
Medical Policy



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***Current Policy Effective Date: 7/1/26**
(See policy history boxes for previous effective dates)

Title: Computer-Aided Evaluation as an Adjunct to Magnetic Resonance Imaging for Prostate Cancer

Description

Computer-aided evaluation (CAE) programs, as an adjunct to magnetic resonance imaging (MRI) systems, are actively being investigated as a means to provide clinical decision support to radiologists in the diagnosis and treatment of prostate cancer. Reading prostate centered MRIs to rule out or locate malignancies requires a high level of expertise and is a time-consuming task.

Medical Policy Statement

The use of computer-aided software as an adjunct to magnetic resonance imaging interpretation of the prostate is considered experimental/investigational. There is insufficient evidence to determine that the technology results in an improvement in net health outcomes.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

76498

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Background

Using CAE as an adjunct to an MRI, the radiologist reviews the image per standard of care, then refers to the CAE interpretation. Based on an algorithm, the CAE technology highlights regions of interest. The radiologist then reviews these regions on the original image more intensely.

Summary:

Studies evaluated the performance of CAE systems in a clinical setting, namely investigating their potential role in improving reader performance when reporting mpMRI for prostate cancer detection. Themes among the industry sponsored publications include the advantages that CAE affords non-experienced radiologists when reading mpMRIs and the benefit of managing and/or streamlining the overall radiologist workload. Per the FDA approvals, the technology is meant to be used concurrently with the PI-RADS v2 system by trained urologists, who are expertly trained to read and interpret prostate mpMRI exams consistent with American College of Radiology recommendations. The system is not meant to be used as a training aid or as a substitute for specialty training in urology. Currently, there is no support from oncologic, radiology or urology organizations for the use of CAE as an adjunct to mpMRI readings as a prostate screening modality. Statistically significant improvements, in sensitivity or specificity of CAE as an adjunct to MRI vs MRI alone, were not noted when utilized by experts utilizing the ACRs recommendations for mpMRI interpretation. Some peer-reviewed, non-sponsored studies warn of serious impairments that can occur from procedures which are used to treat or confirm suspected malignancies. Large, randomized, peer-reviewed, studies are needed which compare the impact of patient outcomes when using CAE as an adjunct with MRI versus MRI alone. There is insufficient evidence in the peer reviewed medical literature regarding how the utilization of CAE would positively affect patient management or improve overall health outcomes.

Rationale

de Rooij et al (2017) reported on a consensus of 44 leading urologists and urogenital radiologists, who are experts in prostate cancer. The recent update of the European Association of Urology guideline and the American Urological Association recommend that biopsy-naïve men who have suspicion of prostate cancer (via elevated PSA or abnormal digital rectal exam) should undergo a mpMRI prior to biopsy. Leading experts have expressed concerns that suboptimal image acquisition and reporting at an individual level will result in clinicians losing confidence in the technique of mpMRI. Therefore, an expert consensus determined that radiologist must attend theoretical and hands-on courses followed by supervised education before utilizing Prostate Imaging-Reporting and Data System version 2 (PI-RADS v2) to interpret prostate MRIs. Furthermore, regular self and external performance assessments were deemed necessary to maintain the expert expectations for uro-radiology regarding prostate cancer. The consensus statements did not discuss the use of software to assist the expert in interpreting the images.

Computer aided evaluation programs have been promoted to help radiologists manage the increase in the prostate MRI workload, streamline the radiology workflow, and detect and characterize prostate cancer.

The current gold standard for interpretation of mpMRIs for prostate cancer consists of utilizing the PI-RADS v2 that was designed in 2015. PI-RADS v2 is a set of guidelines that outline standard acquisition parameters and provide a categorization system for cancer detection. PI-RADS v2 was released to promote global standardization of mpMRI to diminish variation in acquisition, interpretation and reporting. PI-RADS v2 has been widely adopted and can achieve cancer detection rates up to 80-90%; however, it is associated with a steep learning curve.

For prostate cancer screening to be valuable, it must reduce disease-specific morbidity and/or mortality by detecting cancer at an early stage. Unfortunately, detection at an early stage does not necessarily correlate with a clinically beneficial outcome (e.g., decline in morbidity or mortality due to prostate cancer). Increased detection of prostate cancer subjects some individuals to the risks associated with treatments that may not prolong life and that have risks of morbidity.

