

**HIGH INTENSITY FOCUSED ULTRASOUND**

Effective Date: June 1, 2024

Review Dates: 10/12, 10/13, 8/14, 8/15, 5/16, 5/17,  
5/18, 5/19, 5/20, 5/21, 5/22, 5/23, 5/24

Date Of Origin: October 10, 2012

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](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](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**

1. Ahmed HU, Cathcart P, McCartan N, et al. Focal salvage therapy for localized prostate cancer recurrence after external beam radiotherapy: a pilot study. *Cancer* 2012;118:4148-4155.
2. Albisinni S, Aoun F, Bellucci S, et al. Comparing high-intensity focal ultrasound hemiablation to robotic radical prostatectomy in the management of unilateral prostate cancer: a matched-pair analysis. *J Endourol* 2017;31:14-19.
3. American Cancer Society. Cryotherapy, HIFU, and Other Ablative Treatments for Prostate Cancer. Available at

- <https://www.cancer.org/cancer/types/prostate-cancer/treating/cryosurgery.html> (Accessed March 26, 2024).
4. Asimakopoulos AD, Miano R, Virgili G, Vespasiani G, Finazzi Agrò E. HIFU as salvage first-line treatment for palpable, TRUS-evidenced, biopsy-proven locally recurrent prostate cancer after radical prostatectomy: A pilot study. *Urol Oncol*. 2011 Feb 1.
  5. Aus G. Current status of HIFU and cryotherapy in prostate cancer--a review. *Eur Urol*. 2006 Nov;50(5):927-34.
  6. Baco E, Gelet A, Crouzet S, Rud E, Rouvière O, Tonoli-Catez H, Berge V, Chapelon JY, Eggesbø HB. Hemi salvage high-intensity focused ultrasound (HIFU) in unilateral radiorecurrent prostate cancer: a prospective two-centre study. *BJU Int*. 2014 Oct;114(4):532-40. doi: 10.1111/bju.12545. Epub 2014 Apr 16. PMID: 24930692.
  7. Barret E, Ahallal Y, Sanchez-Salas R, Galiano M, Cosset JM, Validire P, Macek P, Durand M, Prapotnich D, Rozet F, Cathelineau X. Morbidity of focal therapy in the treatment of localized prostate cancer. *Eur Urol*. 2013 Apr;63(4):618-22. doi: 10.1016/j.eururo.2012.11.057. Epub 2012 Dec.
  8. Blana A, Murat FJ, Walter B, Thuroff S, Wieland WF, Chaussy C, et al. First Analysis of the Long-Term Results with Transrectal HIFU in Patients with Localised Prostate Cancer. *Eur Urol*. 2007 Nov 5.
  9. Blana A, Walter B, Rogenhofer S, Wieland WF. High-intensity focused ultrasound for the treatment of localized prostate cancer: 5-year experience. *Urology*. 2004 Feb;63(2):297-300.
  10. Boutier R, Girouin N, Cheikh AB, Belot A, Rabilloud M, Gelet A, et al. Location of residual cancer after transrectal high-intensity focused ultrasound ablation for clinically localized prostate cancer. *BJU Int*. 2011 Dec;108(11):1776-81.
  11. Catalona WJ, Han M. Definitive therapy for localized prostate cancer-an overview. Wein: Campbell-Walsh Urology. 10th ed., Philadelphia, PA: Saunders; 2011. Ch 100.
  12. Chaussy CG, Thüroff S. Transrectal high-intensity focused ultrasound for local treatment of prostate cancer: current role. *Arch Esp Urol*. 2011 Jul;64(6):493-506.
  13. Crouzet S, Blana A, Murat FJ, Pasticier G, Brown SCW, Conti GN, Ganzer R, Chapet O, Gelet A, Chaussy CG, Robertson CN, Thuroff S, Ward JF. Salvage high-intensity focused ultrasound (HIFU) for locally recurrent prostate cancer after failed radiation therapy: Multi-institutional analysis of 418 patients. *BJU Int*. 2017 Jun;119(6):896-904. doi: 10.1111/bju.13766. Epub 2017 Mar 10. PMID: 28063191.
  14. Crouzet S, Blana A, Murat FJ, et al. Salvage high-intensity focused ultrasound (HIFU) for locally recurrent prostate cancer after failed radiation therapy: Multi-institutional analysis of 418 patients. *BJU Int* 2017;119:896- 904
  15. Crouzet S, Rebillard X, Chevallier D, Rischmann P, Pasticier G, Garcia G, et al. Multicentric oncologic outcomes of high-intensity focused ultrasound for

