

**Subject:** Radioactive Seed Localization of Nonpalpable Breast Lesions  
**Guideline #:** CG-SURG-58  
**Status:** Reviewed

**Publish Date:** 09/27/2023  
**Last Review Date:** 08/10/2023

## Description

This document addresses the use of radioactive seed localization (RSL). This is a technique used to provide localization of nonpalpable breast lesions before breast-conserving surgery. It can be used as an alternative to wire localization (WL) or radio-guided occult lesion localization.

## Clinical Indications

### Medically Necessary:

Radioactive seed localization of nonpalpable breast lesions is considered **medically necessary** as a method to localize a nonpalpable breast lesion in advance of surgical excision.

Radioactive seed localization is considered **medically necessary** to assist in targeted excision of positive axillary lymph nodes after neoadjuvant therapy.

### Not Medically Necessary:

The use of radioactive seed localization is considered **not medically necessary** when the criteria above have not been met, including but not limited to use as a method to localize palpable breast lesions.

## Coding

*The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. 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.*

### When services may be Medically Necessary when criteria are met:

#### CPT

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
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
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
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

#### ICD-10 Diagnosis

All diagnoses

### When services are Not Medically Necessary:

For the procedure codes listed above when criteria are not met; or when the code describes a procedure or situation designated in the Clinical Indications section as not medically necessary.

## Discussion/General Information

According to the American Cancer Society (ACS), there will be an estimated 297,790 cases of newly diagnosed breast cancer in 2023. Approximately 25% to 35% of identified breast cancers are nonpalpable at detection during mammography or by another method (Lovrics, 2011). Nonpalpable breast lesions may be difficult to locate during follow-up procedures such as surgery. To facilitate identification for later procedures, a variety of localization techniques have been developed, including wire localization, RSL, and radio-guided occult lesion localization. RSL placement is typically done in conjunction with mammography or ultrasonography for confirmation of the seed placement. Locating the  $^{125}\text{I}$  seed is done intraoperatively with a handheld gamma scan probe that can distinguish photons from the radioactive seed and the radiation from the radiotracer utilized for sentinel lymph node mapping. The computer-based control probe is able to provide approximate distance information for the surgeon to extract the  $^{125}\text{I}$  seed along with the surrounding tissue (Barentsz, 2013; Dauer, 2013). Adverse events include migration of the seed, need for additional localization technique, and inability to retrieve the  $^{125}\text{I}$  seed.

The current gold standard technique for localization is wire-guided localization which involves the use of a thin, hooked wire that is inserted into the nonpalpable lesion, and the external portion of the wire is secured against the skin surface. Typically, later on the same day of wire placement, the surgeon then utilizes the wire to locate and resect the breast lesion. Challenges with the WL

procedure include sequential scheduling of the procedures, dislocation of the wire before or during the surgical procedure, and the entry point of the wire is not always in the surgeon's line of excision. Therefore, the surgeon still has to estimate the location of the tip of the wire and the breast lesion (Barentsz, 2013; Dauer, 2013; Lovrics, 2011).

RSL utilizes a low-dose, radio-opaque titanium seed containing iodine-125-labelled ( $I^{125}$ ) which is placed into the center of the nonpalpable breast lesion with imaging guidance (for example, mammography or ultrasound).

#### *Nonpalpable breast lesions*

In 2018, Milligan published the results of a retrospective nonrandomized study comparing  $I^{125}$  RSL (n=100) vs. WL (n=100) for nonpalpable breast carcinoma in breast conserving surgery. Mean total specimen excision weight was significantly lower in the RSL group; 31.55 g vs. 37.42 g (p=0.018). The authors reported that 15 subjects had inadequate surgical resection margins in the WL vs. 13 in the RSL group (p=0.684). Additionally, 10 subjects in the WL group had invasive carcinoma present, resulting in at least one positive margin vs. only 3 RSL subjects (p=0.045). They concluded that RSL was non-inferior to WL for non-palpable carcinoma in patients undergoing breast-conserving surgery.

