

Protocol

Computer-Aided Evaluation of Malignancy With Magnetic Resonance Imaging of the Breast

(60145)

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| Medical Benefit | | Effective Date: 10/01/09 | Next Review Date: 07/15 |
| Preauthorization | No | Review Dates: 09/09, 09/10, 09/11, 09/12, 07/13, 07/14 | |

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required but is recommended if, despite this Protocol position, you feel the service is medically necessary.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

The use of computer-aided evaluation (CAE) may assist radiologists' interpretation of contrast-enhanced magnetic resonance imaging (MRI) of the breast and improve the accuracy of diagnosis of malignancy.

Background

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 or adjunct 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 Protocol are intended to improve the specificity of MRI in detecting or measuring malignant tissue, while maintaining the generally high sensitivity of MRI. An improved ability to identify MRI-detected lesions that are almost certainly benign could potentially reduce biopsy rates. There is anecdotal information that MRI also may reduce reoperation rates among patients undergoing breast-conserving surgery by more clearly identifying the tissue that should be removed. CAE also may reduce 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, how quickly does the lesion enhance up to a certain threshold (e.g., 50%, 100% of the initial value; rapid enhancement above 90% in 90 seconds suggests malignancy)? (2) What is the subsequent pattern of enhancement (i.e., continues to increase, plateaus, or declines [called washout, which is associated with malignancy])? (1) In contrast to computer-aided detection (CAD) systems used with mammography, CAE for MRI is not primarily intended to identify 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 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 pattern of enhancement for each pixel in the breast image, thereby allowing radiologist to analyze enhancement patterns systematically. CAE systems for MRI of the breast were initially called CAD (computer-aided detection) 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 two studies refer to CADstream as a computer-aided evaluation (CAE) program, (2, 3) and that terminology has been adopted in this Protocol.

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). 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.

- The 3TP (3 Time Point) 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™, which was FDA-cleared on July 20, 2012. According to documents filed with the FDA, the 3TP Software Option is “intended to be used as a postprocessing 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 three points in time, which are defined by the software program.
- CADstream™, which is manufactured by Confirma Inc. (Kirkland, WA), was cleared on July 30, 2003; Merger Healthcare (Hartland, WI) subsequently acquired Confirma. 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 postprocessing 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.
- 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.”
- DynaCAD® (MRI Devices Corp, Waukesha, WI; now from Invivo Corp, Orlando, FL) was cleared July 21, 2004.
- z3D Contrast Acuity Software (Clario Medical Imaging Inc., Seattle, WA) was cleared September 5, 2008 and is apparently used in conjunction with CAE for MRI systems.

Policy (Formerly Corporate Medical Guideline)

The use of computer-aided evaluation (CAE) for interpretation of magnetic resonance imaging (MRI) of the breast is considered **investigational**.

Benefit Application

Because the value of providing this service in addition to the breast MRI has not been established, we will not reimburse a separate payment when MRI of the breast has been authorized and performed.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Cheng L, Li X. Breast magnetic resonance imaging: kinetic curve assessment. *Gland Surg* 2013; 2(1):50-53.
2. Lehman CD, Peacock S, DeMartini WB et al. A new automated software system to evaluate breast MR examinations: improved specificity without decreased sensitivity. *AJR Am J Roentgenol* 2006; 187(1):51-6.
3. Williams TC, DeMartini WB, Partridge SC et al. Breast MR imaging: computer-aided evaluation program for discriminating benign from malignant lesions. *Radiology* 2007; 244(1):94-103.
4. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Computer-Aided Detection of Malignancy with Magnetic Resonance Imaging of the Breast. TEC Assessments 2006; Volume 21, Tab 4.
5. Deurloo EE, Peterse JL, Rutgers EJ et al. Additional breast lesions in patients eligible for breast-conserving therapy by MRI: impact on preoperative management and potential benefit of computerised analysis. *Eur J Cancer* 2005; 41(10):1393-401.
6. Demartini WB, Lehman CD, Peacock S et al. Computer-aided detection applied to breast MRI: assessment of CAD-generated enhancement and tumor sizes in breast cancers before and after neoadjuvant chemotherapy. *Acad Radiol* 2005; 12(7):806-14.
7. Meeuwis C, van de Ven SM, Stapper G et al. Computer-aided detection (CAD) for breast MRI: evaluation of efficacy at 3.0 T. *Eur Radiol* 2010; 20(3):522-8.
8. 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? *Clin Radiol* 2009; 64(12):1166-74.
9. Dorrius M, Weide MJ-v, Ooijen PA et al. Computer-aided detection in breast MRI: a systematic review and meta-analysis. *Eur Radiol* 2011; 21(8):1600-08.
10. Shimauchi A, Giger ML, Bhooshan N et al. Evaluation of clinical breast MR imaging performed with prototype computer-aided diagnosis breast MR imaging workstation: reader study. *Radiology* 2011; 258(3):696-704.

