

Cigna Medical Coverage Policy



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Subject Cryoablation of Breast Lesions

Table of Contents

Coverage Policy	1
General Background	1
Coding/Billing Information	5
References	5

Hyperlink to Related Coverage Policies

[Brachytherapy for Breast Cancer](#)
[Emerging Breast Localization/Biopsy Procedures](#)
[Mammography](#)
[Microwave Thermotherapy for Breast Cancer](#)
[Radiofrequency Ablation for Breast Cancer](#)

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Coverage Policy

Cigna does not cover cryoablation of a benign or malignant breast lesion because it is considered experimental, investigational or unproven.

General Background

Cryoablation, also referred to as cryosurgery or cryosurgical ablation, has been proposed as a minimally invasive alternative for the treatment of fibroadenomas and cancers of the breast. Fibroadenomas are benign, solid tumors comprised of glandular breast tissue and stromal (connective) tissue, and are the most common breast tumor in women younger than age thirty. Although fibroadenomas may occur at any age, they are rarely seen as new masses in women after the age of 40–45. Fibroadenomas may stop growing, spontaneously regress, or may increase in size. Simple fibroadenomas do not increase breast cancer risk. Those that contain macrocysts, sclerosing adenosis, calcifications, or apocrine changes are referred to as complex fibroadenomas, and are associated with a slightly increased risk of breast cancer. Most physicians and patients choose conservative management for pathology-confirmed fibroadenomas, with periodic clinical examination and ultrasound or mammography follow-up. Others opt for surgical removal, especially if the mass is growing and the shape of the breast is altered.

Excluding cancers of the skin, breast cancer is the most frequently diagnosed cancer in women. Diagnostic evaluation is usually triggered by symptoms, by the detection of a palpable breast mass by the physician or patient, or by detection of a suspicious mass on screening mammography. Breast cancer is confirmed by histopathological findings obtained during a breast biopsy. Treatment of breast cancer is based on tumor size,

stage, and other characteristics, as well as patient preference. Treatment may include lumpectomy (i.e., surgical removal of the tumor with confirmation of clear margins) or mastectomy (i.e., surgical removal of the breast and selected axillary lymph nodes), and may also include radiation therapy, chemotherapy, hormone therapy, or targeted biologic therapy. Cryoablation has been proposed as a minimally invasive alternative to lumpectomy, and as an alternative to needle wire localization in patients undergoing lumpectomy for breast cancer.

Cryoablation achieves tissue necrosis by alternately freezing and thawing targeted tissue. A cryoprobe is inserted percutaneously into the center of the lesion using ultrasound guidance. A cooling medium is circulated through the probe, and the cells in proximity to the cryoprobe are brought to very low temperatures, resulting in the formation of intracellular ice that in turn shears the cell membranes. Cells located further from the cryoprobe freeze at a slower rate, with ice formation primarily in the extracellular space, creating a hypertonic environment. Water is driven out of the cells, and dehydration causes additional membrane damage. During the thaw, water returns from the extracellular space into the shrunken cells, resulting in intracellular edema and lysis. This destructive process is repeated in a second freeze cycle. The ablative process is completed after several days, as capillary endothelial damage caused by the ultracold temperatures results in leakage, thrombolysis, and target tissue anoxia (Kaufman, 2004b; NCI, 2011; Whitworth, 2005).

U.S. Food and Drug Administration (FDA)

Numerous cryosurgical devices have received FDA approval for various indications through the 510k process. Devices that include treatment of breast fibroadenomas as an approved indication include the Sanarus Visica™ Treatment System (Sanarus Medical, Inc., Pleasanton, CA) and the SeedNet/SeedNetGold System, CryoThera System, Cryo-Hit System, referred to collectively as the SeedNet Family (Galil Medical Ltd, Israel).

Literature Review

Cryoablation of Breast Fibroadenomas

A prospective case series was conducted by Hahn et al. (2012) to evaluate cryoablation of fibroadenomas under ultrasound guidance in the office setting (n=22 patients, 23 fibroadenomas). An office-based cryoablation system was used to treat histologically-confirmed benign fibroadenomas with a maximum dimension of 3 cm. During the procedure, continuous ultrasound monitoring was performed to verify engulfment of the fibroadenoma. The ice ball engulfed the treated fibroadenomas in 91.3% of cases. Minor adverse events included swelling, moderate pain, and skin burn. A sharp reduction in volume was noted at six months and continued more moderately up to one year. At one year, 21 lumps that were assessed as hard prior to treatment were assessed as soft or non-palpable. In two patients, lumps were described as hard at one year, although they had been assessed as soft at six months. Seven of the patients reported pain prior to the procedure, and five of these patients felt transient pain during follow-up. The cosmetic results were rated as excellent or good in 96% of cases.

