6.01.57	Radioactive Seed Localization of Nonpalpable Breast Lesions		
Original Policy Date:	February 27, 2015	**Effective Date:**	November 1, 2023
Section:	6.0 Radiology	**Page:**	Page 1 of 11

Policy Statement

I. 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).

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Based on the currently available evidence, radioactive seed localization of nonpalpable breast lesions is likely to produce outcomes equivalent to wire localization.

Coding
When breast localization device(s) such as radioactive seeds are placed without biopsy, the procedure would be reported with codes 19281-19288, depending on the type of imaging guidance used and whether the lesion is an initial or subsequent lesion. If the breast localization device(s) is placed at the time of image-guided biopsy, it would be reported with codes 19081-19086, depending on the type of imaging guidance used and whether the lesion is an initial or subsequent lesion.

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

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

Description

Radioactive seed localization (RSL) 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 cm to 20cm needle.

These devices are not always used for RSL. 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 (RSL) 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 RSL 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 RSL, 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Radioactive Seed Localization

Clinical Context and Test Purpose

The purpose of implanting localized radioactive seeds in individuals 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 following PICO was used to select literature to inform this review.

Populations
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 (WL) and radio-guided occult lesion localization.

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.

Review of Evidence
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; 2 compared RSL with WL, 6 compared radio-guided occult lesion localization with WL, and 3 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 [RR], 1.00; 95% CI [confidence interval], 0.99 to 1.01) or rates of positive margins (RR , 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, 6 compared RSL with WL, 1 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% to 30.3%) and the average re-excision rate was 14.2% (range, 4% to 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 versus WL (odds ratio [OR], 0.51; 95% CI, 0.36 to 0.72; p<.001) for 5 studies. Reoperations were less likely for RSL (OR , 0.47; 95% CI, 0.33 to 0.69; p<.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=.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=.90).

Randomized Controlled Trials

RCTs published subsequent to the systematic reviews are described below and summarized in Tables 1 (characteristics) and 2 (results).

Chagpar et al (2021) published a secondary analysis of 2 RCTs that included 515 women with stage 0 to 3 breast cancer undergoing localization of no palpable tumors prior to breast conserving surgery.[7,] Localization method was determined by the treating surgeon. No difference was found between RSL and WL in either the positive margin rate (p=.34) or in re-excision rate (p=.96). The analysis also found no difference in postoperative incidence of seroma or hematoma in RSL (0%) and WL (0.9%; p=.63).

Langhans et al (2017) published an RCT comparing RSL (n=207) with WL (n=206).[8,] 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=.65). There was no difference in margin status based on per-protocol analysis (p=.62). There was no significant difference in the duration of surgical procedure (p=.12), the weight of the surgical specimen (p=.54), or the patients' pain perception (p=.28).
Bloomquist et al (2016) published an RCT comparing RSL (n=70) with WL (n=55).[9,] 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 1 (poor convenience) to 5 (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 5 in the RSL group and 3 in the WL group (p<.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=.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=.67). All targeted lesions were successfully excised, and there were no lost seeds or transected wires.

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

Study	Countries	Sites	Dates	Participants	Interventions	
					RSL	*WL*
Chagpar et al (2021)[7,]	U.S.	10	2011-2013; 2016-2018	515 women with stage 0-3 breast cancer requiring localization	50	465
Langhans et al (2017)[8,]	Denmark	2	2014-2016	444 women with nonpalpable breast invasive breast cancer	207	206
Bloomquist et al (2016)[9,]	U.S.	1	2011-2014	125 women with nonpalpable breast lesions	70	55

RSL radioactive seed localization; WL: wire localization.

