Medical Policy
Magnetic Resonance Imaging—Targeted Biopsy of the Prostate

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Policy Number: 747
BCBSA Reference Number: 7.01.152
NCD/LCD: N/A

Related Policies
- Saturation Biopsy for Diagnosis and Staging of Prostate Cancer, #307
- Focal Treatments for Prostate Cancer, #733

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

Magnetic resonance imaging—targeted biopsy of the prostate is considered to be INVESTIGATIONAL.

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products. 
See below for situations where prior authorization may be required or may not be required.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

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CPT Codes / HCPCS Codes / ICD Codes
Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.
The following codes are included below for informational purposes only; this is not an all-inclusive list.

There is no specific CPT code for this procedure.

**Description**

**Prostate Biopsy**

Prostate biopsy typically is performed in men 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).

Biopsies to diagnose prostate cancer 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 overdiagnose 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 men 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 men 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 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) rebiopsy after a first negative standard biopsy in men 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, (2) follow-up for active surveillance to determine initial eligibility for active surveillance and assessing progression disease over time, (3) as initial biopsy, and (4) for local recurrence post radical prostatectomy, post external beam radiotherapy, or after highintensity focused ultrasound.

Summary
The evidence for the use of magnetic resonance imaging–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.

Policy History

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Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:
- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

References


