MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Magnetic Resonance Imaging–Prostate/Multiparametric MRI**
Policy Number	**6.01.46**
Category	**Technology Assessment**
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Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our review and assessment of the peer-reviewed literature, including National Comprehensive Cancer Network (NCCN) clinical guidelines, magnetic resonance imaging (MRI) or MRI/TRUS (transrectal ultrasound) fusion biopsy of the prostate is considered **medically appropriate** for men with suspected prostate cancer who meet **ONE** of the following criteria:

A. Patient is age 40 to 75 years with prostate-specific antigen (PSA) greater than 3 ng/ml or very suspicious digital rectal exam (DRE) and **ONE** of the following high risk features:
   1. African ancestry; **OR**
   2. Germline mutations that increase the risk of prostate cancer; **OR**
   3. Family history of first or second degree relative with prostate, male breast, colorectal, pancreatic, endometrial or female breast cancer at age less than 45 years.

B. Patient is age 45 to 75 years, and **ONE** of the following:
   1. Prostate-specific antigen (PSA) greater than 3ng/ml; **OR**
   2. Very suspicious digital rectal exam (DRE).

C. Patient is more than age 75 years, and **ONE** of the following:
   1. PSA greater than or equal to 4 ng/ml; **OR**
   2. Very suspicious DRE.

D. Patient has had at least one negative/non-diagnostic transrectal ultrasound (TRUS) biopsy, and has **ANY** of the following:
   1. Continued increase in PSA; **OR**
   2. Abnormal DRE; **OR**
   3. Need for confirmatory MR/US fusion biopsy.

E. Patient has at least one lesion classified as Prostate Imaging-Reporting and Data System (PI-RADS) score 4 or 5, which was identified on a recent diagnostic MRI of the pelvis, and planning for biopsy to be done by MRI/TRUS fusion technique.
F. Patient has at least one lesion classified as focal prostatic intraepithelial neoplasm (PIN) 1 or 2.

II. Based upon our review and assessment of the peer-reviewed literature, including NCCN clinical guidelines, MRI is considered **medically appropriate** for initial workup or staging of prostate cancer in men for the following indications:
A. Prostate imaging prior to planned surgery and/or radiation therapy for localized prostate cancer with any of the following risk groups (please refer to Policy Guideline VII for NCCN Initial Risk Stratification):
1. Very Low Risk
2. Low Risk
3. Favorable Intermediate Risk
B. The following imaging combination to include CT Chest with contrast, CT Abdomen with contrast, MRI Pelvis without and with contrast and Bone Scan for localized prostate cancer with any of the following risk groups (please refer to Policy Guideline VII for NCCN Initial Risk Stratification):
1. Unfavorable Intermediate Risk
2. High Risk
3. Very High Risk

III. Based upon our review and assessment of the peer-reviewed literature, including NCCN clinical guidelines, MRI of the prostate is considered **medically appropriate** for restaging or recurrence in patients with one or more of the following:
A. New finding on the most recent CT that was inconclusive; **OR**
B. DRE reveals obvious progression, with plans for prostatectomy or radiation therapy; **OR**
C. Repeat TRUS biopsy for rising PSA shows progression to a higher Gleason score, with plans for prostatectomy or radiation therapy.

IV. Based upon our review and assessment of the peer-reviewed literature, including NCCN clinical guidelines, MRI of the prostate is considered **medically appropriate** as routine monitoring for initiation of an active surveillance program and every twelve months thereafter or when there is suspected progression with **O**of the following:
A. Changes in DRE; **OR**
B. Rising PSA with a negative TRUS biopsy; **OR**
C. Repeat TRUS biopsy shows progression to a higher Gleason score.
Of note, advanced imaging is not routinely indicated for patients being monitored on or off therapy.

V. Based upon our review and assessment of the peer-reviewed literature, including NCCN clinical guidelines, an active surveillance program is considered **medically appropriate** with the following protocol(s):
A. PSA every six months; **AND**
B. DRE every 12 months; **AND**
C. Repeat TRUS-guided prostate biopsy every 12 months; **AND**
D. Repeat multi-parametric MRI (mpMRI) no more often than every 12 months.

Refer to Administrative Policy #AP-03, 3D Rendering of a Tomographic Modality

POLICY GUIDELINES

I. When one or more specific target lesions are detected on mpMRI of the prostate and classified as PIRADS 4 or 5, then 3D rendering at independent workstation (CPT code: 76377), for the radiologist to generate prostate segmentation data image set for target identification on MRI/TRUS fusion biopsy, is appropriate.

II. If there is no target lesion identified on mpMRI, then 3D rendering and MRI/TRUS fusion biopsy is not generally indicated. The urologist may request MRI/TRUS fusion biopsy of a PI-RADS 1 to 3 lesion.

III. A 3D rendering that does not require image post-processing at an independent workstation (CPTcodes: 76376 or 76377) is inclusive to the MRI.

