

Subject: Computer Aided Evaluation (CAE) of Malignancy with Breast MRI and Lung Radiography		Original Effective Date: 1/1/16
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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.¹

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL²²

The term computer-aided detection (CAD) refers to pattern recognition software that identifies suspicious features on the image and brings them to the attention of the radiologist, in order to decrease false negative readings. As currently used, the radiologist first reviews the exam, then activates the CAD software and re-evaluates the CAD-marked areas of concern before issuing the final report. Detection programs analyze digitized images and identify suspicious areas for review by the radiologist. The term computer aided evaluation

(CAE), refers to software that analyses a radiographic finding to estimate the likelihood that the feature represents a specific disease process (e.g. benign versus malignant). These systems are used with MRI to provide easier ways of interpreting the patterns of contrast enhancement across a series of images, which in turn may help identify lesions and their likelihood of being malignant. CAD is used most often in mammography and in chest radiographs for lung cancer screening, but CAE is emerging as an evaluation tool to improve the accuracy of breast MRI for detecting breast cancer. The focus of CAE with MRI of the breast is on improving specificity (distinguishing malignant from benign) rather than increasing sensitivity (i.e., detection), as in mammography.

Two CAD systems have been FDA approved: DynaCAD (Invivo) and CADstream (Merge Healthcare, Inc.). The DynaCAD is a post-processing software package intended for use in viewing and analyzing magnetic resonance imaging (MRI) studies. CADstream is a Computer Aided Detection (CAD) system intended for use in analyzing magnetic resonance imaging studies.²

POSITION STATEMENT³⁻²¹

- ☐ The use of computer aided evaluation (CAE) is considered experimental, investigational and unproven for use with MRI of the breast for the detection of breast lesions because there is insufficient evidence in the peer reviewed medical literature that that have not established safety, efficacy and effect on net health outcomes.
- ☐ The use of computer aided detection (CAD) with chest radiographs for lung cancer screening is considered experimental, investigational and unproven because there is insufficient evidence in the peer reviewed medical literature that that have not established safety, efficacy and effect on net health outcomes.

SUMMARY OF MEDICAL EVIDENCE³⁻²¹

The available evidence consists primarily of non-randomized or controlled prospective, comparison, case series and retrospective studies describing a wide assortment of CAD techniques utilizing various algorithms and parameters, as well as CAD systems specifically designed for analysis of breast MRI and chest radiography. In many of these studies, the primary outcomes measured were focused on the performance of that particular CAD technique/system rather than the overall efficacy of using CAD for breast or lung cancer interpretation. Some studies reported on the evaluation of CAD systems with chest radiography and on average, the sensitivities with and without CAD were 87% and 84%, respectively; the false positive rates per case with and without CAD were 0.19 and 0.17, respectively.¹⁴⁻²¹ Other studies found that using CAD with breast MRI the sensitivity was 96.5% combined with specificity of 75.5%.³⁻¹² Larger, well designed, prospective studies are needed that include relevant clinical populations in order to determine whether computer-aided evaluation results in a clinically significant improvement in diagnostic accuracy. As a result of insufficient published data in the literature, the use of computer-aided evaluation of breast malignancy and lung cancer with MRI is considered investigational. A summary of the most relevant published data is outlined below:

A 2011 systematic review and meta-analysis (Dorrius et al.) evaluated the additional value of computer-aided detection (CAD) in breast MRI by assessing radiologists' accuracy in discriminating benign from malignant breast lesions. The accuracy of the radiologists' performance with and without CAD was presented as pooled sensitivity and specificity. Of 587 articles, 10 met the inclusion criteria, all of good methodological quality. Experienced radiologists reached comparable pooled sensitivity and specificity before and after using CAD (sensitivity: without CAD: 89%; 95% CI: 78-94%, with CAD: 89%; 95%CI: 81-94%) (Specificity: without CAD: 86%; 95% CI: 79-91%, with CAD: 82%; 95% CI: 76-87%). For residents the pooled sensitivity increased from 72% (95% CI: 62-81%) without CAD to 89% (95% CI: 80-94%) with CAD, however, not significantly. Concerning specificity, the results were similar (without CAD: 79%; 95% CI: 69-86%, with CAD: 78%; 95% CI: 69-84%). In conclusion, CAD in breast MRI has little influence on the sensitivity and specificity of experienced radiologists and therefore their interpretation remains essential. However, residents or inexperienced radiologists seem to benefit from CAD concerning breast MRI evaluation.¹⁰

A 2013 RCT (Mazzaone et al.) evaluated lung cancer screening with computer aided detection chest radiography. Study subjects were age 40–75 years with 10+ pack-years of smoking and/or an additional risk for developing lung cancer. Subjects were randomized to receive a PA view chest radiograph or placebo control (went through the process of being imaged but were not imaged). Images were reviewed first without then with the assistance of CAD. Actionable nodules were reported and additional evaluation was tracked. The primary outcome was the rate of developing symptomatic advanced stage lung cancer. 1,424 subjects were enrolled. 710 received a CAD chest radiograph, 29 of whom were found to have an actionable lung nodule on prevalence screening. Of the 15 subjects who had a chest CT performed for additional evaluation, a lung nodule was confirmed in 4, 2 of which represented lung cancer. Both of the cancers were seen by the radiologist unaided and were identified by the CAD chest radiograph. The cumulative incidence of symptomatic advanced lung cancer was 0.42 cases per 100 person-years in the control arm; there were no events in the screening arm. The study concluded that further evaluation is necessary to determine if CAD chest radiography has a role as a lung cancer screening tool.¹⁵

