

Subject:	Prostate <u>Biopsy using MRI Fusion Techniques</u> <u>Multiparametric Magnetic Resonance Imaging</u>
Guideline #:	CG-SURG-98
Status:	Revised

Publish Date: 02/27/202005/21/2020**Last Review Date:**05/21/2020

Description

This document addresses prostate biopsies using a fusion technique in which a the use of multiparametric magnetic resonance imaging (mpMRI) is completed with images then. This technology is a “fusion biopsy system” in which mpMRI images are fused with real-time high definition prostate ultrasound images through the use of specialized equipment and software. This enables the ability to target and biopsy areas suspicious for prostate cancer.

Note: Please see the following related documents for additional information:

- CG-MED-45 Transrectal Ultrasonography
- SURG.00107 Prostate Saturation Biopsy

Clinical Indications

Medically Necessary:

The use of multiparametric magnetic resonance imaging fusion with rectal ultrasound for targeted biopsy of the prostate is considered **medically necessary** for individuals with:

- A persistently elevated or rising prostate specific antigen; **and**
 - Negative prostate biopsy(s), or a prostate biopsy(s) with a Gleason score less than or equal to 6, International Society of Urological Pathology (ISUP) Grade Group 1; and

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Prostate Biopsy using MRI Fusion Techniques Multiparametric Magnetic Resonance Imaging

- An mpMRI with at least one lesion reported on a Likert scale equal to or greater than 3, or scored equal to or greater than 3 according to the Prostate Imaging Reporting and Data System (PI-RADS) scoring system.

Not Medically Necessary:

The use of multiparametric magnetic resonance imaging fusion with rectal ultrasound for targeted biopsy of the prostate is considered **not medically necessary** when the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT

55899

Unlisted procedure, male genital system [when specified as MRI-fusion targeted biopsy of the prostate]

77021

~~Magnetic resonance guidance for needle placement (eg, for biopsy, needle aspiration, injection, or placement of localization device) radiological supervision and interpretation [if billed as a component of an MRI targeted biopsy of the prostate]~~

Note: there is no specific code for MRI-fusion targeted biopsy of the prostate; if CPT codes 76942~~77021~~ plus a prostate biopsy code such as 55700 are used to describe this procedure, the medically necessary criteria will be applied

ICD-10 Diagnosis

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

R97.2

Elevated prostate specific antigen [PSA]

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Z12.5
Z85.46

Encounter for screening for malignant neoplasm of prostate
Personal history of malignant neoplasm of prostate

Discussion/General Information

Prostate cancer is the most common diagnosed cancer, other than skin cancers, in North American men. The American Cancer Society notes that in 2019 there was an estimated 174,650 new cases of prostate cancer and 31,620 disease-related deaths in the United States. Prostate cancer is the second leading cause of cancer death in American men, exceeded only by lung cancer. Men in the United States have about 1 chance in 9 of eventually being diagnosed with this malignancy and about 1 man in 41 will eventually die of the disease (American Cancer Society, 2019).

The standard approach for the detection of prostate cancer in men has traditionally been an ultrasound-guided biopsy via transrectal ultrasound (transrectal ultrasound guided biopsy). Additional technology is now being studied and used for assistance in the diagnosis of prostate cancer. One such approach is the use of multi-parametric magnetic resonance imaging (mpMRI). This technology involves a modification to MRI which selectively combines T2-weighted MRI features (for anatomical imaging) with dynamic contrast enhanced (DCE) and diffusion weighted imaging (DWI) for detailed visualization and characterization, fusing magnetic resonance imaging (MRI) with real time high definition ultrasound images of the prostate with the use of specialized equipment and software to target and biopsy areas suspicious for prostate cancer. The mpMRI, combined with ultrasound imaging, can be used to create a three-dimensional view of the prostate. This allows for targeted biopsies, which have been proposed to improve prostate biopsy precision. The United States Food and Drug Administration (FDA) has cleared several of these devices through their 510(k) premarket process.

