MEDICAL POLICY

Excellus

SUBJECT: MAMMOGRAPHY: DIRECT FULL-FIELD DIGITAL AND DIGITAL BREAST TOMOSYNTHESIS	**EFFECTIVE DATE: 08/16/01** **REVISED DATE: 10/16/02, 10/15/03, 09/16/04, 11/03/04, 09/15/05, 02/16/06, 12/21/06, 11/15/12, 11/21/13** **(ARCHIVED DATE: 10/18/07**
POLICY NUMBER: 6.01.22 **CATEGORY: Technology Assessment**	**EDITED DATE: 12/18/08, 11/19/09, 09/16/10, 09/15/11)** **PAGE: 1 OF: 6**

- ***If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.***
- ***Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.***
- ***Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.***

POLICY STATEMENT:

I. Based upon our criteria and review of the peer-reviewed literature, *direct full-field digital mammography* has been shown to be a **medically appropriate** imaging option in the screening and diagnosis of breast cancer; thus, coverage is provided for all women for direct full-field digital mammography. Of note, in the DMIST trial, this technique was shown to be more accurate than screen-film mammography for the detection of breast cancer in women under age 50 years, women with radiographically dense breasts and premenopausal or perimenopausal women and is thus considered the preferred approach for these women.

II. Based upon our criteria and review of the peer-reviewed literature, *digital breast tomosynthesis* is considered **investigational** in the screening or diagnosis of breast cancer.

Refer to Corporate Medical Policy #6.01.23 regarding Mammography: Computer Aided Detection.

POLICY GUIDELINES:

This policy does not address *computer-aided detection (CAD) mammography*. CAD acts as a second reader of mammograms, and can utilize digital mammograms or can digitize screen-film mammograms. CAD provides computer analysis of digitized mammograms for patterns suggestive of abnormalities.

DESCRIPTION:

Mammograms can be rendered in a digital format in two different ways. Conventional screen-film mammograms (SFM) can be converted to a digital image, referred to as a *digitized* film screen mammogram, or a mammogram can be generated as a digital image initially, referred to as a *direct full-field digital mammogram* (FFDM). This distinction is important, since images are generated in two different ways. Therefore, data regarding their diagnostic performance must be considered separately.

A limitation of screen-film mammography is the film itself. Once a screen-film mammogram is obtained, it cannot be significantly altered. Contrast loss due to film underexposure, especially of dense glandular tissues cannot be regained through film display.

However, if a mammogram is rendered in a digital format, the image can be manipulated in a variety of ways to highlight lesion conspicuity. The radiologist can alter the orientation, magnification, brightness and contrast of the images as desired. Digital images can be viewed in several ways, such as on a high-luminance computer monitor or printed as a film. From the patient's point of view, mammography with a digital system is essentially the same as with the screen-film system. Unlike images on radiographic film, digital images can be stored and transferred electronically which facilitates their quick and easy retrieval as well as allowing remote evaluation by distant specialists.

The outcomes proposed for measuring the efficacy of digital mammography are the potential to detect breast cancer at an earlier stage, reduce the number of patients recalled for additional mammograms, reduce the number of false-positive mammograms, decreased radiation dose to the breast, increased accuracy of images, facilitation of long distance consultations with mammography specialists, and ease of mammography storage.

Digital breast tomosynthesis (DBT) uses existing digital mammography equipment with specialized software to obtain additional radiographic data. The specialized software enables the reader to view x-ray images of the breast tissue as a series of thin reconstructed sections, thus overcoming the problem of tissue overlap which is observed on conventional 2D images. Potential advantages of DBT are similar to those for full field digital mammography; more accurate estimation BI-RADS classification of a lesion (improved conspicuity), reduction of distortions, reduction of false positives associated with glandular clusters, greater security in the study of dense breasts, and the reduction of the number of recalls. Tomosynthesis involves some additional imaging time and radiation exposure.

