Corporate Medical Policy

Magnetic Resonance Imaging (MRI) Targeted Biopsy of the Prostate

File Name:	magnetic_resonance_imaging_mri_targeted_biopsy_of_the_prostate
Origination:	11/2015
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Description of Procedure or Service

The standard diagnostic procedure for prostate biopsy has been transrectal ultrasound (TRUS) guidance with a 12-core sampling strategy. However, this method may over-diagnose clinically insignificant (indolent) cancer and fail to detect clinically significant disease which should be treated. Multiparametric magnetic resonance imaging (mpMRI) with targeted biopsy of clinically significant disease is a proposed method to address these challenges.

An initial prostate biopsy usually occurs because of elevated serum prostate specific antigen (PSA) detected on routine screening or an abnormal digital rectal examination (DRE). 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 needs definitive intervention (higher grade tumors). Patients on active surveillance undergo periodic follow-up biopsies for assessment of cancer progression (upgrading of Gleason score).

If an initial 12-core biopsy is negative, and there is still a clinical suspicion of cancer, subsequent serial 12-core biopsies may be performed, or, other biopsy techniques such as transperineal template-guided or TRUS saturation biopsy (in which 30-80 cores are typically obtained) may be used. These alternative biopsy techniques may allow for anterior and apical sampling and increase cancer detection, but also result in oversampling of insignificant cancers. In addition, transperineal biopsy requires general anesthesia and is associated with increased morbidity.

Fusion imaging of mpMRI with TRUS

mpMRI supplements basic MRI to include four imaging parameters which combine anatomic imaging with functional and physiologic assessment. T1 and T2-weighted, diffusion-weighted, and dynamic contrast-enhanced imaging allow for assessment of differences in tissue and tumor water content and water motion and abnormal blood flow, which can be correlated with tumor grade, directing targeted biopsy to higher grade tumors.

mpMRI-TRUS fusion biopsy entails a planning session prior to the biopsy procedure during which the tumor target(s) are outlined on the MR images, and using vendor-specific software, the target map is loaded into the fusion system. At the time of the biopsy, the MRI target map data is fused to and aligned with the TRUS imaging data. Subsequently, the movement of the TRUS is linked to corresponding movement of the MRI so the biopsy can be performed under TRUS but using MRI guidance.

mpMRI is typically reported using a score which reflects the probability of the presence of clinically significant prostate cancer (ie Prostate Imaging-Reporting and Data System, or PI-RADS score). If a mpMRI is negative for a clinically significant tumor, a biopsy may be deferred, or a TRUS only guided biopsy may be performed, without overlay of the mpMRI and US images.

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).

Related Policies:
Focal Treatments for Prostate Cancer
Prostate Biopsies

This Medical Policy does not address direct (in-bore) MRI-targeted biopsies.

******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

BCBSNC will provide coverage for fusion imaging of multiparametric magnetic resonance imaging (mpMRI) with transrectal ultrasound (TRUS) to guide targeted biopsy of the prostate when it is determined to be **medically necessary** because the medical criteria and guidelines below are met.

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.

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

The use of fusion imaging of multiparametric magnetic resonance imaging (mpMRI) with transrectal ultrasound (TRUS) to guide targeted biopsy of the prostate may be considered **medically necessary** for:

1. Initial diagnosis of prostate cancer when a prior TRUS-guided biopsy is histologically negative or atypical or indeterminate, and
    a. serum prostate specific antigen (PSA) is persistently elevated or rising or
    b. there is an abnormal digital rectal examination (DRE)

OR

2. The patient has a diagnosis of prostate cancer International Society of Urological Pathology [ISUP] Grade Group 1 or Grade Group 2 (see Policy Guidelines) and is a candidate for active surveillance.

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

The use of fusion imaging of multiparametric magnetic resonance imaging (mpMRI) with transrectal ultrasound (TRUS) to guide targeted biopsy of the prostate is considered investigational when the above criteria are not met.

