MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Magnetic Resonance Imaging (MRI) of the Prostate**
Policy Number	**6.01.46**
Category	**Technology Assessment**
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Archive Review Date	**N/A**
Product Disclaimer	• *Services are contract dependent; 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

Suspected Prostate Cancer

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;
      2. Germline mutations that increase the risk of prostate cancer;
      3. Family history of first or second degree relative with prostate, male breast, pancreatic, or ovarian cancer;
      4. Family history of first- or Second degree relative diagnosed at age ≤45 years with female breast cancer;
      5. Family history of first- or Second degree relative diagnosed at age ≤50 years with colorectal or endometrial cancer;
      6. Family history of pancreatic cancer at any age; **or**
      7. Family history of two or more first- or second-degree relatives with breast , prostate (not clinically localized Grade Group 1), colorectal, or endometrial cancer at any age; **or**
   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); **or**
   C. Patient is greater than age 75 years, and **ONE** of the following:
      1. PSA greater than or equal to 4 ng/ml;
      2. Very suspicious DRE; **or**

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

E. Patient has Prostate Imaging-Reporting and Data System (PI-RADS) 4 or 5 lesion, which was identified on a recent diagnostic MRI of the pelvis and planning for biopsy to be done by MRI/TRUS fusion technique; **or**

F. If the patient has one (1)–two (2) focal prostatic intraepithelial neoplasm (PIN) lesions, any **ONE** of the following MRI imaging is appropriate:
   1. MRI Pelvis without contrast;
   2. MRI Pelvis without and with contrast;
   3. MRI/US fusion biopsy; **or**
   4. MRI guided biopsy.

Initial Work-Up/Staging for Prostate Cancer

II. Based upon our review and assessment of the peer-reviewed literature, including NCCN clinical guidelines, MRI Pelvis without and with contrast is considered **medically appropriate** for initial workup or staging of localized prostate cancer in men for **ANY** of the following indications:
   A. **ANY** of the following risk groups (Refer to Policy Guideline VII for NCCN Initial Risk Stratification):
      1. Very low risk
      2. Low risk
      3. Favorable intermediate risk; **and**
         a. **EITHER** of the following indications:
            i. To establish candidacy for active surveillance; **or**
            ii. Prior to planned treatment (surgery and/or radiation therapy); **or**
   B. **ANY** of the following risk groups (Refer to Policy Guideline VII for NCCN Initial Risk Stratification):
      2. Unfavorable intermediate risk
      3. High-risk
      4. Very high-risk; **and**
         a. **ANY ONE** of the following combinations, not all (may be obtained in addition to multi-parametric MRI (mpMRI prostate):
            i. CT Chest with contrast, CT Abdomen and Pelvis with contrast, and Bone scan;
            ii. CT Chest with contrast, CT Abdomen with contrast, MRI Pelvis without and with contrast if not previously performed, and Bone scan; **or**
            iii. PSMA PET/CT scan using the appropriate radiotracers: **or**
   C. Inconclusive bone scan.

Restaging/Recurrence for Prostate Cancer

III. Based upon our review and assessment of the peer-reviewed literature, including NCCN clinical guidelines, MRI of the prostate without and with contrast is considered **medically appropriate** for restaging or recurrence in patients with **ANY** of the following:
   A. Obvious progression by DRE, with plans for prostatectomy or radiation therapy;
   B. Repeat TRUS biopsy for rising PSA shows progression to a higher Gleason score, with plans for prostatectomy or radiation therapy;
   C. Inconclusive findings on CT scan;
   D. Non-metastatic prostate cancer previously treated with prostatectomy, radiation therapy, ablation hormonal therapy or chemotherapy and **ANY ONE** of the following:
      1. Clinical suspicion relapse/recurrence;
      2. PSA fails to become undetectable post prostatectomy;
      3. Palpable anastomotic recurrence;

4. PSA rises above post treatment baseline to greater than 0.2 ng/ml but less than 0.5 ng/ml on two (2) consecutive measurements; **and**
    a. **ANY ONE** of the following combinations:
        i. CT Chest with contrast, CT Abdomen and Pelvis with contrast, and Bone scan;
        ii. CT Chest with contrast, CT Abdomen with contrast, MRI Pelvis without and with contrast, and Bone scan;

E. Non-metastatic prostate cancer previously treated with prostatectomy or radiation therapy, and **ALL** of the following;
1. PSA rises on two (2) consecutive measurements above post-treatment baseline;
2. PSA greater than or equal to 0.5 ng/ml; and
3. Individual is a candidate for salvage local therapy; **and**
    a. **ANY ONE** of the following combinations:
        i. CT Chest with contrast, CT Abdomen and Pelvis with contrast, and Bone scan;
        ii. CT Chest with contrast, CT Abdomen with contrast, MRI Pelvis without and with contrast, and Bone scan; **or**
        iii. PSMA PET/CT scan using the appropriate radiotracers.