In a 2014 study by Siddiqui and colleagues, the authors sought to determine if a standard biopsy was necessary if the targeted-MRI approach was also done. All participants in this study (n=1215) underwent mpMRI and subsequently mpMRI/ultrasound fusion biopsy and standard biopsy. A total of 181 participants did not have lesions, leaving 1034 to proceed with biopsy. After additional exclusions, 1003 participants were included in the study. The targeted mpMRI/ultrasound fusion-directed biopsies diagnosed 461 cases of prostate cancer and the standard, systematic approach to biopsy diagnosed 469 cases of prostate cancer with exact agreement between

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Prostate Biopsy using MRI Fusion Techniques Multiparametric Magnetic Resonance Imaging

approaches for 690 men (69%). When the standard biopsy cores were combined with the targeted mpMRI approach, an additional 103 cases of prostate cancer were diagnosed (of which 83% were considered low risk, 12% were intermediate risk, and 5% were high risk). The predictive ability of targeted biopsy for differentiating low-risk from intermediate- and high-risk disease in 170 men with whole-gland pathology after prostatectomy was greater than that of standard biopsy or the two approaches combined (area under the curve, 0.73, 0.59, and 0.67, respectively; $p<0.05$ for all comparisons). The authors noted that mpMRI/ultrasound fusion was associated with increased detection of high-risk prostate cancer and decreased detection of low-risk prostate cancer, but that additional study would be needed to determine clinical impact, such as recurrence of disease and prostate cancer-specific mortality.

A 2015 study by Kim and colleagues compared targeted mpMRI prostate biopsies to conventional transrectal ultrasound guided biopsies. A total of 34 men received targeted mpMRI biopsy and were individually matched to 34 men who received conventional biopsy. Findings were correlated to Gleason Scores to determine clinical significance. As compared with the conventional ultrasound, mpMRI imaging suspicious biopsies had a significantly higher overall prostate cancer detection (54% vs. 24%, $p<0.01$) and Gleason score ≥ 7 detection (25% vs. 8%, $p<0.01$). When compared with conventional ultrasound, mpMRI had similar detection rates for benign prostate tissue (76% vs. 79%, $p=0.64$), and Gleason score ≤ 6 (16% vs. 14%, $p=0.49$), and Gleason score ≥ 7 detection (8% vs. 7%, $p=1.0$).

Da Rosa (2015) compared mpMRI-targeted fusion biopsy to transrectal ultrasound-guided biopsy in 72 men with prostate cancer in active surveillance with rising prostate specific antigen (PSA) or an appropriate rebiopsy interval. A total of 19 participants were found to have clinically significant prostate cancer (Gleason score greater than 7): 7 with mpMRI-targeted fusion biopsy alone, 2 by transrectal biopsy and 10 cases by both ($p=0.182$). The authors concluded that the mpMRI-targeted fusion biopsy resulted in detection of 7 additional cancers (37% of 19 cases). The proportion of cores positive for Gleason score 7 was 6.3 times higher with mpMRI-targeted fusion biopsy compared with transrectal ultrasound-guided (25% of 141 targeted cores versus 4% of 874 systematic cores, $p<0.001$). Using the Gleason > 6 threshold, 31/72 participants had clinically significant cancer, 10 identified by mpMRI-targeted fusion biopsy alone, 5 by transrectal ultrasound-guided biopsy alone, and 16 by both methods ($p=0.302$). The proportion of cores positive for clinically significant cancer was 6.2 times higher with mpMRI-targeted fusion biopsy compared with transrectal ultrasound-guided (37% of 141 targeted cores versus 6% of 874

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Prostate Biopsy using MRI Fusion Techniques Multiparametric Magnetic Resonance Imaging

systematic cores, $p<0.001$). For the 37 individuals with an mpMRI score ≥ 4 , the authors calculated a positive predictive value for cancer as 49% if they had Gleason score ≥ 7 and positive predictive value at 78% if they had Gleason score equal to 6 with $> 50\%$ involvement in any core. Negative predictive value for the presence of any cancer was 44%. The authors note that “there is a trend toward” detecting more clinically significant cancers.

