



Kansas City

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Radioactive Seed Localization of Nonpalpable Breast Lesions

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Next Review: 11/2019

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for Radioactive Seed Localization of Nonpalpable Breast Lesions when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered

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 Considerations section).

When Policy Topic is not covered

n/a

Considerations

Based on the currently available evidence, radioactive seed localization of nonpalpable breast lesions is likely to produce equivalent outcomes compared with wire localization. Therefore, the “least costly alternative” provision of the medically necessary definition may apply.

State or federal mandates (eg, FEP) may dictate that certain U.S. Food and Drug Administration–approved devices, drugs, or biologics may not be considered investigational, and thus these devices may be assessed only on the basis of their medical necessity.

Radioactive seed localization of nonpalpable breast lesions is likely to produce equivalent outcomes compared with wire localization, but may be more costly. Some plans may use a definition of “medical necessity” that states that a medically necessary service must not be more costly than an alternative service or sequence of services that is at least as likely to produce equivalent health outcomes. In these cases, when it is determined that a strategy using radioactive seed localization is more costly than one using wire localization (as determined by plan pricing, provider charges, and/or other mechanisms), then radioactive seed

localization may be considered **not medically necessary** for localization of nonpalpable breast lesions.

For contracts that do not use this definition of medical necessity, benefit or contract language describing the "least costly alternative" may also be applicable for this choice of treatment.

In addition, other contract provisions including contract language concerning use of out-of-network providers and services may be applied. That is, if the alternative therapy (eg, wire localization) is available in-network but radioactive seed localization is not, radioactive seed localization would not be considered an in-network benefit.

Description of Procedure or Service

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> With a nonpalpable breast lesion who are undergoing a procedure that requires lesion localization 	Interventions of interest are: <ul style="list-style-type: none"> Radioactive seed localization 	Comparators of interest are: <ul style="list-style-type: none"> Wire localization Radio-guided occult lesion localization 	Relevant outcomes include: <ul style="list-style-type: none"> Other test performance measures Resource utilization Treatment-related morbidity

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

For individuals who have a nonpalpable breast lesion who are undergoing a procedure that requires lesion localization who receive radioactive seed localization, the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are other test performance measures, resource utilization, and treatment-related morbidity. There are 3 RCTs comparing radioactive seed localization and wire localization, and overall they have found similar outcomes (eg, rate of successful excision, 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 qualitatively that the technology results in a meaningful improvement in the net health outcome.

Background

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 (BCS; ie, lumpectomy).

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, because 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 and worsen cosmetic outcomes. 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 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 It 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 also is 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 BCS rather than 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.

Rationale

This evidence review was created in September 2013 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through July 20, 2017. The key literature is summarized next.

RADIOACTIVE SEED LOCALIZATION

Systematic Reviews

Several systematic reviews of the literature have compared radioactive seed localization (RSL) with other localization methods. A 2015 Cochrane review evaluated randomized controlled trials (RCTs) comparing localization techniques with 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 (ROLL) 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 was no significant difference in the rate of successful excision with RSL or WL (relative risk [RR], 1.00; 95% CI [confidence interval], 0.99 to 1.01; rate 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 2015 meta-analysis by Pouw et al 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 ROLL, and the remaining studies were uncontrolled. However, this systematic review only reported outcomes for the RSL cases. The primary outcomes were irradiability (ie, positive margins) and for re-excision. In the 16 studies, the average proportion of patients with irradiability was 10.3% (range, 3%-30.3%) and the average re-excision rate was 14.2% (range, 4%-42%).

In 2013, Ahmet et al published a systematic review and meta-analysis of RCTs and controlled nonrandomized studies of RSL and WL.(6) Positive margins for wide local incision were significantly less likely for RSL vs WL (odds ratio [OR], 0.51; 95% CI, 0.36 to 0.72; $p < 0.001$) for 5 studies. Reoperations were less likely for RSL (OR=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

min; 95% CI, -2.32 to -0.32 min; $p=0.01$) 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 cm³; 95% CI, -22.35 to 25.26 cm³; $p=0.90$).

Randomized Controlled Trials

Three RCTs (two included in the Cochrane reviews, one newer RCT) are described below and summarized in Table 1.

Gray et al (2001) randomized 97 U.S. 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 breast-conserving surgery (BCS; 47% of RSL patients, 37% of WL patients). On imaging, 42 patients had calcification, and 55 had a density. Both WL and RSL were performed using ultrasound or mammography guidance. Surgery was performed up to 5 days later. Radiologists and patients rated the difficulty of the procedure after localization on a Likert scale from 1 (easiest) to 10 (most difficult), and surgeons completed the same rating after excision. Margins were considered positive if imprint cytology of the margins demonstrated malignant cells or if final histology demonstrated malignant cells less than 1 mm from any margin; only malignant tumors were included.

Fifty-two patients had invasive carcinoma; 9 had ductal carcinoma in situ (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 (ie, 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%; $p=0.02$).

In 2011, Lovrics et al published findings of an RCT with 205 patients.⁽⁷⁾ Participants had nonpalpable early-stage breast cancer and were undergoing BCS. Randomization to RSL or WL was centralized, concealed, and stratified (by 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, 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 vs 11.8% 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 analyzed factors associated with positive margins, including localization under stereotactic guidance, in situ disease, large tumor size, and multifocal disease.(8)

In 2016, Bloomquist et al 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 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 bias outcomes (eg, patients may remember pain during the procedure differently by the time they had a postoperative visit). Pain was measured on a 1- (no pain) to 5- (severe pain) point Likert-type scale. Convenience was also rated on a 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 ($p < 0.001$).

