Effective November 1, 2023, refer to CMS Reasonable and Necessary for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Magnetic Resonance Imaging (MRI) Targeted Biopsy of the Prostate

Policy #: 615
Latest Review Date: August 2023
Category: Medical
ARCHIVED 11/1/2023

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

Proprietary Information of Blue Cross and Blue Shield of Alabama
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POLICY:

Blue Advantage will treat **magnetic resonance imaging-targeted biopsy of the prostate** as a **covered benefit** and as medically necessary for diagnosis and active surveillance of prostate cancer.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Before a transrectal ultrasound-guided biopsy, a magnetic resonance imaging (MRI) scan can be used to pinpoint the location of suspicious lesions in the prostate. MRI permits a targeted biopsy (as opposed to a blind biopsy, which is the current standard of care). The use of an MRI-guided prostate biopsy serves two functions: (1) to identify areas in the prostate that could harbor a high-grade tumor; and (2) to divert attention from any clinically insignificant cancers not needing treatment. In accomplishing the secondary function, patients are placed into one of two categories: those only needing active surveillance; and those needing definitive intervention.

Prostate Cancer

Prostate cancer is the most commonly diagnosed cancer and the second leading cause of cancer deaths among men in the U.S., with an estimated 268,490 new cases and 34,500 deaths to occur in 2022.

Diagnosis

Diagnosis and grading of prostate cancer are performed by taking a biopsy of the prostate gland. A prostate biopsy typically is performed in men who have an elevated prostate-specific antigen level or who present with symptoms. The purpose of the biopsy is to determine whether cancer is present and to determine the tumor grade. Tumor grade (as measured by the Gleason score) is a major determinate in whether a patient is eligible for active surveillance (lower grade tumors) or definitive intervention (higher-grade tumors). Patients in active surveillance undergo periodic follow-up prostate biopsies to assess cancer progression (upgrading of Gleason score).

Prostate biopsies are commonly 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 underdiagnose 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 (See medical policy #396: Saturation Biopsy for Diagnosis and Staging of Prostate Cancer Policy). Saturation biopsy, which is considered investigational, 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
Multiparametric MRI includes anatomic T2-weighted imaging for localization of the normal gland and cancer foci and two 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 the 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, non-specificity 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 one image into a single image, which may be more informative than any of the images separately. Based on MRI, suspicious areas are identified (i.e., 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, a 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 the 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 two 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 intra-procedure (real-time) ultrasound to direct the biopsy needle to an ultrasound region of interest defined by the mpMRI.

Table 1. Techniques for Magnetic Resonance Imaging-Guided Prostate Biopsy

Method	MRI Requirement(s)	Description
Visual	• Prior MRI of prostate lesion	US operator targets the biopsy needle at the area of the prostate where prior MRI indicated a lesion during TRUS
Direct	• Prior MRI of prostate lesion • Contemporaneous MR images of biopsy needle in prostate lesion location	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
MRI-US fusion (visual targeted or software-based targeted)	• Prior MRI of prostate lesion • Overlay of prior MR image over real-time US	Prior MR image superimposed over an intra-procedure (real-time) US to direct the biopsy needle during TRUS MR: magnetic

MR: magnetic resonance; MRI: magnetic resonance imaging; TRUS: transrectal ultrasound; US: ultrasound.

Currently, there is available evidence comparing these three techniques in terms of their ability to detect overall or clinically significant prostate cancer. There is also evidence about whether the MRI-targeted biopsy should replace the systematic 12-core TRUS biopsy or whether the systematic 12-core TRUS biopsy should still be done.

Proposed clinical indications for use of MRI-guided prostate biopsy include: (1) as initial biopsy, (2) 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, (3) follow-up for active surveillance to determine initial eligibility for active surveillance and

assessing progression disease over time, (4) for local recurrence post radical prostatectomy, post external beam radiotherapy, or after high-intensity focused ultrasound.

KEY POINTS:

The most recent literature update was performed through June 21, 2023.

Summary of Evidence

For individuals who have a suspicion of prostate cancer who receive a magnetic resonance imaging (MRI)-targeted biopsy, the evidence includes numerous prospective and retrospective studies of paired cohorts, randomized controlled trials (RCTs), and systematic reviews and meta-analyses of these studies. Available studies compared MRI-targeted biopsy with transrectal ultrasonography (TRUS)-guided biopsy in detecting overall, clinically significant, and clinically insignificant prostate cancers. Relevant outcomes are overall survival (OS), disease-specific survival, test accuracy, morbid events, and quality of life. Studies on the use of MRI-targeted prostate biopsy have shown that the technology may diagnose more clinically significant cancers than TRUS-guided 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 with clinically significant prostate cancer, leading to changes in management that would be expected to result in clinically meaningful outcomes, such as survival or quality of life. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have prostate cancer and are in active surveillance who receive an MRI-targeted biopsy, the evidence includes a systematic review, an RCT, and observational studies of paired cohorts comparing MRI-targeted biopsy with TRUS-guided biopsy for detection of pathologic progression of prostate cancer in terms of Gleason score and detection of higher grade cancer (Gleason score ≥7). Relevant outcomes are disease-specific survival, test accuracy, morbid events, and quality of life. Current evidence has suggested that, compared with TRUS-guided 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, quality of life) in this population. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

National Comprehensive Cancer Network

National Comprehensive Cancer Network (v.1.2023) guidelines on prostate cancer makes the following statements on the use of multiparametric magnetic resonance imaging (MRI) in the staging of prostate cancer:

"Multiparametric MRI (mpMRI) can be used in the staging and characterization of prostate cancer."