Lee and colleagues (2016) compared diagnostic outcomes between two different techniques for targeting regions-of-interest on mpMRI; MRI-ultrasound fusion (MR-F) and ultrasound guided visually targeted (VT) biopsy. The primary endpoint was the difference in the detection of high-grade (Gleason ≥ 7) and any-grade cancer between VT and MR-F. Secondary endpoints were the difference in detection rate by biopsy location using a logistic regression model, and difference in median cancer length. The authors identified 396 regions-of-interest in 286 men. The difference in high-grade cancer detection between MR-F biopsy and VT biopsy was -1.4% (95% confidence interval [CI], -6.4% to 3.6%; $p=0.6$); for any-grade cancer the difference was 3.5% (95% CI, -1.9% to 8.9%; $p=0.2$). Median cancer length detected by MR-F and VT were 5.5 mm vs. 5.8 mm, respectively ($p=0.8$). MR-F biopsy detected 15% more cancers in the transition zone ($p=0.046$), and VT biopsy detected 11% more high-grade cancer at the prostate base ($p=0.005$). Only 52% of all high-grade cancers were detected by both techniques. The authors concluded that there was insufficient evidence to support a difference in the detection of high-grade or any-grade cancer between VT and MR-F biopsy. However, the performance of each technique varied in specific biopsy locations, and the outcomes of both techniques were complementary. The authors suggest that combining VT biopsy and MR-F biopsy may optimize prostate cancer detection.

A retrospective review by Oberlin and colleagues (2016) reported on 231 men who underwent mpMRI-targeted biopsy; 81 individuals had fusion biopsy and 151 individuals had cognitive biopsy of the prostate. All eligible individuals in the study had an abnormal screening test with an elevated PSA or abnormal digital rectal exam, and active surveillance of prostate cancer. The primary outcome was the overall detection rate of cancer and the secondary outcome was the detection of clinically significant cancer. In the fusion group, 48.1% of the individuals had cancer detected compared to 34.6% in the cognitive group. When the mpMRI fusion group was compared to the conventional transrectal ultrasound biopsy group, the MRI group detected 61.5% of Gleason grade 7-10 cancer compared to 37.5% in the ultrasound group.

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Prostate Biopsy using MRI Fusion Techniques Multiparametric Magnetic Resonance Imaging

In a 2016 retrospective analysis of prospectively generated clinical, imaging and pathologic data, Mariotti and colleagues studied the performance of systematic vs. targeted biopsies in general clinical practice, and reported on 389 men who had mpMRI of the prostate followed by systematic and then MRI-targeted transrectal ultrasound fusion guided biopsy. Targeted biopsies were performed using different fusion systems and a heterogenous group of radiologists and urologists using differing protocols on differing patient populations. Individuals with a previous diagnosis of prostate cancer were excluded. Suspected prostate cancer was diagnosed in 202/389 men using the systematic approach, 182/389 men using the targeted approach, and 235/389 men had prostate cancer diagnosed using the combined targeted and systematic approach. The targeted biopsy diagnosed 11% more intermediate- to high-risk tumors when compared to the systematic biopsy ($p<0.0001$) and 16% fewer low-risk tumors ($p<0.0001$). The results were replicated when data from men who were biopsy-naïve and those who had previous negative biopsies were analyzed.

Hansen and colleagues (2016) reported on transperineal biopsy and mpMRI and transrectal ultrasound fusion imaging for 534 individuals with Gleason score ≤ 6 : 107 had no previous prostate biopsy, 295 had a prior benign transrectal-guided biopsy, and 159 were on active surveillance for low-risk cancer. A total of 378 participants had Likert 3-5 MRI lesions reported, cancer was detected in 249 participants, and 157 participants had a new Gleason score 7-10 cancer. Gleason 7-10 cancer was detected in 45% of individuals on active surveillance for low-risk cancer, 27% in individuals with a previous benign biopsy, and 39% in individuals with no previous biopsy. The positive predictive value for detecting Gleason 7-10 was: for Likert 3, 0.15; for Likert 4, 0.43 and for Likert 5, 0.63. The negative predictive value of predicting Likert 1-2 findings was 0.60 for excluding any cancer, 0.87 for excluding Gleason 7-10 and 0.97 for excluding Gleason $\geq 4+3$. The authors further note that “Not all men with moderately elevated PSA values and an unsuspicious prostate mpMRI read by experienced radiologists need prostate biopsies.”