Over-diagnosis and over-treatment of low-risk prostate cancer can potentially be harmful when complications such as incontinence and erectile dysfunction are the result. Although multi-parametric MRI (mpMRI) has increased the detection of clinically significant disease and reduced the number of unnecessary biopsies, it has been criticized because of variability in quality of exams and inconsistent interpretations across clinical centers and physicians.

CAE assistance in prostate cancer detection has been compared with conventional (multiparametric magnetic resonance imaging) mpMRI interpretation using PI-RADS v2 in both industry and non-industry sponsored trials. A diverse set of readers with varying levels of experience have been evaluated using PI-RADSV2 and again with the adjunctive use of the CAE system. Guar et al (2018) found that moderately experienced readers achieved comparable sensitivity with mpMRI vs CAE at 93.3% vs 92.8% ($p=0.864$) while highly experienced readers achieved mpMRI sensitivity 96.7% vs CAE at 90.7% ($p=0.007$). Overall

agreement was not different with CAE assistance (mpMRI-alone index of specific agreement 90% vs CAD-assisted 92%, $p=0.401$), and this pattern was consistent across comparisons between readers of each experience level. For all readers, CAE-assisted read times improved (4.6 vs 3.4 minutes, $p<0.001$). Authors identified trust as a major factor in reducing the effectiveness of CAE. Experienced radiologist who were confident in their ability to identify lesions were found to mistrust the technology and chose not to rely on its algorithms. However, less experienced radiologist who were uncertain about their ability to identify lesions were overly reliant on the technology. The CAE system was found to benefit non-experienced radiologists more than senior radiologists in reading mpMRI scans for prostate cancer. Furthermore, a reasonable concern addressed whether or not a CAE system can be used to identify lesions in a population beyond the one which was used for creating the algorithms. Readers with different experience levels detected index lesions with comparable sensitivity to non-assisted interpretations.

Giannini et al (2021) focused on inexperienced readers using 3 resident radiologist, all with 1 year of MRI experience. Sensitivity significantly increased in the computer assisted mode for individuals with at least 1 clinically significant lesion ($GS > 6$) (68.7% vs. 78.1%, $p = 0.018$). Overall specificity was not statistically different between unassisted and assisted sessions (94.8% vs. 89.6, $p = 0.072$). The use of the CAE system significantly increased the per-individual sensitivity of inexperienced readers in the detection of clinically significant prostate cancer, without negatively affecting specificity, while significantly reducing overall reporting time. Furthermore, different reading behaviors were observed with inexperienced readers. On a per-patient basis, 1 reader had the lowest sensitivity gain when reporting with the CAE system, while retaining a 100% specificity. Conversely, reader 2 and 3 showed a larger sensitivity increase when assisted by the CAE system but had different results in terms of specificity, i.e., reader 2 performed better without CAE, while only a minimal decrease in specificity was noted for reader 3. Finally, when reporting with the CAE, reader 3 obtained a significantly higher AUC than that of the other 2 readers (p -values = 0.029 and 0.017, respectively). While reader 3 definitively showed good performances both sensitivity and specificity-wise, in the authors opinion the 2 other readers differed essentially for their trustworthiness. Zhu et al (2019) agreed that CAE is helpful in assisting the diagnostic sensitivity of prostate cancer detection and can decrease reading time among inexperienced radiologists.

Supplemental Information

American Cancer Society

The American Cancer Society (2025) does not address the use of computer-aided software as an adjunct to mpMRI when discussing tests used to diagnose and stage prostate cancer. They refer to the Prostate Imaging Reporting and Data System (PI-RADS) used by specially trained urologists.

American College of Radiology

The American College of Radiology (2019) recommends that high-quality Prostate Imaging Reporting and Data System (PI-RADS)-compliant multiparametric MRI should be performed before prostate biopsy in most men who are suspected of having clinically significant disease and are likely to be offered active treatment. Computer-aided diagnostic systems are not mentioned.

