Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
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Plan: AmeriHealth Caritas Pennsylvania & Keystone First	Submission Date: 10/1/2025
Policy Number: CCP.1496	Effective Date: 10/1/2021 Revision Date: 9/1/2025
Policy Name: Computer-aided detection and diagnosis for chest imaging	

Type of Submission:	Type of Policy:
☐ New Policy	☒ Prior Authorization Policy
☒ Revised Policy*	☐ Base Policy
☐ Annual Review- no revisions	☒ Experimental/Investigational Policy
	☐ Statewide PDL
	☐ Other:

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any clarifying information for the policy below:

Name of Authorized Individual (Please type or print):	Signature of Authorized Individual:
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Computer-aided detection and diagnosis for chest imaging

Clinical Policy ID: CCP.1496

Recent review date: 9/2025

Next review date: 1/2027

Policy contains: chest radiography; ClearRead; computer-aided detection; computer-aided diagnosis; computed tomography; lung cancer; RapidScreen; solitary pulmonary nodule.

Coverage policy

Computer-aided detection or computer-aided diagnosis for chest imaging is investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- Unaided chest radiography.
- Unaided chest computed tomography.

Background

A solitary pulmonary nodule represents an early-stage T1 round or oval lesion in the lung parenchyma measuring less than 3 cm in diameter with discrete margins and no associated abnormality. Most often, solitary pulmonary nodules are screen-detected or incidental findings on chest radiography. They present a diagnostic challenge in the absence of a biopsy, as these lesions are often benign and asymptomatic, and the differential diagnosis can be extensive. The objective of the workup is to differentiate malignancies requiring intervention from benign lesions that can be observed safely (Wyker, 2024).

Low-dose computed tomography is the recommended screening modality for lung cancer, as it has sufficient sensitivity and specificity to detect early–stage disease in high-risk populations and could prevent a substantial number of lung cancer–related deaths (Krist, 2021). The harms associated with low-dose computed tomography are false-positive results leading to unnecessary tests and invasive procedures, incidental findings, short-term increases in distress due to indeterminate results, overdiagnosis, and radiation exposure (Jonas, 2021). Current nodule evaluation protocols on computed tomography (e.g., Lung CT Screening Reporting & Data System [Lung-RADS]) are designed to reduce false-positive results and associated invasive procedures (American College of Radiology, 2022).

Compared to computed tomography, chest radiography is more widely available and less costly, and offers lower radiation exposure (Jonas, 2021). However, false positive findings are common, and it lacks sufficient resolution to detect the earliest, smallest stage lung cancers or provide reliable information on other nodule characteristics visible on computed tomography, which could confound malignancy assessment. Therefore, chest radiography is insufficiently sensitive to serve as an effective screening modality for reducing lung cancer mortality but can provide information on nodule size and location, presence of calcium in the nodule, and growth over time, which can inform the probability of malignancy.

A computer-aided detection system is dedicated computer software that detects potential abnormalities on diagnostic radiology exams (U.S. Food and Drug Administration, 2022). Through pattern recognition and data analysis, the system highlights suspicious areas of irregularity on a previously acquired and interpreted medical image for the radiologist to reassess, with the goal of improving reader performance in the intended use population. It acts as a "second reader" and may overcome the limitations of chest radiography and avoid the risks associated with computed tomography and biopsy by improving sensitivity and reducing the number of false positive findings.

Computer-aided diagnosis refers to software that both identifies suspicious regions and characterizes the lesion (e.g., benign versus malignant) (U.S. Food and Drug Administration, 2022). Computer-aided diagnosis systems assess user-selected regions of interest in terms of the likelihood of malignancy or by disease type, severity, stage, or recommended intervention. These systems integrate nodule characteristics and most often use the area under the receiver operating characteristic curve measurement to distinguish the nodule.