In a 2017 study by Hoffman and colleagues, 99 men with elevated PSA, at least one prior negative standard core biopsy and no previous pretreatment of prostate cancer underwent mpMRI followed by ultrasound-fusion-guided perineal biopsy. MpMRI results indicated that 6 participants had presumed benign disease, 21 participants had ambiguous diagnostic findings, and 72 participants displayed PIRADS/PR scores suggestive of malignancy. A total of 33 participants did not show any signs of malignancy upon histopathological exam following fusion guided targeted biopsy while the remaining 66 participants had prostate cancer diagnosed in the suspicious regions. Only 2

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Prostate Biopsy using MRI Fusion Techniques Multiparametric Magnetic Resonance Imaging

subjects had cancer diagnosed through random biopsy. The overall sensitivity for mpMRI to differentiate between low- and high-grade lesion differentiation (GS less than or equal to 7a vs. greater than or equal to 7b) via PR was 88%, with a negative predictive value of 70% ($p=0.74$; Fisher's exact test). While this was a relatively small group of participants at a single center, the mpMRI followed by ultrasound fusion biopsy showed higher detection rates of prostate malignancy than conventional diagnostic procedures.

A 2017 study by Simmons and colleagues reported on the diagnostic accuracy of mpMRI in participants requiring a repeat prostate biopsy at an expert referral center. A total of 249 participants had previous transrectal ultrasound biopsy and were advised to undergo further biopsies. All 249 participants then underwent mpMRI. Radiologists were blinded to the initial biopsies. Using Likert score greater than or equal to 3, a total of 214 participants had a positive prostate mpMRI. When correlated to biopsy findings, this yielded a sensitivity of 97.1% (95% CI: 92-99), specificity of 21.9% (15.5-29.5), NPV 91.4% (76.9-98.1), and PPV 46.7% (35.2-47.8). When a Likert score greater than or equal to 4 was used, a total of 129 participants had a positive mpMRI, yielding a sensitivity of 80.6% (71.6-87.7), specificity of 68.5% (60.3-75.9), negative predictive value (NPV) 83.3% (75.4-89.5), and positive predictive value (PPV) 64.3% (55.4-72.6). The authors cautioned that insignificant cancers can be detected when an mpMRI threshold score of 3 is used to designate suspicious mpMRI, noting as well that among other published studies wide ranges are used in mpMRI protocols, study populations, reference standards, and mpMRI reporting.

In a 2018 study by Kasivisvanathan and colleagues, 500 participants were randomized to either mpMRI targeted biopsy ($n=252$) or standard biopsy ($n=248$). Of the participants in the mpMRI targeted group, 71 had MRI results that were not indicative of prostate cancer and did not have biopsy, compared to 235 participants in the standard biopsy group. A total of 95 participants (39%) in the mpMRI group were found to have clinically significant prostate cancer and 23 (9%) with insignificant cancers, compared to 64 participants (27%) in the standard biopsy group with 55 (22%) insignificant cancers. Using MRI-targeted biopsy, 78 (31%) of participants were able to avoid biopsy and fewer men in the MRI-targeted biopsy group than in the standard biopsy group received a diagnosis of clinically significant cancer (adjusted difference, -13 percentage points, 95% CI, -19 to -7; $p<0.001$). The authors conclude that the use of risk assessment with MRI before biopsy and MRI-targeted biopsy was superior to standard transrectal ultrasonography-guided biopsy in men at clinical risk for prostate cancer who had not undergone biopsy previously. However, the authors caution that there is room for improvement in attaining consistency in reporting the results of mpMRI and further research is necessary regarding standardization and reproducibility.

