MEDICAL POLICY

Medical Policy Title	**Magnetic Resonance Imaging (MRI) of the Prostate**
Policy Number	**6.01.46**
Current Effective Date	**May 15, 2026**
Next Review Date	**January 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

POLICY STATEMENT(S)

Suspected Prostate Cancer

I. Magnetic resonance imaging (MRI) pelvis with or without contrast is considered **medically appropriate** for men with suspected prostate cancer, used to determine the need for MR fusion biopsy and who meet **ANY** of the following indications:

   A. Patient is 40 to 75 years old 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;

   B. Patient is 45 to 75 years old, 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 greater than 75 years old, and **ONE** of the following:

      1. PSA greater than or equal to 4 ng/ml;
      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. Rising PSA;
2. Abnormal DRE;
3. Need for confirmatory MR/US fusion biopsy;

E. Patient has a solitary (one [1]) prostatic intraepithelial neoplasm (PIN) lesions, any **ONE** of the following MRI imaging is appropriate to be repeated in one (1) year:

1. MRI Pelvis without contrast;
2. MRI Pelvis without and with contrast; **or**
3. MRI/US fusion biopsy.

II. MR guidance for needle placement is **not medically necessary** for prostate biopsy.

Initial Work-Up/Staging for Prostate Cancer

III. 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 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);

B. **ANY** of the following risk groups (Refer to Policy Guideline for NCCN Initial Risk Stratification):

1. Unfavorable intermediate risk;
2. High-risk;
3. 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;

C. Known diffuse metastatic prostate cancer (including prior to biopsy).

Restaging/Recurrence for Prostate Cancer

IV. 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; **or**
        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, and **ALL** of the following:

1. Persistent detectable PSA after prostatectomy;
2. Undetectable PSA that subsequently becomes detectable with two (2) consecutive increases in PSA (to any amount);
3. Any increase in PSA to 0.1 ng/ml or higher;
4. 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.

F. Non-metastatic prostate cancer previously treated with radiation therapy and **BOTH** of the

following criteria have been met;

1. Two (2) consecutive increases in PSA above nadir (lowest point); **and**
2. Individual is a candidate for salvage local therapy.

Follow-Up On Active Surveillance for Prostate Cancer

V. 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; **or**
   C. Repeat TRUS biopsy shows progression to a higher Gleason score.

VI. Serial MRIs are considered **not medically necessary** when monitoring an elevated prostate-specific antigen (PSA) for suspected prostate cancer

RELATED POLICIES

Administrative Policy

AP-03, 3D Rendering of a Tomographic Modality

POLICY GUIDELINE(S)

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. Prostate cancer screening begins at age 45 for individuals at average risk of prostate cancer. However, individuals at high-risk may begin screening at age 40. High-risk features include:
   A. African ancestry.
   B. germline mutations (BRCA1 or 2, HOXB13, ATM, CHEK2, or mismatch repair genes - MLH1, MSH2, MSH6, PMS2) that increase the risk of prostate cancer.
   C. family history of first or second-degree relative with prostate, male breast, colorectal, pancreatic, endometrial or female breast cancer at age <45 years.

III. Requests for imaging based on PSA must provide a recent PSA.

IV. Monitoring an elevated prostate-specific antigen level (PSA) with serial MRI is not indicated for suspected prostate cancer.

V. Individuals with high-risk adverse clinical and pathological factors may benefit from a more aggressive diagnostic and therapeutic approach at the time of relapse after initial treatment. These factors include pre-treatment Gleason score of ≥8, pretreatment clinical stage of cT3b or higher, positive surgical margins, post-treatment PSA doubling time of <3 months, and an interval to biochemical failure of <3 years after initial treatment.

International Society of Urological Pathology (ISUP) Prostate Cancer Grade Groups (2019)

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

NCCN Initial Risk Stratification Categories

Risk Group	**Clinical/Pathologic Features**
Very Low	Has **ALL** of the following: • cT1c • Grade Group 1 • PSA <10 ng/mL • <3 prostate biopsy fragments/cores positive, ≤50% cancer in each fragment/core. • PSA density <0.15 ng/mL/g
Low	Has **ALL** of the following but does not qualify for very low risk: • Clinical T Stage- cT1–cT2a (palpable tumor limited to ≤1/2 of one side) • Gleason Grade Group 1

