Anthem

Medical Policy

Subject: Focal Laser Ablation for the Treatment of Prostate Cancer
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Description/Scope

This document addresses the use of focal laser ablation, also known as laser interstitial therapy or laser interstitial photocoagulation, to treat localized prostate cancer. The procedure is frequently performed with real-time magnetic resonance imaging (MRI) which also allows the use of magnetic resonance (MR) thermometry to monitor the lesion and surrounding tissue during treatment.

Note: Please see the following related documents regarding other minimally invasive treatments of prostate cancer:

- CG-MED-81 Ultrasound Ablation for Oncologic Indications
- CG-SURG-61 Cryosurgical, Radiofrequency, Microwave or Laser Ablation to Treat Solid Tumors Outside the Liver

Position Statement

Investigational and Not Medically Necessary:

Focal laser ablation is considered **investigational and not medically necessary** for the treatment of prostate cancer.

Rationale

No randomized controlled trials (RCTs) evaluating focal laser ablation for treating prostate cancer have been published. The published evidence on focal laser ablation consists largely of uncontrolled studies, many of which have small sample sizes and limited follow-up (Lee, 2014; Lepor, 2015; Natarajan, 2016; Oto, 2013). There have been some small published studies with longer-term results, however, these studies have been limited by being single institution studies and non-standard protocols, limiting the quality and generalizability of the results (Chao, 2021; Mehralivand, 2021).

A single center prospective study published by Walser and colleagues (2019) evaluated the oncologic outcomes and preserved sexual and urinary function in individuals with low to intermediate-risk prostate cancer who received focal laser ablation. Individuals with T1c-T2b, Gleason score of 7 or less, no metastases and an ECOG performance score of 0 underwent focal laser ablation (n=120), and were followed for a mean of 34 months (17 to 55 months). At 1 year post-treatment, 17% of the individuals needed additional oncologic treatment, with all tumors reoccurring at the margins or at the site of prior ablation. In a small group of individuals with larger margins (n=16), the rate of clinically significant residual tumor at 1 year was 6.8%. There was no significant change in quality of life or urologic function. The results of this study do not report the number of individuals who were lost during follow-up. Further studies are needed with standardized treatment protocols, such as specific treated margins and a larger treated population.

In 2019, Zheng and associates compared the mid-term survival outcomes of individuals with localized prostate cancer who were treated with radical prostatectomy (n=12,433) or focal laser ablation (n=442). Following propensity score matching, there were 321 pairs of matched individuals; there were no significant differences in baseline characteristics between the groups. The mean follow-up was 62.26 months in the laser ablation group and 59.62 months in the radical prostatectomy group. The laser ablation had higher all-cause mortality and lower statistically insignificant cancer-specific mortality compared to radical prostatectomy (hazard ratio [HR], 0.82; 95% confidence interval [CI], 0.18-3.67; p=0.7936) and (HR, 2.35; 95% CI, 1.38-3.98; p=0.0016), respectively.

In a similar analysis, Zhou and colleagues (2020) compared the overall survival and prostate cancer-specific mortality in the long term of individuals who were treated with radiotherapy (n=93,041) or laser ablation (n=428). The population included individuals with low or intermediate-risk localized prostate cancer. A total of 81,015 individuals in the radiotherapy group died and 1303 of those individuals died from prostate cancer-specific reasons. In the laser ablation group, 356 individuals died and 7 of those individuals died of prostate cancer-specific reasons. In a multivariate regression analysis of the two groups, there was no obvious difference between the groups in reducing cancer-specific mortality (HR=1.73; 95% CI, 0.82-3.64; p=0.147). The laser ablation group was associated with worse overall survival outcomes compared to the radiotherapy group (HR=1.91; 95% CI, 1.51-2.40; p<0.001). Following propensity score matching in which the statistical differences between the groups were eliminated, the radiotherapy group benefit in overall survival remained (HR=1.50; 95% CI, 1.17–1.93; p=0.001). There was still no significant difference between the groups in cancer-specific mortality (HR=1.48; 95% CI, 0.66–3.32; p=0.336). The study population included individuals diagnosed between 2004 and 2015, and some of the individuals receiving radiotherapy were treated with outdated radiotherapy techniques. Radiotherapy still outperformed laser ablation with better survival outcomes. The authors suggest that the advantages of radiotherapy over laser ablation may be more pronounced if laser ablation was compared to intensity modulated radiation therapy (IMRT) only.

In 2023, Nicoletti and colleagues published a systematic review of uncontrolled or controlled studies evaluating focal therapy for prostate cancer. No controlled studies evaluating focal laser ablation were identified. There were 10 single-arm studies, with a total of 308 participants. The authors did not pool study findings.