11. Cho N, Kim SM, Park JS et al. Contralateral lesions detected by preoperative MRI in patients with recently diagnosed breast cancer: application of MR CAD in differentiation of benign and malignant lesions. *Eur J Radiol* 2012; 81(7):1520-6.
12. Lehman CD, Blume JD, DeMartini WB et al. Accuracy and Interpretation time of computer-aided detection among novice and experienced breast MRI readers. *Am J Roentgenol* 2013; 200(6):W683-W89.
13. Baltzer PA, Renz DM, Kullnig PE et al. Application of computer-aided diagnosis (CAD) in MR-mammography (MRM): do we really need whole lesion time curve distribution analysis? *Acad Radiol* 2009; 16(4):435-42.
14. Yuan Y, Giger ML, Li H et al. Multimodality computer-aided breast cancer diagnosis with FFDM and DCE-MRI. *Acad Radiol* 2010; 17(9):1158-67.
15. Ko ES, Choi HY, Lee BH et al. Central washout sign in computer-aided evaluation of breast MRI: preliminary results. *Acta Radiol* 2011; 52(3):256-63.
16. Holli K, Laaperi AL, Harrison L et al. Characterization of breast cancer types by texture analysis of magnetic resonance images. *Acad Radiol* 2010; 17(2):135-41.
17. Huang Y-H, Chang Y-C, Huang C-S et al. Computer-aided diagnosis of mass-like lesion in breast MRI: Differential analysis of the 3-D morphology between benign and malignant tumors. *Comput. Methods Programs Biomed.* 2013; 112(3):508-17.
18. Yang Q, Li L, Zhang J et al. Computer-aided diagnosis of breast DCE-MRI Images using bilateral asymmetry of contrast enhancement between two breasts. *J Digit Imaging* 2013.
19. Bhooshan N, Giger ML, Jansen SA et al. Cancerous breast lesions on dynamic contrast-enhanced MR images: computerized characterization for image-based prognostic markers. *Radiology* 2010; 254(3):680-90.
20. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology - Breast Cancer, version 3.2013. Available online at: www.nccn.org. Last accessed December, 2013.
21. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology - Genetic/Familial High-Risk Assessment: Breast and Ovarian, version 4.2013. Available online at: www.nccn.org. Last accessed December, 2013.
22. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology - Breast Cancer Risk Reduction, version 1.2013. Available online at: www.nccn.org. Last accessed December, 2013.
23. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology - Breast Cancer Screening and Diagnosis, version 2.2013. Available online at: www.nccn.org. Last accessed December, 2013.
24. American College of Radiology. ACR Practice Guideline for the Performance of Magnetic Resonance Imaging-Guided Breast Interventional Procedures, revised 2011 (resolution 26). Available online at: <http://www.acr.org/Quality-Safety/Standards-Guidelines/Practice-Guidelines-by-Modality/Breast-Imaging>. Last accessed December, 2013.
25. Sardanelli F, Boetes C, Borisch B et al. Magnetic resonance imaging of the breast: recommendations from the EUSOMA working group. *Eur J Cancer* 2010; 46(8):1296-316.