



Cigna Medical Coverage Policy

Subject Radiofrequency Ablation for Breast Cancer

Effective Date 7/15/2014
Next Review Date 7/15/2015
Coverage Policy Number 0449

Table of Contents

Coverage Policy	1
General Background	1
Coding/Billing Information	3
References	3

Hyperlink to Related Coverage Policies

- [Cryoablation of Breast Lesions](#)
- [Emerging Breast Localization/Biopsy Procedures](#)
- [Microwave Thermotherapy for Breast Cancer](#)
- [Prophylactic Mastectomy](#)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna companies. Coverage Policies are intended to provide guidance in interpreting certain **standard** Cigna benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supersedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of Cigna. Copyright ©2014 Cigna

Coverage Policy

Cigna does not cover radiofrequency ablation for the treatment of breast cancer because it is considered experimental, investigational or unproven.

General Background

Breast cancer is the most common form of cancer among women. In situ breast cancer is confined within the ducts (i.e., ductal carcinoma in situ) or lobules (i.e., lobular carcinoma in situ). Invasive or infiltrating carcinomas start in the ducts or lobules and invade the surrounding fatty tissue.

Treatment of breast cancer depends on the type and stage of cancer, patient's age and comorbidities, and the risks and benefits associated with the various treatment options. Surgical intervention is the primary treatment option for most breast cancers and includes breast-sparing surgery (e.g., lumpectomy, segmental mastectomy, partial mastectomy) and total mastectomy. Surgical treatment may be combined with other therapies, such as chemotherapy, radiation therapy, immunotherapy and/or monoclonal antibody therapy.

The goal of breast-conserving treatment is to remove the malignant tumor and surrounding margin of tissue in the least invasive manner. Radiofrequency ablation (RFA) has been proposed as a less invasive alternative to surgical excision for breast cancer. RFA is performed by positioning a probe in the tumor using ultrasound guidance or computerized tomography (CT). Prongs, or electrodes, are extruded from the end of the probe and a current is emitted from the tips. The heating destroys the surrounding tissue by thermal coagulation and protein denaturation. Ablation times may vary based on breast size, tumor location, and composition and vascularity of the tissue. With variation in the prong array, a section of three to five centimeters (cm) can be

treated. In most studies, general anesthesia has been administered, but in some clinical trials RFA has been successfully performed in an outpatient setting using local anesthesia (Agnese and Burak, 2005; Huston and Simmons, 2005; Fornage, et al., 2004; Burak, 2003; Singletary, et al., 2002).

RFA is generally well tolerated and may provide a better post-procedure cosmetic result compared to more invasive procedures. It has also been associated with minimal reported complications (e.g., minor pain, bruising, low-grade fever and skin burns). The major disadvantage of RFA is the inability to determine if the surrounding margin of tissue is free of viable cancer cells. RFA is not an established treatment modality for breast cancer.

U.S. Food and Drug Administration (FDA)

Ablation systems are approved by the FDA under the 510(k) process as a Class II electrosurgical cutting and coagulation accessory device. An example of this device is the Cool-tip™ RF Ablation System (Valleylab, Boulder, CO). The Cool-tip device is approved for use in “percutaneous, laparoscopic, intraoperative coagulation and ablation of tissue, such as partial or complete ablation of non-resectable liver lesions and osteoma tumors” (FDA, 2006).

Literature Review

There is insufficient evidence in the published peer-reviewed scientific literature to support the effectiveness of RFA for the treatment of breast cancer. Available studies are primarily in the form of case series or retrospective reviews with small, heterogeneous patient populations, short-term follow-up, various tumor sizes, variations in selection criteria and RFA techniques, and do not compare RFA to established minimally invasive procedures. In many studies, viable tumor cells were present following ablation (Klimberg, et al., 2014; Shah, et al., 2013; Noguchi, et al., 2012; Wilson, et al., 2012; Palussiere, et al., 2012; Mackey, et al., 2012; Santoro, et al., 2012; Ohtani, et al., 2011; Kinoshita, et al., 2011; Tsuda, et al., 2011; Yamamoto, et al., 2011; Garbay, et al., 2008; Medina-Franco, et al., 2008; Earashi, et al., 2007; Khatri, et al., 2007; Oura, et al., 2007).

Earlier studies reporting on RFA for the treatment of breast cancers included various tumor sizes: 2.0 cm or less (n=21) (Fornage, et al., 2004), 0.8-1.6 cm (n=10) (Burak, et al., 2003), less than 3.0 cm (n=23) (Hayashi, et al., 2003) and 0.7-3.0 cm (n=26) (Izzo, et al., 2001). In all studies viable cancer cells were found in patients following RFA. One study reported that three tumors had incomplete ablation of the index tumor (Hayashi, et al., 2003). RFA long-term outcomes are unknown and patient selection criteria have not been established.