In 2022, an updated American Urological Association (AUA)/ American Society for Radiation Oncology (ASTRO) guideline was published on clinically localized prostate cancer (Eastham, 2022), which provides the following guidance:

> Clinicians should inform patients with intermediate-risk prostate cancer considering whole gland or focal ablation that there is a lack of high-quality data comparing ablation outcomes to radiation therapy, surgery, and active surveillance. (Expert Opinion)
>
> Clinicians should not recommend whole gland or focal ablation for patients with high-risk prostate cancer outside of a clinical trial. (Expert Opinion)

The National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines for prostate cancer (V.4.2023) notes that focal laser ablation is an emerging therapy, but does not include any recommendation regarding its use. Treatment recommendations vary based upon the individuals risk group. Treatment varies from active surveillance in the very low and low risk group to external beam radiation therapy, brachytherapy, radical prostatectomy, pelvic node dissection and androgen deprivation therapy for the higher risk

groups.

Background/Overview

Prostate cancer is one of the most common types of cancer diagnosed in the United States (U.S.). The American Cancer Society estimates 288,200 newly diagnosed cases and 34,700 deaths from prostate cancer in the U.S. in 2023.

Prostate cancers can be broadly categorized as:

- Localized: Cancer is limited to the prostate;
- Regional: Cancer is limited to the prostate and nearby structures or lymph nodes;
- Distant: Metastatic cancer.

In addition to the broad categories listed above, localized prostate cancer is also stratified by risk assessment. Individual risk level provides prognostic information and guides further diagnostic and therapeutic planning. Prostate cancer risk levels are characterized by the results of digital rectal exam, the clinical T stage, Gleason score, extent of cancer and serum PSA levels (NCCN Prostate Cancer, V1.2023). The NCCN stratifies risk into 5 levels: very low, low, intermediate, high and very high. An estimated 74% of all cases of prostate cancer are categorized as low or intermediate risk (Zhou, 2020). Generally, active surveillance is recommended for individuals with localized disease who are in the very low and low risk groups (NCCN Prostate Cancer, V1.2023; Stabile, 2019). However, approximately 94% of individuals diagnosed with low-risk cancers undergo radical treatment, such as radiation or surgery (Colin, 2012). These treatments are associated with long term quality of life issues, such as incontinence and impotence. Focal therapy has been proposed as an alternative to active surveillance and surgery or radiation.

Focal laser ablation therapy is a type of focal therapy which involves the destruction of prostate tissue while preserving surrounding tissue and structures, such as neurovascular bundles, bladder neck, and urethral sphincter (Zheng, 2019). The laser uses coagulative necrosis to remove targeted tissue and avoids cavitation, carbonization or vaporization (Natarajan, 2016). Prostate cancer is multifocal in up to 75% of all cases (Stabile, 2019). Treatment can involve the destruction of multiple lesions within the prostate or a significant single index lesion. It has been proposed that the index lesion, which is associated with the most aggressive nidus of cancer within the prostate gland, drives the natural course of disease. Focal therapy can also be used to ablate half of the gland containing the tumor (hemi-ablation) or ablate a volume greater than half of the prostate (sub-total ablation) (Stabile, 2019). In addition to the lack of demonstrable oncologic efficacy, there are additional concerns related to the use of focal laser ablation. Focal therapy is susceptible to multiple technical errors, such as poor navigation, inadequate imaging or imprecise tissue destruction, which increases the risk of incomplete tumor tissue ablation (Zheng, 2019; Zhou, 2020).

The U.S. Food and Drug Administration (FDA) cleared the Visualase® Thermal Therapy System (Bio Tex, Inc., Houston, TX, now Medtronic) in 2007. The device is indicated for use in necrotizing or coagulating soft tissue through interstitial irradiation or thermal therapy under MRI guidance. A more recent version of the device, cleared in 2008, allowed for better temperature control limits to be set.

In 2015, the FDA cleared the Tranberg Thermal Therapy System (Clinical Laserthermia Systems AB, Edmond, OK) for marketing. According to the FDA, the device is indicated for “surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in areas of surgery…”. There was not a specific clearance or approval for treatment of prostate cancer.

Definitions

Focal therapy: The use of ablative techniques, such as laser, to destroy a predefined area of tissue with minimal damage to surrounding tissue.

Initial Risk Stratification for Clinically Localized Disease*

Risk Group	Clinical/ Pathologic Features
Very Low	Has all of the following: • T1c • Grade Group 1 • PSA < 10 ng/mL • Fewer than 3 prostate biopsy fragments/cores positive, ≤ 50% cancer in each fragment/core • PSA density <0.15 ng/mL/g
Low	Has all of the following but does not qualify for very low risk: • T1-T2a • Grade Group 1 • PSA < 10 ng/mL

Intermediate	Has all of the following:
	• No high-risk group features
	• No very-high-risk group features
	• Has one or more intermediate risk factors (IRF)
	  ◦ T2b-T2c
	  ◦ Grade Group 2 or 3
	  ◦ PSA 10-20 ng/mL

	Favorable Intermediate Has all of the following: • 1 IRF • Grade Group 1 or 2 • <50% biopsy cores positive