European Association of Urology (EAU)-European Association of Nuclear Medicine (EANM)-European Society for Radiotherapy and Oncology (ESTRO)-European Society of Urogenital Radiology (ESUR)-International Society of Geriatric Oncology (SIOG)
The EAU, EANM, ESTRO, ESUR and SIOG guidelines for prostate cancer indicate that it is still too early to predict whether quantitative approaches and computer-aided diagnostic systems will improve the characterization of lesions seen on MRI.

National Comprehensive Cancer Network

The NCCN's guidelines for early detection of prostate cancer point out that although the vast majority of published evidence using MRIs for prostate cancer diagnosis comes from high volume centers, the generalizability of the findings is not yet clear. The panel recommends multiparametric MRI be performed before biopsy if available, however they do not mention the use of computer aided software but do emphasize the need for high-quality MRI scans and for radiologic expertise to ensure optimal reading.

American Urological Association (AUA) and Society of Urologic Oncology (SUO)

The AUA/SUO guideline (2023) indicates that radiologists should utilize the Prostate Imaging - Reporting and Data System (PI-RADS) in the reporting of multi-parametric MRI (mpMRI) imaging. (Moderate Recommendation; Evidence Level: Grade C). No mention of computer-aided evaluation systems was made.

European Society for Medical Oncology (ESMO)

The ESMO (2020) recommends the use of PI-RADS when reporting mpMRI when used for the diagnosis, treatment and follow-up of prostate cancer. The use of computer-aided evaluation systems are not mentioned.

Regulatory Status

Quantib Prostate (Quantib BV) received FDA 510(k) approval in April 2023 (K230772) for marketing of the post-imaging software which facilitates the analysis and study review of MR data sets. It provides additional mathematical and/or statistical analysis. Quantib Prostate is intended to be used by trained medical professionals and provides information that, in a clinical setting, may assist in the interpretation of prostate MR studies. Diagnosis should not be made solely based on the analysis performed using Quantib Prostate. Product code: LLZ

ProstatID™ (ScanMed, LLC) received FDA 510(k) approval in July 2022 (K212783) for marketing of the radiological computer assisted detection and diagnostic software device. ProstatID software is intended as a concurrent reading aid for radiologists qualified to read and interpret prostate MRI exams consistent with American College of Radiology (ACR) recommendations in the context of Prostate Imaging–Reporting and Data System Version 2 (PI-RADS v2). Use is intended to identify regions suspicious for prostate cancer and assess their likelihood of malignancy in patients presenting with high-risk screening or diagnostic imaging, from compatible MRI systems. Analysis by ProstatID is not intended as a replacement for interpreting prostate abnormalities using MR image data consistent with clinical recommendations (including dynamic contrast-enhanced); nor should patient management decisions be made solely on the basis of ProstatID. Product code: QDQ

National:

The determination does not address the use of computer-aided software in the interpretation of mpMRIs for prostate cancer.

No local determination noted that addresses the use of computer-aided software in the interpretation of mpMRIs for prostate cancer.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

- Focal Treatments for Prostate Cancer
- Prostate Cancer Early Detection: Biomarkers Prior to Biopsy
- Saturation Biopsy for the Diagnosis and Staging of Prostate Cancer
- Spectral Analysis of Prostate Tissue

- American Cancer Society. Tests to Diagnose and Stage Prostate Cancer. 2025. <https://www.cancer.org/cancer/types/prostate-cancer/detection-diagnosis-staging/how-diagnosed.html>. Accessed: March 25, 2026.
- American College of Radiology. Prostate MRI Model Policy. n.d. <https://www.acr.org/-/media/ACR/Files/Advocacy/AIA/Prostate-MRI-Model-Policy72219.pdf>. Accessed: February 1, 2024.
- Centers for Medicare & Medicaid Services. National Coverage Determination: Magnetic Resonance Imaging. 220.2. 2018. <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=177&ncdver=6&>. Accessed: March 25, 2026.
- de Rooij M, Israël B, Tummers M, et al. ESUR/ESUI consensus statements on multi-parametric MRI for the detection of clinically significant prostate cancer: quality requirements for image acquisition, interpretation and radiologists' training. *Eur Radiol*. 2020 Oct;30(10):5404-5416. doi: 10.1007/s00330-020-06929-z. Epub 2020 May 19. PMID: 32424596.
- European Association of Urology (EAU)-European Association of Nuclear Medicine (EANM)-European Society for Radiotherapy and Oncology (ESTRO)-European Society of Urogenital Radiology (ESUR)-International Society of Geriatric Oncology (SIOG): Guidelines on prostate cancer (2024). <https://uroweb.org/guidelines/prostate-cancer/chapter/diagnostic-evaluation>. Accessed: March 25, 2026.
- Food and Drug Administration. 501(k) premarket notification: ProstatID™. K212783. July 2022. https://www.accessdata.fda.gov/cdrh_docs/pdf21/K212783.pdf. Accessed: March 25, 2026.