The U.S. Food and Drug Administration (2004, 2025) has issued 510(k) clearance to one computer-aided detection system using lung radiography and several computer-aided diagnosis systems using lung computed tomography. Approval criteria vary by system based on the intended population (e.g., screening versus diagnosis) and system requirements.

Findings

Guidelines

According to the American College of Radiology, computer-aided detection and computer-aided diagnosis in lung imaging show potential for improving diagnostic accuracy, particularly in identifying small nodules and reducing interpreter error. However, the current body of evidence is limited by variability in study designs and the retrospective nature of most research, leading to uncertainties regarding the impact on clinical outcomes. Computer-aided detection systems may enhance the detection and characterization of incidentally detected indeterminate pulmonary nodules on high-resolution computed tomography, but its role in interpreting chest radiography was not addressed (American College of Radiology, 2023a).

The American College of Radiology, the Society of Advanced Body Imaging, the Society for Pediatric Radiology, and the Society of Thoracic Radiology published a practice parameter for the performance of thoracic computed tomography. The practice parameter provides guidance for performing high-quality thoracic computed tomography scans, emphasizing the need for knowledge in normal anatomy, pathophysiology, and computed tomography techniques. The document addresses the role of computer-aided diagnosis software, which can assist in the evaluation of lung nodules, airways, emphysema, coronary artery calcification, and pulmonary emboli (American College of Radiology, 2023b).

The National Institute for Health and Care Excellence (2023, 2025) found insufficient evidence to recommend adjunctive artificial intelligence-derived software to analyze chest radiographs for suspected lung cancer in adults referred from primary care or to analyze chest computed tomography in patients presenting with or without signs or symptoms suggestive of lung cancer. However, such software may be beneficial for a targeted lung cancer screening population using chest computer tomography, but providers are advised to generate additional evidence to make sure the potential benefits of using the software are realized in practice and to allow comparisons of the different technologies.

<u>Evidence review</u>

Computer-aided detection and computer-aided diagnosis in lung imaging show potential for improving diagnostic accuracy, particularly in identifying small nodules and reducing interpreter error. However, the current body of evidence is limited by variability in study designs and the retrospective nature of the research, leading to uncertainties regarding the impact on clinical management and patient outcomes. Study investigators call for prospective trials to address gaps in the research.

Computer-aided diagnosis using computed tomography

A systematic review by Amir (2016) evaluated the accuracy of computer-aided diagnosis across 14 low-to-moderate quality studies involving 1,868 computed tomography scans. Computer-aided radiologists' interpretation significantly improved accuracy, with eight out of nine studies showing a receiver operating characteristic curve area of 0.8 or higher.

A systematic review analyzed 75 studies published between 2017 and 2022 on machine learning algorithms for computer-aided diagnosis of lung nodules in chest computed tomography images. The review found that deep learning methods, particularly convolutional neural networks, outperformed conventional machine learning approaches, achieving 100% sensitivity for nodule detection, a dice similarity coefficient of 0.9906 for nodule segmentation, and an accuracy of 99.17% for classifying nodules as benign or malignant (Jin, 2023).

A large, retrospective analysis compared the diagnostic outcomes of low-dose computed tomography scans with computer-aided diagnosis (n = 944) versus a conventional reading system (n = 301) in a screening population at elevated risk of lung cancer. The study found significantly higher diagnosis rates using computer-aided diagnosis (11% vs. 7%, *P* = .0345), but the specificity and negative predictive values were similar. Notably, computer-aided diagnosis had lower sensitivity for ground-glass nodules and similar sensitivity for part-solid nodules than that of the conventional reading system. Study limitations were attributed to retrospective design (the datasets of the conventional reading and computer-aided diagnosis systems were different), lack of cross-sectional analysis, and variation in underlying risk among patients (Wang, 2022).

A systematic review of 19 cohort studies and one case-control study examined the diagnostic performance of stand-alone deep learning algorithms versus expert readers in adults with lung cancer of various nodule types. Compared to expert reviewers, stand-alone deep learning algorithms exhibited comparable sensitivity (82% vs. 81%, *P* = .06) and higher specificity (75% versus 69%, *P* < .01). The diagnostic performance of deep learning algorithms varied across different imaging modalities (low-dose versus high-resolution) and tasks (Wang, 2024).