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

A 2018 study by Tomašković and colleagues reported on whether the application of magnetic resonance–ultrasound (MR-US) fusion biopsy resulted in improved detection of prostate cancer compared to repeat conventional biopsy (control group) in individuals with previous negative systematic transrectal ultrasound (TRUS)-guided biopsy and persistently elevated or rising PSA levels. A total of 101 men were included in this prospective study. Twenty-four (24) men had previous mpMRI, followed by cognitive fusion biopsy of the prostate with 8-10 systematic biopsy cores and 1-3 targeted biopsy cores according to mpMRI findings. Seventy-seven (77) men underwent only a classic, repeated TRUS biopsy without prior image processing. Lesions were classified according to the PI-RADS system. Cancer detection rate according to PI-RADS-v2 in men with detected lesion on mpMRI was: PI-RADS 1, n=0; PI-RADS 2, n=0; PI-RADS 3, n=0; PI-RADS 4, n=6/8 (75%); and PI-RADS 5, n=2/3 (67%). In the group of men who underwent MR-TRUS cognitive fusion biopsy, the prostate cancer detection rate was 8/24 (33%) and in the control group the detection rate was 12/77 (16%). There are limitations to this study including its small, prospective case design. Referrals for mpMRI was done according to their physician preferences. Biopsies were performed by one urologist and all MRIs were interpreted by an experienced uroradiologist. The authors caution that less experienced urologists and radiologists might not achieve the same diagnostic yield. Taking into account the operator dependent reading and interpretation, as well as diagnostic accuracy of biopsy itself, when there is a prior negative biopsy with persistent suspicion of prostate cancer, the lesions found on mpMRI are better visualized which allows for better sampling.

In a 2019 three-armed multicenter randomised controlled trial by Wegelin and colleagues, the authors compared the overall prostate cancer and clinically significant prostate cancer detection rates of three MRI targeted biopsy techniques and sought to identify whether there was a superior technique regarding diagnostic efficacy in a repeat biopsy setting. Included were 665 men with prior negative systematic biopsy and a persistent suspicion of prostate cancer. All participants underwent 3-T mpMRI evaluated with PI-RADS version 2. The participants with imaging showing PI-RADS greater than or equal to 3 lesions (n=234), were randomized to one of three MRI targeted biopsy techniques; MRI-transrectal ultrasound fusion (n=79), cognitive registration (n=78), or in-bore MRI (n=77). There were 115 prostate cancers and 78 clinically significant prostate cancers detected using targeted biopsy. None of the three groups showed a significant difference in the detection rates of overall prostate cancer (MRI-transrectal ultrasound fusion 49.4%, cognitive registration 43.6%, and in-bore MRI 54.5%) or in the detection of clinically significant prostate cancer (transrectal ultrasound fusion 34.2%, cognitive registration 33.3%, and in-bore MRI

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Prostate Biopsy using MRI Fusion Techniques Multiparametric Magnetic Resonance Imaging

32.5%). One study limitation is the relatively low number of participants with PIRADS greater than or equal to 3 lesions on mpMRI leading to underpowering for the primary endpoint. Also to note is the lack of a consensus on the definition of clinically significant prostate cancer. Generalisability may not be possible since there was an expert team of urologists and radiologists involved in this study regarding prostate cancer diagnosis. For those individuals with a prior negative prostate biopsy and persistent suspicion of prostate cancer, the rate of cancer suspicious regions on mpMRI was 35%. If targeted biopsy of these regions is done, the detection rate would be 49% for prostate cancer and 33% for clinically significant prostate cancer.

In a 2019 retrospective review of charts by Lo and colleagues, the primary objective was to estimate the negative predictive value of mpMRI in detecting clinically significant prostate cancer for individuals with an elevated PSA or abnormal digital rectal exam but a negative preMRI transrectal ultrasound guided biopsy. A secondary objective was to estimate the overall negative predictive value, positive predictive value, sensitivity and specificity of mpMRI for detecting clinically significant prostate cancer at an intermediate to long-term follow-up. There were 121 mpMRI scans done in subjects with a prior negative systemic biopsy. The median PSA was 9.5 ng/dl. With a median follow-up of 6.7 years, subjects with negative mpMRI remained free of clinically significant prostate cancer. Overall negative predictive value of mpMRI was 86%, positive predictive value was 54%, sensitivity was 92%, specificity was 40% with a prevalence of clinically significant prostate cancer of 44%. The study has several limitations including its retrospective design, differing imaging intervals and MRI protocols, and the inability to correlate a positive biopsy with the same lesion found on MRI. The scans in this study were done prior to the advent of the PI-RADS v2 scoring system. A prospective cohort should be used to verify the ability of mpMRI in evaluating negative predictive value in a clinical setting.

