

Corporate Medical Policy

High-Intensity Focused Ultrasound for Treatment of Prostate Cancer

File Name: high_intensity_focused_ultrasound_for_treatment_of_prostate_cancer
Origination: 06/2008
Last CAP Review: 6/2011
Next CAP Review: 6/2012
Last Review: 6/2011

Description of Procedure or Service

Prostate cancer continues to be the most common cancer diagnosis except skin cancer and, despite a decreasing trend in mortality, remains second only to lung cancer. There are several viable treatment options, including watchful waiting, surgery, radiation, and thermal or hormonal therapies.

Radical prostatectomy has long been regarded as appropriate therapy for men with organ-confined prostate cancer. Despite excellent five to ten year survival rates after radical prostatectomy for organ-confined disease, surgery is associated with significant morbidity, including blood loss due to transfusion-related complications, erectile dysfunction and stress incontinence. In addition, surgical intervention is not typically considered for men whose life expectancy is less than ten years.

For men whose life expectancy is less than ten years or who are not appropriate for surgery, three-dimensional radiotherapy, brachytherapy and cryosurgical ablation of the prostate are alternative treatment options. However, in the case of treatment failure, these treatments cannot be repeated except for cryotherapy. And salvage radical prostatectomy is associated with a high morbidity rate.

High-intensity focused ultrasound (HIFU) is a noninvasive technique that delivers intense ultrasound energy with consequent heat destruction of tissue at a specific focal distance from the probe without damage to tissue in the path of the ultrasound beam and without an increase in metastasis formation. HIFU induces complete coagulative necrosis of a tumor without surgical exposure or insertion of instruments into the lesion.

The patient is given either spinal or general anesthesia and depending on which device is used, is placed in either the dorsal lithotomy position or on his right side. The HIFU probe is inserted transrectally to the prostate gland. The probe emits a precise ultrasound beam creating a sudden temperature rise that destroys the targeted tissue. Real-time monitoring is done by ultrasound or magnetic resonance imaging (MRI). The procedure takes one to three hours.

See also related policy: "MRI-Guided High Intensity Ultrasound Ablation of Uterine Fibroids"

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

High-intensity focused ultrasound (HIFU) for the treatment of prostate cancer is considered investigational. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

High-Intensity Focused Ultrasound for Treatment of Prostate Cancer

When High-Intensity Focused Ultrasound for Treatment of Prostate Cancer is covered

Not applicable.

When High-Intensity Focused Ultrasound for Treatment of Prostate Cancer is not covered

The use of high-intensity focused ultrasound (HIFU) for the treatment of prostate cancer is considered investigational.

Use for the palliative treatment of bone metastases is also considered investigational.

Policy Guidelines

The available peer-reviewed published literature consists mostly of non-randomized studies and uncontrolled case series studies. The long-term efficacy and safety of HIFU prostate cancer treatment has not been established in controlled clinical trials.

MRgFUS is only FDA-approved for the treatment of uterine fibroids. MRgFUS is being investigated for use in several applications that are not currently approved by the FDA. There are preliminary reports of safety and efficacy in small numbers of patients. Due to a lack of regulatory approval and insufficient evidence of the impact on health outcomes, MRgFUS is considered investigational for treatment of other benign and malignant tumors including the palliative treatment of bone metastases.

HIFU is increasingly used for limited application in Asia and Europe; however, these studies have all been preliminary, and further investigation will be necessary before the widespread use of HIFU can be recommended.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: no specific code

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Gardner TA, Koch MO. Prostate cancer therapy with high-intensity focused ultrasound. *Clin Genitourin Cancer*. 2005; 4(3): 187-192

Uchida T, Baba S, Irie A, Soh S, Masumori N, Tsukamoto T, et al. Transrectal high-intensity focused ultrasound in the treatment of localized prostate cancer: a multicenter study. *Hinyokika Kyo*. 2005 Oct; 51(10): 651-8

Uchida T, Ohkusa H, Nagata Y, et al. Treatment of localized prostate cancer using high-intensity focused

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ultrasound. *BJU International* 2006; 97(1): 56-61

National Institute for Clinical Excellence (NICE). Guidance for high-intensity focused ultrasound for prostate cancer. Interventional Procedure Guidance 118. London, UK: NICE; March 2005. Retrieved 5/29/08 from <http://www.nice.org.uk/nicemedia/pdf/ip/IPG118guidance.pdf>

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Ahmed HU, Zacharakis E, Dudderidge T, et al. High-intensity-focused ultrasound in the treatment of primary prostate cancer: the first UK series. *Br J Cancer*. 2009; 101: 19-26.

Dubinsky TJ, Cuevas C, Dighe MK, et al. High-intensity focused ultrasound: current potential and oncologic applications. *AJR Am J Roentgenol*. 2008 Jan; 109(1): 191-9.

Policy Implementation/Update Information

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| 7/28/08 | New policy issued. High-intensity focused ultrasound is considered investigational for the treatment of prostate cancer. (adn) |
| 01/05/09 | Coding update. Added code 0197T to the Billing/Coding section. (adn) |
| 3/30/09 | Code 0197T removed from policy. (adn) |
| 6/22/10 | Policy Number(s) removed (amw) |
| 9/28/10 | Added the following statement to the When HIFU Is Not Covered section: Use for the palliative treatment of bone metastases is also considered investigational. Updated Policy Guidelines section. Specialty Matched Consultant Advisory Panel review meeting 8/25/10. No change in policy statement. (adn) |
| 7/19/11 | Policy Guidelines and References updated. No change in policy statement. Specialty Matched Consultant Advisory Panel review 6/29/11. Policy accepted as written. (adn) |

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.