Name of Policy:
Computer-aided Detection (CAD) Mammography

Policy #: 112
Category: Radiology

Latest Review Date: October 2010
Policy Grade: **Active Policy but no longer scheduled for regular literature reviews and updates.**

### Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
**Description of Procedure or Service:**
Computer-aided detection (CAD) mammography has been investigated as a technique to improve the sensitivity of screening mammograms. The CAD system consists of two units: the processing unit, which digitizes and analyzes the film images; and the display unit, which displays low-resolution digital images of the exam. A detection algorithm recognizes a pattern in the digital image that warrants evaluation by a radiologist. Two types of marks are used: an asterisk indicates a pattern suggestive of a mass or area of architectural distortion, and a solid triangle indicates an area of clustered bright spots suggestive of microcalcifications.

These CAD mammography systems have been approved by the U.S. Food and Drug Administration (FDA) for use in the U.S.: The Image Checker System® by R2 Technology, approved June 1998; The MammoReader® by Intelligent Systems Software, Inc., approved January 2002; and the Second Look® by CADx Medical Systems, Inc., approved January 2002.

**Policy:**

**Effective for dates of service on or after May 1, 2003:**
Computer-aided detection (CAD) mammography as an adjunct to single-reader interpretation of a digitized screen-film mammogram meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

Computer-aided detection (CAD) mammography as an adjunct to single-reader interpretation on a direct, full-field digital mammogram (i.e., not screen film mammogram) does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

**Key Points:**
Burhenne, et al., did a retrospective review to determine the false-positive rate in screening mammography, the capability of CAD to identify these missed lesions, and whether or not CAD increases the radiologists’ recall rate. They looked at all available screening mammograms that led to the detection of biopsy-proven cancer (n = 1083) and the most recent corresponding prior mammograms (n = 427) from 13 facilities from 1994 through 1996. Of the 427 prior mammograms, 286 (67%) had evidence of the subsequently diagnosed cancer (visible prior mammograms).
A panel of 20 radiologists performed an independent, blinded review of these 286 visible prior mammograms to determine whether there was evidence of an “actionable lesion”. They determined that 27% (115 of 427) of cases were “actionable prior mammograms” but were missed by the original radiologist. So, the sensitivity of the original radiologists was 79% (427 of [427 + 115]) with a corresponding false negative rate of 21% (115 of [427 + 115]).

All of the original 1083 mammograms and 286 visible prior mammograms were analyzed by the CAD system. The results showed 906 of 1083 (84%) were correctly marked by this system. This system also correctly marked 171 of 286 (60%) visible prior mammograms. The system also detected 89 of 115 (77%) cancers that were considered actionable by the panel radiologists.

There was no statistically significant increase in the radiologists’ recall rate as a group or individually with the use of CAD at the threshold level (8.3% vs. 7.6%).

Freer and Ulissey performed a prospective trial to assess the effect of CAD on interpretation of screening mammograms. Over a 12-month period, 12,860 screening mammograms were initially interpreted by a radiologist without CAD, then analyzed by the CAD system and immediately re-evaluated. A total of 986 patients were recalled for further evaluation (830 per radiologists’ interpretation, 156 per CAD with agreement by radiologist). So, the CAD increased the number of actionable findings by 19% and increased the recall rate from 6.5% to 7.7%. Ultimately, 128 actionable findings in 124 patients were subjected to biopsy. Of these, 79 patients (62%) had benign lesions and 49 patients (38%) had malignant lesions.

The use of CAD resulted in a 19.5% increase (8 of 41) in the number of malignancies detected. All 8 of these malignancies were found to be stage 0 or I at surgery. Of note is that 97% of all computer marks were dismissed by the radiologist as insignificant. The current CAD systems are designed to be heavily biased toward sensitivity, with low specificity, so that the radiologist must focus his attention on specific areas where suspicious findings may have been overlooked.

The New England Journal of Medicine (NEJM) published an article by Fenton et al in April 2007, regarding the use of computer-aided detection when performing screening mammography. The sensitivity, specificity, positive predictive value, cancer-detection rate, biopsy rate, and overall accuracy of screening mammography with and without the use of computer-aided detection were evaluated. Data from 222,135 women with a total of 429,345 mammograms from 43 facilities in three states were used. This data included 2351 women who received a diagnosis of breast cancer within 1 year after screening during the study time frame. During this study period, seven facilities implemented computer-aided detection. Diagnostic specificity decreased from 90.2% before implementation of CAD to 87.2% after implementation of CAD. Positive predictive value decreased from 4.1% to 3.2% and the biopsy rate increased by 19.7%. An increase in sensitivity from 80.4% before implementation of CAD to 84.0% after implementation was not significant. The change in the cancer-detection rate was not significant. Data analysis from all facilities showed that the use of CAD was associated with significantly lower overall accuracy than was nonuse. The authors concluded that the use of computer-aided detection is associated with reduced accuracy of interpretation of screening mammograms. CAD was determined to be associated with increases in potential harms of screening mammography, including higher recall and biopsy rates, and was of uncertain clinical benefit. The use of CAD
remained significantly associated with decreased specificity, decreased positive predictive value, and decreased overall accuracy in analyses that adjusted for differences in characteristics of patients, radiologists, and facilities. The association between the use of CAD and the observed changes in performance could be explained by factors that were not measured. Since the use of CAD is used in the screening of healthy women, larger studies are needed to judge more precisely whether benefits or routine use of computer-aided detection outweigh its harms.

