

Corporate Medical Policy

Computer-Aided Evaluation of Malignancy with MRI of the Breast

File Name:	computer_aided_evaluation_of_malignancy_with_mri_of_the_breast
Origination:	08/2007
Last CAP Review:	6/2011
Next CAP Review:	6/2012
Last Review:	6/2011

Description of Procedure or Service

The use of computer-aided evaluation (CAE) is proposed to assist radiologists' interpretation of contrast-enhanced magnetic resonance imaging (MRI) of the breast. MRI of the breast is suggested as an alternative to mammography or other screening and diagnostic tests because of its high sensitivity in detecting breast lesions. However, it has a high false-positive rate because of the difficulty in distinguishing between benign and malignant lesions. MRI may be used to screen women at high genetic risk of breast cancer or to look for more extensive disease in women diagnosed with breast cancer who are eligible for breast-conserving surgery; it is also being studied to gauge the impact of cancer treatment. The CAE systems reviewed in this policy are intended to improve the specificity of MRI in detecting or measuring malignant tissue, while maintaining the generally high sensitivity of MRI. This could potentially reduce biopsy rates if it improves the ability to identify which MRI-detected lesions are almost certainly benign. There is anecdotal information that MRI may also be used in an effort to reduce re-operation rates among patients undergoing breast-conserving surgery by more clearly identifying the tissue that should be removed. The use of CAE may also shorten the time needed to interpret breast MRI images, which currently takes longer than reading mammograms.

CAE systems for MRI essentially 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. Two key aspects of enhancement (also called kinetics) are examined: 1) within the first minute or so, does the lesion enhance up to a certain threshold (e.g., 50%, 100% of the initial value)? and 2) what is the subsequent pattern of enhancement (continues to increase, plateaus, or declines [called "washout"])? In contrast to computer-aided detection (CAD) systems used with mammography, CAE for MRI is not aimed primarily at identifying lesions for consideration by a radiologist. Unlike the subtle appearance of lesions on mammography, most cancers enhance on MRI. The challenge is determining which lesions are benign and which are malignant. A large number of images are produced during MRI of the breast: images are taken at varying "depths" throughout each breast multiplied by the number of times the breast is imaged to capture different time points in the enhancement process; this can produce hundreds of images. Radiologists view the images to detect suspicious areas, and then they can pick a region of interest and look at the enhancement pattern. However, there may be variations across radiologists in the regions of interest selected and in the precise definition of the region of interest. CAE systems, in contrast, use color-coding and differences in hue to indicate the patterns of enhancement for each pixel in the breast image, thereby allowing the radiologist to analyze the enhancement patterns systematically.

CAE systems for MRI of the breast were initially called CAD systems, the same terminology used for mammography. However, the focus with MRI of the breast is on improving specificity (distinguishing malignant from benign) rather than increasing sensitivity (i.e., detection), as in mammography. The authors of 2 recent studies refer to CADStream as a computer-aided evaluation (CAE) program, and that terminology has been adopted in this policy.

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Regulatory Status

Several CAE systems for use with MRI of the breast have 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA). The 3TP Software Option, manufactured by 3TP LLC (now called CAD Sciences, White Plains, NY), was cleared on June 23, 2003. iCAD acquired CAD Sciences in 2008 and is now marketing a system called SpectraLook™ with CADVue™. CADstream™, which is manufactured by Confirma, Inc. (Kirkland, WA), was cleared on July 30, 2003; Merger Healthcare (Hartland, WI) subsequently acquired Confirma. A third system called Aegis (Sentinelle Medical Inc, Toronto, Ontario, Canada) received 510(k) marketing clearance from the FDA on February 9, 2007, as substantially equivalent to CADStream Version 4.0. However, in the 510(k) documents, the manufacturer states that the primary goal of Aegis is “to identify where and how deep a biopsy or localization needle should be inserted into an imaged breast.” Additional products include DynaCAD (MRI Devices Corporation, Waukesha, WI; now apparently from Invivo Corp, Orlando, FL), which was cleared July 21, 2004; and Z3D Contrast Acuity Software (Clario Medical Imaging, Inc., Seattle, WA), which was cleared September 5, 2008, and is apparently used in conjunction with CAE for MRI systems. Some of these systems may have broader uses beyond breast MRI. There also may be some overlap in the functions performed by these devices and other image-processing systems.