RATIONALE:

Digital Mammography

Digital mammography systems have been approved by the U.S. Food and Drug Administration (FDA) for use in the U.S., such as but not limited to, the Senographe Essential Full-Field Digital Mammography System® (GE Medical Systems), the SenoScan® Full Field Digital Mammography System (Fisher Imaging), Selenia® Dimensions™ 2D full-field digital mammography system (Hologic, Inc.) and the Mammomat Novation^{DR} Full Field Digital Mammography system (Siemens Medical Solutions USA, Inc).

The FDA has approved digital mammography for clinical use, and has concluded that this technology performs no better than standard plain screen-film mammography. The peer reviewed medical literature has not demonstrated clinical superiority of digital mammography over standard screen-film mammography for diagnosis and screening of breast cancer, and no professional organizations have recommended its use over standard screen-film mammography. However digital mammography may be considered equivalent to screen film mammography.

A three-year, randomized, multi-center study of 42,760 women in 33 sites in the U. S. and Canada compared the diagnostic accuracy of five different types of full-field digital mammography (FFDM) and screen-film mammography (SFM) in asymptomatic women who presented for breast cancer screening. Women randomized to Arm I received 2-view SFM then 2-view FFDM on each breast. Those randomized to Arm II received 2-view FFDM, then 2-view SFM on each breast. The Digital Mammographic Imaging Screening Trial (DMIST) found there was no significant difference in the diagnostic accuracy of the two techniques overall. Sensitivity 70% FFDM, 66% SFM (p=0.37); specificity 92% FFDM, 9%2 SFM (p=0.74); PPV 5% FFDM, 5% SFM. However, subset analyses found digital mammography to be more accurate in women under 50 years of age (test accuracy 84% FFDM, 69% SFM [p=0.002]), women with extremely dense breasts (78% FFDM, 69% SFM [p= 0.003]), and women who were pre- or perimenopausal (82% FFDM, 67% SFM [p=0.002]). The study did not use CAD (computer aided detection) for SFM interpretation. Authors plan to publish additional analyses performed on the trial data including a forthcoming cost-effectiveness and quality of life analyses.

A clinical trial of 24,911 women aged 45-69 years randomized participants to either conventional screen film mammography (SFM) or full-field digital mammography (FFDM). Recall rates, positive predictive values and cancer detection rates were compared for two age groups (45-49 and 50-69 years). There was no statistically significant difference in the detection rate between the two techniques, either overall or for the two different age groups. Recall rates were significantly higher for FFDM though positive predictive value was similar. Limitations in the study design and execution limited conclusions. Despite randomization, it is not clear that similar groups were achieved. The study provides no baseline characteristics comparison of participants who received FFDM s. SFM so it cannot be determined whether the participant groups were actually similar.

A randomized trial of 23, 929 women prospectively compared performance indicators of screen-film mammography (SFM) and full-field digital mammography (FFDM) in a population-based screening program. This study was follow-up and final results of the Oslo II study. FFDM resulted in a significantly higher cancer detection rate (59%) than SFM (38%). The positive predictive value was comparable for FFDM (28.3%) and SFM (27%).

Digital Breast Tomosynthesis

On February 11, 2011, the U.S. Food and Drug Administration (FDA) approved Hologic, Inc. to market its Selenia Dimensions 2D Full Field Digital Mammography (FFDM) and Digital Breast Tomosynthesis (DBT) system. This DBT is the first mammography system that provides 3D images of the breast for breast cancer screening and diagnosis. Since the date of the FDA approval, a number of facilities in the U.S. have been using the Selenia Dimensions 2D (with the DBT locked). Facilities that have an accredited (or have applied to be accredited) Selenia Dimensions 2D unit can activate the DBT modality of the unit after applying to and obtaining FDA approval to extend its certificate to include the DBT modality.