Da Silva (2018) also published the results of a retrospective nonrandomized study comparing  $I^{125}$  RSL (n=98) vs. WL (n=74) for nonpalpable breast lesions or lesions that radiologically extended beyond the palpated area undergoing breast conservation surgery. The authors reported that subjects who underwent WL were 3.9 times more likely to undergo re-excision compared to patients in RSL group (OR, 3.9). Initial and total specimen volumes did not significantly differ between the two groups (p=0.4). Subjects were significantly more likely to undergo a mastectomy in the WL group vs. the RSL group (24% vs 7%; p<0.01). They concluded that RSL serves as an alternative to WL, and RSL was associated with a decreased re-excision rate and a lower rate of mastectomy when compared to WL.

Langhans (2017) published the results of a prospective randomized controlled trial (RCT) involving 378 subjects with 390 breast lesions. Subjects were assigned to undergo WL (n=192) or RSL (n=186). The authors reported that there were no significant differences between groups with regard to resection margins (p=0.65), margin status (p=0.62), duration of surgery (p=0.12), weight of the surgical specimen (p=0.54) or pain perception (p=0.28). They concluded that, "RSL offers a major logistic advantage, as localization can be done several days before surgery without any increase in positive resection margins compared with WGL."

Bloomquist and colleagues (2016) reported the results of an RCT involving 125 subjects randomized to either RSL (n=75) or wires localization (n=55). The authors reported no significant differences between groups with regard to main specimen volume (p = 0.67), volume of the first surgery (p=0.67), or rate of positive margins (p=0.53).

In a 2019 retrospective cohort study by Angarita and colleagues, the authors compared positive margin rates between WL and RSL in nonpalpable breast lesions. They also looked for differences in specimen volume, and time of operation. There were 747 participants in the WL group. The invasive positive margin rate was 12.3%, mean overall specimen volume was 30.2 cm<sup>3</sup>, and mean operation time in the overall population was 68.7 minutes. With 577 participants in the RSL group, the invasive positive margin rate was 8.1%, mean overall specimen volume was 21.4 cm<sup>3</sup>, and mean overall surgery time was 39.5 minutes. While the retrospective nature of the study is a limitation, and there were no differences in positive margin rates, RSL was noted to have smaller surgical specimens and shorter operation time when compared to WL.

A randomized controlled trial performed at three participating centers enrolled 333 individuals who had planned for localization and breast conserving surgery for confirmed invasive or ductal carcinoma in situ (DCIS) (Lovrics, 2011). The WL group included 153 randomized participants and the RSL group had 152 participants, all who were treated between 2004 and 2010. There was no significant difference in the rates of positive margins between the groups (10.5% RSL vs. 11.8% WL; p=0.99). The mean excised tumor size was similar for both groups. The RSL group had a significantly shorter operative time of 19.4 minutes compared to the WL group's 22.2 minutes (p<0.001). The satisfaction survey for radiologists and the participants did not show any significant differences. However, the surgeons had a satisfaction rating that favored RSL (p=0.008). Seed migration was reported in one RSL case and the wire migrated in two cases. In one case, the wire fell out during surgery. The surgeons were able to remove 100% of the index lesions successfully.

Donker and colleagues (2013) reported the results of a study comparing radio-guided occult lesion localization (ROLL) with technetium-99 m colloid to RSL. This retrospective nonrandomized or blinded study involved 154 subjects being treated with neoadjuvant systemic treatment who underwent breast-conserving surgery with the ROLL (n=83) or RSL (n=71). The authors reported no significant differences between groups with regard to median weight of the resected specimen (53 vs. 48 g), the median smallest margin (3.5 vs. 3.0 mm), and the risk for additional surgery for incomplete resections (7% vs. 8%). They concluded that ROLL and RSL demonstrated comparable results when used to perform breast-conserving surgery after neoadjuvant systemic treatment. Furthermore, they noted that because RSL does not require additional radiological localization shortly before surgery, it simplifies surgery scheduling.

Another RCT by Dauer (2013), involved the use of RSL in 1127 subjects. They reported that the median length of time from RSL implant to surgical excision was 2 days. They also reported on that the median  $I^{125}$  activity at time of implant was 3.1 MBq (1.9 to 4.6). The median dose rate from individuals with a single seed was 9.5  $\mu$ Sv h<sup>-1</sup> and 0.5  $\mu$ Sv h<sup>-1</sup> at contact and 1 m, respectively. The maximum contact dose rate was 187  $\mu$ Sv h<sup>-1</sup> from a superficially-placed seed. They concluded that RSL performed greater than 1 day before surgery is a viable alternative to WL, allowing flexibility in scheduling, minimizing day of surgery procedures, and improving workflow in breast imaging and surgery.

