Magnetic Resonance Imaging (MRI) Targeted Biopsy of the Prostate

Prostate biopsy typically is performed in individuals who have an elevated prostate-specific antigen (PSA) level or who present with symptoms. The purpose of the biopsy is to determine whether cancer is present and to determine tumor grade. Tumor grade (Gleason score) is a major determinate in whether a patient is eligible for active surveillance (lower grade tumors) or factor for determining definitive intervention (higher grade tumors). Patients on active surveillance undergo periodic follow-up biopsies for assessment of cancer progression (upgrading of Gleason score).

Prostate biopsies are currently performed using transrectal ultrasound (TRUS) guidance with a 12-core sampling strategy. TRUS was introduced in the late 1980s; with this technique, tissue cores are obtained systematically under ultrasound guidance throughout the whole prostate, although this approach still represents blind biopsy of the prostate as to the location of possible cancer. Prior to the 12-core sampling, 6-core (sextant) sampling was thought to miss too many cases of cancer. However, the 12-core sampling method may over-diagnose clinically insignificant disease and miss diagnosis of clinically significant disease. Compared with subsequent prostatectomy, TRUS underestimates tumor grade up to 40% of the time and too often detects clinically insignificant disease.

Therefore, the ideal biopsy strategy would only identify individuals with prostate cancer of clinical significance to direct interventional therapy, and to minimize the detection of clinically insignificant prostate cancer and the risk of consequent overtreatment.

For individuals undergoing an initial biopsy for an elevated PSA, the systematic 12-core TRUS biopsy detection rate for prostate cancer is approximately 40% to 45%. If an initial 12-core biopsy is negative, and there is still a clinical suspicion of cancer, subsequent serial 12-core biopsies may detect cancer, or, other biopsy techniques such as transperineal template-guided saturation biopsy (in which 30-80 cores are typically obtained) may be used. Saturation biopsy allows for anterior and apical sampling and may detect significant cancer, but also results in oversampling of insignificant cancers. In addition, transperineal biopsy requires general anesthesia and is associated with increased morbidity.

Multiparametric magnetic resonance imaging (mpMRI) includes anatomic T2-weighted imaging for localization of the normal gland and cancer foci and 2 functional imaging techniques: diffusion-weighted and perfusion imaging. The mpMRI evaluation permits identifying tumor location and extent, oversampling areas of interest, undersampling or not sampling nontarget areas, and sampling of clinically significant disease (higher grade tumor). T2-weighted images reflect water content of tissues and can define the zonal anatomy of the prostate and the presence of prostate cancer as focal areas of low-signal intensities. Degree of intensity decrease differs with Gleason score; higher Gleason score prostate cancer shows lower signal intensities. False-positive findings can occur with benign abnormalities, including prostatitis, atrophy, fibrosis, gland hyperplasia, or irradiation or hormonal treatment effects. Diffusion-weighted images measure the random motion of water molecules. Low diffusion coefficients are associated with prostate cancer, and there is an inverse correlation between these values and Gleason score; however, confidence intervals overlap. Perfusion imaging allows assessment of contrast kinetics in focal lesions; prostate cancer typically enhances faster and to a
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greater extent than the surrounding prostate; however, nonspecificity of patterns limits the usefulness of this technique in isolation.

Several methods of MRI guidance are available for prostate biopsy: cognitive (or visual), direct (“in-bore”), and MRI-ultrasound (US) fusion (visual targeted or software-based targeted). Image fusion is the process of combining information from more than 1 image into a single image, which may be more informative than any of the images separately. To date, no prospective comparison of the 3 methods has been made. Based on MRI, suspicious areas are identified (ie, regions of interest) and subjected to targeted biopsy.

With the visual method, the ultrasound operator simply aims the biopsy needle at the area of the prostate where prior MRI indicated the lesion. This method requires the MRI unit, a conventional TRUS facility, and an ultrasound operator with no additional training beyond TRUS biopsy. The disadvantage is the potential for human error in the extrapolation from MRI to TRUS without an overlay of the images.

Direct (in-bore) MRI-targeted biopsy requires the MRI tube, fusion of a prior MRI demonstrating a lesion with a contemporaneous MRI to confirm biopsy needle location, and needles introduced into the regions of interest. Serial MRI scans are performed to confirm biopsy needle placement. Studies have demonstrated that in-bore MRI-targeted biopsies have a median cancer detection rate significantly higher than random biopsies; however, this technique is time-consuming and costly, including the in-bore time and the 2 MRI sessions necessary. In addition, only suspicious lesions are sampled, because tissues with a “normal” appearance on MRI are not obtained.