“mpMRI may be used to better risk stratify patients who are considering active surveillance. Additionally, mpMRI may detect large and poorly differentiated prostate cancer (Grade Group ≥2) and detect extracapsular extension (T staging) and is preferred over CT for abdominal/pelvic staging. mpMRI has been shown to be equivalent to CT scan for pelvic lymph node evaluation.”

American College of Radiology
In 2022, the American College of Radiology issued appropriateness criteria for pretreatment detection, surveillance, and staging that stated:

"the clinical paradigm for prostate cancer diagnosis undoubtedly is rapidly moving toward MRI-targeted biopsies, based on abundant evidence that this can improve pretreatment evaluation of prostate cancer in many aspects, such as MRI-targeted biopsies are more concordant with radical prostatectomy in determining Gleason score; better selected candidates for active surveillance; and improved risk stratification"

"clinical pathways that incorporate MRI-targeted biopsy have been shown to increase the detection rate of clinically significant cancers, especially in patients who had a prior negative [transrectal ultrasound]-guided biopsy with continuous suspicion for prostate cancer and even in biopsy-naïve patients"

"MRI-targeted biopsy may be useful in a subset of patients with Gleason 3 + 4 for the purpose of identifying “favorable intermediate-risk” who may be considered for active surveillance"

"MRI-targeted biopsies have shown increasing usage for active surveillance during the past decade for reclassification of disease as part of determining eligibility or during followup....because some tumors are invisible on MRI and missed by MRI-targeted biopsies, even when performing an MRI-targeted biopsy as part of active surveillance, concurrent systemic biopsies cannot be omitted at the moment."

In 2022, the American College of Radiology issued appropriateness criteria for post-treatment follow-up of prostate cancer, noting that MRI-targeted biopsy may be appropriate for follow-up status post radical prostatectomy when there is clinical concern for residual disease. For follow-up in patients with clinical concern for residual or recurrent disease following nonsurgical local and pelvic treatments, MRI-targeted biopsy is usually appropriate.

National Institute for Health and Care Excellence
The National for Health and Care Excellence (2019) published guidelines on the diagnosis and management of prostate cancer with the following recommendations:

- “Do not routinely offer multiparametric MRI to people with prostate cancer who are not going to be able to have radical treatment.”
- “Offer multiparametric MRI as the first-line investigation for people with suspected clinically localised prostate cancer. Report the results using a 5-point Likert scale.”
- “Offer multiparametric MRI-influenced prostate biopsy to people whose Likert score is 3 or more.”

- "Consider omitting a prostate biopsy for people whose multiparametric MRI Likert score is 1 or 2, but only after discussing the risks and benefits with the person and reaching a shared decision. If a person opts to have a biopsy, offer systematic prostate biopsy."

American Urological Association and Society of Abdominal Radiology
In 2016, the American Urological Association and Society of Abdominal Radiology published a joint consensus statement on prostate MRI and MRI-targeted biopsy in patients with prior negative biopsy. The Association recommended:

"If a biopsy is recommended, prostate MRI and subsequent MRI-targeted cores appear to facilitate the detection of CS disease over standardized repeat biopsy. Thus, when high-quality prostate MRI is available, it should be strongly considered in any patient with a prior negative biopsy who has persistent clinical suspicion for prostate cancer and who is undergoing a repeat biopsy."

American Urological Association
In 2020, the American Urological Association published an update of the standard operating procedure on the use of multiparametric MIRI for the diagnosis, staging, and management of prostate cancer. The statement concluded that "data support prostate MRI use in men with a previous negative biopsy and ongoing concerns about increased risk of prostate cancer. Sufficient data now exist to support the recommendation of MRI before prostate biopsy in all men who have no history of biopsy. Currently, the evidence is insufficient to recommend MRI for screening, staging, or surveillance of prostate cancer."

U.S. Preventive Services Task Force Recommendations
No U.S. Preventive Services Task Force recommendations for MRI-guided or MRI/ultrasound fusion biopsy of the prostate have been identified.

KEY WORDS:
MRI/US fusion, MRI/TRUS fusion, fusion MRI, prostate cancer, prostate biopsy, MRI targeted biopsy

APPROVED BY GOVERNING BODIES:
Magnetic resonance imaging (MRI)–guided or MRI/ultrasound (US) fusion biopsy is a medical procedure that uses MRI and ultrasound devices previously approved by the U.S. Food and Drug Administration (FDA). Prostate biopsy is a surgical procedure and, as such, it is not subject to regulation by FDA.

FDA product code, ultrasound devices: IYN, ITX, IYO. FDA product code, MRI devices: LNH, LNI, MOS.

Several MRI-US fusion software-based targeted prostate biopsy platform specifications have been cleared from marketing by FDA through the 510(k) marketing process. Fusion software and

(manufacturers) include: Artemis™ (Eigen), BioJet™ (D&K Technologies), BiopSee® (MedCom), Real-time Visual Sonography (Hitachi), UroNav™ (Invivo/Philips), Urostation® (Koelis), and Virtual Navigator (Esaote).

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

There is no specific CPT code for this procedure. It would likely be reported with a prostate biopsy code (55700-55705) and the MRI guidance code 77021.

For information on saturation biopsy, please refer to medical policy #396: Saturation Biopsy for Diagnosis and Staging of Prostate Cancer.

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POLICY HISTORY:

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Medical Policy Group, August 2018 **(4)**: Updates to Description, Key Points, and References. No change to policy statements.
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This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.