Follow-Up On Active Surveillance for Prostate Cancer

IV. Based upon our review and assessment of the peer-reviewed literature, including NCCN clinical guidelines, MRI Pelvis without or without and with contrast is considered **medically appropriate** for follow-up on active surveillance for **ANY** of the following:
A. To use for routine monitoring for individuals on active surveillance protocol;
B. Progression is suspected based on DRE changes or rising PSA and a recent TRUS biopsy was negative;
C. Repeat TRUS biopsy shows progression to a higher Gleason score.

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

POLICY GUIDELINES

I. Active surveillance program according to NCCN clinical guidelines for Prostate Cancer, state patients who choose active surveillance should have regular follow-up, and key principles include:
A. PSA every (6) six months;
B. DRE every 12 months;
C. Repeat TRUS-guided prostate biopsy every 12 months; and
D. Repeat multi-parametric MRI (mpMRI) no more often than every 12 months (unless clinically indicated).

II. 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 as subsequent separate standalone request or as a retrospective request for medically necessity.

III. For MRI/TRUS fusion biopsy of a PIRADS 1-3 lesion, approval of 3D rendering at independent workstation can be considered on a case-by-case basis.

IV. If there is no target lesion identified on MRI then on 3D rendering and MRI/TRUS fusion biopsy is generally not indicated.

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 combine to form both 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

The National Comprehensive Cancer Network (NCCN) guidelines for Prostate Cancer Early Detection Version 2.2024 recommend:

- Atypical Intraductal proliferation (AIP) without invasive carcinoma-Repeat biopsy using MRI targeting and systematic biopsy to look for invasive carcinoma.
- mpMRI is appropriate for further evaluation and indications for biopsy when there is a high suspicion for clinically significant cancer.

The NCCN guidelines for Prostate Cancer Version 4.2024 recommend:

- MRI is appropriate for initial risk stratification and staging workup for clinically localized disease.
- Standard MRI techniques can be used for examination of the pelvis and/ or abdomen for initial evaluation and as part of workup for recurrence or progression.
- MRI (mpMRI) can be used in the staging and characterization of prostate cancer.
- MRI may be considered in patients after radical prostatectomy when PSA does not fall to undetectable levels or when an undetectable PSA becomes detectable and increases on two or more subsequent determinations, or after radiation therapy for increasing PSA or positive DRE if the patient is a candidate for additional local therapy. MRI-ultrasound fusion biopsy may improve the detection of higher grade (Grade Group ≥2) cancers.
- Repeat mpMRI no more often than every 12 months unless clinically indicated.
- MRI can be considered for equivocal results on initial bone imaging.

The recommendations included in the 2017 American Urology Association (AUA) Policy Statement on the Use of Multiparametric MRI in the diagnosis, staging and management of prostate cancer support:

- The use of magnetic resonance imaging in patients with a previous negative biopsy and ongoing concerns about increased risk of prostate cancer. The data regarding its usefulness for initial biopsy suggest a possible role for

magnetic resonance imaging in some circumstances. There is currently insufficient evidence to recommend magnetic resonance imaging for screening, staging or surveillance of prostate cancer.

The 2021 National Institute for Health and Care Excellence (NICE) guidelines for prostate cancer: diagnosis and management (NG131) recommendations are:

- 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 localized 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 (see box 1). If a person opts to have a biopsy, offer systematic prostate biopsy.
- Offer multiparametric MRI to people having active surveillance who have not had an MRI previously. If the MRI results do not agree with the biopsy findings, offer a new MRI-influenced biopsy.

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.

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
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
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

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

REFERENCES

2021 exceptional surveillance of prostate cancer: diagnosis and management (NICE guideline NG131) [Internet]. London: National Institute for Health and Care Excellence (NICE); 2021 Feb 11.