In a 2018 retrospective cohort study by Aljohani and colleagues, the authors compared the rates of margin positivity and in-breast recurrence between RSL and WL in nonpalpable breast lesions for participants undergoing breast-conserving surgery. With a cohort of 1083 participants, WL was done in 771 subjects and RSL was done in 312 subjects. In the WL cohort, negative surgical margins were found in 655 with positive surgical margins found in 111. Local recurrence occurred in 11 participants, regional recurrence occurred in 14 participants and there was no recurrence in 745. Mastectomy was done in 18 participants and re-excision was done in 118 participants. In the RSL cohort, negative surgical margins occurred in 274 participants and positive margins were found in 38 participants. Local recurrence was found in 1 participant, regional recurrence was found in 3 participants, and there was no recurrence in 308. Mastectomy was done in 5 participants and re-excision was done in 30 participants. The authors found no significant differences in margin positivity or local recurrence based on the type of localization method.

In a 2020 study Agahozo and colleagues, the authors compared the efficacy of wire-guided localization (WGL) to RSL for subjects treated with breast-conserving surgery for DCIS. There were 2187 subjects treated with WGL and 1851 subjects treated with RSL. The authors report no significant differences in resection margin status (p=0.505) nor the number of re-excisions between both groups (p=0.429). However, when re-excision was done, the subjects in the RSL group were more often treated with breast-conserving surgery than in the WGL group (69.2% vs. 59.7% respectively).

In another retrospective study, Jumaa and colleagues (2020) compared WL to RSL for nonpalpable breast lesions. There were 292 WL procedures and 194 RSL procedures completed. Data was collected regarding time from diagnosis to surgery, time from

localization to surgery, resection margins, specimen size, seed loss, biopsy, and postoperative histology. For the WL surgeries, the mean time from diagnosis to surgery was  $42.6 \pm 18.8$  days and WL were inserted on the day of surgery. Positive margins were present in 34 (17.2%) of 198 malignant lesions. Close margins ( $\leq 1$  mm) were present in 31 (15.6%). Specimen size for malignant lesions was  $6.8 \pm 2.8$  cm and  $4.6 \pm 1.7$  cm for benign lesions. For the RSL surgeries, the mean time from diagnosis to surgery was  $39.0 \pm 15.0$  days and a mean time from RSL insertion to surgery of  $4.0 \pm 2.8$  days. Positive margins were present in 15 (10.3%) of 146 malignant lesions. Specimen size for malignant lesions was  $6.9 \pm 2.9$  cm and  $5.4 \pm 2.7$  cm for benign lesions. Close margins ( $\leq 1$  mm) were present in 1 (0.6%). Seeds fell out of the specimen in six of the RSL cases with no seed loss recorded. More lumpectomies were performed with RSL as evidenced by a mean increment in the number of surgeries per month from  $4.4 \pm 2.6$  for WL to  $6.9 \pm 3.5$  for RSL.

A randomized, controlled trial by Taylor and colleagues (2021) examined the re-excision and positive margin rates after localization with either RSL or WL in participants with non-palpable breast cancer. The authors also reported on resection volumes and weights. There were 327 participants in the RSL group and 332 participants in the WL group. The re-excision rate was 13.9% in the RSL group compared to 18.9% in the WL group. There were no significant differences in rates of positive margins between the two groups nor in volumes and weights of tissue specimens.

A 2021 retrospective chart review by Law and colleagues looked at 300 RSL cases and 300 WL cases and compared surgical margins, re-excision rate, re-operation, localization accuracy, major complications, and operative times between the two groups. Positive margin rates for invasive carcinoma were 7% for RSL and 6% for WL. Positive margin rates for in situ carcinoma were 6% for RSL and 8% for WL. Re-excision rate for RSL was 19% and 21% for WL. Reoperation rate was 11% for RSL and 17% for WL. There were no reported complications following RSL and 11 reported complications following WL. Operative times were not significantly different between the two groups.

A population-based registry study by Schermers and colleagues reported on 28,370 participants with non-palpable breast cancer who had a localization technique and was then assessed for the probability of reoperation. During the 5-year study period, the percentage of participants who had wire-guided localization decreased from 75.4% to 31.6% while the percentage of those having radioactive seed localization increased from 15.7% to 61.1%. The authors noted that there were no statistically significant differences between the localization techniques (wire-guided versus radioactive seed) and rates of reoperation.

