

HIGH INTENSITY FOCUSED ULTRASOUND

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Status: Current

Summary of Changes

- Clarifications: Moved I.10. a. to I.B as a separate section and reworded criteria for clarity.

I. POLICY/CRITERIA

A. High intensity focused ultrasound (HIFU), including magnetic resonance-guided focused ultrasound, is experimental and investigational for the following indications because of insufficient evidence of its long term effectiveness (not an all-inclusive list):

1. Atrial fibrillation (*See Electrophysiology Testing & Catheter Ablation for Cardiac Arrhythmias medical policy #91314*)
2. Benign prostatic hypertrophy
3. Central nervous system diseases/disorders (e.g., brain cancer and stroke)
4. Fractures
5. Liver metastasis from colon and stomach cancer
6. Osteosarcoma/bone tumors
7. Palliation of bone metastases
8. Pancreatic cancer
9. Primary liver cancer
10. Prostate cancer, primary therapy
11. Renal cancer
12. Thyroid nodules
13. Vulvar dystrophy

B. HIFU as secondary local therapy for recurrent prostate cancer after definitive radiotherapy, in the absence of metastatic disease, may be medically necessary according to NCCN guidelines.

C. Other local therapies for the treatment of prostate cancer, including vascular targeted photodynamic therapy (VTP) are experimental and investigational.

For MRI-guided ultrasound ablation of uterine fibroids, see medical policy *Uterine Fibroid Treatment #91573*.

II. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the [Priority Health Provider Manual](#).

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- ❖ **HMO/EPO:** *This policy applies to insured HMO/EPO plans.*
- ❖ **POS:** *This policy applies to insured POS plans.*
- ❖ **PPO:** *This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.*
- ❖ **ASO:** *For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.*
- ❖ **INDIVIDUAL:** *For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.*
- ❖ **MEDICARE:** *Coverage is determined by the Centers for Medicare and Medicaid Services (CMS) and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.*
- ❖ **MEDICAID/HEALTHY MICHIGAN PLAN:** *For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.*

IV. DESCRIPTION

High-intensity focused ultrasound (HIFU) uses externally generated sonic waves to create a sharply delineated area of thermal energy that destroys the target tissue. In contrast to traditional ultrasound, which is mainly used for imaging and diagnostics, HIFU focuses high-energy sonic waves at a single point, leading to rapid temperature elevation in the targeted tissue (Hayes, 2023). Ultrasound-guided HIFU can be used for salvage treatment in patients with localized recurrence of prostate cancer after external beam radiotherapy or radical prostatectomy. HIFU can be used to thermally ablate either the entire prostate

gland or the cancer-containing part of the gland, with the goal of achieving complete tumor control to improve survival. The role of ablation with HIFU as an alternative to radical prostatectomy or radiation therapy remains uncertain.

The French Urological Association initiated a prospective IDEAL multi-institutional study (2009-2015), to evaluate HIFU-hemiablation to evaluate the ability of HIFU to achieve local control of the tumor in patients with unilateral localized prostate cancer (Rischmann, 2017). The authors found at 1 year, HIFU-hemiablation was efficient with 95% absence of clinically significant cancer associated with low morbidity and preservation of quality of life. Radical treatment-free survival rate was 89% at 2 year.

HIFU also has been studied for treatment of radiation recurrence. Ahmed et al (2012) conducted a registry-based analysis of 430 patients who underwent HIFU. Thirty-nine patients received focal salvage therapy for localized recurrence after external beam radiotherapy. The actuarial progression-free survival rate (including PSA nonresponders) was 69% at 1 year and 49% at 2 years according to Phoenix criteria. Excluding PSA nonresponders, these rates were 74% and 58%, respectively (Phoenix criteria). In a retrospective registry analysis of 150 men who underwent focal salvage HIFU (FS-HIFU) (Sonablate 500), Kanthabalan et al (2017) concluded that focal salvage HIFU conferred a relatively low complication and side effect rate. CEFS and biochemical control in the short to medium term were reasonable, especially in this relatively high-risk cohort, but still low compared with current whole-gland salvage therapies.

National Comprehensive Cancer Network® (NCCN®): The 2024 NCCN Clinical Practice Guidelines in Oncology, Prostate Cancer, recommends HIFU and cryosurgery as options for secondary therapy for prostate cancer recurrence in the absence of metastatic disease.

American College of Radiology (ACR) Appropriateness Criteria®: The 2017 Work Group's guideline on locally advanced (high-risk) prostate cancer does not mention the use of HIFU in the list of treatment options. The summary states that HIFU is currently an experimental therapy.

American Cancer Society (ACS): HIFU is mentioned as an ablative treatment for early-stage prostate cancer. The ACS states that new treatments could be used either as the first type of treatment for early-stage prostate cancer that are at low risk or after radiation therapy in cases where it was not successful. However, it's not yet clear how the long-term effectiveness of HIFU compares to surgery or radiation therapy. (ACS, 2023).

National Cancer Institute (NCI): In the 2024 Prostate Cancer Treatment health professional version Physician Data Query (PDQ) HIFU is not listed as a

treatment option under clinical evaluation for patients with stage I and II prostate cancer.

V. CODING INFORMATION

ICD-10 Codes that support medical necessity:

C61 Malignant neoplasm of prostate
R97.21 Rising PSA following treatment for malignant neoplasm of prostate
Z92.3 Personal history of irradiation

CPT/HCPCS codes:

55880 Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance
61715 Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation of target, intracranial, including stereotactic navigation and frame placement, when performed (*Not covered for commercial products*)

Not covered

27599 Unlisted procedure, femur or knee
47399 Unlisted procedure, liver
48999 Unlisted procedure, pancreas
50549 Unlisted laparoscopy procedure, renal
55899 Unlisted procedure, male genital system [*when specified as destruction of prostate tissue by high intensity focused ultrasound*]
58999 Unlisted procedure, female genital system (nonobstetrical)
60699 Unlisted procedure, endocrine system
64999 Unlisted procedure, nervous system
76999 Unlisted ultrasound procedure (eg, diagnostic, interventional) -
Explanatory notes must accompany claims billed with unlisted codes

VI. REFERENCES

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