Medical Policy Manual Surgery, Policy No. 240

Percutaneous Laser Ablation of Benign and Malignant Breast Tumors

Effective: July 1, 2025

Next Review: May 2026
Last Review: June 2025

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Percutaneous laser ablation refers to the destruction of breast tumors using a focused beam of electromagnetic radiation emitted from a laser fiber as an alternative to surgery. The laser fiber is inserted through the skin of the breast and imaging guidance is used to direct it to the tumor so that the laser precisely targets and heats the tumor, causing it to break down and be absorbed by the body. Other terms for percutaneous laser ablation include photothermal therapy, laser interstitial therapy, and laser interstitial photocoagulation.

MEDICAL POLICY CRITERIA

The use of percutaneous laser ablation to treat breast tumors, including benign (e.g., fibroadenoma) and malignant tumors is considered **investigational**.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Laser Interstitial Thermal Therapy, Medicine, Policy No. 177
2. Radiofrequency Ablation (RFA) of Tumors Other than Liver, Surgery, Policy No. 92

3. Cryosurgical Ablation of Miscellaneous Solid Tumors Outside the Liver, Surgery, Policy No. 132
4. Magnetic Resonance (MR) Guided Focused Ultrasound (MRgFUS) and High Intensity Focused Ultrasound (HIFU) Ablation, Surgery, Policy No. 139
5. Microwave Tumor Ablation, Surgery, Policy No. 189
6. Focal Laser Ablation of Prostate Cancer, Surgery, Policy No. 222

BACKGROUND

BREAST TUMORS

Breast tumors are classified as benign and malignant types. Benign breast tumors, such as fibroadenomas, are non-cancerous growths that are typically well-defined and mobile within the breast tissue. Fibroadenomas are the most common benign tumors in young women and are characterized by their firm, smooth texture. They do not spread to other parts of the body and are usually considered harmless, although they can sometimes cause discomfort and may need to be removed if symptomatic. Surgery and cryoablation are used to remove symptomatic fibroadenomas.

Malignant breast tumors are cancerous and have the potential to invade surrounding tissues and metastasize. Surgical treatment options for early-stage breast cancer include lumpectomy, which removes the tumor and some surrounding tissue, and is typically followed by radiation therapy; and mastectomy, which involves removal of the entire breast.

REGULATORY STATUS

In February, 2016, the Novilase® Laser Therapy System received initial marketing clearance by the FDA through the 510(k) pathway (K160392) for the treatment of fibroadenomas of the breast in women age 15 years and older with single or multiple fibroadenoma sizes up to 20 mm, that measure at least 5 mm away from the skin; and “for general surgery procedures including incision, excision and ablation of soft tissues; and coagulative necrosis and interstitial laser coagulation of soft tissues.”[1]

EVIDENCE SUMMARY

BENIGN BREAST TUMORS

No studies were identified that compared the use of percutaneous laser ablation (PLA) to other techniques (e.g., surgery, cryoablation) used to treat breast fibroadenoma or other benign breast tumors. The American Breast Laser Ablation Therapy Evaluation (ABLATE) registry aims to determine the safety and efficacy of laser ablation for benign breast conditions, mainly fibroadenoma. Results from the ABLATE registry findings have not been published.[2]

MALIGNANT BREAST TUMORS

Systematic Reviews

Matsumoto (2025) published a systematic review of PLA in the treatment of early-stage breast cancer.[3] The study goals were to identify methodologic and other factors to inform patient selection for PLA, and to determine if PLA is a viable alternative to surgery. The review included 17 studies involving 310 participants. Tumor ablation rates ranged from 33% to 87%. Patient-selection factors associated with higher tumor ablation rates included tumor size <2 cm confirmed with MRI, distance from skin and chest wall >0.5 cm, and pure invasive ductal carcinoma without in situ or lobular components. Methodologic factors associated with higher

ablation rates included the use of a laser diode (vs. Nd:YAG laser). No studies directly compared PLA to surgery and the authors noted the lack of standardization of PLA technique. The authors also acknowledged the need for surgical assessment of lymph nodes for most people with breast cancer, which limits the potential for PLA to replace surgical treatment.

Mauri (2017) published a systematic review and meta-analysis of minimally invasive imaging-guided percutaneous ablation treatments for breast cancer.[4] The analysis included 45 studies, of which seven used PLA. The overall pooled technique efficacy of minimally invasive ablative techniques was 75%, with high heterogeneity noted (I^2 = 78%, p<0.001). For laser ablation the pooled technique efficacy was 59% (95% CI 35-79). Significantly higher efficacy was noted for radiofrequency ablation (82%) and cryoablation (75%). Complication rates were not significantly different. The authors concluded that imaging-guided percutaneous ablation techniques show promise but additional research is needed to know if they are superior to surgery, the current standard of care.