In a 2020 retrospective review by Fujii and colleagues, the authors reported on 131 biopsy-naïve Japanese men with an elevated serum PSA to assess the benefits of mpMRI/TRUS targeted fusion biopsy. Prior to biopsy, mpMRI and real-time TRUS images were obtained and then fused together. Targeted biopsy was done first followed by 10-core standard biopsy. The overall cancer detection rate was 61.1% in both standard biopsy and targeted biopsy. Clinically significant prostate cancer was detected in 57 participants (43.5%) by targeted biopsy versus 47 participants (35.9%) by standard biopsy. Clinically insignificant prostate cancer was detected in 23 participants (17.6%) by targeted biopsy versus 33 participants (25.2%) by standard biopsy. There were 1310 cores collected by standard biopsy and 489 cores collected by targeted biopsy. The overall cancer detection rate was 42.3% for the

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Prostate Biopsy using MRI Fusion Techniques Multiparametric Magnetic Resonance Imaging

targeted biopsy cores versus 17.9% for the standard biopsy cores. While this study has limitations including the retrospective and single facility design, there was an improvement in the detection of clinically significant prostate cancer and reduction of clinically insignificant prostate cancer by targeted biopsy compared to standard biopsy.

In a joint consensus statement by the American Urological Association and Society of Abdominal Radiology (Rosenkrantz, 2016) regarding individuals with prostate MRI and MRI-targeted biopsy, the authors advocate the use of an MRI ultrasound fusion biopsy for repeat biopsy after a prior negative biopsy citing that obtaining concurrent systematic cores can be performed in the same session and it allows collaboration between the radiologist identifying the location of the MRI-defined targets while the urologist performs the biopsy.

The National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for prostate cancer (2019) notes that mpMRI can be used in staging and characterization of prostate cancer.

There has been discussion in the literature regarding whether or not a prostate biopsy should be done prior to mpMRI fusion with rectal ultrasound. Current peer-reviewed literature and expert consensus opinion concur that the use of mpMRI fusion techniques prior to prostate biopsy can be effective in detecting clinically significant prostate cancer that a non-targeted biopsy might miss.

While some experts have advocated for incorporation of a prebiopsy MRI into the diagnostic pathway for a clinically suspected prostate cancer, there is no consensus on which people with a negative prostate MRI can forego biopsy, and in many cases, those with an elevated PSA and a negative MRI are still referred for TRUS guided biopsy.

Definitions

Biopsy: The removal of a sample of tissue for examination under a microscope for diagnostic purposes.

Gleason Grading System: A prostate cancer grading system developed by the 2014 International Society of Urological Pathology (ISUP) Consensus Conference, based on the architectural features of the cancer. Numbers

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Prostate Biopsy using MRI Fusion Techniques Multiparametric Magnetic Resonance Imaging

range from 1 to 5. The higher the number, the more undifferentiated the cancer and the more likely the cancer has extended outside of the prostate.

Gleason score: Represents the sum of the two most common Gleason grades observed by the pathologist on a specimen, the first number is the most frequent grade seen.

Magnetic resonance imaging (MRI): A diagnostic technique that uses a cylindrical magnet and radio waves to produce high quality multiplanar images of organs and structures within the body without x-rays or radiation.

Multiparametric magnetic resonance imaging (mpMRI): Combined conventional MRI with diffusion-weighted MRI (DWI), dynamic contrast-enhanced MRI (DCEI), and/or magnetic resonance spectroscopy imaging (MRSI) is known as multiparametric MRI.

Prostate Imaging Reporting and Data System (PI-RADS): Using a 1-5 score, this is a way for radiologists to report how likely it is that a suspicious area is a clinically significant cancer.

Prostate: A walnut-shaped gland in men that extends around the urethra at the neck of the urinary bladder and supplies fluid that goes into semen.