The available evidence indicates that RSL, WL, and radio-guided localization of nonpalpable breast lesions are at least as likely to produce equivalent therapeutic results when used to localize a nonpalpable breast lesion in advance of surgical excision.

#### *Targeted excision of positive axillary lymph nodes*

The use of RSL has been proposed for use in assisting the targeting of positive axillary lymph nodes after neoadjuvant therapy prior to excision. Diego and others (2016) published a retrospective review of 30 subjects with biopsy-proven lymph nodes who had RSL placement prior to excision following neoadjuvant chemotherapy. The authors noted that all radioactive seeds were successfully retrieved and 29 of 30 nodes were successfully localized with RSL. Nineteen subjects had no residual axillary disease; 11 had persistent disease. All subjects who remained node positive had disease in the biopsied nodes. The authors concluded that RSL combined with sentinel lymph node biopsy is a promising approach for axillary staging after neoadjuvant chemotherapy in individuals whose disease becomes cN0, and that the status of the lymph node after neoadjuvant chemotherapy predicted nodal status, suggesting that localization of the lymph node may be more accurate than SLNB alone for staging the axilla in the cN0 patient after neoadjuvant chemotherapy.

Another study by Caudle and others (2016) described the use of RSL in 208 subjects with biopsy confirmed lymph node breast cancer metastases who were treated with neoadjuvant chemotherapy. All subjects had  $^{125}$  seeds placed in the biopsied nodes under ultrasound guidance 1-5 days prior to surgery. This study evaluated the role of targeted axillary dissection in patients with breast cancer after neoadjuvant chemotherapy vs. removal of all axillary lymph nodes. While no data is provided regarding the impact of RSL in this population, its use as a preferred method of localization over the use of wire localization should be noted.

In a 2023 retrospective review by Clark and colleagues, the authors evaluated the accuracy of RSL of axillary lymph node and compared the response to neoadjuvant chemotherapy in the breast and sampled axillary lymph nodes. There were 174 participants total; 93 participants had biopsy-documented metastatic carcinoma in an axillary lymph node, 35 participants had a negative biopsy of axillary lymph node before neoadjuvant chemotherapy, and 46 participants did not have a pre-therapy axillary lymph node biopsy. For those with positive lymph nodes, therapy-related changes were more frequent in the breast (82/85, 96% cases) than the sampled lymph nodes (67/85, 79%). Of the 93 participants with a biopsy-documented metastatic carcinoma, 38 showed no residual carcinoma in the lymph nodes. Of the 35 participants with a negative lymph node biopsy, retrieval of the biopsied lymph node was confirmed through presence of biopsy clip and/or biopsy site changes in 26/35 (74%) cases overall, and 7/7 cases (100%) in which RSL was used. The authors conclude use of RSL to assist in excision of positive axillary lymph nodes after neoadjuvant chemotherapy improves retrieval of previously biopsied lymph nodes.

## References

### Peer Reviewed Publications:

1. Agahozo MC, Berghuis SAM, van den Broek E, et al. Radioactive seed versus wire-guided localization for ductal carcinoma in situ of the breast: comparable resection margins. *Ann Surg Oncol*. 2020; 27(13):5296-5302.
2. Ahmed M, Douek M. Radioactive seed localisation (RSL) in the treatment of non-palpable breast cancers: systematic review and meta-analysis. *Breast*. 2013; 22(4):383-388.
3. Al-Hilli Z, Glazebrook KN, McLaughlin SA, et al. Utilization of multiple I-125 radioactive seeds in the same breast is safe and feasible: a multi-institutional experience. *Ann Surg Oncol*. 2015; 22(10):3350-3355.
4. Aljohani B, Jumaa K, Kornecki A, Brackstone M. Clinical utility of radioactive seed localization in nonpalpable breast cancer: A retrospective single institutional cohort study. *Int J Surg*. 2018; 60:149-152.
5. Angarita FA, Acuna SA, Down N, et al. Comparison of radioactive seed localized excision and wire localized excision of breast lesions: a community hospital's experience. *Clin Breast Cancer*. 2019; 19(2):e364-e369.
6. Barentsz MW, van den Bosch MA, Veldhuis WB, et al. Radioactive seed localization for non-palpable breast cancer. *Br J Surg*. 2013; 100(5):582-588.
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*. 2016; 22(2):151-157.
8. Caudle AS, Yang WT, Krishnamurthy S, et al. Improved axillary evaluation following neoadjuvant therapy for patients with node-positive breast cancer using selective evaluation of clipped nodes: implementation of targeted axillary dissection. *J Clin Oncol*. 2016; 34(10):1072-1078.
9. Clark BZ, Johnson RR, Berg WA, et al. Response in axillary lymph nodes to neoadjuvant chemotherapy for breast cancers: correlation with breast response, pathologic features, and accuracy of radioactive seed localization. *Breast cancer research and treatment*. 2023; 200(3):363-373

