



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Computer-Aided Detection of Chest Radiographs

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Spiral Computed Tomography for Lung Cancer Screening

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Coverage Policy

CIGNA does not cover computer-aided detection of chest radiographs for any indication, including but not limited to lung cancer screening, because it is considered experimental, investigational or unproven.

General Background

Computer-aided detection (CAD) systems for digital chest x-rays, are software programs that subtract one lung from another to reveal subtle asymmetric opacities, and perform temporal subtraction of prior chest x-rays from the current exam. The basic concept of computer-aided detection (CAD) is to provide computerized image recognition to assist and improve radiologist's interpretation. Through algorithms, CAD technology provides radiologists with regions of interest (ROI) for their interpretation. Although CAD is used most often in mammography, many different types of CAD technologies and/or devices are being developed for detection of various lesions in medical imaging, including conventional x-ray, computed tomography (CT), magnetic resonance imaging (MRI), and ultrasound.

Proponents of computer-aided detection with chest x-ray state that diagnostic accuracy is improved with the use of a CAD program and that CAD can expedite screening of at-risk individuals at an earlier and more curable stage of lung cancer. Potential risks of using CAD with chest x-rays may include the generation of false-positive and false-negative results leading to over- and under-diagnosis. Abnormalities (e.g., scars from smoking, areas of inflammation, or other noncancerous conditions) can mimic lung cancer on x-ray. Subsequent additional

testing may cause anxiety for the patient or may lead to unnecessary biopsy or surgery and increase medical costs. Also, the use of CAD programs in screening for lung cancer may detect small tumors that would never become life-threatening, putting a patient at risk for unnecessary treatments for cancer, such as chemotherapy or radiation.

U.S. Food and Drug Administration (FDA)

Deus Technologies received FDA premarket approval for its RapidScreen™ CAD system in July 2001. Its intended use is “to identify and mark regions of interest on digital or digitized frontal chest radiographs. It identifies features associated with solitary pulmonary nodules from 9–30 millimeters (mm) in size, which could represent early-stage lung cancer. The device is intended for use as an aid only after the physician has performed an initial interpretation of the radiograph. The device is of little value when used for patients who are not at high risk for lung cancer.” In 2007, Deus Technologies manufacturer Riverain Medical Group (Miamisburg, OH) received approval for a new trade name. The device, as modified, will be marketed under the trade name OnGuard™ and is indicated “to identify and mark ROIs on frontal chest radiographic films from adult males with an increased risk for lung cancer to bring ROI to the attention of the radiologist after the initial reading has been completed. Thus the system assists the radiologist in minimizing observational oversights by identifying areas on the original chest films that may warrant a second review.” Currently, Riverain Medical’s OnGuard™ CAD System is the only FDA-approved CAD systems with a Product Device Description of “Analyzer, Medical Image” for chest x-rays (Product Code MYN). Other CAD systems (for example, mammography or lung computed tomography) are listed under this same device description.

The FDA approved EDDA Technology’s (Princeton Junction, NJ) “IQQA® Chest Software Package” in October 2004 under the Product Device Description of Picture Archiving and Communications System (PACS). It uses a real-time interactive pulmonary nodule analysis system for chest digital radiographic image softcopy reading. Intended use states it is “used during the review of digital chest radiographic images. Combining image viewing, evaluation and reporting tools, the software is designed to support the physician in the identification of lung lesions (e.g. nodules), as well as the confirmation, evaluation and documentation of such physician-identified lesions. The IQQA-Chest software package supports a workflow based on automated segmentation for the visual identification of possible lesions. The tools also allow for regional analysis of possible lesions in terms of size, shape and position, thus aiding the physician in the characterization of physician-identified suspicious lesions.” Philips Medical Systems (Hamburg, Germany) has licensed EDDA Technology’s IQQA® Chest software and markets it under the name xLNA (x-ray lung node assessment) Enterprise.