Prostate-specific antigen: A blood test that measures the amount of a specific prostate-related protein in blood, used to screen for prostate cancer and other conditions. A high PSA level in the blood has been linked to an increased chance of having prostate cancer.

Transrectal ultrasound: An ultrasound test in which the sound waves are produced by a probe inserted into the rectum. In men, the structures most commonly examined with this test are the prostate, bladder, seminal vesicles and ejaculatory ducts.

References

Peer Reviewed Publications:

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Prostate Biopsy using MRI Fusion Techniques Multiparametric Magnetic Resonance Imaging

1. Ahmed HU, El-Shater Bosaily A, Brown LC, et al. Diagnostic accuracy of multi-parametric MRI and TRUS biopsy in prostate cancer (PROMIS): a paired validating confirmatory study. Lancet. 2017; 389(10071):815-822.
2. Bjurlin MA, Mendhiratta N, Wysock JS, Taneja SS. Multiparametric MRI and targeted prostate biopsy: Improvements in cancer detection, localization, and risk assessment. Cent European J Urol. 2016; 69(1):9-18.
3. Da Rosa MR, Milot L, Sugar L, et al. A prospective comparison of MRI-US fused targeted biopsy versus systematic ultrasound-guided biopsy for detecting clinically significant prostate cancer in patients on active surveillance. J Magn Reson Imaging. 2015; 41(1):220-225.
4. Del Monte M, Leonardo C, Salvo V, et al. MRI/US fusion-guided biopsy: performing exclusively targeted biopsies for the early detection of prostate cancer. Radiol Med. 2018; 123(3):227-234.
5. Fujii S, Hayashi T, Honda Y, et al. Magnetic resonance imaging/transrectal ultrasonography fusion targeted prostate biopsy finds more significant prostate cancer in biopsy-naïve Japanese men compared with the standard biopsy. Int J Urol. 2020; 27(2):140-146.
- 5.6. Hansen N, Patruno G, Wadhwa K, et al. Magnetic resonance and ultrasound image fusion supported transperineal prostate biopsy using the Ginsburg Protocol: Technique, Learning Points, and Biopsy Results. Eur Urol. 2016; 70(2):332-340.
- 6.7. Hoffmann MA, Taymoorian K, Ruf C, et al. Diagnostic performance of multiparametric magnetic resonance imaging and fusion targeted biopsy to detect significant prostate cancer. Anticancer Res. 2017; 37(12):6871-6877.
- 7.8. Kasivisvanathan V, Rannikko AS, Borghi M, et al. MRI-targeted or standard biopsy for prostate-cancer diagnosis. N Engl J Med. 2018; 378:1767-1777.
- 8.9. Kim EH, Vemana G, Johnson MH, et al. Magnetic resonance imaging-targeted vs. conventional transrectal ultrasound-guided prostate biopsy: single-institution, matched cohort comparison. Urol Oncol. 2015; 33(3):109.e1-e6.
- 9.10. Lee DJ, Recabal P, Sjoberg DD, et al. Comparative effectiveness of targeted prostate biopsy using MRIUS fusion software and visual targeting: a prospective study. J Urol. 2016; 196(3):697-702.
- 10.11. Lo G, Burton KR, Haider MA, et al. Negative predictive value of prostate multiparametric magnetic resonance imaging among men with negative prostate biopsy and elevated prostate specific antigen: a clinical outcome retrospective cohort study. J Urol. 2019; 202(6):1159-1165.

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Prostate Biopsy using MRI Fusion Techniques Multiparametric Magnetic Resonance Imaging

11.12. Mariotti GC, Costa DN, Pedrosa I, et al. Magnetic resonance/transrectal ultrasound fusion biopsy of the prostate compared to systematic 12-core biopsy for the diagnosis and characterization of prostate cancer: multi-institutional retrospective analysis of 389 patients. *Urol Oncol.* 2016; 34(9): 416. e9-e14.

12.13. Oberlin DT, Casalino DD, Miller FH, et al. Diagnostic value of guided biopsies: fusion and cognitive-registration magnetic resonance imaging versus conventional ultrasound biopsy of the prostate. *Urology.* 2016; 92:75-79.

