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Citation

Authors’ objectives
The aim of this review was to assess the evidence on the use of computer-aided detection (CAD) with magnetic resonance imaging (MRI) of the breast by comparing the sensitivity, specificity, and recall rate of MRI with and without the use of commercially available CAD systems in detecting malignant lesions, evaluating the extent of disease in women with cancer, or gauging the impact of treatment.

Authors’ conclusions
Based on the available evidence, the Blue Cross and Blue Shield Association Medical Advisory Panel made the following judgments about whether the computer-aided detection of malignancy with MRI of the breast meets the Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) criteria.

1. The technology must have final approval from the appropriate governmental regulatory bodies. Two CAD systems for use with MRI of the breast have 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA).

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes. There are no high quality, current published studies of the impact of commercially available CAD systems on the sensitivity and specificity of MRI of the breast. The few studies and abstracts available focus primarily on the development of the CAD system or they include samples of women that are highly selective and usually have far more cases of cancer than would be encountered in a screening population.

3. The technology must improve the net health outcome; and

4. The technology must be as beneficial as any established alternatives. There is insufficient evidence to assess whether the use of CAD 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 CAD on health outcomes such as treatment success among breast cancer patients or survival.

5. The improvement must be attainable outside the investigational settings. Whether the use of CAD with MRI of the breast improves outcomes has not been established in the investigational setting.

For the above reasons, computer-aided detection of malignancy with MRI of the breast does not meet the TEC criteria.

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