<table>
<tr><td></td><td colspan="2">• PSA <10 ng/mL</td></tr>
<tr><td>Intermediate</td><td>Has ALL of the following:
• No high-risk group features.
• No very-high-risk group features.
Has one or more intermediate risk factors (IRFs):
• cT2b–cT2c
• Grade Group 2 or 3
• PSA 10–20 ng/mL</td><td>Favorable intermediate
Has ALL of the following:
• 1 IRF
• Grade Group 1 or 2
• <50% biopsy cores
• positive (e.g., <6 of 12 cores)</td></tr>
<tr><td></td><td></td><td>Unfavorable intermediate
Has one or more of the following:
• 2 or 3 IRFs
• Grade Group 3
• ≥ 50% biopsy cores positive (e.g., ≥ 6 of 12 cores).</td></tr>
<tr><td>High</td><td colspan="2">Has one or more high-risk features but does not meet the criteria for very high risk.
• cT3a-cT4
• Grade Group 4 or Grade Group 5
• PSA >20 ng/mL</td></tr>
<tr><td>Very High</td><td colspan="2">Has at least two of the following:
• cT3–cT4
• PSA greater than 40 ng/ml
• Primary Gleason Group = 5
• Grade Group 4 or 5</td></tr>
</table>

DESCRIPTION

Prostate Cancer (PCa)

Prostate cancer (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. Current methods to screen for prostate cancer or to assess the risk of prostate cancer include PSA, DRE, and TRUS-guided prostate biopsy.

Multi-Parametric MRI (mpMRI)

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.

SUPPORTIVE LITERATURE

Fazekas et al (2024) conducted a systematic review and meta-analysis of 80,114 screened men from 12 studies. They evaluated the existing evidence regarding screening pathways incorporating MRI with targeted biopsy and the diagnostic value that it holds compared with PSA based screening with systematic biopsies. Compared with standard PSA-based screening, the MRI pathway (sequential screening, PI-RADS score ≥3 cutoff for biopsy) was associated with higher odds of clinically significant PCa (csPCa) when tests results were positive, decreased odds of biopsies, and insignificant cancers detected without significant differences in the detection of csPCa. Implementing a PI-RADS score of 4 or greater threshold for biopsy selection was associated with a further reduction in the odds of detecting insignificant PCa and biopsies performed without differences in csPCa detection. It was found that using MRI in PCA screening pathways is associated with a reduced number of unnecessary biopsies and over diagnosis of insignificant PCa while maintaining csPCa detection as compared to detecting only with PSA.

Rouvière et al (2019) conducted a prospective, multicenter, paired diagnostic study to investigate whether multiparametric MRI improves the detection of clinically significant prostate cancer and avoids the need for systematic biopsy in biopsy-naive patients. 275 men were enrolled; they had a PSA concentration of 20 ng/mL or less and stage T2c or lower prostate cancer. The primary outcome was the detection of clinically significant PCa of International Society of Urological Pathology grade group 2 or higher (csPCa-A) analyzed in all patients who received both systematic and targeted biopsies and whose results from both were available for pathological central review, including patients who had protocol deviations. 24 (9%) were excluded from the analysis. 53 (21%) of 251 patients analyzed had negative (Likert ≤2) multiparametric MRI. csPCa-A was detected in 94 (37%) of 251 patients. 13 (14%) of these 94 patients were diagnosed by systematic biopsy only, 19 (20%)

by targeted biopsy only, and 62 (66%) by both techniques. Detection of csPCa-A by systematic biopsy and targeted biopsy did not differ significantly. csPCa-A would have been missed in 5.2% of patients had systematic biopsy not been done, and in 7.6% of patients had targeted biopsy not been done. Four grade 3 post-biopsy adverse events were reported (3 cases of prostatitis, and 1 case of urinary retention with hematuria). The study found that obtaining a mpMRI before biopsy in biopsy-naïve patients can improve detection of clinically significant cancer, although systematic biopsies are not avoided.