MRI-TRUS fusion biopsy, done visually or using software, superimposes preprocedure (stored) MRI over an intraprocedure (real-time) ultrasound to direct the biopsy needle to an ultrasound region of interest defined by the mpMRI.

Proposed clinical indications for use of MRI-guided prostate biopsy include: (1) as initial biopsy, (2) rebiopsy after a first negative standard biopsy in individuals with persistent suspicion of disease, including those with persistently increased PSA, suspicious digital rectal exam, previous biopsy with an atypical focus on histology, or extensive high-grade prostatic intraepithelial neoplasia, (3) follow-up for active surveillance to determine initial eligibility for active surveillance and assessing progression disease over time, and (4) for local recurrence post radical prostatectomy, post external beam radiotherapy, or after high-intensity focused ultrasound.

Several MRI-US fusion software-based targeted prostate biopsy platform specifications have received 510(k) marketing clearance from the FDA. Fusion software include: Artemis™ (Eigen), BioJet™ (D&K Technologies), BiopSee® (MedCom), Realtime Visual Sonography (Hitachi), UroNav™ (Invivo/Philips), Urostation® (Koelis), and Virtual Navigator (Esaote).

***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

Magnetic Resonance Imaging (MRI) Targeted Biopsy of the Prostate is considered investigational for all applications. 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.
Magnetic Resonance Imaging (MRI) Targeted Biopsy of the Prostate

When Magnetic Resonance Imaging (MRI) Targeted Biopsy of the Prostate is covered

Not applicable.

When Magnetic Resonance Imaging (MRI) Targeted Biopsy of the Prostate is not covered

Magnetic resonance imaging (MRI) targeted biopsy of the prostate is considered investigational for all applications.

Policy Guidelines

Magnetic resonance imaging (MRI) allows for targeted biopsy of suspicious lesions in the prostate, rather than blind biopsy, as is done with the current standard of care, transrectal ultrasound (TRUS)-guided biopsy. The use of MRI-guided prostate biopsy may identify areas in the prostate that harbor high-grade tumor, minimizing the detection of clinically insignificant cancers and possible overtreatment and distinguishing individuals more appropriately managed by active surveillance from individuals recommended for definitive intervention.

The evidence for the use of MRI-targeted diagnostic or surveillance biopsy of the prostate includes numerous prospective and retrospective studies of paired cohorts and systematic reviews and meta-analyses of these studies. Relevant outcomes are overall survival, disease-specific survival, test accuracy, morbid events, and quality of life. Systematic reviews of the use of MRI-guided prostate biopsy have shown the technology may diagnose more high-grade cancers than TRUS biopsy and fewer low-grade cancers, which may stratify patients for treatment versus active surveillance. In active surveillance, it has not been shown that this technique can detect patients who have progressed and need definitive intervention. It is unknown whether use of this technique will translate into positive clinically meaningful outcomes in terms of survival or quality of life. Further prospective evaluation of MRI-guided techniques is needed to determine whether this approach results in improved health outcomes, whether this approach would replace the standard biopsy protocol, or whether it would be performed in addition to TRUS-guided biopsy. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 service codes: No specific code

It would likely be reported with a prostate biopsy code (55700, 55705) and the MRI guidance code (77021).

Add-on code 0443T was developed for the Precision Biopsy ClariCore Optical Biopsy System® which is not yet approved for use by the FDA. It would be used with code 55700 and is reported only once per session.

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.
Magnetic Resonance Imaging (MRI) Targeted Biopsy of the Prostate

Scientific Background and Reference Sources

Sr. Medical Director review 10/2015

Policy Implementation/Update Information

11/24/15  New medical policy issued. Magnetic resonance imaging (MRI) targeted biopsy of the prostate is considered investigational. Sr. Medical Director review 10/2015. (lpr)

7/26/16  Updated Billing/Coding section: Add-on code 0443T was developed for the Precision Biopsy ClariCore Optical Biopsy System® which is not yet approved for use by the FDA. It would be used with code 55700 and is reported only once per session. Specialty Matched Consultant Advisory Panel review 6/29/2016. No change to policy statement. (an)

12/30/16  Minor changes to description section. No change to policy statement. (an)

6/30/17  Specialty Matched Consultant Advisory Panel review 5/26/2017. No change to policy statement. (an)

6/29/18  Minor revisions to Description section. Specialty Matched Consultant Advisory Panel review 5/23/2018. No change to policy statement. (an)

11/9/18  Code 55706 removed from Billing/Coding section. (an)

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.