy	200	Oct 2019
NCT02522468	A Trial of RSL Versus WL for Malignant Breast Disease (BCS-RSL-001)	400	Jul 2020

NCT: national clinical trial.

References

1. Gray RJ, Salud C, Nguyen K, et al. Randomized prospective evaluation of a novel technique for biopsy or lumpectomy of nonpalpable breast lesions: radioactive seed versus wire localization. *Ann Surg Oncol.* Oct 2001;8(9):711-715. PMID 11597011
2. Hughes JH, Mason MC, Gray RJ, et al. A multi-site validation trial of radioactive seed localization as an alternative to wire localization. *Breast J.* Mar-Apr 2008;14(2):153-157. PMID 18248562
3. Ahmed M, Douek M. ROLL versus RSL: toss of a coin? *Breast Cancer Res Treat.* Jul 2013;140(2):213-217. PMID 23793603
4. Chan BKY, Wiseberg-Firtell JA, Jois RHS, et al. Localization techniques for guided surgical excision of non-palpable breast lesions. *Cochrane Database of Systematic Reviews.* Jan 2015(12):CD009206. PMID 26718728
5. Pouw B, de Wit-van der Veen LJ, Stokkel MP, et al. Heading toward radioactive seed localization in non-palpable breast cancer surgery? A meta-analysis. *J Surg Oncol.* Feb 2015;111(2):185-191. PMID 25195916
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):383-388. PMID 23673078
7. Bloomquist EV, Ajkay N, Patil S, et al. A randomized prospective comparison of patient-assessed satisfaction and clinical outcomes with radioactive seed localization versus wire localization. *Breast J.* Mar-Apr 2016;22(2):151-157. PMID 26696461

8. Lovrics PJ, Goldsmith CH, Hodgson N, et al. A multicentered, randomized, controlled trial comparing radioguided seed localization to standard wire localization for nonpalpable, invasive and in situ breast carcinomas. *Ann Surg Oncol*. Nov 2011;18(12):3407-3414. PMID 21533657
9. Reedijk M, Hodgson N, Gohla G, et al. A prospective study of tumor and technical factors associated with positive margins in breast-conservation therapy for nonpalpable malignancy. *Am J Surg*. Sep 2012;204(3):263-268. PMID 22794705
10. American College of Radiology (ACR). ACR practice guideline for the imaging management of DCIS and invasive breast carcinoma. 2014; https://www.acr.org/-/media/ACR/Files/Practice-Parameters/DCIS.pdf. Accessed August 3, 2018
11. Blue Cross Blue Shield Association. Medical Policy Reference Manual, No. 6.01.57 (September 2019).

Documentation for Clinical Review

Please provide the following documentation (if/when requested):

- History and physical and/or consultation notes including:
  - Prior imaging studies (e.g., mammogram, MRI, CT, Ultrasound; as applicable)
  - Reason for procedure

Post Service

- Procedure report

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

MN/NMN

The following services may be considered medically necessary when policy criteria are met. Services may be considered not medically necessary when policy criteria are not met.

Type	Code	Description
CPT®	19081	Biopsy, breast, with placement of breast localization device(s) (e.g., 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) (e.g., 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) (e.g., 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) (e.g., 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) (e.g., clip, metallic pellet), when performed, and imaging of the biopsy

Type	Code	Description
		specimen, when performed, percutaneous; first lesion, including magnetic resonance guidance
	19086	Biopsy, breast, with placement of breast localization device(s) (e.g., 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) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including mammographic guidance
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	19288	Placement of breast localization device(s) (e.g. clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including magnetic resonance guidance (List separately in addition to code for primary procedure)
HCPCS	A4648	Tissue marker, implantable, any type, each
ICD-10 Procedure	0HHT31Z	Insertion of Radioactive Element into Right Breast, Percutaneous Approach
	0HHU31Z	Insertion of Radioactive Element into Left Breast, Percutaneous Approach
	0HHV31Z	Insertion of Radioactive Element into Bilateral Breast, Percutaneous Approach

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
02/27/2015	BCBSA Medical Policy adoption	Medical Policy Committee
11/01/2016	Policy revision without position change	Medical Policy Committee
11/01/2017	Policy revision without position change	Medical Policy Committee
11/01/2018	Policy revision without position change	Medical Policy Committee
12/01/2019	Policy revision without position change	Medical Policy Committee

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.