Nurko et al. (2005) evaluated six- and twelve-month data in the FibroAdenoma Cryoablation Treatment (FACT) registry. A total of 249 of 444 treated fibroadenomas were evaluated at least six months post-procedure, and 92 were evaluated at least 12 months post-procedure. Prior to cryoablation, 75% of fibroadenomas were palpable by the patient, and 100% were visualized on ultrasound. The treated site remained palpable in 46% of cases at six months, and in 32% of cases at 12 months. The remaining lesion was visible on ultrasound in 36% of cases at six months, and in 29% of cases at 12 months. Patient satisfaction was rated at 91% at six months and 88% at 12 months. The authors noted that patients should be made aware of the likely prolonged persistence of a palpable mass in the treated area. This is particularly important when the mass is not palpable prior to the procedure, since cryoablation-induced changes may result in the mass becoming palpable following the procedure.

Littrup et al. (2005) conducted a case series to assess freezing protocols, imaging, and clinical outcomes of percutaneous ultrasound-guided cryotherapy in 29 patients with 42 biopsy-confirmed breast fibroadenomas. Real-time ultrasound guidance was used to document fibroadenoma size and to guide thermocouple and probe placement, and monitor iceball formation. The average pretreatment fibroadenoma volume was 4.2 cubic centimeters (cm³) ± 4.7 prior to treatment and was reduced to 0.7 cm³ ± 0.8 at 12 months (p<.001). A total of 37 fibroadenomas had at least one year of follow-up. Ultrasound provided excellent ice visualization beyond the tumor margins, and cytotoxic temperatures approximately 5 mm beyond the visible leading edge were confirmed by thermocouples. At six months, three young patients had a residual mass visible on ultrasound that was palpable on physical examination as a soft but larger area. The authors postulated that an exacerbated healing reaction may have been the cause. One patient continued ultrasound monitoring of this residual mass. One

patient elected resection of the entire area and one underwent large-core needle biopsy. In both cases biopsy showed a shrunken hyaline matrix with preserved collagenous architecture.

Kaufman et al. published several case series evaluating cryoablation in the treatment of benign breast disease (2002, 2004a, 2004b, 2005). It is unclear how many of the same patients are included in each analysis. The 2002 report included 50 patients with 57 biopsy-proven fibroadenomas treated with two freeze cycles. Six-month data available for 20 patients demonstrated a median tumor volume decrease of 65%. Four patients were more than 12 months post-treatment. Three of these patients showed a 92% reduction in median tumor volume. The authors stated that patients were highly satisfied with the procedure.

The 2004a Kaufman case series reported 12 month follow-up of cryoablation of 70 fibroadenomas in 47 patients. Nine of 70 fibroadenomas were excluded from the efficacy analysis due to protocol deviations, including shortened freezes, proximity to skin, or chest wall, and targeting inaccuracies, and four patients were lost to follow-up. At one year, 75% of the fibroadenomas included in the analysis were non-palpable and demonstrated an 89% median tumor reduction as measured by ultrasound. Complications were minor and included post-procedure pain, hematoma, and transient mild thermal injury. Lesions were excised in two patients after 12 months, with no fibroadenoma found on pathology. The 2004b case series reported results of cryoablation treatment of 78 lesions in 63 patients. Lesions included fibroadenomas, other benign breast nodules, and nodular fibrocystic changes. Sixty four of 78 lesions were followed for 12 months. Nine lesions were excluded from analysis due to protocol deviations, including inadequate treatment times, probe failure, and probe placement inaccuracy, and five patients were lost to follow-up. The 64 lesions included in the 12-month analysis included 53 fibroadenomas. Tumor volume resorption was 88.3% overall (87.3% for fibroadenomas), and 73% of masses became non-palpable to clinician and patient (75% for fibroadenomas).

The 2005 Kaufman case series reported outcomes of cryoablation treatment of fibroadenomas at a mean follow-up of 2.6 years (range 1.3–3.8 years). Of 70 fibroadenomas (57 patients), efficacy data was reported for 29 patients (32 fibroadenomas). Of 29 patients, five could still feel a residual mass, with three reporting progressive shrinkage of the treated area. Small fibroadenomas (≤ 2.0 cm) became non-palpable sooner than large fibroadenomas. Serial ultrasound confirmed resorption of the cryoablation debris. The median volume reduction of the residual debris was 89% at one year and 99% at a mean of 2.6 years. Gradual resorption was related to the original tumor size. Fifteen mammograms were available at follow-up. None had artifact from cryoablation that would adversely affect interpretation. Two had calcifications classified as benign and one had an asymmetric density attributed to probable nonspecific fibroglandular tissue.

Cryoablation for Breast Cancer

Zhou and Wu (2010) conducted a systematic review of the literature to evaluate minimally invasive thermal ablation techniques for the treatment of breast cancer. A total of 38 studies (844 patients) met the inclusion criteria. The included studies evaluated radiofrequency ablation, laser ablation, microwave ablation, and cryoablation. Most studies of cryoablation have been conducted in research settings for the evaluation of technical safety and feasibility, and have not been used alone in clinical practice. The authors noted that a number of problems with thermal ablation remain to be resolved, including a lack of ability to precisely determine tumor size, determination of 100% tumor killing, ability to follow local recurrence, and cosmetic outcome. The authors concluded that large randomized controlled studies are required to assess the long-term advantage of minimally invasive thermal ablation techniques.

van Esser et al (2007) conducted a review of the literature to evaluate minimally invasive ablative therapies for invasive breast cancer. The four studies of cryoablation consisted of pilot and feasibility studies, including the studies by Pusztaszeri et al. and Sabel, discussed below. The authors stated that at this stage, the different ablative techniques have been shown to be feasible for breast cancer treatment, but there has been no long-term follow-up. These modalities should be further assessed in the context of large clinical trials.