10. Da Silva M, Porembka J, Mokdad AA, et al. Bracketed radioactive seed localization vs bracketed wire-localization in breast surgery. *Breast J.* 2018; 24(2):161-166.
11. Dauer LT, Thornton C, Miodownik D, et al. Radioactive seed localization with 125I for nonpalpable lesions prior to breast lumpectomy and/or excisional biopsy: methodology, safety, and experience of initial year. *Health Phys.* 2013; 105(4):356-365.
12. Diego EJ, McAuliffe PF, Soran A, et al. Axillary staging after neoadjuvant chemotherapy for breast cancer: a pilot study combining sentinel lymph node biopsy with radioactive seed localization of pre-treatment positive axillary lymph nodes. *Ann Surg Oncol.* 2016; 23(5):1549-1553.
13. Diego EJ, Soran A, McGuire KP, et al. Localizing high-risk lesions for excisional breast biopsy: a comparison between radioactive seed localization and wire localization. *Ann Surg Oncol.* 2014; 21(10):3268-3272.
14. Donker M, Drukker CA, Valdés Olmos RA, et al. Guiding breast-conserving surgery in patients after neoadjuvant systemic therapy for breast cancer: a comparison of radioactive seed localization with the ROLL technique. *Ann Surg Oncol.* 2013; 20(8):2569-2575.
15. Gobardhan PD, de Wall LL, van der Laan L, et al. The role of radioactive iodine-125 seed localization in breast-conserving therapy following neoadjuvant chemotherapy. *Ann Oncol.* 2013; 24(3):668-673.
16. 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.* 2001; 8(9):711-715.
17. Horwood CR, Grignol V, Lahey S, et al. Radioactive seed vs wire localization for nonpalpable breast lesions: a single institution review. *Breast J.* 2019; 25(2):282-285.
18. 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):153-157.
19. Jumaa K, Johani BA, Brackstone M, Kornecki A. A single-institute experience with radioactive seed localization of breast lesions-a retrospective study. *Can Assoc Radiol J.* 2020; 71(1):58-62.
20. 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.* 2017; 266(1):29-35.
21. Law W, Cao X, Wright FC, et al. Adequacy of invasive and in situ breast carcinoma margins in radioactive seed and wire-guided localization lumpectomies. *Breast J.* 2021; 27(2):134-140.
22. 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.* 2011; 18(12):3407-3414.
23. McGhan LJ, McKeever SC, Pockaj BA, et al. Radioactive seed localization for nonpalpable breast lesions: review of 1,000 consecutive procedures at a single institution. *Ann Surg Oncol.* 2011; 18(11):3096-3101.
24. Milligan R, Pieri A, Critchley A, et al. Radioactive seed localization compared with wire-guided localization of non-palpable breast carcinoma in breast conservation surgery- the first experience in the United Kingdom. *Br J Radiol.* 2018; 91(1081):20170268.
25. Moreira IC, Ventura SR, Ramos I, et al. Preoperative localisation techniques in breast conservative surgery: A systematic review and meta-analysis. *Surg Oncol.* 2020; 35:351-373.
26. Murphy JO, Moo TA, King TA, et al. Radioactive seed localization compared to wire localization in breast-conserving surgery: initial 6-month experience. *Ann Surg Oncol.* 2013; 20(13):4121-4127.
27. 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.* 2015; 111(2):185-191.
28. Schermers B, van Riet YE, Schipper RJ, et al. Nationwide registry study on trends in localization techniques and reoperation rates in non-palpable ductal carcinoma in situ and invasive breast cancer. *Br J Surg.* 2021; 109(1):53-60.
29. Simons JM, van Nijnatten TJA, van der Pol CC, et al. Diagnostic accuracy of radioactive iodine seed placement in the axilla with sentinel lymph node biopsy after neoadjuvant chemotherapy in node-positive breast cancer. *JAMA surgery.* 2022; 157(11):991-999.
30. Stelle L, Schoenheit T, et al. Radioactive seed localization versus wire localization for nonpalpable breast lesions: a two-year initial experience at a large community hospital. *Ann Surg Oncol.* 2018; 25(1):131-136.
31. Sung JS, King V, Thornton CM, et al. Safety and efficacy of radioactive seed localization with I-125 prior to lumpectomy and/or excisional biopsy. *Eur J Radiol.* 2013; 82(9):1453-1457.
32. Taylor DB, Bourke AG, Westcott EJ, et al. Surgical outcomes after radioactive 125I seed versus hookwire localization of non-palpable breast cancer: a multicentre randomized clinical trial. *Br J Surg.* 2021; 108(1):40-48.
33. Theunissen CI, Rust EA, Edens MA, et al. Radioactive seed localization is the preferred technique in nonpalpable breast cancer compared with wire-guided localization and radioguided occult lesion localization. *Nucl Med Commun.* 2017; 38(5):396-401.
34. Tran VT, David J, Patocska E, et al. comparative evaluation of iodine-125 radioactive seed localization and wire localization for resection of breast lesions. *Can Assoc Radiol J.* 2017; 68(4):447-455.
35. van Riet YE, Jansen FH, van Beek M, et al. Localization of non-palpable breast cancer using a radiolabelled titanium seed. *Br J Surg.* 2010; 97(8):1240-1245.
36. Wang GL, Tsikouras P, Zuo HQ, et al. Radioactive seed localization and wire guided localization in breast cancer: a systematic review and meta-analysis. *J BUON.* 2019; 24(1):48-60.