Randomized Controlled Trials

No randomized controlled trials have compared PLA to breast conserving surgery in the treatment of breast cancer.

Nonrandomized Studies

Schwartzberg (2018) published a phase II open-label trial to determine the efficacy of PLA to treat invasive breast cancer (IDC).[5] Participants with IDC tumors sized ≤20 mm served as their own controls by undergoing laser ablation followed 28 days later by magnetic resonance imaging (MRI), then surgical resection. The study compared post-ablation MRI to surgical pathology. The overall success rate for complete tumor ablation was 84% (51/61). The rate of residual tumor at the targeted site was 16% (10/61). Surgery found that one patient was mistargeted and two had undiagnosed multifocal disease. Adverse events included lump, seroma, and fat necrosis. All adverse events resolved. There were no serious adverse events, but the researchers noted a steep learning curve. The authors concluded that PLA is a potential alternative to surgery for early-stage invasive breast cancer.

SUMMARY OF EVIDENCE

For people with benign breast tumors, there is a paucity of data to inform on the use of PLA. For people with malignant breast tumors, the evidence includes one phase II open-label study and systematic reviews that are noted to have high heterogeneity. No high-quality studies directly compare PLA to surgery in the treatment of benign or malignant breast tumors.

PRACTICE GUIDELINE SUMMARY

The American Society of Breast Surgeons (ASBrS)

The ASBrS published a Clinical Consensus Statement in 2018; The Use of Transcutaneous and Percutaneous Ablation for the Treatment of Benign and Malignant Tumors of the Breast.[6] The consensus recommendations do not include laser ablation for any indication.

National Comprehensive Cancer Network (NCCN)

The NCCN Guidelines for Breast Cancer Screening and Diagnosis (v2.2025) do not address the use of laser ablation after benign pathology is determined with core needle biopsy.[7]

The NCCN Guidelines for Breast Cancer (v4.2025) do not address the use of laser ablation as an alternative to surgical treatment for breast cancer.[8]

SUMMARY

There is not enough research to show that percutaneous laser ablation improves health outcomes for people with benign breast tumors or breast cancer. No clinical guidelines based on evidence recommend percutaneous laser ablation for the treatment of any type of breast tumor. Therefore, percutaneous laser ablation is considered investigational for the treatment of benign and malignant breast tumors.

REFERENCES

1. Food and Drug Administration (FDA). Novilase Laser Therapy System, Model LTS-2. 2/16/2016 [cited 5/12/2025]. 'Available from:' https://www.accessdata.fda.gov/cdrh_docs/pdf16/K160392.pdf.
2. ClinicalTrials.gov. American Breast Laser Ablation Therapy Evaluation (ABLATE). 08/04/2023 [cited 5/14/2025]. 'Available from:' https://clinicaltrials.gov/study/NCT00807924#publications.
3. Matsumoto DRM, Facina G. Incorporating Percutaneous Laser Ablation for Early Breast Cancer Treatment: A Systematic Review. *Technol Cancer Res Treat.* 2025;24:15330338241300743. PMID: 39800923
4. Mauri G, Sconfienza LM, Pescatori LC, et al. Technical success, technique efficacy and complications of minimally-invasive imaging-guided percutaneous ablation procedures of breast cancer: A systematic review and meta-analysis. *Eur Radiol.* 2017;27(8):3199-210. PMID: 28050693
5. Schwartzberg B, Lewin J, Abdelatif O, et al. Phase 2 Open-Label Trial Investigating Percutaneous Laser Ablation for Treatment of Early-Stage Breast Cancer: MRI, Pathology, and Outcome Correlations. *Ann Surg Oncol.* 2018;25(10):2958-64. PMID: 29987603
6. The American Society of Breast Surgeons Clinical Consensus Statement. The Use of Transcutaneous and Percutaneous Ablation for the Treatment of Benign and Malignant Tumors of the Breast. [cited 5/12/2025]. 'Available from:' https://www.breastsurgeons.org/docs/statements/asbrs-ccs-treatment-of-benign-and-malignant-tumors-of-the-breast.pdf.
7. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology; Breast Cancer Screening and Diagnosis (v2.2025). [cited 5/12/2025]. 'Available from:' https://www.nccn.org/professionals/physician_gls/pdf/breast-screening.pdf.
8. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology; Breast Cancer (v.4.2025). [cited 5/12/2025]. 'Available from:' https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf.

CODES

Codes	Number	Description
CPT	0970T	Ablation, benign breast tumor (eg, fibroadenoma), percutaneous, laser, including imaging guidance when performed, each tumor
	0971T	Ablation, malignant breast tumor(s), percutaneous, laser, including imaging guidance when performed, unilateral
HCPCS	None	

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