Percutaneous Laser Ablation of Benign and Malignant Breast Tumors

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded 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.

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals*	None

National Coverage Determinations (NCDs)*	None
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles*	None
Medical Policy Manual	*Medicare coverage guidance is not available for percutaneous laser ablation of breast tumors. Therefore, the health plan's medical policy is applicable.* Percutaneous Laser Ablation of Benign and Malignant Breast Tumors, Surgery, Policy No. 240

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (*Medicare IOM Pub. No. 100-04, Ch. 23, §30 A*). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

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.

Note, the fact a new service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, Medicare or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

1. Laser Interstitial Thermal Therapy, Medicine, Policy No. M-177
2. Radiofrequency Ablation (RFA) of Tumors Other Than the Liver, Surgery, Policy No. M-92
3. Focal Laser Ablation of Prostate Cancer, Surgery, Policy No. M-222

REFERENCES

None

CODING

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	

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*