13.14. Rastinehad AR, Abboud SF, George AK, et al. Reproducibility of multiparametric magnetic resonance imaging and fusion guided prostate biopsy: multi-institutional external validation by a propensity score matched cohort. *J Urol.* 2016; 195(6):1737-1743.

14.15. Siddiqui MM, Rais-Bahrami S, Turkbey B, et al. Comparison of MR/ultrasound fusion-guided biopsy with ultrasound-guided biopsy for the diagnosis of prostate cancer. *JAMA.* 2015; 313(4):390-397.

15.16. Simmons LAM, Kanthabalan A, Arya M, et al. The PICTURE study: diagnostic accuracy of multiparametric MRI in men requiring a repeat prostate biopsy. *Br J Cancer.* 2017; 116(9):1159-1165.

16.17. Tomašković I, Pezelj I, Bolanča Čulo K, et al. Diagnostic value of cognitive-registration multiparametric magnetic resonance guided biopsy for the detection of prostate cancer after initial negative biopsy. *Acta Clin Croat.* 2018; 57(Suppl 1):40-45.

17.18. Wegelin O, Exterkate L, van der Leest M, et al. The FUTURE trial: a multicenter randomised controlled trial on target biopsy techniques based on magnetic resonance imaging in the diagnosis of prostate cancer in patients with prior negative biopsies. *Eur Urol.* 2019; 75(4):582-590.

Government Agency, Medical Society, and Other Authoritative Publications:

1. American College of Radiology. ACR Appropriateness Criteria®. Available at: <https://acsearch.acr.org/list>. Accessed on April~~November~~ 6, 202019.
 - Prostate cancer – pretreatment detection staging and surveillance (2016).
2. American Urological Association. Guidelines for the Management of Clinically Localized Prostate Cancer: 2017. Available at: <http://www.auanet.org/guidelines>. Accessed on April~~November~~ 6, 202019.
3. NCCN Clinical Practice Guidelines in Oncology®. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on April~~November~~ 6, 202019.
 - Prostate Cancer (V.4.2019). Revised April 27, 2020~~August 19, 2019~~.

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

Prostate Biopsy using MRI Fusion Techniques

Multiparametric Magnetic Resonance Imaging

4. Rosenkrantz AB, Verma S, Choyke P, et al. Prostate MRI and MRI-targeted biopsy in patients with a prior negative biopsy: a consensus statement of the American Urological Association and the Society of Abdominal Radiology's Prostate Cancer Disease-Focused Panel. *J Urol.* 2016; 196(6):1613-1618.

Websites for Additional Information

1. American Cancer Society. Available at: <http://www.cancer.org/>. Accessed on AprilNovember 6, 202019.
2. National Cancer Institute (NCI). Available at: <http://www.cancer.gov/>. Accessed on AprilNovember 6, 202019.

Index

Artemis™

BioJet™

BiopSee®

mpMRI

UroNav™

Urostation®

Virtual Navigator

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
<u>Revised</u>	<u>05/14/2020</u>	<u>Medical Policy & Technology Assessment Committee (MPTAC) review. Title change to "Prostate Biopsy using MRI Fusion Techniques." Revised MN statement; remove prostate biopsy requirement prior to imaging. Revision to NMN statement by adding "when the above criteria are not met." Updated</u>

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

		<u>Description, Discussion/General Information, and References sections. Updated Coding section; removed code 77021 not applicable.</u> <u>Medical Policy & Technology Assessment Committee (MPTAC) review.</u> Clarification to Clinical Indications 2 nd bullet point regarding prostate biopsy(s) and 3 rd bullet point regarding Likert scale and PI-RADS scoring system.
Revised	02/20/2020	Updated Discussion/General Information, Definitions, and References sections. MPTAC review.
New	03/21/2019	Hematology/Oncology Subcommittee review. Initial document development.
New	03/20/2019	Moved content of RAD.00066 Multiparametric Magnetic Resonance Fusion Imaging Targeted Prostate Biopsy to new clinical utilization management guideline document with the new title.

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.