- localized prostate cancer in 803 patients. *Eur Urol*. 2010 Oct;58(4):559-66. Epub 2010 Jul 3.
16. Dubinsky TJ, Cuevas C, Dighe MK, Kolokythas O, Hwang JH. High-intensity focused ultrasound: current potential and oncologic applications. *AJR Am J Roentgenol*. 2008 Jan;190(1):191-9.
  17. 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. *J Urol*. 2022;208(1):10-18.
  18. Eastham JA, Auffenberg GB, Barocas DA, et al. Clinically localized prostate cancer: AUA/ASTRO guideline, part II: principles of active surveillance, principles of surgery, and follow-up. *J Urol*. 2022;208(1):19-25.
  19. Eastham JA, Auffenberg GB, Barocas DA, et al. Clinically localized prostate cancer: AUA/ASTRO guideline. Part III: principles of radiation and future directions. *J Urol*. 2022;208(1):26-33.
  20. ECRI Institute. Hotline Response [database online]. Plymouth Meeting (PA): ECRI Institute; 2011 Nov 10. High-intensity Focused Ultrasound for Prostate Cancer. Available at URL address: <http://www.ecri.org>
  21. El Fegoun AB, Barret E, Prapotnich D, Soon S, Cathelineau X, Rozet F, et al. Focal therapy with high-intensity focused ultrasound for prostate cancer in the elderly. A feasibility study with 10 years follow-up. *Int Braz J Urol*. 2011 Mar-Apr;37(2):213-9; discussion 220-2.
  22. Fujisue Y, Azuma H, Inamoto T, Komura K, Agarwal PK, Masuda H, et al. Neoadjuvant hormonal therapy does not impact the treatment success of high-intensity focused ultrasound for the treatment of localized prostate cancer. *World J Urol*. 2011 Oct;29(5):689-94.
  23. Ganzer R, Robertson CN, Ward JF, Brown SC, Conti GN, Murat FJ, et al. Correlation of prostate-specific antigen nadir and biochemical failure after high-intensity focused ultrasound of localized prostate cancer based on the Stuttgart failure criteria - analysis from the @-Registry. *BJU Int*. 2011; 108(8 Pt 2):E196-201.
  24. Hayes, Inc. Ultrasound-Guided High-Intensity Focused Ultrasound for Primary Treatment of Localized Prostate Cancer. September 8, 2016 (Annual Review August 16, 2017).
  25. Hayes, Inc. High-Intensity Focused Ultrasound for Salvage Therapy of Recurrent Prostate Cancer. Medical Technology Directory. March 30, 2017.
  26. Hayes, Inc. Magnetic Resonance-Guided Focused Ultrasound Therapy (ExAblate; InSightec Ltd.) for Palliation of Painful Bone Metastases, March 3, 2016
  27. Hummel S, Paisley S, Morgan A, Currie E, Brewer N. Clinical and cost-effectiveness of new and emerging technologies for early localised prostate cancer: a systematic review. *Health Technol Assess*. 2003;7(33): iii, ix-x, 1-157.
  28. Inoue Y, Goto K, Hayashi T, Hayashi M. Transrectal high-intensity focused ultrasound for treatment of localized prostate cancer. *Int J Urol*. 2011 May;18(5):358-62.



