



## Focal Laser Ablation of Prostate Cancer

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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, including care that may be both medically reasonable and necessary.*

*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 Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. 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 a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.*

*Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). 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. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.*

## DESCRIPTION

Focal laser ablation is the destruction of tissue using a focused beam of electromagnetic radiation emitted from a laser fiber. Other terms for focal laser ablation include photothermal therapy, laser interstitial therapy, and laser interstitial photocoagulation.

## MEDICARE ADVANTAGE POLICY CRITERIA

<b>CMS Coverage Manuals*</b>	None
<b>National Coverage Determinations (NCDs)*</b>	None

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**Noridian Healthcare Solutions  
(Noridian) Local Coverage  
Determinations (LCDs) and  
Articles (LCAs)\***

None

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**Medical Policy Manual**

*Medicare coverage guidance is not available for focal laser ablation of the prostate. Therefore, the health plan's medical policy is applicable.*

Focal Laser Ablation of Prostate Cancer, Surgery,  
[Policy No. 222](#) (see "NOTE" below)

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**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).

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## POLICY GUIDELINES

### REGULATORY STATUS

In 2020, the Avenda Health Treatment System was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for use in surgical applications requiring ablation, vaporization, excision, incision, and coagulation of soft tissue in multiple areas of surgery including urology at a wavelength of 980nm. In 2010, the Visualase® Thermal Therapy System (Medtronic) and, in 2015, the TRANBERG<sup>CLS</sup> Laser fiber (Clinical Laserthermia Systems) were cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy under MRI guidance for multiple indications including urology, at wavelengths from 800 to 1064 nm.

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

[Investigational \(Experimental\) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services](#), Medicine, Policy No. M-149

[Magnetic Resonance \(MR\) Guided Focused Ultrasound \(MRgFUS\) and High Intensity Focused Ultrasound \(HIFU\) Ablation](#), Surgery, Policy No. M-139

## REFERENCES

None

## CODING

Codes	Number	Description
CPT	0655T	Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with MR-fused images or other enhanced ultrasound imaging
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.