



Status

Active

Medical and Behavioral Health Policy

Section: Surgery

Policy Number: IV-118

Effective Date: 01/22/2014

Blue Cross and Blue Shield of Minnesota medical policies do not imply that members should not receive specific services based on the recommendation of their provider. These policies govern coverage and not clinical practice. Providers are responsible for medical advice and treatment of patients. Members with specific health care needs should consult an appropriate health care professional.

ULTRASOUND-GUIDED HIGH-INTENSITY FOCUSED ULTRASOUND ABLATION FOR TREATMENT OF PROSTATE CANCER AND OTHER TUMORS

Description: Ultrasound-guided high-intensity focused ultrasound (HIFU) ablation is a minimally invasive technique that delivers intense ultrasound energy with subsequent heat destruction of tissue at a specific focal distance from the probe. A proposed benefit of this treatment is that it allows treatment of a tumor without damaging intervening and surrounding tissue, eliminating the need for incisions and possibly shortening healing time. Although ultrasound-guided HIFU has been investigated for treatment of several different types of tumors, prostate cancer is the primary indication under investigation at this time.

In the prostate cancer setting, ultrasound-guided HIFU is being studied as primary treatment of clinically localized prostate cancer, as well as salvage therapy after radical prostatectomy and external-beam radiation therapy. It may be used alone or in conjunction with transurethral resection of the prostate (TURP). Under ultrasound guidance, the HIFU probe is inserted transrectally to the prostate gland where it emits a precise ultrasound beam and creates a sudden temperature that destroys the targeted tissue. The procedure takes one to three hours to complete.

To date, no device using ultrasound-guided HIFU technology has received premarket approval (PMA) or 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) for the treatment of prostate cancer or any other cancer. Two ultrasound-guided transrectal devices are currently under investigation: the Sonablate 500 (Focus Surgery, Inc.) and the Ablatherm (EDAP-TMS).

Note: MRI-Guided High-Intensity Focused Ultrasound Ablation for Uterine Fibroids and Other Tumors is discussed in a separate policy (IV-119).

Policy: The use of ultrasound-guided high-intensity focused ultrasound (HIFU) ablation for treatment of prostate cancer, or any other cancer, is considered **INVESTIGATIVE** due to the lack of necessary regulatory approval from the U.S. Food and Drug Administration (FDA).

Coverage: Blue Cross and Blue Shield of Minnesota medical policies apply generally to all Blue Cross and Blue Plus plans and products. Benefit plans vary in coverage and some plans may not provide coverage for certain services addressed in the medical policies.

Medicaid products and some self-insured plans may have additional policies and prior authorization requirements. Receipt of benefits is subject to all terms and conditions of the member's summary plan description (SPD). As applicable, review the provisions relating to a specific coverage determination, including exclusions and limitations. Blue Cross reserves the right to revise, update and/or add to its medical policies at any time without notice.

For Medicare NCD and/or Medicare LCD, please consult CMS or National Government Services websites.

Refer to the Pre-Certification/Pre-Authorization section of the Medical Behavioral Health Policy Manual for the full list of services, procedures, prescription drugs, and medical devices that require Pre-certification/Pre-Authorization. Note that services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial of claims may result if criteria are not met.

Coding: *The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.*

CPT:

76999 Unlisted ultrasound procedure (eg, diagnostic, interventional)

Policy History: **Developed January 12, 2011**

Most recent history:

Reviewed January 11, 2012

Reviewed January 9, 2013

Reviewed January 8, 2014

Cross Reference: MRI-Guided High-Intensity Focused Ultrasound Ablation of Uterine Fibroids and Other Tumors, IV-119

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