According to documents filed with the FDA, the 3TP Software Option is “intended to be used as a post-processing software package designed to provide a reliable means for visualizing the presence and pattern of contrast-induced enhancement on MR datasets.” It provides a color-coded image that indicates the likelihood that each pixel shows malignant or benign tissue based on the changes in enhancement at 3 points in time, which are defined by the software program. CADstream is described as a “Computer Aided Detection (CAD) system intended for use in analyzing magnetic resonance imaging (MRI) studies. CADstream automatically registers serial patient image acquisitions to minimize the impact of patient motion, segments and labels tissue types based on enhancement characteristics (parametric image maps), and performs other user-defined post-processing functions (image subtractions, multiplanar reformats, maximum intensity projections). When interpreted by a skilled physician, this device provides information that may be useful in screening and diagnosis...Patient management should not be based solely on the results of the CADstream analysis.” It also provides automated determination of volumes of interest. In addition, CADstream can be used during MRI-guided biopsies.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

The use of computer-aided evaluation (CAE) for interpretation of contrast-enhanced magnetic resonance imaging (MRI) of the breast is considered investigational. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Computer-Aided Evaluation of Malignancy with MRI of the Breast is covered

Not applicable

Computer-Aided Evaluation of Malignancy with MRI of the Breast

When Computer-Aided Evaluation of Malignancy with MRI of the Breast is not covered

Computer-aided evaluation of malignancy with MRI of the breast is not covered. It is considered investigational.

Policy Guidelines

The literature on the use of CAE with MRI of the breast was sparse overall, and few addressed the specific situations in which CAE with MRI is used in a clinical setting. Furthermore, the literature as a whole is not clear on how the CAE system is to be used. The impact of CAE on the accuracy of MRI of the breast will likely depend on how the CAE results are incorporated into the reading and diagnostic process. This information is still not known.

The June 2006 TEC Assessment concluded that there are no high quality, current published studies of the impact of commercially available CAE systems on the sensitivity and specificity of MRI of the breast. Also, there is insufficient evidence to assess whether the use of CAE systems would maintain or increase the sensitivity, specificity, and recall rates of MRI of the breast. Given the inability to evaluate these intermediate outcomes, it is not possible to assess the impact of CAE on health outcomes such as treatment success among breast cancer patients or survival. Whether the use of CAE with MRI of the breast improves outcomes has not been established in the investigational setting. For these reasons, computer-aided detection of malignancy with MRI of the breast does not meet the TEC criteria.

A literature search through May 2010 did not identify any new studies that would alter the conclusions above.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 0159T

This code would be used in addition to the code for breast MRI - 77058 – 77059

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.45, 10/10/06.

BCBSA TEC Assessment [Electronic Version]. June 2006.

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.45, 4/9/08.

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.45, 6/10/10

Policy Implementation/Update Information

8/13/07 New policy issued. The use of computer-aided detection (CAD) for interpretation of contrast-enhanced magnetic resonance imaging (MRI) of the breast is considered investigational. (adn)

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- 6/30/08 Specialty Matched Consultant Advisory Panel review 5/15/08. No change to policy statement. (adn)
- 6/22/10 Policy Number(s) removed (amw)
- 9/28/10 Name of policy changed from Computer-Aided *Detection* to Computer Aided *Evaluation*. The word “detection” changed to “evaluation” throughout the policy. Acronym “CAD” changed to “CAE” throughout the policy. Description section extensively revised. Specialty Matched Consultant Advisory Panel review 8/25/10. No change in policy statement. Draft policy approved as written. (adn)
- 7/19/11 Routine annual review. No changes. Specialty Matched Consultant Advisory Panel review 6/29/11. Draft policy approved as written. (adn)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.