IV. Several MRI-TRUS fusion software-based targeted prostate biopsy platform specifications have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the Section 510(k) process. Fusion software includes Artemis (Eigen, Grass Valley, CA), BioJet (D&K Technologies, Gurajat, India), BiopSee (MedCom, Columbia, SC), Real-time Visual Sonography (Hitachi, Tokyo, Japan), UroNav (Invivo/Philips, Gainesville, FL), Urostation (Koelis, Auburndale, MA), and Virtual Navigator (Esaote, Genoa, Italy).

V. A 3D rendering (CPT codes: 76376 or 76377) for the TRUS component of the fusion is a part of the UroNavFusion Equipment Software and, therefore, is considered inclusive.

VI. International Society of Urological Pathology (ISUP) Prostate Cancer Grade Groups:

Grade Group	Gleason Score	Gleason Pattern
1	≤ 6	≤ 3+3
2	7	3+4
3	7	4+3
4	8	4+4, 3+5, 5+3
5	9 or 10	4+5, 5+4, or 5+5

VII. NCCN Initial Risk Stratification Categories:

A. Very Low Risk

ALL of the following features are present:

1. Tumor not clinically palpable, but present on one or both lobes on biopsy (cT1a, cT1b, or cT1c); and
2. PSA (ng/mL) less than 10; and
3. Gleason Grade Group equals 1; and
4. Less than 3 prostate biopsy cores positive, less than 50% cancer in each core; and
5. PSA Density less than 0.15 ng/mL/g.

B. Low Risk

ALL of the following features are present, but does not qualify for very low risk:

1. Clinical T Stage equals cT1-cT2a (palpable tumor limited to less than 1/2 of one side); and
2. PSA (ng/mL) less than 10 ng/mL; and
3. Gleason Grade Group equals 1.

C. Favorable Intermediate Risk

ALL of the following features are present:

1. Gleason Grade Group equals 1 or 2; and
2. Less than 50% biopsy cores positive (e.g., less than 6 of 12 cores): and
3. And only **ONE** of the following features is present:
   a. Clinical T Stage equals cT2b-cT2c (palpable disease confined to one or both lobes of the prostate); or
   b. PSA (ng/mL) equals 10-20 ng/mL.

D. Unfavorable Intermediate Risk

Any **ONE** of the following are present:

1. Gleason grade group equals 3; or
2. Less than 50% biopsy cores positive (e.g., less than 6 of 12 cores); or
3. Presence of at **least two** of the following three features:
   a. PSA (ng/mL) equals 10-20 ng/mL; and/or
   b. Gleason Grade Group equals 2 or 3; and/or
   c. Clinical T Stage equals cT2b-cT2c (palpable disease confined to one or both lobes of the prostate).

E. High Risk
Only **ONE** of the following high risk features is present:
1. Clinical T Stage equals cT3a (unilateral or bilateral extra-prostatic extension that is not fixed and does not invade the seminal vesicles); or
2. PSA (ng/mL) greater than 20 ng/mL; or
3. Gleason Grade Group equals 4 or 5.

F. Very High Risk
At least **ONE** of the following features is present:
1. Clinical T stage equals cT3b-cT4 (extension into the seminal vesicles or invasion into adjacent structures); or
2. Primary Gleason Pattern equals 5; or
3. Gleason Grade Group equals 4 or 5 in greater than 4 cores; or
4. Presence of 2 or 3 high risk features (noted above).

DESCRIPTION

Prostate cancer, or PCa, is the most commonly diagnosed cancer and the third leading cause of cancer deaths among men in the United States. Prostate cancer is a complex, heterogeneous disease, ranging from microscopic tumors unlikely to be life-threatening to aggressive tumors that can metastasize, leading to morbidity or death. A major concern related to prostate cancer screening and early detection is over-diagnosis and over-treatment of indolent disease. Strategies to reduce over-diagnosis are necessary, as are strategies to differentiate indolent from aggressive tumors. Better options are needed to stratify patients and to confirm the type of prostate cancer, so that patients with aggressive disease receive treatment while those with a less aggressive disease may be treated more conservatively. Current methods to screen for prostate cancer or to assess the risk of prostate cancer include PSA, DRE, and TRUS-guided prostate biopsy. These methods are limited by lack of specificity and ability to determine clinically significant prostate cancer.

Multi-parametric MRI (mpMRI) was developed to guide initial diagnosis of prostate cancer, pretreatment risk assessment and staging, to guide and monitor active surveillance, and to direct or target the prostate biopsy. An mpMRI consists of three imaging pulse sequences: T2 weighted imaging, diffusion weighted imaging (DWI), and dynamic contrast enhanced imaging (DCE), each with a specific function and result, which combgine to form bgoth anatomic and functional images. If lesions are observed on mpMRI, they are assigned a PI-RADS score ranging from 1 to 5. The PI-RADS score indicates the likelihood of clinically significant prostate cancer, with a score of one being the least suspicious and five having the highest suspicion for significant prostate cancer. Evidence suggests that mpMRI detects more aggressive disease and less indolent cancer. Used as the "gatekeeper" or triage test, mpMRI can improve the patient pathway by reducing the number of TRUS biopsies. Likewise, men can avoid the potential for over-diagnosis and over-treatment of prostate cancer that can result when a biopsy is performed. MRI can be obtained using a 1.5T or 3.0T magnet, with or without the use of an endorectal coil.