Literature Review

There is insufficient evidence in the published, peer-reviewed scientific literature addressing the accuracy and clinical utility of CAD of chest x-rays. The accuracy and clinical utility have not been established. Although studies are primarily retrospective analyses of registry data, there is concern regarding unacceptable false-positive rates. Well-designed clinical trials are lacking. Retrospective registry studies address multiple variables that may impact accuracy such as experience and training of radiologist using the CAD program, type of chest x-ray utilized (e.g., temporal subtraction, dual energy subtraction) and region of interest (ROI) identification parameters in the algorithms themselves (e.g., nodules size, bone suppression, and nodule-in-center or nodule-in-circle criterion). The clinical utility of CAD of chest x-rays, including for lung cancer screening, is not established; nor the utility of screening for lung cancer. Although the FDA wording regarding RapidScreen™ CAD systems states “the device is of little value when used for patients who are not at high risk for lung cancer”, the ACCP notes that no lung screening modality has been shown to alter mortality outcomes for high-risk populations.

OnGuard/RapidScreen/Riverain Medical: Meziane et al. (2010) retrospectively compared RapidScreen 1.1 and OnGuard 3.0, 4.0, and 5.0 in a sample of 200 patients. Of the 200 patients, 100 had at least one computed tomography scan and/or pathology proven nodule; 100 did not have nodules. The sensitivity and number of false-positives were compared between the different versions. There was a significant increase in sensitivity with OnGuard 3.0 relative to RapidScreen 1.1 (44.2% vs. 62.5%, $p=0.002$). There was a significant decrease in the average number of false-positives per patient (FPI) with each new version relative to its predecessor: 3.9 FPI with RapidScreen 1.1, versus 3.3 FPI with OnGuard 3.0 ($p<0.0001$), 3.3 FPI with OnGuard 3.0 versus 2.6 FPI with OnGuard 4.0 ($p<0.0001$), and 2.6 FPI with OnGuard 4.0 versus 2.0 with OnGuard 5.0 ($p<0.0001$). A similar trend was observed for patients with nodules and for patients without nodules. The most common causes for false-positives with all four CAD versions were vessels and rib crossings. The authors noted this study was

an incremental step toward future studies aimed at testing the effect of CAD on observers' diagnostic performances.

Szucs-Farkas et al. (2010) retrospectively evaluated the performance of a CAD program for the detection of pulmonary nodules in original and energy-subtracted (ES) chest radiographs, with special regard to the number of false-positives. Results were compared with findings by human observers. A total of 83 patients were included, 58 with pulmonary nodules and images of 25 control subjects with no nodules. Computerized tomography was used as the reference standard. CAD results were compared to the five readers' findings. CAD used with ES images produced significantly fewer false-positives than with non-subtracted images: 1.75 and 2.14 false-positives per image, respectively ($p=0.029$). Depending on the reader's experience, CAD detected between 11 and 21 nodules missed by readers. Human observers found three to 16 lesions missed by the CAD software.

White et al. (2009) gathered and reviewed registry data. From a registry, x-rays with nodules that were already biopsy confirmed, were identified ($n=3100$). Next, previous x-rays for that patient were evaluated; these were surveyed to determine whether the lesion was visible in retrospect. A total of 89 patients with missed lung cancer were found on the basis of review of the lung cancer registries. All x-rays were processed by OnGuard version 3.0 (designed primarily to detect solitary pulmonary nodules between 0.9 and 3.0 cm in size). Results showed CAD correctly marked the overlooked lesion on at least one x-ray in 46 (52%) of the 89 patients. On a per-image basis, the CAD software correctly identified the missed lesion on 53 (47%) of the 114 images. To determine the number of false-positive findings at CAD in a group of patients without cancer, an age- and sex-matched control group was identified, though control groups were not matched for confounding parenchymal features such as fibrosis. An average of 3.9 false-positive results occurred per x-ray; an average of 2.4 false-positive results occurred per x-ray for the control group. The authors noted that the current algorithm still has a somewhat high rate of false-positive results compared with an earlier algorithm.

