Protocol

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

(60145)

Medical Benefit		**Effective Date**: 10/01/09	**Next Review Date**: 07/18
Preauthorization	No	**Review Dates**: 09/09, 09/10, 09/11, 09/12, 07/13, 07/14, 07/15, 07/16, 07/17	

This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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.

Populations	Interventions	Comparators	Outcomes
Individuals: • With risk of breast cancer, with suspected breast cancer or diagnosed with breast cancer	Interventions of interest are: • Computer-aided evaluation of breast malignancy with magnetic resonance imaging	Comparators of interest are: • Magnetic resonance imaging of the breast without computer-aided evaluation	Relevant outcomes include: • Disease-specific survival • Test accuracy • Test validity • Resource utilization

Description

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

Summary of Evidence

For individuals with risk of breast cancer, with suspected breast cancer, or diagnosed with breast cancer, who receive CAE of breast malignancy with magnetic resonance imaging MRI, the evidence includes diagnostic accuracy studies and systematic reviews. Relevant outcomes are disease-specific survival, test accuracy and validity, and resource utilization. The most recent systematic review (2011) did not find a statistically significant improvement in sensitivity and specificity with MRI plus CAE versus MRI alone. Moreover, retrospective studies published in the last five years generally did not find that CAE resulted in statistically significant improvement in diagnostic accuracy compared with MRI alone. Studies were generally conducted in women already diagnosed with breast cancer; there is less literature on breast cancer detection. In addition, there are no comparative studies evaluating the impact of CAE with MRI on patient management decisions or health outcomes compared to MRI alone. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy

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

Background

The use of CAE is proposed to assist radiologists' interpretation of contrast-enhanced 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 it is difficult to distinguish between benign and malignant lesions. MRI may be used to screen women at high 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.

CAE systems reviewed here are intended to improve the specificity of MRI in detecting or measuring malignant tissue, while maintaining the generally high sensitivity of MRI. Improved ability to identify MRI-detected lesions that are almost certainly benign could potentially reduce biopsy rates. There is anecdotal evidence that MRI also may reduce reoperation rates among patients undergoing breast-conserving surgery by more clearly identifying 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 provide an easier way to interpret 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% or 100% of the initial value; rapid enhancement [> 90% in 90 seconds] suggests malignancy)? (2) What is the subsequent pattern of enhancement (i.e., continues to increase [persistently ascending], plateaus, or declines [called washout, which is associated with malignancy])?[1]

In contrast to computer-aided detection 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 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 radiologists to analyze enhancement patterns systematically.

Regulatory Status

Several computer-aided evaluation systems for use with MRI of the breast have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process, some systems of which may have broader uses beyond breast MRI. Examples of FDA-cleared devices include:

- SpectraLook®, part of iCAD's VersaVue® Enterprise Suite (iCAD, Nashua, NH) was cleared for marketing by FDA through the 510(k) process in 2012. The VersaVue® Enterprise Suite is intended for postprocessing of magnetic resonance images as a means for visualizing these images. A previous version of this device, 3TP (3Time Point), was cleared in 2008.
- CADstream® (Merge Healthcare, Milwaukee, WI) was cleared for marketing by FDA through the 510(k) process in 2003, at which time it was distributed by Confirma (Kirkland, WA).
- Aegis™ Breast (Hologic Inc., Marlborough, MA; previously owned by Sentinelle Medical) was cleared for marketing by FDA through the 510(k) process in 2007. However, in the 510(k) documents, the manufacturer

stated that the primary goal of the technology is "to identify where and how deep a biopsy or localization needle should be inserted into an imaged breast."

- DynaCAD for Breast (MRI Devices, Waukesha, WI; now from Invivo, Gainesville, FL) was cleared for marketing by FDA through the 510(k) process in 2004.

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.

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