MEDICAL POLICY

Excellus

SUBJECT: MAGNETIC RESONANCE IMAGING– PROSTATE/MULTIPARAMETRIC MRI	EFFECTIVE DATE: 06/21/18
POLICY NUMBER: 6.01.46 CATEGORY: Technology Assessment	PAGE: 1 OF: 5

- ***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 product, covers a specific service, medical policy criteria apply to the benefit.***
- ***If a Medicare 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.***

POLICY STATEMENT:

I. Based upon our review and assessment of peer-reviewed literature including National Comprehensive Cancer Network (NCCN) clinical guidelines, MRI of the prostate is considered medically appropriate for initial workup or staging in men with *one or more* of the following high risk criteria:
A. Any Gleason score with palpable disease outside of the prostate capsule (T3 or T4 disease); or
B. PSA greater than 20 ng/ml; or
C. Gleason score greater than or equal to 7; or
D. Gleason score of 6 and:
1. Tumor involving greater than 50% of one lobe (T2b); or
2. Tumor involving both lobes (T2c); or
3. PSA greater than 10ng/ml.

II. Based upon our review and assessment of peer-reviewed literature including National Comprehensive Cancer Network (NCCN) clinical guidelines MRI of the prostate is considered medically appropriate for diagnosis with at least one negative/non-diagnostic TRUS biopsy with documented plans for MRI guided biopsy or MRI/TRUS fusion biopsy and one of the following.
A. Continued increase in PSA; or
B. Abnormal DRE;
Or
C. Focal Prostatic Intraepithelial Neoplasia (PIN) 1-2 lesions or *atypical small acinar proliferation (ASAP)*

III. Based upon our review and assessment of peer-reviewed literature including National Comprehensive Cancer Network (NCCN) clinical guidelines, MRI of the prostate is considered medically appropriate as part of an active surveillance program when there is suspected progression and one of the following:
A. Changes in DRE; or
B. Rising PSA with a negative TRUS biopsy; or
C. TRUS biopsy which revealed progression of Gleason score;
And
D. MRI is not used to determine if biopsy should be performed.

IV. Based upon our review and assessment of peer-reviewed literature including National Comprehensive Cancer Network (NCCN) clinical guidelines, MRI of the prostate is considered medically appropriate in patients with prior radical prostatectomy and any of the following:
A. Palpable anastomotic recurrence
B. PSA remains >0.2 after at least 2 PSAs
C. Initial undetectable PSA increasing on 2 consecutive PSAs

V. Based upon our review and assessment of peer-reviewed literature including National Comprehensive Cancer Network (NCCN) clinical guidelines, MRI of the prostate is considered medically appropriate in patients with prior radiation therapy and any of the following:
A. Clinical suspicion of relapsed disease
B. PSA increasing on at least 2 consecutive values above post-XRT baseline

VI. Based upon our review and assessment of peer-reviewed literature including National Comprehensive Cancer Network (NCCN) clinical guidelines, MRI of the prostate is considered medically appropriate in all patients with one or more 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.

POLICY GUIDELINES:

I. 3D-rendering of MRI for MRI/Ultrasound fusion biopsy is appropriate to generate prostate segmentation data image set for target identification on MRI/TRUS fusion biopsy.

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

III. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Prostate cancer 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 (PCa) screening and early detection is over diagnosis and overtreatment 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, digital rectal exam (DRE), and TRUS-guided prostate biopsy. These methods are limited by lack of specificity and ability to determine clinical significant prostate cancer.

Multi-parametric MRI (mpMRI) was developed to guide initial diagnosis of prostate cancer, pretreatment risk assessment and staging, guide and monitor active surveillance and to direct or target the prostate biopsy. mpMRI is composed of 3 imaging pulse sequences which combine to form both anatomic and functional images; T2 weighted imaging, diffusion weighted imaging (DWI), and dynamic contrast enhanced imaging (DCE), each with a specific function and result. If lesions are observed on mpMRI, they are assigned a PI-RADS score ranging from 1 to 5. The PI-RADS score indicate the likelihood of clinical significant prostate cancer with a score of 1 being the least suspicious to 5 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, multi-parametric MRI 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 and with or without the use of an endorectal coil.

RATIONALE:

Faria et al., examined the cost effectiveness of MR Imaging compared with current treatment guidelines. Data for the m odel was obtained from the Prostate MR Imaging Study, the largest accuracy study on the use of mpMRI and transrectal ultrasound-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 a strategy 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 evidence presented 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 National Comprehensive Cancer Network Prostate Cancer (NCCN) (2017) guidelines make the following state ment on the use of mpMRI in the staging of prostate cancer: Emerging data suggest that, in men undergoing initial biopsy, targeting using MRI/ultrasound fusion may significantly increase the detection of clinically significant, high risk (Gleason grade >=4+3) disease while lowering the detection of lower risk (Gleason sum 6 or lower volume Gleason grade 3+4=7) disease. Regarding use of MRI transrectal ultrasound (TRUS) fusion biopsy among patients on active surveillance National Comprehensive Cancer Network guidelines mentions that MRI-TRUS fusion biopsy may improve the detection of higher grade (Gleason score ≥7) cancers.

The AUA Policy Statement on the Use of Multiparametric MRI in the diagnosis, staging and management of prostate cancer recommendations include an investigational statement for mpMRI used alone for screening of prostate cancer for routine prostate screening. There is insufficient evidence to recommend mpMRI in every biopsy naïve patient considering biopsy. There is minimal evidence and a lack of a consensus statement for MRI and MRI targeted biopsy in men with previous negative biopsy but 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, but 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 multi-parametric MRI for men with previous negative prostate biopsy who have suspicious DRE or rising PSA or in men with a suspicious biopsy who are undergoing a subsequent biopsy.

The 2014 National Institute for Health and Care Excellence guidelines on the diagnosis and treatment of prostate cancer (CG175) recommends 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.

CODES: Number Description

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:	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 (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation
	77021	Magnetic resonance guidance for needle placement (eg, for biopsy, needle aspiration, injection, or placement of localization device) radiological supervision and interpretation
	72195	Magnetic resonance (eg, proton) imaging, pelvis; without contrast material(s)
	72197	Magnetic resonance (eg, proton) imaging, pelvis; without contrast material(s), followed by contrast material(s) and further sequences

HCPCS: No specific code(s)

ICD10:	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
	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

SYNOPSIS OF CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently no National Coverage Determinations (NCD) or Local Coverage Determinations (LCD) for Magnetic Resonance Imaging of the prostate or Multiparametric MRI.