Balkman et al. (2010) conducted a retrospective study to evaluate the impact of standard compared to dual energy subtraction (DES) x-rays on CAD performance. Balkman et al. gathered records for patients meeting the following inclusion criteria: posteroanterior (PA) standard and dual energy subtraction (DES) chest x-rays, biopsy-proven lung carcinoma, and lung nodules 8 to 30 mm in size ($n=36$). Next, the CAD program was applied. The sensitivity of the CAD program with the DES PA x-ray was 67% and standard PA x-ray sensitivity was 46%. A total number of 86 false-positive CAD marks across the 36 standard PA chest x-rays decreased to 59 marks when DES was applied. This overall decrease of 27 false-positives reflects both a loss of 64 false-positives and a gain of 37 new false-positives between the standard PA and ST x-rays. Additional results were not stated. The type of technology applied to chest x-rays can impact the effectiveness of the CAD program.

Li et al (2008) retrospectively reviewed chest x-ray records stored in the cancer registry. The authors identified all patients ($n=821$) who received a diagnosis of lung cancer over a period of time. The records of all patients ($n=314$) with chest x-rays on file prior to treatment were reviewed, and the relevant x-rays and reports were analyzed. From these 314 patients, the authors identified 34 patients — with 34 posteroanterior digital x-rays — who had a nodular cancer that was apparent on the posteroanterior image in retrospect but had not been mentioned in the report. If a nodular cancer had been mentioned in the report but was misdiagnosed, the associated chest x-ray was not included. Before Riverain's CAD program was applied, two radiologists independently graded the radiologist-missed cancers for subtlety (extremely subtle to extremely obvious) on a 10-point scale. The CAD results were analyzed to determine the number of true cancers marked (sensitivity), as well as the number of false-positive detections. The relationships between CAD performance and radiologist-assigned nodule groups and ratings and between CAD performance and presence of underlying abnormalities were analyzed. The authors stated for all x-rays, the CAD program had a sensitivity of 35% for cancer detection, identifying the missed cancer on 12 of the 34 images. There was no observed significant difference in the number of false positive CAD marks ($n =199$) between the x-rays with and those without underlying abnormalities ($p=.23$). The sensitivity of CAD detection of relatively obvious cancers (grade > 3) was 45% (five of 11 cancers), which was slightly higher than the sensitivity for the detection of very subtle cancers (grade 1-3): 30% (seven of 23 cancers) ($p =.21$). There are several limitations to this study including its design and methodology; the cohort examined was a pre-selection of "missed" x-rays, creating selection bias with the inability to accurately assess for true false-positives against a screening population.

The marks produced by OnGuard CAD system to denote regions of interest (ROI) consisted of 5 centimeter (cm) diameter circles. In 2010, Li et al. compared nodule-in-center criterion (used in the 2008 study above)

compared to nodule-in-circle criterion. In 2008, Li et al. utilized a strict nodule-in-center criterion, which required that the center of a circle was within the lesion boundary for it to be considered a true detection. In 2010, Li et al. also utilized nodule-in-circle criterion, in which the center point of the circle was not required to be within the lesion boundary but the lesion was required only to be located at least partially within the circle. The database of records reviewed consisted of 36 chest x-rays with subsequently biopsy-proven nodules, a nodular cancer that was apparent on the posteroanterior (PA) image in retrospect but had been mentioned in the x-ray report (the 2008 study included 34 patients who the nodule had not been mentioned in the report). For the 36 nodules, the sensitivities by the version 1.0 system were 53% and 67%, and the sensitivities by the version 3.0 system were 72% and 75%, while reducing the number of false-positive marks by half (5.7 and 5.5 vs. 2.7 and 2.6), based on the nodule-in-center criterion and the nodule-in-circle criterion, respectively. The authors concluded that the choice of performance criteria can substantially influence the apparent accuracy of a CAD system.