Kasivisvanathan et al (2018) conducted a multicenter randomized, noninferiority controlled trial assessing if MR-targeted biopsy is non-inferior to standard TRUS guided biopsy for the diagnosis of clinically significant PCa in men without prior biopsy. A total of 500 men with clinical suspicion of prostate cancer who have not undergone a previous biopsy and having them undergo an MRI, with or without targeted biopsy, or standard TRUS biopsy. The men in the MRI-targeted biopsy group, biopsy was only taken if MRI was suggestive of PCa. The primary outcome was the proportion of men who received a diagnosis of clinically significant cancer. Secondary outcomes included the proportion of men who received a diagnosis of clinically insignificant cancer. In the MRI biopsy group 71 of 252 men (28%) did not have a biopsy as the MRI results did not suggest PCa. In the MRI targeted biopsy group, 95 men (38%) found clinically significant cancer, compared to the standard biopsy group 64 of 248 (26%). MRI, with or without targeted biopsy, was noninferior to standard biopsy. Fewer men in the MRI-targeted biopsy group than in the standard-biopsy group received a diagnosis of clinically insignificant cancer. The use of risk assessment with MRI before biopsy and MRI-targeted biopsy was found to be superior to standard TRUS–guided biopsy in men at clinical risk for PCa who had not undergone biopsy previously.

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.

PROFESSIONAL GUIDELINE(S)

The National Comprehensive Cancer Network (NCCN) Guidelines for Prostate Cancer Early Detection Version 2.2025 recommend:

- Atypical Intraductal proliferation (AIP) without invasive carcinoma-Repeat biopsy using MRI targeting and systematic biopsy to look for invasive carcinoma.
- Atypia, suspicion for cancer if no prior high quality mpMRI was completed.
- mpMRI is appropriate for further evaluation and indications for biopsy when there is a high suspicion for clinically significant cancer.

- Any individual with a PSA >3 ng/mL undergoes workup for benign disease, a repeat PSA, and a DRE (if not performed during initial risk assessment) to inform decisions about whether to proceed with image-guided biopsy or additional testing with other biomarkers and/or multiparametric MRI. The panel strongly recommends that multiparametric MRI should precede biopsy, if available.

The NCCN Guidelines for Prostate Cancer Version 3.2026 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 2023 AUA/Society of Urologic Oncology (SUO) Guidelines for Early Detection of Prostate Cancer states:

- "Clinicians may use magnetic resonance imaging (MRI) prior to initial biopsy to increase the detection of Grade Group (GG) 2+ prostate cancer. (Conditional Recommendation; Evidence Level: Grade B)"
- "Radiologists should utilize PI-RADS in the reporting of multi-parametric MRI (mpMRI) imaging. (Moderate Recommendation; Evidence Level: Grade C)"
- "In patients undergoing repeat biopsy with no prior prostate MRI, clinicians should obtain a prostate MRI prior to biopsy. (Strong Recommendation; Evidence Level: Grade C)"

The updated 2023 version of the AUA/SUO Advanced Prostate Guidelines state:

- "In patients with PSA recurrence after failure of local therapy who are at higher risk for the development of metastases (e.g., PSADT less than 12months), clinicians should perform periodic staging evaluations consisting of cross-sectional imaging (CT, MRI) and technetium bone scan, and/or preferably PSMA PET imaging. (Clinical Principle"

The 2022 AUA/American Society for Radiation Oncology (ASTRO) Guidelines for Clinically Localized Prostate Cancer recommendations state:

- "For staging, clinicians should obtain a bone scan and either pelvic multi-parametric magnetic resonance imaging (mpMRI) or CT scan for patients with high-risk prostate cancer. (Strong Recommendation; Evidence Level: Grade B)"
- "In patients selecting active surveillance, clinicians should utilize mpMRI to augment risk stratification, but this should not replace periodic surveillance biopsy. (Expert Opinion)"

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. 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."

REGULATORY STATUS

Not Applicable

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

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
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
Not Applicable	

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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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

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

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, 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 HISTORY/REVISION

Committee Approval Dates

08/15/19, 10/22/20, 08/19/21, 09/15/22, 08/17/23, 01/18/24, 12/19/24, 06/26/25, 01/22/26

Date	Summary of Changes
01/22/26	• Off cycle review, removed indication for known or clinically oligo- or low volume suspected metastatic prostate cancer. Removed policy criteria regarding patients with PI-RADS 4 or 5 lesions and now only allows for solitary PIN lesions. Added a new not medically necessary policy statement for serial MRIs.
06/26/25	• Off cycle review, new criteria for MRI of the prostate for suspected metastatic prostate cancer. Codes 76376, 76377 and 76942 were removed due to being unmanaged.
01/01/25	• Summary of changes tracking implemented.
06/21/18	• Original effective date