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 cm² in the RSL group and 67.4 cm² in the WL group ($p = 0.67$). All targeted lesions were successfully excised, and there were no lost seeds or transected wires.

Table 1. Summary of Randomized Controlled Trials Comparing RSL With WL

Measure	Gray et al (2001)	Lovrics et al (2011)	Bloomquist et al (2016)
Patient population	Undergoing excisional biopsy or	Undergoing BCS	Undergoing BCS

	BCS		
Sample size	97	205	125
Migration of localization device	No substantial migration for either	<ul style="list-style-type: none"> ▪ RSL: 1 seed ▪ WL: 2 wires; 1 wire fell out 	<ul style="list-style-type: none"> ▪ RSL: 6 displaced seeds ▪ WL: 7 displaced wires
Removal of suspicious lesion	100% for both	100% for both	100% for both
Volume of extracted tissue	RSL=55.7 mL vs WL=73.5 mL (<i>NS</i>)	RSL=191.1 cc vs WL=83.8 cc (<i>NS</i>)	<i>NS</i>
Time for localization, min	<i>NS</i>	<i>NS</i>	NR
Time for surgery, min	<i>NS</i>	RSL=19.4 vs WL=22.2; ($p<0.001$)	NR
Positive margins	RSL=26% vs WL=57% ($p=0.02$)	(RSL=10.5% vs WL=11.8% (<i>NS</i>))	RSL=19.4% vs WL=15.3% (<i>NS</i>)
Re-excision	NR	RSL=11.2% vs WL=13.1% (<i>NS</i>)	NR
Postoperative complications	NR	<i>NS</i>	No major postoperative complications
Mastectomy numbers	NR	RSL=3.9% vs WL=2.9% (<i>NS</i>)	NR
Radiologist rating of difficulty	<i>NS</i>	<i>NS</i>	NR
Surgeon rating of difficulty	<i>NS</i>	RSL easier than WL ($p=0.008$)	NR
Patient rating	<i>NS</i>	Pain with RSL less than with WL ($p=0.038$) Anxiety (<i>NS</i>)	Pain (<i>NS</i>) Convenience: Significantly higher for RSL than WL ($p<0.001$)

BSC: breast-conserving surgery; NR: not reported; RCT: randomized controlled trial; RSL: radioactive seed localization; WL: wire localization.

Section Summary: Radioactive Seed Localization

Three RCTs and meta-analyses have generally not found statistically significant differences in outcomes with RSL and the generally accepted standard, WL. In all cases reported in RCTs, the suspicious lesions were successfully removed using either method. The rates of positive margins also did not differ significantly between RSL and WL. There are fewer data on other outcomes (eg, re-excision rates, complication rates), but the available studies do not suggest significant differences between RSL and WL. Additional adequately powered and well-conducted RCTs would further clarify any differences in outcomes between RSL and WL. Other RCTs included in a Cochrane review found similar outcomes with ROLL and WL; however, RCTs directly comparing RSL with ROLL would strengthen the evidence base.

SUMMARY OF EVIDENCE

Three randomized controlled trials have compared radioactive seed localization and wire localization, and overall they have found similar outcomes (eg, rate of successful excision, 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

In 2013 (amended in 2014), the American College of Radiology issued practice guidelines for imaging management of ductal carcinoma in situ and invasive breast carcinoma.(10) 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 provide guidance to the surgeon.

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 unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02522468	A Trial of RSL Versus WL for Malignant Breast Disease (BCS-RSL-001)	400	Jul 2020
NCT02800317	Primary Radioactive Iodine Seed Localisation in the Axilla in Axillary Node Positive Breast Cancer Combined With Sentinel Node Procedure (RISAS) Following Neoadjuvant Chemotherapy	200	Oct 2018
Unpublished			
NCT01901991	Localization of Nonpalpable Breast Lesions	410	Feb 2016 (completed)

NCT: national clinical trial.

References

- 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
- 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
- Ahmed M, Douek M. ROLL versus RSL: toss of a coin? *Breast Cancer Res Treat.* Jul 2013;140(2):213-217. PMID 23793603
- Chan BK, Wiseberg-Firtell JA, Jois RH, et al. Localization techniques for guided surgical excision of non-palpable breast lesions. *Cochrane Database Syst Rev.* 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
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8. 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
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*. Mar-Apr 2016;22(2):151-157. PMID 26696461
10. American College of Radiology (ACR). Practice guideline for the imaging management of DCIS and invasive breast carcinoma, 2013, amended 2014 (resolution 39). <http://www.acr.org/Quality-Safety/Standards-Guidelines/Practice-Guidelines-by-Modality/Breast-Imaging>. Accessed August 8, 2016.

Billing Coding/Physician Documentation Information

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

ICD-10 Codes

- C50.011-** Malignant neoplasm of breast, code range
C50.929
- D05.00-** Carcinoma in situ, breast, code range
D05.92
- D48.60-** Neoplasm of uncertain behavior of breast, code range
D48.62

Additional Policy Key Words

N/A

Policy Implementation/Update Information

- 11/1/16 New Policy, considered Medically Necessary.
11/1/17 No policy statement changes.
11/1/18 No policy statement changes.

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