Zhao and Wu (2010) conducted a systematic review of the literature to evaluate minimally-invasive thermal ablation, including radiofrequency ablation, for the treatment of breast cancer. Twelve studies utilizing radiofrequency ablation met inclusion criteria. Nine studies (n=5-34) were feasibility studies and reported complete coagulation necrosis in 76%–100% of patients who then underwent surgical excision. Three pilot studies (n=3-52) with short-term follow-ups (n=15–29.4 months) reported no breast cancer recurrence following RFA. Some patients were also treated with hormone or radiation therapy following RFA. The authors noted that long-term follow-ups of tumor regression and survival rates are unknown.

In a systematic review, van der Ploeg et al. (2007) identified over 150 articles on RFA for breast cancer. Only six phase II studies with an equal level of evidence met inclusion criteria for analysis and comparison. The studies were comprised of small patient populations (n=5–26) and involved tumors less than or equal to 3.0 cm, with the exception of one study that included five patients with 4–7 cm tumors. Surgical excision was performed immediately after or between weeks one and three following RFA. H&E was used to assess tumor margins, and NADH-diaphorase staining was used to assess cell viability. Complete tumor ablation was reported in 80–100% of cases. The authors stated that the studies were difficult to compare because of variations in selection criteria, RFA technique, time interval between RFA and surgical excision of the tumor, heterogeneity of breast size, tumor location, and composition and vascularity of the breasts. They also explained that more research is “clearly needed” to determine target temperature and duration of RFA, as well as shape, size and design of electrodes. Due to technical limitations, only small breast lesions are candidates for RFA. Additional research is needed to establish effects on surrounding tissue, recurrence rates, optimal technique and long-term effects.

Professional Societies/Organizations

The National Cancer Institute (2013), National Comprehensive Cancer Network® (2014), and American Cancer Society (2014) do not discuss radiofrequency ablation (RFA) as a treatment option for breast cancer.

Use Outside of the US

The European Society of Medical Oncology practice guideline for primary breast cancer does not mention radiofrequency ablation as a treatment for breast cancer (Senkus, et al., 2013).

Summary

There is insufficient evidence in the published, peer-reviewed scientific literature to support radiofrequency ablation (RFA) for the treatment of breast cancer. Limitations of the studies include small, heterogeneous patient populations, short-term follow-ups, and lack of comparison of RFA to established breast-conserving therapies. There are limited and variable outcome data on loco-regional and distant recurrence rates, as well as disease-free survival rates. Well-designed, prospective, randomized clinical trials are needed to determine the long-term outcomes and the effectiveness of RFA for the treatment of breast cancer.

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 radiofrequency ablation for breast cancer:

CPT* Codes	Description
19499	Unlisted procedure, breast

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

References

1. Agnese DM, Burak WE Jr. Ablative approaches to the minimally invasive treatment of breast cancer. *Cancer J.* 2005 Jan-Feb;11(1):77-82.
2. American Cancer Society (ACS). Breast cancer. Accessed June 2, 2014. Available at URL address: <http://www.cancer.org/Cancer/index>
3. American Society of Breast Surgeons. Position statement on ablative and percutaneous treatment of breast cancer. April 24, 2002. Accessed June 2, 2014. Available at URL address: <http://www.breastsurgeons.org/statements/index.php>
4. Burak WE Jr, Agnese DM, Povoski SP, Yanssens TL, Bloom KJ, Wakely PE, Spigos DG. Radiofrequency ablation of invasive breast carcinoma followed by delayed surgical excision. *Cancer.* 2003 Oct 1;98(7):1369-76.
5. Earashi M, Noguchi M, Motoyoshi A, Fujii H. Radiofrequency ablation therapy for small breast cancer followed by immediate surgical resection or delayed mammotome excision. *Breast Cancer.* 2007;14(1):39-47.
6. European Society of Medical Oncology, ESMO clinical practice guidelines. Primary breast cancer. 2013. Accessed June 2, 2014. Available at URL address: <http://www.esmo.org/Guidelines-Practice/Clinical-Practice-Guidelines>
7. European Society of Medical Oncology, ESMO clinical recommendations. Locally recurrent or metastatic breast cancer. 2012. Accessed May 28, 2013. Available at URL address: <http://www.esmo.org/research/esmo-clinical-practice-guidelines.html#c3338>