An editorial by Hall was published in the same issue of NEJM. Hall addresses issues for the radiologists who have taken on the task of reading the screening mammograms and cites as a flaw in the study the failure to assess the time it takes to adjust to CAD. He states adjustment to CAD could take weeks to years. Hall comments on start-up costs for CAD and digital mammography and possible legal implications of using CAD in breast imaging. The author did recommend that larger, controlled studies of CAD be conducted that assess cancer diagnosis but also the gold standard of mortality.

**November 2008 Update**

Gilbert, et al, reported on the results of an equivalence trial performed in the United Kingdom with matched-pair comparisons between the cancer-detection rates achieved by single reading with computer-aided detection and those achieved by double reading. In the study, 31,057 women undergoing routine screening by film mammography were randomly assigned to double reading and single reading with computer-aided detection. The primary outcome measures were the proportion of cancers detected according to regimen and the recall rates within the group receiving both reading regimens. Trial mammograms were digitized and analyzed by a software detection algorithm of a computer-aided detection system. The proportion of cancers detected was 199 of 227 (87.7%) for double reading and 198 of 227 (87.2%) for single reading with computer-aided detection (P = 0.89). The overall recall rates were 3.4% for double reading and 3.9% for single reading with computer-aided detection; the difference between the rates was small but significant (P < 0.001). The estimated sensitivity, specificity, and positive predictive value for single reading with computer-aided detection were 87.2%, 96.9% and 18.0%, respectively. The corresponding values for double reading were 87.7%, 97.4%, and 21.1%. There were no significant differences between the pathological attributes of tumors detected by single reading with the computer-aided detection alone. Single reading with CAD could be an alternative to double reading and could improve the rate of detection from screening mammograms read by a single reader. The trial demonstrated that the cancer-detection rates of a single reader using CAD and of two readers are similar. The strengths of this study are that it was a multicenter, prospective trial with more than 30,000 women randomly assigned to one of three reading groups and that readers were unaware of the reading assignments. The authors also stated that comparison between the performance of computer-aided detection in full-field digital mammography and its performance in film mammography will be required.

**October 2010 Update**

No further updates required.

**Key Words:**
Computer-aided detection (CAD) mammography
**Approved by Governing Bodies:**

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: FEP does not consider investigational if FDA approved. May be reviewed for medical necessity. Special benefit consideration may apply. Refer to member’s benefit plan.
Pre-certification/Pre-determination requirements: Not applicable

### Current Coding:

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<tr>
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<th>Description</th>
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<tr>
<td>77051</td>
<td>Computer-aided detection (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation, with or without digitization of film radiographic images; diagnostic mammography (Effective 01/01/2007)</td>
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<tr>
<td>77052</td>
<td>Computer-aided detection (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation, with or without digitization of film radiographic images; screening mammography (Effective 01/01/2007)</td>
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### Previous Coding:

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<td>76082</td>
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<td>76083</td>
<td>Computer-aided detection (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation, with or without digitization of film radiographic images; screening mammography (Deleted effective 01/01/2007)</td>
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<tr>
<td>76085</td>
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### HCPCS:

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<td>G0236</td>
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for lesion detection, or computer analysis of digital mammogram for lesion detection, and further physician review for interpretation, diagnostic mammography (list separately in addition to code for primary procedure) (Deleted effective 01/01/2004)

S8075 Computer analysis of full-field digital mammogram and further physician review for interpretation, mammography (Deleted effective 07/01/2006)

References:
**Policy History:**
Medical Policy Group, May 2003 (2)
Medical Policy Administration Committee, May 2003
Available for comment June 3-July 18, 2003
Medical Policy Group, May 2005 (1)
Medical Policy Group, May 2007 (1)
Medical Policy Group, October 2008 (1)
Medical Policy Administration Committee, November 2008
Medical Policy Group, October 2010 (1): Active Policy but no longer scheduled for regular literature reviews and updates effective October 1, 2010

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case by case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.