Kakeda et al. (2004) retrospectively evaluated the Riverain Medical CAD system. For patients with cancer, 45 cases with solitary lung nodules up to 25 mm in diameter (nodule size range 8–25 mm in diameter) were used. For healthy patients, 45 cases were selected on the basis of confirmation on chest CT. All chest x-rays were obtained with a computed radiography system. The computer output images were produced with a newly developed computer-aided diagnosis system. Eight radiologists (four board-certified radiologists and four radiology residents) interpreted both the original x-rays and computer output images using a sequential testing method. Receiver operating characteristic (ROC) analysis was used for comparison of observer performance in the detection of lung nodules without and with CAD output images. There were 315 false-positive detections on 100 x-rays with normal findings with an average of 3.15 false-positives per image. The average area under the ROC curve (Az) value increased significantly from 0.924 without, to 0.986 with, computer-aided output images. Individually, the use of computer-aided images was more beneficial to radiology residents than to board-certified radiologists. This study was not designed to blindly compare a CAD program across a screening population.

IQQA Chest/xLNA/EDDA Technology/Phillips: Moore et al. (2010) conducted a retrospective review, gathering computed tomographic angiogram (CTA) and chest x-ray results from a varied population referred for CTA of the chest. CTA was utilized as a reference standard. Moore et al. next cross referenced for patients who had a posterior–anterior (PA) x-ray within a 24 hour time frame. A total of 240 patients fit this selection criterion; all were included in the study. All chest x-rays (n=240) were processed by the CAD system IQQA Chest v2.0 (EDDA Technology, Princeton, NJ). There were a total of 69 CTA confirmed nodules in 49 patients. Of these nodules, two were found to be malignant. There were a total of 165 CAD findings or regions of interest (ROIs) on chest x-ray, of which 49 represented actual nodules seen by CTA. These nodules were seen in 36 patients. The CAD system achieved an overall accuracy of 55.5%. When a thoracic radiologist with five years of experience who had approximately 10 months of experience with the CAD device reviewed all chest x-ray CAD images, the resultant accuracy was 73.7%.

Van Beek et al (2008) prospectively investigated CAD for nodule detection on chest xrays obtained on patients under surveillance for metastatic disease. The study included 214 patients referred for chest x-rays with known extrapulmonary primary malignancies. The CAD program was IQQA Chest. Chest examinations were reviewed by one pulmonary radiologist, who recorded their interpretations before and after the CAD program was executed. Following the CAD review, readers either accepted or discounted CAD identified “lesions” specifically as false-negative initial readings (pre-CAD) and false-positive CAD interpretations. CAD provided an average of 2.7 false-positive hits per examination, many of which were easily discounted. Most of the false-positive ROIs reflected confluence of shadows relating to overlapping ribs or costochondral calcification. Pulmonary nodules that were obviously benign, such as calcified granulomas, were excluded from the analysis. For reference standard, a follow-up chest x-ray at least six months following the initial examination or a follow-up CT of the chest within three months was used to establish diagnostic accuracy. Chest CTs were usually obtained after suspicious initial chest x-rays. The radiologist’s results without the use of the CAD were compared with the post-CAD interpretation. Results indicated an overall sensitivity and specificity of the combined radiologist/CAD reading were 92.7% and 96.2%, respectively. Statistical analysis using McNemar’s test was significant for improved sensitivity ($p < .0001$), whereas specificity did not reach statistical significance. Limitations of this study include short follow-up period and the potential for selection bias based upon inclusion criteria.

