Molina Clinical Policy
High-Intensity Focused Ultrasound (HIFU) for Prostate Cancer: Policy No. 295

Last Approval: 4/13/2022
Next Review Due By: April 2023

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

High-Intensity Focused Ultrasound (also known as HIFU, focused ultrasound surgery, acoustic ablation, or sonablation) is a minimally invasive treatment that ablates prostatic tissue using high-intensity convergent ultrasound delivered via an endorectal probe. HIFU signifies an intensity of > 5 watts per square centimeter, which produces coagulation necrosis of tissue and is most often utilized for HIFU ablation. When HIFU is deposited via an ultrasound transducer in a focal area, the induced thermal lesions are well circumscribed, with an intermediate zone comprising a few layers of cells between the intact and ablated cells. The entire prostate gland is ablated using a series of ultrasonic shots. Surrounding normal tissue is not affected due to the low acoustic energy density in these areas. The ultrasound causes a sharp rise in temperature of up to 90 degrees Celsius. A cooling balloon surrounding the transrectal probe protects the rectum from thermal damage. Real-time guidance is provided by diagnostic ultrasound or MRI. Computer guidance software defines the exact target volume such that the sound wave beam is delivered with a high degree of precision, thus minimizing the impact on surrounding tissue and intervening structures. (Ward et al., 2021; Hayes, 2017; Hayes, 2016).

According to the **Food and Drug Administration (FDA)** HIFUs are regulated as class II devices under the product code PLP (high intensity ultrasound system for prostate tissue ablation). These devices are designed to use high intensity ultrasound to heat target tissue within the prostate gland, causing coagulation necrosis of the tissue. The following HIFU devices have received FDA clearance for marketing in the United States:

- Sonablate (SonaCare Medical LLC; K160942) was approved on December 21, 2016 for the indication of transrectal HIFU ablation of prostatic tissue.
- Ablatherm Integrated Imaging High-Intensity Focused Ultrasound (HIFU) device (K153023), approved November 6, 2015 for transrectal HIFU ablation of prostate tissue.

COVERAGE POLICY

HIFU **is considered experimental, investigational, and unproven** for the treatment of prostate cancer due to insufficient evidence in the peer reviewed literature.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

A small body of low-quality evidence found that salvage HIFU leads to acceptable efficacy outcomes in patients with localized prostate cancer that has recurred following primary treatment with EBRT or RP. There are no RCTs comparing HIFU with other standard therapies for primary localized prostate cancer such as prostatectomy, EBRT, or active surveillance. The best available studies of ultrasound-guided salvage HIFU for localized, recurrent prostate cancer in patients with no signs of metastatic disease at the time of treatment have found that most patients experience a reduction in serum PSA level, acceptable local tumor control, remain free of disease progression, and survive for 5 years or longer after treatment. The treatment appears to be relatively safe, although it can negatively affect urinary and sexual function, as can primary treatments for prostate cancer. The body of evidence is from uncontrolled prospective and retrospective studies, systematic reviews. (Duijzentkunst, 2016; Ramsay et al., 2015; Veereman et al., 2015; Golan et al., 2017; Valerio et al., 2017; Rebillard et al., 2008). Comparative studies were also included that evaluated HIFU with an alternative technology (salvage cryoablation). Additional, well-designed studies are needed to further compare HIFU for localized, recurrent prostate cancer with alternative and established salvage therapies before a determination can be made as to its long-term safety and effectiveness, mainly with regard to prostate cancer recurrence and mortality.

