

# MEDICAL POLICY



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| <b>SUBJECT: MAMMOGRAPHY: COMPUTER-AIDED DETECTION (CAD)</b>   | <b>EFFECTIVE DATE: 03/28/02</b><br><b>REVISED DATE: 04/24/03, 05/19/04, 04/21/05, 02/16/06, 12/21/06</b><br><b>ARCHIVED DATE: 10/18/07</b><br><b>EDITED DATE: 12/18/08, 11/19/09, 09/16/10, 09/15/11, 09/20/12, 09/19/13, 08/21/14, 09/17/15, 07/21/16, 07/20/17, 08/16/18</b> |
| <b>POLICY NUMBER: 6.01.23</b><br><b>CATEGORY: Technology Assessment</b>   | <b>PAGE: 1 OF: 4</b>   |
| <ul style="list-style-type: none"><li>• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i></li><li>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i></li><li>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i></li></ul> |  |

## **POLICY STATEMENT:**

Based upon our criteria and review of the peer-reviewed literature, digitalized computer-aided detection (CAD) mammography has been medically proven to be effective and therefore **medically appropriate** to identify and mark regions of interest on mammographic views to bring them to the attention of the radiologist after the initial reading has been completed.

*Refer to Corporate Medical Policy #6.01.22 regarding Digital Mammography: Digital Breast Tomosynthesis.*

## **POLICY GUIDELINES:**

This policy does not address *digital mammography*. Digital mammography produces digital images as an option to conventional film screen mammography. Refer to Corporate Medical Policy 6.01.22, Mammography: Digital Breast Tomosynthesis.

## **DESCRIPTION:**

Computer-aided detection (CAD) has been suggested as an adjunct to screening mammograms to decrease errors in perception (e.g., failure to see abnormality). The use of CAD systems requires a digital image, either generated by digitization of a prior screen-film mammogram (digitized mammogram), or generated directly (direct full-field digital mammogram). Commercially available CAD systems then use computerized algorithms for identifying suspicious regions of interest on the digital image. The locations of the abnormalities are marked so the reader can then reference the same areas in the original mammogram for further review. The intent of CAD is to aid in detection of potential abnormalities for the radiologist to re-review. The radiologist, not CAD, makes the determination if a clinically significant abnormality exists and whether further diagnostic evaluation is warranted.

## **RATIONALE:**

Several CAD mammography systems have been approved by the U.S. Food and Drug Administration (FDA) for use in the U.S., including but not limited to the Cenova™ (Hologic, Inc.), MammoReader® (Intelligent Systems Software, Inc.), PowerLook Advanced Mammography Platform (iCAD Inc.), and RapidScreen™ RS-2000 (Deus Technologies).

The available evidence suggests that the use of CAD as an adjunct to the radiologists' interpretation of screen-film mammography improves net health outcomes compared with single reader radiologist interpretations, by increasing true positive rate without a disproportionate increase in the false positive rate.

A prospective study (Birdwell 2005) of 8,682 patients assessed the effect of CAD on screening mammogram interpretation by comparing radiologist interpretation of screen film mammograms followed by immediate re-evaluation of the mammograms with CAD information. Authors concluded that prospective clinical use of CAD resulted in a 7.4% increase in cancers detected.

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Another prospective study of 6,111 women (Khoo 2005) evaluated recall and cancer detection rates with and without CAD. Screen film mammograms for 6,111 women were digitized and analyzed using CAD and then all mammograms were independently double-read by a consulting radiologist. Authors concluded that CAD increased sensitivity of single reading by 1.3%, however, double reading increased sensitivity by 8.2%.

A third prospective, historically controlled study (Cupples 2005) assessed the effect of CAD on screening outcomes (recall, biopsy and cancer detection rates in addition to type, size and stage of cancers found) by comparing 7,872 screening mammograms without CAD with 19,402 screening mammograms interpreted with CAD. Authors concluded that an increased detection rate, a younger age at diagnosis, and a significantly earlier stage of invasive cancer detection were consistent with a positive screening impact of CAD.

**CODES:**      Number                      Description

*Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*

**CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.**

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

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| <b>CPT:</b> | 77065 | unilateral mammography with CAD          |
|             | 77066 | bilateral mammography with CAD           |
|             | 77067 | bilateral screening mammography with CAD |

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**HCPCS:**      No specific code(s)

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|---------------|-----------------|--|
| <b>ICD10:</b> | C50.011-C50.019 | Malignant neoplasm of nipple and areola (code range)                     |
|               | C50.111-C50.119 | Malignant neoplasm of central portion of breast (code range)             |
|               | C50.211-C50.219 | Malignant neoplasm of upper-inner quadrant of breast (code range)        |
|               | C50.311-C50.319 | Malignant neoplasm of lower-inner quadrant of breast (code range)        |
|               | C50.411-C50.419 | Malignant neoplasm of upper-outer quadrant of breast (code range)        |
|               | C50.511-C50.519 | Malignant neoplasm of lower-outer quadrant of breast (code range)        |
|               | C50.611-C50.619 | Malignant neoplasm of axillary tail of breast (code range)               |
|               | C50.811-C50.819 | Malignant neoplasm of overlapping site of breast (code range)            |
|               | C50.911-C50.919 | Malignant neoplasm of breast unspecified site (code range)               |
|               | C79.81          | Secondary malignant neoplasm of breast                                   |
|               | C79.89          | Secondary malignant neoplasm of other specified sites                    |
|               | C79.9           | Secondary malignant neoplasm of unspecified site                         |
|               | D05.00-D05.92   | Carcinoma in situ of breast (code range)                                 |
|               | D48.60-D48.62   | Neoplasm of uncertain behavior of breast (code range)                    |
|               | D49.3           | Neoplasm of unspecified behavior of breast                               |
|               | R92.8           | Other abnormal and inconclusive findings on diagnostic imaging of breast |

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| Z12.31 | Encounter for screening mammogram for malignant neoplasm of breast |
| Z12.39 | Encounter for other screening for malignant neoplasm of breast     |
| Z80.3  | Family history of malignant neoplasm of breast                     |
| Z85.3  | Personal history of malignant neoplasm of breast                   |

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**KEY WORDS:**

CAD mammography, Digitalized computer-aided detection mammography.

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## **CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

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Based on our review, computer-aided detection mammography is not addressed in National or Regional Medicare coverage determinations or policies.