8. Fornage BD, Sneige N, Ross MI, Mirza AN, Kuerer HM, Edeiken BS, et al. Small (< or = 2-cm) breast cancer treated with US-guided radiofrequency ablation: feasibility study. *Radiology*. 2004 Apr;231(1):215-24.
9. Garbay JR, Mathieu MC, Lamuraglia M, Lassau N, Balleyguier C, Rouzier R. Radiofrequency thermal ablation of breast cancer local recurrence: a phase II clinical trial. *Ann Surg Oncol*. 2008 Nov;15(11):3222-6.
10. Hayashi AH, Silver SF, van der Westhuizen NG, Donald JC, Parker C, Fraser S, et al. Treatment of invasive breast carcinoma with ultrasound-guided radiofrequency ablation. *Am J Surg*. 2003 May;185(5):429-35.
11. Huston TL, Simmons RM. Ablative therapies for the treatment of malignant diseases of the breast. *Am J Surg*. 2005 Jun;189(6):694-701.
12. Izzo F, Thomas R, Delrio P, Rinaldo M, Vallone P, DeChiara A, et al. Radiofrequency ablation in patients with primary breast carcinoma: a pilot study in 26 patients. *Cancer*. 2001 Oct 15;92(8):2036-44.
13. Khatri VP, McGahan JP, Ramsamooj R, Griffey S, Brock J, Cronan M, Wilkendorf S. A Phase II Trial of Image-Guided Radiofrequency Ablation of Small Invasive Breast Carcinomas: Use of Saline-Cooled Tip Electrode. *Ann Surg Oncol*. 2007 May;14(5):1644-52.
14. Kinoshita T, Iwamoto E, Tsuda H, Seki K. Radiofrequency ablation as local therapy for early breast carcinomas. *Breast Cancer*. 2011 Jan;18(1):10-7.
15. Klimberg VS, Ochoa D, Henry-Tillman R, Hardee M, Boneti C, Adkins LL, et al. Long-term results of phase II ablation after breast lumpectomy added to extend intraoperative margins (ABLATE I) trial. *J Am Coll Surg*. 2014 Apr;218(4):741-9.
16. Klimberg VS, Kepple J, Shafirstein G, Adkins L, Henry-Tillman R, Youssef E, et al. eRFA: excision followed by RFA-a new technique to improve local control in breast cancer. *Ann Surg Oncol*. 2006 Nov;13(11):1422-33.
17. Klimberg VS, Boneti C, Adkins LL, Smith M, Siegel E, Zharov V, et al. Feasibility of percutaneous excision followed by ablation for local control in breast cancer. 2011 Oct;18(11):3079-87.
18. Mackey A, Feldman S, Vaz A, Durrant L, Seaton C, Klimberg VS. Radiofrequency ablation after breast lumpectomy added to extend intraoperative margins in the treatment of breast cancer (ABLATE): a single-institution experience. *Ann Surg Oncol*. 2012 Aug;19(8):2618-9.
19. Medina-Franco H, Soto-Germes S, Ulloa-Gómez JL, Romero-Trejo C, Uribe N, Ramirez-Alvarado CA, Robles-Vidal C. Radiofrequency ablation of invasive breast carcinomas: a phase II trial. *Ann Surg Oncol*. 2008 Jun;15(6):1689-95.
20. National Cancer Institute. Breast cancer treatment (PDQ®). Health professional version. Last modified April 4, 2013. Accessed May 28, 2013. Available at URL address:
<http://www.cancer.gov/cancertopics/pdq/treatment/breast/healthprofessional/allpages/print>
21. National Comprehensive Cancer Network® (NCCN). NCCN GUIDELINES™ Clinical Guidelines in Oncology™. Breast cancer. V3.2014. © National Comprehensive Cancer Network, Inc. 2014, All Rights Reserved. Accessed June 2, 2014. Available at URL address:
http://www.nccn.org/professionals/physician_gls/f_guidelines.asp
22. National Institute for Clinical Excellence. CG80 Early and locally advanced breast cancer: full guideline. Feb 25, 2009. Accessed May 28, 2013. Available at URL address:
<http://guidance.nice.org.uk/CG80/Guidance/pdf/English>