Siddiqui et al. (2015) compared the morbidity of whole gland salvage ablation using cryotherapy (CRYO) and high-intensity focused ultrasound (HIFU) for radio recurrent prostate cancer at a single centre over a 17-year period. Patients were divided in 3 cohorts. Group 1 included the first 65 patients treated with CRYO (1995-1998); Group 2 included the last 65 patients treated with CRYO (2002-2004), and Group 3 included 65 patients treated with HIFU (2006-2011). We analyzed the complications reported within at least 90 days of treatment or up to the last follow-up. The results outlined Clavien grade complications. For Groups 1, 2 and 3, the following Clavien I-II complications were recorded: 78, 49 and 13, respectively. For Clavien grade IIIa, 2, 5 and 4 for Groups 1, 2 and 3, respectively. For Clavien grade IIIb, 8, 2 and 3 for Groups 1, 2 and 3, respectively. Clavien grade II complications were statistically higher in Group 1 versus Group 2 ($p = 0.005$) and in Group 2 versus Group 3 ($p = 0.0001$). The rate of mild-moderate incontinence was significantly higher in the CRYO group compared to the HIFU cohort ($p \leq 0.05$). The rate of urinary retention was significantly higher in Group 2 compared to Group 3 ($p = 0.0005$). The rates of severe incontinence (range: 1.5%-5%), need for surgical intervention (uniform at 1.5%), and recto-urethral fistulae (range: 1.5%-3%) were not statistically different. CRYO was associated with higher overall morbidity. The morbidity during the early experience with HIFU was lower than both subgroups of CRYO and may reflect the advancement of technology or cumulative learning experience.

Liu et al. (2016) conducted a prospective, single-institutional comparison for primary whole gland cryoablation and high-intensity focused ultrasound (HIFU) in localized prostate cancer with respect to oncological and functional outcomes. The study included a total of 114 and 120 patients with primary whole gland cryoablation and HIFU for localized prostate cancer, respectively. Functional outcomes included complications and serial International Index of Erectile Function (IIEF)-5 scores, International Prostate Symptom Score (IPSS), and related quality of life (QoL) scores. During mean follow-up duration of approximately two years, the PSA biochemical recurrence rates of the two groups were similar (cryoablation 25%, HIFU 18%). In terms of functional outcomes, patients with HIFU had significantly lower IPSS (5.70 vs. 9.04 at 24 months), lower erectile dysfunction rate (66 vs. 88.0%), and higher IIEF-5 score (9.36 vs. 4.18 at 24 months) than patients with cryoablation. In this study, both primary whole gland cryoablation and HIFU demonstrated good oncological outcomes for localized prostate cancer. Safety was validated of the two treatment modalities and identified the importance of combined HIFU and transurethral resection of the prostate. The HIFU patients experienced better urinary function improvement and more possible sexual function preservation than cryoablation patients; HIFU may provide better quality of life for patients with localized prostate cancer.

Two systematic reviews from 2017 summarized that long-term data are needed to evaluate oncologic efficacy and functional outcomes and will aid in identifying the optimal candidates for therapy. Standardization of outcomes definitions will allow for better comparison between studies and among treatment modalities and that the oncological outcome has yet to be evaluated against standard of care. (Golan et al., 2017; Valerio et al., 2017).

Duijzentkunst et al. (2016) conducted a systematic review to assess the safety and efficacy of focal salvage therapy for treatment of localized, recurrent prostate cancer following radiotherapy. The review compared partial salvage therapy with whole-gland salvage therapy. A total of eight studies were included, two of which evaluated the use of

HIFU for focal salvage treatment. Several limitations are noted, including small sample sizes, lack of RCTs, lack of blinding, lack of standardized definitions, and variations in assessment modalities. Despite the limitations, researchers concluded that focal salvage therapy is comparable to whole-gland salvage therapy, with the benefit of a decrease in severe toxicity and preservation of erectile function and highlight the need for additional research.

Another systematic review by Veereman et al. (2015) examined the safety and efficacy of ultrasound guided HIFU for treatment of localized prostate cancer. This review of low-quality evidence suggested an OS rate after HIFU with the Ablatherm device (accounting for 14 primary studies) ranging from 80% to 89% for > 5 years. The prostate cancer–specific survival rate ranged from 97% to 99% for > 5 years. Biochemical disease-free survival (BDFS) ranged from 64.2% to 85% within 5 years of follow-up, and from 60% to 79% for > 5 years of follow-up.