Bley et al. (2008) retrospectively evaluated 117 patients who had undergone both x-ray and CT assessment of potential pulmonary metastases within a four week time frame. CAD was performed using a xLNA system (Philips Medical Systems; Hamburg, Germany). The reference standard was established by a consensus reading of the thoracic CT scans. Patients were not included if CT reflected nodule size (larger than 15

millimeter [mm]) or a high number of nodules (more than five nodules). “Sixty nodules smaller than 5 mm and 21 nodules larger than 15 mm were detected by the reference panel and excluded from the statistical evaluation because of their size since the CAD system only detects nodules from 5 to 15 mm.” The differences in the detection performance between the individual reader and the CAD system and in terms of nodule location were evaluated. P values <0.05 were considered to indicate statistically significant results. Sensitivity of the CAD system was 39.4%, when compared with 18.2% to 30.3% of three radiologists. There were 288 false-positive detections of the CAD system found with an average of 2.5 false-positives per image. Further prospective receiver operating characteristic studies are warranted to define the incremental value of the tested CAD system when used as a second opinion in detection of subtle pulmonary nodules on chest x-rays.

Other: There are published studies and reviews in the scientific literature that address other various algorithms/detection software programs that are not yet named/branded (Hardie, et al., 2008; Shiraishi, et al., 2007; Schilham, et al., 2006; Shiraishi, et al., 2006; Suzuki, et al., 2005). These authors review the components of the various proposed algorithms/detection programs; some studies compare the proposed algorithm with a publicly available radiographic database. At this time it is unclear if other CAD systems for lung cancer detection on chest x-ray are pursuing FDA approval.

Professional Societies/Organizations

Professional society opinion is lacking on the use of computer-aided detection of chest x-rays for detection of lung cancer.

The United States Preventive Services Task Force (USPSTF, 2004) and the National Cancer Institute (NCI, 2010) state screening for lung cancer with chest x-ray and/or sputum cytology does not reduce mortality from lung cancer and that screening could lead to false-positive tests and unnecessary invasive diagnostic procedures and treatments.

The American Cancer Society (Smith, et al., 2011) does not recommend testing for the early detection of lung cancer in asymptomatic individuals.

The American College of Chest Physicians (ACCP) Screening for Lung Cancer Guideline notes studies of lung cancer screening with chest radiograph (x-ray) and sputum cytology have failed to demonstrate that screening lowers lung cancer mortality rates. For high-risk populations, no screening modality has been shown to alter mortality outcomes. “We recommend against the use of serial chest x-rays to screen for the presence of lung cancer” (Bach, et al., 2007).

Summary

The accuracy and clinical utility of using computer-aided detection (CAD) systems with chest radiographs have not been demonstrated in the published peer-reviewed scientific literature. Large, well-designed, controlled clinical trials comparing radiograph CAD results to additional manual radiologist review (i.e., second opinion) results or computed tomography (CT) results (with and without CT CAD) are needed to determine whether the addition of CAD improves the interpretation of chest radiographs and ultimately, has an impact on meaningful health outcomes. Also, studies are needed to determine if early detection of lung cancer—by CAD of chest radiographs in comparison with other methods of detection—will lead to an improvement in life expectancy.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
0174T	Computer aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed concurrent with primary interpretation (List separately in addition to code for primary procedure.)

0175T	Computer aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed remote from primary interpretation.
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ICD-9-CM Diagnosis Codes	Description
162.0-162.9	Malignant neoplasm of trachea, bronchus, and lung
176.4	Kaposi's sarcoma of lung
197.0	Secondary malignant neoplasm of respiratory and digestive systems, Lung
212.3	Benign neoplasm of respiratory and intrathoracic organs, Bronchus and lung
235.7	Neoplasm of uncertain behavior of digestive and respiratory systems, Trachea, bronchus, and lung
239.1	Neoplasm of unspecified nature of respiratory system
793.1	Nonspecific (abnormal) findings on radiological and other examination of body structure, Lung field
V76.0	Special screening for malignant neoplasm of the respiratory organs
	All other codes

*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	5/15/2008	0451	Computer-Aided Detection of Chest Radiographs for Lung Cancer Screening

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