23. National Institutes of Health. Radiology and imaging sciences. Radiofrequency ablation. June 9, 2010. Accessed May 28, 2013. Available at URL address: <http://clinicalcenter.nih.gov/drdrfa/>
24. Noguchi M, Earashi M, Fujii H, Yokoyama K, Harada K, Tsuneyama K. Radiofrequency ablation of small breast cancer followed by surgical resection. *J Surg Oncol.* 2006 Feb;193(2):120-8.
25. Noguchi M, Motoyoshi A, Earashi M, Fujii H. Long-term outcome of breast cancer patients treated with radiofrequency ablation. *Eur J Surg Oncol.* 2012 Nov;38(11):1036-42. doi: 10.1016/j.ejso.2012.08.006. Epub 2012 Sep 2.
26. Ohtani S, Kochi M, Ito M, Higaki K, Takada S, Matsuura H, et al. Radiofrequency ablation of early breast cancer followed by delayed surgical resection--a promising alternative to breast-conserving surgery. *Breast.* 2011 Oct;20(5):431-6. Epub 2011 Jun 8.
27. Oura S, Tamaki T, Hirai I, Yoshimasu T, Ohta F, Nakamura R, Okamura Y. Radiofrequency ablation therapy in patients with breast cancers two centimeters or less in size. *Breast Cancer.* 2007;14(1):48-54.
28. Palussière J, Henriques C, Mauriac L, Asad-Syed M, Valentin F, Brouste V, et al. Radiofrequency ablation as a substitute for surgery in elderly patients with nonresected breast cancer: pilot study with long-term outcomes. *Radiology.* 2012 Aug;264(2):597-605.
29. Santoro G, Avossa M, Della Corte M. Radiofrequency thermoablation in locally advanced breast cancer. *Breast.* 2012 Aug;21(4):601-3.
30. Senkus E, Kyriakides S, Penault-Llorca F, Poortmans P, Thompson A, Zackrisson S, Cardoso F; ESMO Guidelines Working Group. Primary breast cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Ann Oncol.* 2013 Oct;24 Suppl 6:vi7-23.
31. Shah DR, Green S, Elliot A, McGahan JP, Khatri VP. Current oncologic applications of radiofrequency ablation therapies. *World J Gastrointest Oncol.* 2013 Apr 15;5(4):71-80. doi: 10.4251/wjgo.v5.i4.71.
32. Singletary SE, Fornage BD, Sneige N, Ross MI, Simmons R, Giuliano A, et al. Radiofrequency ablation of early-stage invasive breast tumors: an overview. *Cancer J.* 2002 Mar-Apr;8(2):177-80.
33. Society of Interventional Radiology (SIR). Minimally invasive treatments for breast cancer. 2014. Accessed June 2, 2014. Available at URL address: <http://www.sirweb.org>
34. Tsuda H, Seki K, Hasebe T, Sasajima Y, Shibata T, Iwamoto E, Kinoshita T. A histopathological study for evaluation of therapeutic effects of radiofrequency ablation in patients with breast cancer. *Breast Cancer.* 2011 Jan;18(1):24-32.
35. U.S. Food and Drug Administration (FDA). Summary of safety and effectiveness information. Cool-tipTM RF Ablation System. K052796. Feb 3, 2006. Accessed June 2, 2014. Available at URL address: http://www.accessdata.fda.gov/cdrh_docs/pdf5/K052796.pdf
36. van der Ploeg IM, van Esser S, van den Bosch MA, Mali WP, van Diest PJ, Borel Rinkes IH, van Hillegersberg R. Radiofrequency ablation for breast cancer: A review of the literature. *Eur J Surg Oncol.* 2007 Mar 16.
37. Wilson M, Korourian S, Boneti C, Adkins L, Badgwell B, Lee J, Suzanne Klimberg V. Long-term results of excision followed by radiofrequency ablation as the sole means of local therapy for breast cancer. *Ann Surg Oncol.* 2012 Oct;19(10):3192-8.
38. Yamamoto N, Fujimoto H, Nakamura R, Arai M, Yoshii A, Kaji S, Itami M. Pilot study of radiofrequency ablation therapy without surgical excision for T1 breast cancer: evaluation with MRI and vacuum-assisted core needle biopsy and safety management. *Breast Cancer.* 2011 Jan;18(1):3-9.

39. Zhao Z, Wu F. Minimally-invasive thermal ablation of early-stage breast cancer: a systemic review. Eur J Surg Oncol. 2010 Dec;36(12):1149-55.

The registered marks "Cigna" and the "Tree of Life" logo are owned by Cigna Intellectual Property, Inc., licensed for use by Cigna Corporation and its operating subsidiaries. All products and services are provided by or through such operating subsidiaries and not by Cigna Corporation. Such operating subsidiaries include Connecticut General Life Insurance Company, Cigna Health and Life Insurance Company, Cigna Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of Cigna Health Corporation.