A third systematic review (Ramsay et al., 2015) aimed to determine the relative clinical effectiveness and cost-effectiveness of ablative therapies compared with radical prostatectomy (RP), external beam radiotherapy (EBRT) and active surveillance (AS) for primary treatment of localized prostate cancer, and compared with RP for salvage treatment of localized prostate cancer which has recurred after initial treatment with EBRT. For primary therapy, the ablative therapies were cryotherapy, HIFU, brachytherapy and other ablative therapies. The comparators were AS, RP and EBRT. For salvage therapy, the ablative therapies were cryotherapy and HIFU. The comparator was RP. Outcomes were cancer related, adverse effects (functional and procedural) and quality of life. Two reviewers extracted data and carried out quality assessment. Meta-analysis used a Bayesian indirect mixed-treatment comparison. Data were incorporated into an individual simulation Markov model to estimate cost-effectiveness. There was no robust evidence that mortality (4-year survival 93% for cryotherapy, 99% for HIFU, 91% for EBRT) or other cancer-specific outcomes differed between treatments. For functional and quality-of-life outcomes, the paucity of data prevented any definitive conclusions from being made, although data on incontinence rates and erectile dysfunction for all ablative procedures were generally numerically lower than for non-ablative procedures. The safety profiles were comparable with existing treatments. Studies reporting the use of focal cryotherapy suggested that incontinence rates may be better than for whole-gland treatment. Data on AS, salvage treatment and other ablative therapies were too limited. The cost-effectiveness analysis confirmed the uncertainty from the clinical review and that there is no technology which appears superior, on the basis of current evidence, in terms of average cost-effectiveness. The analyses suggest that a number of ablative techniques are worthy of further research. The main limitations were the quantity and quality of the data available on cancer-related outcomes and dysfunction. The findings indicate that there is insufficient evidence to form any clear recommendations on the use of ablative therapies in order to influence current clinical practice. Research efforts in the use of ablative therapies in the management of prostate cancer should now be concentrated on the performance of RCTs and the generation of standardized outcomes.

National and Specialty Organizations

The **National Cancer Institute (NCI)** (2022) published a Physician Data Query (PDQ) on *Prostate Cancer.* The PDQ contains a cancer information summary as well as drug information summaries on cancer-related drugs to treat prostate cancer.

The **National Comprehensive Cancer Network (NCCN)** (2022) published a guideline *Prostate Cancer* which includes information on treatment. This includes recommended treatment options such as HIFU and cryosurgery ~~as~~ for treating localized, biopsy-confirmed recurrence following external beam radiotherapy (EBRT) in the absence of metastatic disease. HIFU is included as an option for salvage therapy in patients with a positive prostate biopsy and low suspicion of distant metastases, along with observation or radical prostatectomy with lymph node dissection.

The **American Urological Association (AUA)** published guidelines for the management of prostate cancer state that there are minimal data available on the following interventions: HIFU, cryotherapy, high-dose-rate interstitial prostate brachytherapy, and primary hormonal therapy. Conclusions regarding outcomes of these treatments cannot be made. The panel did not include these treatment options in the analysis and recommendations due to a combination of factors, including limited published experience and short-term follow-up, and similar issues that affected evaluations of other treatment options. The AUA/ASTRO/SUO guidelines states for low, intermediate and high-risk prostate cancer patients considering focal therapy or high intensity focused ultrasound (HIFU) that these interventions are not standard care options due to a lack of comparative outcome evidence. ([1-2]Sanda et al., 2018; AUA, 2017).

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
0398T	Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed
55899	Unlisted procedure, male genital system

HCPCS Code

HCPCS	Description
C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (MR) guidance

ICD-10 Codes

ICD-10	Description
C61	Malignant neoplasm of prostate
D07.5	Carcinoma in situ of prostate
D40.0	Neoplasm of uncertain behavior of prostate
N42.3	Dysplasia of prostate

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

4/13/2022	Policy reviewed, no changes to coverage policy, updated References.
4/5/2021	Policy reviewed, no changes, updated references.
6/17/2020	Policy reviewed, no changes.
6/19/2019	Policy reviewed, no changes to criteria, updated professional society guidelines and references.
7/10/2018	Policy reviewed, no changes to criteria, updated professional society guidelines and references.
5/17/2017	New policy.

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Government Agencies

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Peer Reviewed Publications

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National and Specialty Organizations

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Evidence Based Reviews and Publications

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Other Peer Reviewed and National Organization Publications (used in the development of this policy)

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*