

**HIGH INTENSITY FOCUSED ULTRASOUND**

**Effective Date:** August 25, 2017

**Review Dates:** 10/12, 10/13, 8/14, 8/15, 5/16, 5/17, 5/18

**Date Of Origin:** October 10, 2012

**Status:** Current

**I. POLICY/CRITERIA**

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

- Benign prostatic hypertrophy
- Central nervous system diseases/disorders (e.g., brain cancer and stroke)
- Fractures
- Liver metastasis from colon and stomach cancer
- Osteosarcoma/bone tumors
- Pancreatic cancer
- Primary liver cancer
- Prostate cancer, primary therapy (HIFU for salvage therapy may be considered medically necessary as per NCCN guidelines; see section IV. Description)

Note: Other emerging local therapies for prostate cancer, including Vascular Targeted Photodynamic Therapy (VTP), warrant further study and are also considered experimental and investigational.

- Renal cancer
- Thyroid nodules
- Vulvar dystrophy
- Palliation of bone metastases

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

**II. MEDICAL NECESSITY REVIEW**

Required

Not Required

Not Applicable

### 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); 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. The role of ablation with HIFU as an alternative to radical prostatectomy or RT remains uncertain.

**National Comprehensive Cancer Network® (NCCN®):** While the 2017 NCCN Clinical Practice Guidelines in Oncology, Prostate Cancer, do not include HIFU among the primary therapeutic options for localized prostate cancer, they do include HIFU among the salvage therapeutic options for localized prostate cancer.

**American Urological Association (AUA):** The AUA Guideline for the Management of Clinically Localized Prostate Cancer reports that standard options for the management of clinically localized prostate cancer include watchful waiting and active surveillance, interstitial prostate brachytherapy, external beam radiotherapy, radical prostatectomy, as well as primary hormonal therapy. The panel did not include other treatment options in the analysis and recommendations

due to a combination of factors, including limited published experience and short-term follow-up as well as the similar issues that affected evaluations of other treatment options (Thompson, et al., 2007). This guideline was reviewed and the validity confirmed in 2011.

**American College of Radiology (ACR) Appropriateness Criteria®:** The 2011 American College of Radiology Expert Panel on Radiation Oncology-Prostate 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 a newer treatment for early stage prostate cancer. The ACS states that new treatments could be used either as the first type of treatment or after radiation therapy in cases where it was not successful. HIFU treatment has been used more in Europe, but it is not available outside of clinical trials in the United States at this time. Studies are now under way to determine its safety and effectiveness (ACS, 2012).

**National Cancer Institute (NCI):** HIFU is not discussed in the 2012 Prostate Cancer Treatment health professional version Physician Data Query (PDQ). In the 2011 Prostate Cancer Treatment patient version Physician Data Query (PDQ) HIFU is listed as a new type of treatment being tested in clinical trials.

## V. CODING INFORMATION

### ICD-10 Diagnosis:

*See criteria above.*

### CPT/HCPCS codes:

Not covered

C9734 Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with or without magnetic resonance (MR) guidance (*OP facility claims only*)

C9747 Ablation of prostate, transrectal, high intensity focused ultrasound (HIFU) including image guidance (*May be covered for salvage therapy per NCCN guidelines.*)

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*

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