A systematic review and meta-analysis of 17 studies (n = 8,553, 9,884 nodules) showed deep learning-based computer-aided diagnostic models were 11.6% more sensitive, but equally specific, than physician judgement alone, and 14.5% more sensitive and 7.4% more specific than clinical risk models alone. Factors affecting diagnostic performance included heterogeneity among algorithms and study populations (screening versus incidental detection, nodule types), and the threshold cut-off point used to predict the risk of malignancy (Wulaningsih, 2024).

Computer-aided detection using chest radiography

A systematic review of seven studies found computer-aided detection using chest radiography averaged a sensitivity of 58.67% with a mean false positive rate of 2.22 per image. However, the review failed to confirm a correlation between sensitivity and false positive rates, with most studies being retrospective and inconclusive, requiring further validation through larger, prospective analyses (Haber, 2020).

Toda's 2023 retrospective analysis confirms Haber's findings. The investigators reviewed the performance of computer-aided detection software available in Japan in diagnosing pulmonary nodules and masses in 453 participants, showing a significant improvement in detecting nodules and masses by reducing the number of missed lesions. However, the prevalence of abnormal findings in this study was higher than in a routine clinical population. Computer-aided detection software was more beneficial to non-pulmonology physicians and junior residents than to more experienced radiologists and pulmonologists in terms of their ability to correctly identify and localize more clinically significant lesions (Toda, 2023).

A systematic review commissioned by the National Institute for Health and Care Excellence found no applicable evidence that addressed the use of adjunctive artificial intelligence software for the detection of suspected lung cancer on chest radiography in individuals referred from primary care either for symptoms suggestive of lung cancer or for reasons unrelated to lung cancer. Six studies that did not meet the inclusion criteria provided some contextual evidence of improved sensitivity for lung cancer detection (but not nodule detection) among radiology specialists who used artificial intelligence software-aided interpretation. There were no significant differences between those who did and did not use the software in terms of specificity, positive predictive value, or number of cancers detected. Therefore, evidence of improved test accuracy, clinical decision making, or patient outcomes with the use of adjunctive artificial intelligence software is lacking (Colquitt, 2024).

Other lung indications

Two systematic reviews/meta-analyses examined the diagnostic accuracy of computer-aided detection chest radiography for pulmonary tuberculosis screening. The results suggest good overall sensitivity (90%) for detecting tuberculosis but with false positive rates of up to 30%; specificity was more variable ranging from 60%

to 80%. Included studies were limited in number, retrospective, conducted in Asia, and heterogeneous with respect to proprietary algorithms used and indications (Emoru, 2025; Han, 2025).

Finally, a systematic review examined the use of computer-aided detection in diagnosing pneumoconiosis, further expanding the evidence base for computer-aided detection applications in various pulmonary conditions. Despite these promising results, the retrospective nature and variability in inclusion criteria across studies remain key limitations, leaving uncertainty about the impact of computer-aided detection on clinical outcomes, particularly in differentiating between asymptomatic screening populations and clinical populations with a higher pre-imaging probability of malignancy (Devnath, 2022).

In 2024, we reorganized the findings section and added a new practice parameter document by the American College of Radiology and others and a new systematic review (Jin, 2023). No policy changes were warranted.

In 2025, we updated the references with no policy changes warranted.

References

On July 3, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were "radiographic image interpretation, computer-assisted (MeSH)," "image processing, computer assisted (MeSH)," "solitary pulmonary nodule (MeSH)," and "computer-aided detection." We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

9/2021: initial review date and clinical policy effective date: 10/2021

9/2022: Policy references updated.

9/2023: Policy references updated.

9/2024: Policy references updated.

9/2025: Policy references updated.