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
77048	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; unilateral
77049	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; bilateral
0174T	Computer-aided detection (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 codes for primary procedure)
0175T	Computer-aided detection (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

HCPCS	Description
C8937	Computer-aided detection, including computer algorithm analysis of breast mri image data for lesion detection/characterization, pharmacokinetic analysis, with further physician review for interpretation (list separately in addition to code for primary procedure)

ICD-10	Description: [For dates of service on or after 10/01/2015]
	Any/All

REFERENCES

Government Agency

- Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. National coverage determination (NCD) Search. Accessed at: <https://www.cms.gov/medicare-coverage-database/new-search/search.aspx>
- U.S. Food & Drug Administration (FDA). Premarket approval data base. Enter product categories (MYN or LLZ) in the search field of the PMA and 510(k) databases. Accessed at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>

Peer Reviewed Publications

Breast MRI

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- Liu YH; Xu L et al. 3.0T MR-CAD: Clinical Value in Diagnosis of Breast Tumor Compared with Conventional MRI. Journal of Cancer. 5(7):585-9, 2014.
- Pan J(1), Dogan BE, Carkaci S, et al. Comparing performance of the CADstream and the DynaCAD breast MRI CAD systems: CADstream vs. DynaCAD in breast MRI. J Digit Imaging. 2013 Oct;26(5):971-6. doi: 10.1007/s10278-013-9602-y.
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- Meeuwis C; van de Ven SM; Stapper G et al. Computer-aided detection (CAD) for breast MRI: evaluation of efficacy at 3.0 T. European Radiology. 20(3):522-8, 2010 Mar.
- Dorrius MD(1), Jansen-van der Weide MC, van Ooijen PM et al. Computer-aided detection in breast MRI: a systematic review and meta-analysis. Eur Radiol. 2011 Aug;21(8):1600-8. doi: 10.1007/s00330-011-2091-9. Epub 2011 Mar 15.
- Arazi-Kleinman T; Causer PA; Jong RA et al. Can breast MRI computer-aided detection (CAD) improve radiologist accuracy for lesions detected at MRI screening and recommended for biopsy in a high-risk population? Clinical Radiology. 64(12):1166-74, 2009 Dec.

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13. Ku YJ, Kim HH et al. Predicting the level of tumor-infiltrating lymphocytes in patients with triple-negative breast cancer: Usefulness of breast MRI computer-aided detection and diagnosis. *J Magn Reson Imaging*. 2018 Mar;47(3):760-766. doi: 10.1002/jmri.25802. Epub 2017 Jul 4.

Chest Radiography

14. Buhmann S, Herzog P, Liang J, et al. Clinical evaluation of a computer-aided diagnosis (CAD) prototype for the detection of pulmonary embolism. *Acad Radiol*. 2007 Jun;14(6):651-8.
15. Mazzone PJ, Obuchowski N, Phillips M et al. Lung cancer screening with computer aided detection chest radiography: design and results of a randomized, controlled trial. *PLoS One*. 2013;8(3):e59650. doi: 10.1371/journal.pone.0059650. Epub 2013 Mar 20.
16. Sahiner B1, Chan HP, Hadjiiski LM et al. Effect of CAD on radiologists' detection of lung nodules on thoracic CT scans: analysis of an observer performance study by nodule size. *Acad Radiol*. 2009 Dec;16(12):1518-30. doi: 10.1016/j.acra.2009.08.006.
17. Meziane M1, Mazzone P, Novak E et al. A comparison of four versions of a computer-aided detection system for pulmonary nodules on chest radiographs. *J Thorac Imaging*. 2012 Jan;27(1):58-64. doi: 10.1097/RTI.0b013e3181f240bc.
18. Schalekamp S1, van Ginneken B, Heggelman B et al. New methods for using computer-aided detection information for the detection of lung nodules on chest radiographs. *Br J Radiol*. 2014 Apr;87(1036):20140015. doi: 10.1259/bjr.20140015. Epub 2014 Feb 17.
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21. Vassallo L, Traverso A et al. A cloud-based computer-aided detection system improves identification of lung nodules on computed tomography scans of patients with extra-thoracic malignancies. *Eur Radiol*. 2018 Jun 15. doi: 10.1007/s00330-018-5528-6. [Epub ahead of print]

Hayes and TEC Assessment

22. Hayes a TractManager Company. Winifred Hayes Inc. Lansdale, PA.
 - Computer-Aided Detection (CAD) with Full-Field Digital Mammography (FFDM) for Breast Cancer Screening. Updated 2018. [Archived 2020]
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 - Breast Cancer. v3. 2021
 - Lung Cancer Screening. v1.2021

25. American College of Radiology (ACR): ACR Practice Guideline for the Performance of Contrast-Enhanced Magnetic Resonance Imaging (MRI) of the Breast. Revised 2018. Accessed at: www.acr.org

Other Resources:

26. UpToDate: [Website] Waltham, MA: Walters Kluwer Health; 2021
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REVIEW/REVISION HISTORY

1/1/16: New Policy

6/22/17: Policy reviewed, no changes

3/8/18: Policy reviewed, clinical criteria has not changed.

6/19/19: Policy reviewed, no new published evidence, topic remains experimental, investigational and unproven. Updated coding & references.

6/17/20, 6/9/21: Policy reviewed, no changes. A search of PubMed did not identify any new literature.