Policy Guidelines

In 2014, a new prostate cancer histologic grading system derived from Gleason score was developed by the International Society of Urological Pathology (ISUP). The grade groups are meant to better inform risk stratification of clinically localized prostate cancer and limit overtreatment. The grade groups range from 1-5, with grade group 1: Gleason score ≤6 (≤3+3) and grade group 2: Gleason score 7 (3+4).

For individuals who have a suspicion of prostate cancer who receive an MRI-targeted biopsy, the evidence includes numerous prospective and retrospective studies of paired cohorts, two randomized controlled trials and systematic reviews and meta-analyses of these studies comparing MRI-targeted biopsy with transrectal ultrasound (TRUS)-guided biopsy in detecting overall, clinically significant and insignificant prostate cancers. The relevant outcomes are overall survival, disease-specific survival, test accuracy, morbid events, and quality of life (QOL). Studies on the use of MRI-targeted prostate biopsy have shown that the technology may diagnose more clinically significant cancers than TRUS biopsy and fewer clinically insignificant cancers, which might stratify patients for treatment and active surveillance. Considering the prognostic value of risk stratification based on prostate biopsy, better diagnostic accuracy is likely to identify patients more accurately with clinically significant prostate cancer leading to changes in management that would be expected to result in clinically meaningful outcomes in terms of survival or QOL. The evidence is sufficient to determine that the technology results in a meaningful improvement in net health outcome.

For individuals who have prostate cancer and in active surveillance who receive an MRI-targeted biopsy, the evidence includes a systematic review and observational studies of paired cohorts comparing MRI-targeted biopsy with TRUS biopsy in detecting pathologic progression of prostate cancer in terms of Gleason score and detection of higher grade (Gleason score ≥7) cancer. The relevant outcomes are overall survival, disease-specific survival, test accuracy, morbid events, and QOL. Current evidence has suggested that, compared with TRUS biopsy, an MRI-targeted biopsy is better at detecting those patients in active surveillance who have progressed and need definitive intervention. With the greater ability to detect prostate cancer with a Gleason score 7 or higher, which is a critical parameter for definitive therapy in prostate cancer, use of this biopsy guidance technique is likely to translate into positive clinically meaningful outcomes (eg, survival, QOL) in this population. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version] 7.01.152, 10/15/15

Sr. Medical Director review 10/2015

BCBSA Medical Policy Reference Manual [Electronic Version] 7.01.152, 8/10/2017

BCBSA Medical Policy Reference Manual [Electronic Version] 7.01.152, 8/9/2018

Kasivisvanathan V, Rannikko AS, Borghi M, et al. PRECISION Study Group Collaborators. MRI-Targeted or Standard Biopsy for Prostate-Cancer
Diagnosis. N Engl J Med. 2018 May 10;378(19):1767-1777.

Drost FH, Osses DF, Nieboer D, et al. Prostate MRI, with or without MRI-targeted biopsy, and systematic biopsy for detecting prostate cancer. Cochrane Database Syst Rev. 2019 Apr 25;4:CD012663.

Rosenkrantz AB, Verma S, Choyke P, et al. Prostate Magnetic Resonance Imaging and Magnetic Resonance Imaging Targeted Biopsy in Patients with a Prior Negative Biopsy: A Consensus Statement by AUA and SAR. J Urol. 2016
Dec;196(6):1613-1618.

Jayadevan R, Felker ER, Kwan L, et al. Magnetic Resonance Imaging-Guided Confirmatory Biopsy for Initiating Active Surveillance of Prostate Cancer. JAMA Netw Open. 2019 Sep 4;2(9):e1911019.

BCBSA Medical Policy Reference Manual [Electronic Version] 7.01.152, 8/8/2019

National Comprehensive Cancer Network. Prostate Cancer. Version 4.2019.
https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed 23 September 2019

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)

7/1/19 Description section updated. Reference added. Specialty Matched Consultant Advisory Panel review 5/15/2019. No change to policy statement. (an)

10/1/19 Description and Policy Guidelines updated. Change to Policy statements to include medically necessary criteria for coverage of MRI-targeted biopsy of the prostate after an intial negative TRUS guided biopsy or in a patient who is a candidate for active surveillance. Medical director review. (hb)