Ahdoot M, et al. MRI-targeted, systematic, and combined biopsy for prostate cancer diagnosis. N Engl J Med 2020;382:917-28.

Callender T, et al. Benefit, harm, and cost-effectiveness associated with magnetic resonance imaging before biopsy in age-based and risk-stratified screening for prostate cancer. JAMA Network Open 2021;4(3):e2037657. doi:10.1001.

Cancer Care Ontario. Prostate Cancer Diagnosis Pathway. 2018 v.03. [https://www.cancercareontario.ca/sites/ccocancercare/files/assets/DPMProstateDiagnosis.pdf] accessed 10/16/24.

Fam MM, et al. Increasing utilization of multiparametric magnetic resonance imaging in prostate cancer active surveillance. Urology 2019 Aug;130:99-105.

Gallagher KM, et al. Four-year outcomes from a multiparametric magnetic resonance imaging (MRI)-based active surveillance programme: PSA dynamics and serial MRI scans allow omission of protocol biopsies. BJU Int 2019 Mar;123(3):429-438.

Glass AS and Dall'Era MA. Use of multiparametric magnetic resonance imaging in prostate cancer active surveillance. BJU Int 2019 Nov;124(5):730-737.

Hugosson J, et al. Prostate cancer screening with PSA and MRI followed by targeted biopsy only. N Engl J Med 2022 Dec 8;387(23):2126-2137.

Klotz L, et al. Active surveillance magnetic resonance imaging study (ASIST): results of a randomized multicenter prospective trial. Eur Urol 2019 Feb;75(2):300-309.

Klotz L, et al. Comparison of multiparametric magnetic resonance imaging–targeted biopsy with systematic transrectal ultrasonography biopsy for biopsy-naive men at risk for prostate cancer: A phase 3 randomized clinical trial. JAMA Oncol 2021;7(4):534-542.

*National Comprehensive Cancer Network. Clinical practice guidelines in oncology. Prostate cancer early detection. Version 2.2024 [https://www.nccn.org/professionals/physician_gls/pdf/prostate_detection.pdf] accessed 10/16/24.

*National Comprehensive Cancer Network. Clinical practice guidelines in oncology. Prostate cancer. Version 4.2024 [https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf] accessed 10/16/24.

*Prostate cancer: diagnosis and management. London: National Institute for Health and Care Excellence (NICE); 2021 Dec 15.

Rouvière O, et al. Use of prostate systematic and targeted biopsy on the basis of multiparametric MRI in biopsy-naïve patients (MRI-FIRST): a prospective, multicenter, paired diagnostic study. Lancet Oncol 2019 Jan;20(1):100-109.

Sathianathen NF, et al. Difference in MRI-guided biopsy cancer detection rates between individual clinicians. Urol Onc 2019 May;37(5):299.

Shah TT, et al. Magnetic resonance imaging and targeted biopsies compared to transperineal mapping biopsies before focal ablation in localized and metastatic recurrent prostate cancer after radiotherapy. European Urology 2022;81:598–605.

Soeterik TF, et al. Multiparametric magnetic resonance imaging should be preferred over digital rectal examination for prostate cancer local staging and disease risk classification. Urology 2021 Jan;147:205-212.

*Thompson J, et al. The role of magnetic resonance imaging in the diagnosis and management of prostate cancer. BJU Int 2013 Nov;112 Suppl 2:6-20.

Triquell M, et al. Magnetic resonance imaging-based predictive models for clinically significant prostate cancer: a systematic review. Cancers (Basel) 2022 Sep 29;14(19):4747.

Tu X, et al. Transperineal magnetic resonance imaging targeted biopsy may perform better than transrectal route in the detection of clinically significant prostate cancer: systematic review and meta-analysis. Journal of Clinical Genitourinary Cancer 2019 May;006.

Venderink W, et al. Multiparametric magnetic resonance imaging and follow-up to avoid prostate biopsy in 4259 men. BJU Int 2019;124:775-784.

Xie J, et al. MRI/Transrectal ultrasound fusion-guided targeted biopsy and transrectal ultrasound-guided systematic biopsy for diagnosis of prostate cancer: a systematic review and meta-analysis. Frontiers in Oncology 2022 May;12:A880336.

*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.