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. 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 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®): The 2019 NCCN Clinical Practice Guidelines in Oncology, Prostate Cancer, recommends HIFU and cryosurgery as options for radiation therapy recurrence in the absence of metastatic disease.

American Urological Association (AUA): The 2017 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 recommends that clinicians should inform low-risk prostate cancer patients who are considering focal therapy or high intensity focused ultrasound (HIFU)
that these interventions are not standard care options because comparative outcome evidence is lacking.

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, 2016).

National Cancer Institute (NCI): In the 2019 Prostate Cancer Treatment health professional version Physician Data Query (PDQ) HIFU is listed as a treatment option under clinical evaluation for patients with stage I and II prostate cancer. It been reported in case series to produce good local disease control. However, it has not been directly compared with more standard therapies, and experience with it is more limited. HIFU is not discussed in the 2012 Prostate Cancer Treatment health professional version PDQ. In the 2011 Prostate Cancer Treatment patient version 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:
C9747 Ablation of prostate, transrectal, high intensity focused ultrasound (HIFU) including image guidance  (May be covered for salvage therapy per NCCN guidelines.)

Not covered
C9734 Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with or without magnetic resonance (MR) guidance (OP facility claims only)

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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All Current Procedure Terminology (CPT) codes, descriptions, and other data are copyrighted by the American Medical Association.

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Priority Health’s medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan’s ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

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