29. Izadifar Z, Izadifar Z, Chapman D, Babyn P. An Introduction to High Intensity Focused Ultrasound: Systematic Review on Principles, Devices, and Clinical Applications. *J Clin Med*. 2020 Feb 7;9(2):460. doi: 10.3390/jcm9020460. PMID: 32046072; PMCID: PMC7073974.
30. Kanthabalan A, Peters M, Van Vulpen M, et al. Focal salvage high intensity focused ultrasound in radiorecurrent prostate cancer. *BJU Int* 2017;120:246-256.
31. Koch MO, Gardner T, Cheng L, Fedewa RJ, Seip R, Sanghvi NT. Phase I/II trial of high intensity focused ultrasound for the treatment of previously untreated localized prostate cancer. *J Urol*. 2007 Dec;178(6):2366-70; discussion 2370-1.
32. Koch MO. High intensity focused ultrasound treatment for prostate cancer. Wein: Campbell-Walsh Urology. 10th ed. W. B. Saunders. Philadelphia, PA; 2011.
33. Lawrentschuk N, Finelli A, Van der Kwast TH, Ryan P, Bolton DM, Fleshner NE, et al. Salvage radical prostatectomy following primary high intensity focused ultrasound for treatment of prostate cancer. *J Urol*. 2011 Mar;185(3):862-8. Epub 2011 Jan 15.
34. Lukka H, Waldron T, Chin J, Mayhew L, Warde P, Winkquist E, et al. High-intensity focused ultrasound for prostate cancer: a practice guideline. *Can Urol Assoc J*. 2010 Aug;4(4):232-6.
35. Lukka H, Waldron T, Chin J, Mayhew L, Warde P, Winkquist E, et al.; Genitourinary Cancer Disease Site Group of Cancer Care Ontario's Program in Evidence-Based Care. High-intensity focused ultrasound for prostate cancer: a systematic review. *Clin Oncol (R Coll Radiol)*. 2011 Mar;23(2):117-27. Epub 2010 Oct 6.
36. McLaughlin PW, Liss AL, Nguyen PL, et al; Expert Panel on Radiation Oncology Prostate. ACR Appropriateness Criteria® Locally Advanced, High-Risk Prostate Cancer. *Am J Clin Oncol*. 2017 Feb;40(1):1-10. PMID: 28059930.
37. Misraï V, Rouprêt M, Chartier-Kastler E, Comperat E, Renard-Penna R, Haertig A, et al. Oncologic control provided by HIFU therapy as single treatment in men with clinically localized prostate cancer. *World J Urol*. 2008 Oct;26(5):481-5.
38. Muto S, Yoshii T, Saito K, Kamiyama Y, Ide H, Horie S. Focal therapy with high-intensity-focused ultrasound in the treatment of localized prostate cancer. *Jpn J Clin Oncol*. 2008 Mar;38(3):192-9.
39. National Cancer Institute (NCI). Prostate Cancer (PDQ®): Treatment. Health Professional Version. Updated March 11, 2024. Available at: [https://www.cancer.gov/types/prostate/hp/prostate-treatment-pdq#\\_84](https://www.cancer.gov/types/prostate/hp/prostate-treatment-pdq#_84). (Accessed March 25, 2024)
40. National Comprehensive Cancer Network® (NCCN). Clinical Guidelines in Oncology™. Prostate Cancer Version 3.2024. Available at (Accessed March 25, 2024).

41. Palermo G, Totaro A, Sacco E, et al. High intensity focused ultrasound as first line salvage therapy in prostate cancer local relapse after radical prostatectomy: 4-year follow-up outcomes. *Minerva Urol Nefrol* 2017;69:93-100
42. Rischmann P, Gelet A, Riche B, et al. Focal high intensity focused ultrasound of unilateral localized prostate cancer: a prospective multicentric hemiablation study of 111 patients. *Eur Urol* 2017;71:267-273.
43. Schmid FA, Schindele D, Mortezaei A, Spitznagel T, Sulser T, Schostak M, et al. Prospective multicentre study using high intensity focused ultrasound (HIFU) for the focal treatment of prostate cancer: Safety outcomes and complications. *Urol Oncol.* 2020 Apr;38(4):225-230. Shah TT, Peters M, Kanthabalan A, McCartan N, Fatola Y, van der Voort van Zyp J, van Vulpen M, Freeman A, Moore CM, Arya M, Emberton M, Ahmed HU. PSA nadir as a predictive factor for biochemical disease-free survival and overall survival following whole-gland salvage HIFU following radiotherapy failure. *Prostate Cancer Prostatic Dis.* 2016 Sep;19(3):311-6. doi: 10.1038/pcan.2016.23. Epub 2016 Jul 19. PMID: 27431499; PMCID: PMC4983180.
44. Uddin Ahmed H, Cathcart P, Chalasani V, et al. Whole-gland salvage high-intensity focused ultrasound therapy for localized prostate cancer recurrence after external beam radiation therapy. *Cancer* 2012;118:3071- 3078

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