High-Intensity Focused Ultrasound for Prostate Cancer

Policy Number:	**M20200625073**
Effective Date:	**8/1/2020**
Sponsoring Department:	**Health Care Services**
Impacted Department(s):	**Health Care Services**

Type of Policy: ☐ Internal ☒ External

Data Classification: ☐Confidential ☐Restricted ☒Public

Applies to (Line of Business):

☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒MediSource; ☒MediSource Connect; ☐Child Health Plus; ☒Essential Plan
☒ Medicare, if yes, which plan(s): ☒MAPD; ☐PDP; ☒ISNP; ☒CSNP
☒ Commercial, if yes, which type: ☒Large Group; ☒Small Group; ☒Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes ☐ No☒

Purpose and Applicability:

To set forth Independent Health's medical necessity criteria for **High-Intensity Focused Ultrasound (HIFU)** for **prostate cancer**.

Policy:

Commercial, Self-Funded and Medicare Advantage:

1. Whole gland HIFU is considered medically necessary as a local treatment for recurrent prostate cancer following radiation therapy (RT) when ALL of the following criteria are met:
    - Life expectancy greater than five (5) years; AND
    - Low-Risk (Low risk is defined as PSA <10ng/ml AND Gleason Score less than 7 AND Clinical stage T1-T2a);
    - AND

- Positive biopsy, recent (i.e., repeat), completed due to suspicion of local recurrence of prostate cancer; AND
- Absence of metastatic disease.

- Documentation provided by the requesting provider includes consensus of appropriate treatment from the patient's surgeon, oncologist, and radiologist. The requesting provider may contribute to the consensus provided his/her specialty is surgery, oncology, or radiology. Included in the documentation are the specialists' names providing the consensus.

2. Exclusion Criteria (NONE of the below are allowed)
   - Life expectancy < 10 years
   - Prostate cancer subtype other than adenocarcinoma
   - Post-radiation therapy androgen deprivation therapy
   - Post-radiation therapy anal/rectal stenosis or rectal wall thickness >6 mm by TRUS or MRI

MediSource, MediSource Connect and Essential Plan:
MediSource, MediSource Connect and Essential Plan cover HIFU for prostate cancer utilizing the Commercial and Self-Funded criteria above.

Background:
Prostate cancer, which has a median age at diagnosis is 66 years, may be cured when localized, and frequently responds to treatment when widespread. The rate of tumor growth varies from very slow to moderately rapid, and some patients may have prolonged survival even after the cancer has metastasized to distant sites, such as bone.

Treatment of prostate cancer is variable depending on the stage and grade of the disease. Treatment options can range from active surveillance in the case of slow-growing tumors to radical prostatectomy for aggressive prostate cancers. Currently, usual treatment options include surgery, radiation therapy, hormone therapy, chemotherapy, biologic therapy, and bisphosphonate therapy.

The goals of the minimally invasive therapy ultrasound guided HIFU for localized prostate cancer are to use focused ultrasound waves to thermally ablate the cancerous prostate gland and achieve complete tumor control, while avoiding the morbidity associated with more invasive therapies like prostatectomy, such as adverse effects on urinary and sexual function. Common side effects included impotence, infravesical obstruction, urethral stricture, and urinary incontinence. The Food and Drug Administration has approved several HIFU devices in the 510 (k) approval process.

The National Comprehensive Cancer Network (NCCN) recommends only cryosurgery and high-intensity focused ultrasound (HIFU) as options for recurrent prostate cancer previously treated with radiation therapy in the absence of metastatic disease. The NCCN guidelines provide criteria for the use of HIFU.

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

Pre-Authorization Required? Yes ☒ No ☐

Pre-authorization is required for this service.

Definitions

High-Intensity Focused Ultrasound (HIFU) is a minimally invasive (transrectal) treatment that generates heat through sound energy to destroy tumor tissue. Sound waves produced by an ultrasonic transducer mounted on an endorectal probe penetrate the rectal wall and ablate either the entire prostate gland or focal areas containing tumor while avoiding damage to normal tissue.

Prostate cancer is commonly detected through routine screening of prostate-specific antigen (PSA) levels. In its early stages, prostate cancer is generally asymptomatic; however, in more advanced stages, symptoms of prostate cancer may include urinary obstruction, hematospermia, prostatic bleeding, erectile dysfunction, and bone pain.

References

Related Policies, Processes and Other Documents

N/A

Non-Regulatory references

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Pisters L, Spiess P. Cryotherapy and other ablative techniques for the initial treatment of prostate cancer. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed onNovember 1, 2023)

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New York State Department of Health [web site]. New York State Medicaid Program Physician Procedure Codes. Section 5 – Surgery. April 2023 . Available at: https://www.emedny.org/ProviderManuals/Physician/PDFS/Physician%20Procedure%20Codes%20Sect5.pdf Accessed November 1, 2023

United States Food and Drug Administration (FDA) [web site]. Ablatherm 510 (k) Premarket Notification. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K153023 Accessed November 1, 2023

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This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No☐

Revision Date	Owner	Notes
1/1/2024	Health Care Services	Revised
1/1/2023	Health Care Services	Revised
7/1/2022	Health Care Services	Reviewed
8/1/2021	Health Care Services	Revised