#### Government Agency, Medical Society, and Other Authoritative Publications:

1. American Cancer Society. How common is breast cancer? January 12, 2023. Available at: <https://www.cancer.org/cancer/breast-cancer/about/how-common-is-breast-cancer.html>. Accessed on July 11, 2023.
2. NCCN Clinical Practice Guidelines in Oncology®. 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on July 11, 2023.
  - Breast Cancer Screening and Diagnosis (V1.2023). Revised June 19, 2023.
3. United States Food and Drug Administration. Approval letter for BrachySciences Radioactive Seed Localization Needle with AnchorSeed®. K111979. October 18, 2011. Available at: [http://www.accessdata.fda.gov/cdrh\\_docs/pdf11/K111979.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf11/K111979.pdf). Accessed on July 11, 2023.
4. United States Food and Drug Administration. Approval letter for Best® Localization Needle with I-125 Seed. K122704. January 9, 2013. Available at: [http://www.accessdata.fda.gov/cdrh\\_docs/pdf12/k122704.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf12/k122704.pdf). Accessed on July 11, 2023.

## Index

AnchorSeed®

Best® Localization Needle

**The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.**

## History

Status	Date	Action
Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion/General Information and References sections.
Reviewed	08/11/2022	MPTAC review. Updated Discussion/General Information and References sections.
Reviewed	08/12/2021	MPTAC review. Updated Discussion/General Information and References sections.
Reviewed	08/13/2020	MPTAC review. Updated Discussion/General Information and References sections. Reformatted Coding section.
Reviewed	08/22/2019	MPTAC review. Updated Discussion/General Information and References sections.
Revised	09/13/2018	MPTAC review. Updated Rationale and Reference sections.
Revised	11/02/2017	MPTAC review.
Revised	11/01/2017	Hematology/Oncology Subcommittee review. The document header wording updated from "Current Effective Date" to "Publish Date." Updated Rationale and Reference sections.
Revised	11/03/2016	MPTAC review.
Revised	11/02/2016	Hematology/Oncology Subcommittee review. Added MN statement for when RSL is used to assist in targeted axillary excision of positive lymph nodes after neoadjuvant therapy. Updated Rationale and Reference sections.
New	08/04/2016	MPTAC review. Initial document development.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

© CPT Only - American Medical Association