7. Food and Drug Administration. 501(k) premarket notification: Quantib Prostate. K230772. April 2023. https://www.accessdata.fda.gov/cdrh_docs/pdf23/K230772.pdf. Accessed: March 25, 2026.
8. Gaur S, Lay N, Harmon SA, et al. Can computer-aided diagnosis assist in the identification of prostate cancer on prostate MRI? a multi-center, multi-reader investigation. *Onco target*. 2018 Sep 18;9(73):33804-33817. doi: 10.18632/oncotarget.26100. PMID: 30333911.
9. Giannini V, Mazzetti S, Cappello G, et al. Computer-Aided Diagnosis Improves the Detection of Clinically Significant Prostate Cancer on Multiparametric-MRI: A Multi-Observer Performance Study Involving Inexperienced Readers. *Diagnostics (Basel)*. 2021 May 28;11(6):973. doi: 10.3390/diagnostics11060973. PMID: 34071215.
10. National Comprehensive Cancer Network. Prostate Cancer Early Detection. 2.2026. https://www.nccn.org/professionals/physician_gls/pdf/prostate_detection.pdf. Accessed: March 25, 2026.
11. Parker, C., Castro, E., Fizazi, K., et al. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Ann of Onc*. Sept 2020;31(9):1097-1276.
12. Wagaskar, V.G.; Levy, M.; Ratnani, P.; et al. Clinical Utility of Negative Multiparametric Magnetic Resonance Imaging in the Diagnosis of Prostate Cancer and Clinically Significant Prostate Cancer. *Eur. Urol. Open Sci*. 2021, 28, 9–16.
13. Wei JT, Barocas D, Carlsson S, et al. Early detection of prostate cancer: AUA/SUO guideline part I: prostate cancer screening. *J Urol*. 2023;210(1):45-53. <https://www.auanet.org/guidelines-and-quality/guidelines/early-detection-of-prostate-cancer-guidelines>. Accessed March 25, 2026.
14. Wei JT, Barocas D, Carlsson S, et al. Early detection of prostate cancer: AUA/SUO guideline part II: considerations for a prostate biopsy. *J Urol*. 2023;210(1):54-63. <https://www.auanet.org/guidelines-and-quality/guidelines/early-detection-of-prostate-cancer-guidelines>. Accessed March 25, 2026.
15. Weinreb JC, Barentsz JO, Choyke PL, et al. PI-RADS Prostate Imaging - Reporting and Data System: 2015, Version2. *Eur Urol*. 2016; 69:16-40.
16. Zhu L, Gao G, Liu Y, Han C, Liu J, Zhang X, Wang X. Feasibility of integrating computer-aided diagnosis with structured reports of prostate multiparametric MRI. *Clin Imaging*. 2020 Mar;60(1):123-130. doi: 10.1016/j.clinimag.2019.12.010. Epub 2019 Dec 13. PMID: 31874336.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 3/25/26, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/24	4/16/24		• Joint policy established • Vendor managed: N/A • Replacement of IMP – CAD of malignancy with contrast enhanced MRI of the prostate
7/1/25	4/15/25		• Routine maintenance • Vendor managed: N/A
7/1/26	4/21/26		• Routine maintenance (slp/no) • Vendor managed: N/A • Formatting updated • MPS language updated

Next Review Date: 2nd Qtr, 2027

BLUE CARE NETWORK BENEFIT COVERAGE

POLICY: COMPUTER-AIDED EVALUATION AS AN ADJUNCT TO MAGNETIC RESONANCE IMAGING FOR PROSTATE CANCER

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.