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

Outcome	Chagpar et al (2021)[7]	Langhans et al (2017)[8]	Bloomquist et al (2016)[9]
Localization device migration			
RSL	NR	NR	6 seeds
WL	NR	NR	7 wires
Removal of suspicious lesion	NR	100% for both	100% for both
Positive margin rate, n (%)			
RSL	14 (28.0)	23 (11.8)	14 (19.4)
WL	176 (37.8)	26 (13.3)	9 (15.3)
p	.34	.65	.53
Re-excision rate, n (%)			
RSL	12.0%	NR	NR
WL	13.3%	NR	NR
p	.96	NR	NR
Patient rating	NR	Pain (NS)	Pain (NS)
Patient rating	NR	Pain (NS)	Pain (*NS*) Convenience: Significantly higher for RSL than WL (p<.001)

NR: not reported; NS: not significant; RSL: radioactive seed localization; WL: wire localization.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Radiology

The American College of Radiology practice parameter (updated 2021) for performing stereotactic breast interventional procedures indicates that stereotactic-guided localization, including radioactive seed localization, may be used as an alternative to standard localization using mammography for identification of lesions prior to surgical procedures.[10]

Canadian Agency for Drugs and Technology in Health

A 2019 rapid evidence review conducted by the Canadian Agency for Drugs and Technology in Health (CADTH) identified no evidence-based guidelines on radioactive seed localization for nonpalpable breast lesions.[11]

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			
NCT02759133	Preoperative Localization of Infraclinical Breast Tumors: Isotopic Localization by iodine125 Seed Versus Standard Localization Using a Metal Wire: A Randomized Prospective Trial	350	Aug 2023
Unpublished			
NCT02800317	Primary Radioactive Iodine Seed Localisation in the Axilla in Axillary Node PositiveBreast Cancer Combined With Sentinel Node Procedure (RISAS) Following Neoadjuvant Chemotherapy	200	Jul 2020
NCT02522468	A Trial of RSL Versus WL for Malignant Breast Disease (BCS-RSL-001)	400	Dec 2021

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): 711-5. 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. 2008; 14(2): 153-7. PMID 18248562
3. Ahmed M, Douek M. ROLL versus RSL: toss of a coin?. Breast Cancer Res Treat. Jul 2013; 140(2): 213-7. PMID 23793603
4. Chan BK, Wiseberg-Firtell JA, Jois RH, et al. Localization techniques for guided surgical excision of non-palpable breast lesions. Cochrane Database Syst Rev. Dec 31 2015; 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): 185-91. 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): 383-8. PMID 23673078
7. Chagpar AB, Garcia-Cantu C, Howard-McNatt MM, et al. Does Localization Technique Matter for Non-palpable Breast Cancers?. Am Surg. Dec 2022; 88(12): 2871-2876. PMID 33856948
8. 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
9. 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. 2016; 22(2): 151-7. PMID 26696461
10. ACR Practice Parameter for the performance of preoperative image-guided localization in the breast. Updated 2021. Accessed August 4, 2023.
11. Preoperative seed placement for breast cancer surgery: clinical effectiveness, cost-effectiveness, and guidelines. Ottawa: CADTH; 2019 Apr. (CADTH rapid response report: summary of abstracts). Accessed August 4, 2023.

Documentation for Clinical Review

Please provide the following documentation:

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

Post Service (in addition to the above, please include the following):

- 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.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

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 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)

Type	Code	Description
	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)
HCPCS	A4648	Tissue marker, implantable, any type, each
	C7501	Percutaneous breast biopsies using stereotactic guidance, with placement of breast localization device(s) (e.g., clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, all lesions unilateral and bilateral (for single lesion biopsy, use appropriate code) ***(Code effective 1/1/2023)***
		Percutaneous breast biopsies using magnetic resonance guidance, with placement of breast localization device(s) (e.g., clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, all lesions unilateral or bilateral (for single lesion biopsy, use appropriate code) ***(Code effective 1/1/2023)***

Policy History

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

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

Effective Date	Action
11/01/2023	Policy reactivated. Previously archived from 08/01/2020 to 10/31/2023.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

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 and Feedback (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 at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

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.

Appendix A

POLICY STATEMENT	
BEFORE	**AFTER**
Reactivated Policy **Policy Statement:** N/A	**Radioactive Seed Localization of Nonpalpable Breast Lesions 6.01.57** **Policy Statement:** I. 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).