RATIONALE

Faria et al. (2018) examined the cost-effectiveness of MRI compared with current treatment guidelines. Data for the model was obtained from the Prostate MR Imaging Study, the largest accuracy study on the use of mpMRI and TRUS-guided biopsy in the diagnosis of prostate cancer. Results showed that the use of mpMRI first, and then up to two MRI-targeted TRUS biopsies, detects more clinically significant cancers per pound spent than using TRUS biopsy first (sensitivity = 0.95 [95% confidence interval {CI} 0.92–0.98] vs 0.91 [95% CI 0.86–0.94]) and is cost-effective (ICER = £7,076 [€8350/QALY gained]). The presented evidence suggests that mpMRI is cost-effective as the first test for the diagnosis of prostate cancer, when followed by an MRI-targeted TRUS biopsy in men in whom the mpMRI suggests a suspicion for clinically significant cancer.

The current NCCN guidelines V4.2022 state that, before starting on an active surveillance program, mpMRI and/or prostate biopsy should be considered, to confirm candidacy for active surveillance if not performed during initial workup. Men with PI-RADS 4 or 5 lesions on mpMRI have an increased risk of biopsy progression during active surveillance. The current NCCN recommendations for the active surveillance program include PSA no more often than every six months unless clinically indicated; DRE no more often than every 12 months unless clinically indicated, repeat prostate biopsy no more often than every 12 months unless clinically indicated, and repeat mpMRI no more often than every 12 months

unless clinically indicated. Repeat molecular tumor analysis is discouraged during active surveillance. Early experience supports the utilization of mpMRI in biopsy protocols, to better risk-startify men under active surveillance; however, more recent studies have shown that a significant proportion of high-grade cancers are detected with systematic biopsy, and not targeted biopsy, in men on active surveillance.

The recommendations included in the American Urology Association (AUA) Policy Statement on the Use of Multiparametric MRI in the diagnosis, staging and management of prostate cancer include an investigational statement for mpMRI used alone for screening of prostate cancer for routine prostate screening. The AUA noted that there is insufficient evidence to recommend mpMRI in every biopsy-naive patient considering biopsy. There is minimal evidence and lack of a consensus regarding MRI and MRI targeted biopsy in men with previous negative biopsy; however, there is evidence to support mpMRI in men with increasing PSA following a negative biopsy. There is limited evidence of the diagnostic accuracy of mpMRI in follow-up of men after radical prostatectomy or focal therapies. There is a lack of evidence that mpMRI can be used as a primary test for surveillance; however, MRI, combined with a biopsy, may improve outcomes as part of an active surveillance program. This area is evolving, with a need for more data and studies.

The Ontario Cancer Care Prostate Cancer Diagnosis Pathway (2015) suggests mpMRI for men with previous negative prostate biopsy who have suspicious DRE or rising PSA, and in men with a suspicious biopsy who are undergoing a subsequent biopsy.

The 2014 National Institute for Health and Care Excellence (NICE) guidelines on the diagnosis and treatment of prostate cancer (CG175) recommend considering mpMRI (using T2- and diffusion-weighted imaging) for men with a negative TRUS 10- or 12-core biopsy, to determine whether another biopsy is needed. Another biopsy should not be offered if the mpMRI is negative, unless additional risk factors are present. The 2019 NICE guidelines (CG175) recommend pre-biopsy mpMRI as the primary method to investigate suspected prostate cancer based on PSA and/or DRE findings.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
76376	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation
76377	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; requiring image postprocessing on an independent workstation
76942	Ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation
77021	Magnetic resonance imaging guidance for needle placement (e.g., for biopsy, needle aspiration, injection, or placement of localization device) radiological supervision and interpretation
72195	Magnetic resonance (e.g., proton) imaging, pelvis; without contrast material(s)
72197	Magnetic resonance (e.g., proton) imaging, pelvis; without contrast material(s), followed by contrast material(s) and further sequences

HCPCS Codes

Code	Description
No specific code(s)	

ICD10 Codes

Code	Description
C61	Malignant neoplasm of prostate
D07.5	Carcinoma in situ of prostate
D29.1	Benign neoplasm of prostate
D40.0	Neoplasm of uncertain behavior of prostate
N40.2	Nodular prostate without lower urinary tract symptoms
N40.3	Nodular prostate with lower urinary tract symptoms
N42.30	Unspecified dysplasia of prostate
N42.31	Prostatic intraepithelial neoplasia
N42.32	Atypical small acinar proliferation of prostate
N42.39	Other dysplasia of prostate
R97.20	Elevated prostate specific antigen (PSA)
R97.21	Rising PSA following treatment for malignant neoplasm of prostate
Z12.5	Encounter for screening for malignant neoplasm of prostate
Z85.46	Personal history of malignant neoplasm of prostate

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*Key Article

KEY WORDS

Multiparametric MRI, MRI/US fusion biopsy, MRI targeted prostate biopsy, MRI pelvis

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, Magnetic Resonance Imaging of the Prostate or Multiparametric MRI is not addressed in National or Regional Medicare coverage determinations or policies.