	Unfavorable Intermediate Has one or more of the following; • 2 or 3 IRFs • Grade Group 3 • ≥ 50% biopsy cores positive
High	Has no very-high-risk features and has at least one high-risk feature: • T3a • Grade Group 4 or Grade Group 5 OR • PSA > 20 ng/ML
Very High	Has at least one of the following: • T3b-T4 • Primary Gleason pattern 5 • 2 or 3 high-risk features • > 4 cores with Grade Group 4 or 5

* National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines). Prostate Cancer V1.2023.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure and diagnosis codes; or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

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

ICD-10 Procedure

0V503ZZ	Destruction of prostate, percutaneous approach [when specified as focal laser ablation of the prostate]

ICD-10 Diagnosis

C61	Malignant neoplasm of prostate
D07.5	Carcinoma in situ of prostate

References

Peer Reviewed Publications:

1. Bates AS, Ayers J, Kostakopoulos N, et al. A systematic review of focal ablative therapy for clinically localised prostate cancer in comparison with standard management options: limitations of the available evidence and recommendations for clinical practice and further research. Eur Urol Oncol. 2021; S2588-9311(20)30216-9.
2. Chao B, Lepor H. 5-year outcomes following focal laser ablation of prostate cancer. Urology. 2021; 155:124-129.
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7. Mehralivand S, George AK, Hoang AN, et al. MRI-guided focal laser ablation of prostate cancer: a prospective single-arm, single-center trial with 3 years of follow-up. Diagn Interv Radiol. 2021; 27(3):394-400.
8. Natarajan S, Raman S, Priester AM, et al. Focal laser ablation of prostate cancer: Phase I clinical trial. J Urol. 2016; 196(1):68-75.
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10. Oto A, Sethi I, Karczmar G, et al. MR imaging-guided focal laser ablation for prostate cancer: phase I trial. Radiology. 2013; 267(3):932-940.
11. Stabile A, Moschini M, Montorsi F, et al. Focal therapy for prostate cancer - index lesion treatment vs. hemiablation. A matter of definition. Int Braz J Urol. 2019; 45(5):873-876.
12. Walser E, Nance A, Ynalvez L, et al. Focal laser ablation of prostate cancer: Results in 120 patients with low- to intermediate-risk disease. J Vasc Interv Radiol. 2019; 30(3):401-409.
13. Zheng X, Jin K, Qiu S, et al. Focal laser ablation versus radical prostatectomy for localized prostate cancer: Survival outcomes from a matched cohort. Clin Genitourin Cancer. 2019; 17(6):464-469.e3.
14. Zhou X, Jin K, Qiu S, et al. Comparative effectiveness of radiotherapy versus focal laser ablation in patients with low and intermediate risk localized prostate cancer. Sci Rep. 2020; 10(1):9112.

Government Agency, Medical Society, and Other Authoritative Publications:

1. American Cancer Society. 2023. Key Statistics for Prostate Cancer. Available at:

https://www.cancer.org/cancer/types/prostate-cancer/about/key-statistics.html. Accessed on December 1, 2023.
2. Eastham JA, Auffenberg GB, Barocas DA, et al. Clinically Localized Prostate Cancer: AUA/ASTRO Guideline, Part I: Introduction, Risk Assessment, Staging, and Risk-Based Management. Journal of Urology. 2022; 208(1):10-18.
3. NCCN Clinical Practice Guidelines in Oncology®. ©2023 National Comprehensive Cancer Network, Inc. Prostate Cancer V1.2023. Last review September 7, 2023. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on December 1, 2023.
4. U.S. Food and Drug Administration 510(k) Premarket Notification Database. Visualase Thermal Therapy System. 510K Summary/ No. K071328. Rockville, MD: FDA. August 31, 2007. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf7/K071328.pdf. Accessed on December 1, 2023.

Websites for Additional Information

1. Centers for Disease Control and Prevention. Prostate Cancer. Last reviewed July 17, 2023. Available at: https://www.cdc.gov/cancer/prostate/index.htm. Accessed on December 7, 2023.
2. National Institute of Health. National Cancer Institute. Lasers to Treat Cancer. Updated June 16, 2021. Available at: https://www.cancer.gov/about-cancer/treatment/types/surgery/lasers-fact-sheet. Accessed on December 7, 2023.
3. U.S. National Library of Medicine. Medline Plus. Prostate Cancer. Last updated March 4, 2022. Available at: https://medlineplus.gov/prostatecancer.html. Accessed on December 7, 2023.

Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Description, Rationale, Background/Overview, Definition, References and Index sections.
Reviewed	02/16/2023	MPTAC review. Updated Rationale, Index and References sections.
Reviewed	02/17/2022	MPTAC review. Updated Rationale and References sections. Updated Coding section to remove NOC CPT code 55899 no longer applicable.
New	02/11/2021	MPTAC review. Initial document development.

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.