Pusztaszeri et al. (2007) evaluated histopathological aspects in 11 patients with small breast cancers (< 2.0 cm) who had undergone cryotherapy followed by lumpectomy. According to the authors, tumor response was variable and unpredictable. Only two patients (20%) had complete response without remnants of viable tumor cells, six (60%) had partial response with some degree of tumor downstaging, and two (20%) had no apparent tumor response. One patient could not be evaluated due to inaccessibility of the tumor to adequate needle positioning. Tumor destruction was not associated with size or other histological measures. Complications included skin ulceration and/or necrosis in five patients. The authors stated that cryotherapy of breast cancer is

an attractive minimally invasive technique that might be used as an adjuvant or neoadjuvant treatment, or to guide lumpectomy. As with all ablative techniques, however, randomized trials are needed to determine its long-term effectiveness.

Tafra et al. (2006) conducted a randomized controlled trial to compare the surgical results of cryo-assisted localization (CAL) and needle-wire localization (NWL) in patients undergoing lumpectomy for breast cancer. Patients were randomized on a two to one basis to intraoperative CAL or NWL. For patients assigned to the CAL group, a cryoprobe was inserted under ultrasound guidance, an ice ball created an 8–10 mm margin around the lesion, and the palpable ice ball was dissected. For patients in the NWL group, NWL was performed according to each institution's protocol, and standard resection was performed. Positive margin status did not differ between the two groups. The volume of tissue removed was significantly less in the CAL group (49 ml vs. 66 ml, $p=.002$). Re-excision rates for positive margins were similar in both groups. CAL was superior in ease of lumpectomy, quality of specimen, acute surgical cosmesis, invasive positive margin rate (11% vs. 20%, $p=.035$). CAL, however, had a higher observed ductal carcinoma in situ-positive margin rate that approached statistical significance (11% vs. 18%, $p=.052$).

Sabel et al. (2004) conducted a multi-institutional pilot safety study of cryoablation in the treatment of primary breast carcinomas. Twenty-nine patients with ultrasound-visible primary invasive breast cancer ≤ 2.0 cm were enrolled. In two patients, the cryoprobe could not be placed accurately within the tumor. Twenty-seven (93%) patients successfully underwent ultrasound-guided cryoablation. Standard surgical resection with histological documentation of specimen findings was performed in an average of 14 days post-cryoablation. Based on histopathological specimen review, 100% of cancers ≤ 1.0 cm were destroyed. One hundred percent of tumors between 1.0 and 1.5 cm were destroyed only in patients with invasive ductal carcinoma without a significant ductal carcinoma in situ (DCIS) component. For unselected tumors > 1.5 cm, cryoablation was not reliable. Patients with non-calcified DCIS were the cause of most cryoablation failures. The authors stated that assessing margin status and the presence of non-calcified DCIS in the healthy-appearing tissue surrounding the tumor remains a dilemma for all ablative technologies. Further research is needed to evaluate the most appropriate clinical use of cryoablation in the treatment of early-stage breast cancer.

Professional Societies/Organizations

American Cancer Society (ACS): Cryoablation is not included as a treatment option in either of the following ACS Cancer Reference Information websites:

- Detailed Guide: Breast Cancer
- Non-Cancerous Breast Conditions};

National Comprehensive Cancer Network (NCCN): Cryoablation is not included as a treatment option in current (v1.2013) NCCN breast cancer clinical practice guidelines (NCCN website).

National Cancer Institute (NCI): Cryotherapy is not mentioned as a treatment option in the Breast Cancer Treatment PDQ[®], updated in 2013.

Summary

There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy, and long-term outcomes of cryoablation for the treatment of breast lesions. Studies of cryoablation for the treatment of fibroadenomas consist primarily of nonrandomized case series with a large percentage of patients lost to follow-up. Evidence from well-designed clinical trials is needed to determine how this approach compares to the alternatives of either surgical excision or watchful waiting with periodic clinical examination and mammography or ultrasound follow-up. Studies of cryoablation for the treatment of breast cancer consist primarily of small pilot studies and feasibility studies. There is insufficient evidence to demonstrate that cryoablation of breast cancer lesions, performed in lieu of or in conjunction with lumpectomy, is equivalent to the current accepted treatment of lumpectomy (i.e., surgical removal of the tumor with confirmation of clear margins) or mastectomy (i.e., surgical removal of the breast and selected axillary lymph nodes) in terms of survival, cancer recurrence or tissue response to adjuvant therapy.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

Experimental/Investigational/Unproven/Not Covered when used to report cryoablation of benign or malignant breast lesions:

CPT* Codes	Description
19105	Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each fibroadenoma
19499	Unlisted procedure, breast

***Current Procedural Terminology (CPT®) © 2013 American Medical Association: Chicago, IL.**

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