Because DBT is a new mammographic modality, facilities wanting to use DBT on patients must meet all Mammography Quality Standards Act (MQSA) applicable requirements: (1) personnel must obtain at least 8 hours of DBT training; (2) the unit must undergo a mammography equipment evaluation prior to use; and (3) the facility must follow the manufacturer's recommended quality control procedures.

The Selenia Dimensions 3D DBT is a hardware and software upgrade to the Selenia Dimensions 2D FFDM system, which is FDA approved for conventional mammography imaging (P010025/S013, approved December 22, 2008).

The FDA approved new tomosynthesis software (May 2013) that enables a 2D image (called C view) to be created from the tomosynthesis images. As a result, the radiation dose will be lowered since both the tomosynthesis and the 2D mammography can be created from one procedure versus two. Studies are still needed to determine if the combined C view and 3D reconstruction to digital tomosynthesis alone are comparable.

A 2013 Blue Cross Blue Shield TEC Assessment, "Use of digital breast tomosynthesis with mammography for breast cancer screening or diagnosis" concluded that recent studies have provided some evidence that adding breast tomosynthesis to mammography may increase the accuracy (and possibly the sensitivity) of screening while reducing the number of women who are recalled unnecessarily. However studies with longer follow-up of women with negative screening results are needed. Digital breast tomosynthesis as an addition to diagnostic mammography (such as spot views) has the potential to screen out some women with false-positive results. As a consequence the number of women who are biopsied may be reduced. The body of evidence on the use of breast tomosynthesis to evaluate women who are recalled for a diagnostic work-up after a suspicious finding on screening mammography is weaker than that on adding breast tomosynthesis to mammography for screening. In addition, diagnostic mammography is not the only imaging modality used during the diagnostic work-up. Thus assessing the value of tomosysnthesis compared to the available set of different diagnostic tests (e.g., ultrasound, MRI) is problematic.

The American College of Obstetricians Technical Assessment (2013) on digital breast tomosynthesis concluded clinical data suggest that digital mammography with tomosynthesis produces a better image, improved accuracy, and lower recall rates compared with digital mammography alone. Further study will be necessary to confirm whether digital mammography with tomosynthesis is a cost-effective approach capable of replacing digital mammography alone as the first-line screening modality of choice for breast cancer screening.

In summary, the use of digital breast tomosynthesis in generating images for screening or diagnosis of breast cancer is considered investigational. Studies of outcomes (including accuracy and recall rate) with use in clinical practice are needed. In addition, there are unanswered questions about the number of images needed as well as concerns about radiation dose and time for interpretation.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT: No codes

HCPCS:	G0202	Screening mammography producing direct digital image, bilateral, all views
	G0204	Diagnostic mammography, direct digital image, bilateral, all views
	G0206	Diagnostic mammography, direct digital image, unilateral, all views
ICD9:	174.0-174.9	Malignant neoplasm of female breast (code range)
	198.89	Secondary malignant neoplasm, axilla, axillary
	198.81	Secondary malignant neoplasm of breast
	233.0	Carcinoma in situ of breast
	238.3	Neoplasm of uncertain behavior; breast
	239.3	Neoplasms of unspecified nature; breast
	793.80	Abnormal mammogram, unspecified
	V10.3	Personal history of malignant neoplasm, breast
	V16.3	Family history of malignant neoplasm, breast
	V76.10	Special screening for malignant neoplasm, breast screening, unspecified
	V76.11	Special screening for malignant neoplasm, screening mammogram for high-risk patient
	V76.12	Special screening for malignant neoplasm, other screening mammogram
	V76.19	Special screening for malignant neoplasm, other screening breast examination
ICD10:	C50.011-C50.019	Malignant neoplasm of nipple and areola, female (code range)
	C50.111-C50.119	Malignant neoplasm of central portion of breast, female (code range)
	C50.211-C50.219	Malignant neoplasm of upper-inner quadrant of breast, female (code range)
	C50.311-C50.319	Malignant neoplasm of lower-inner quadrant of breast, female (code range)
	C50.411-C50.419	Malignant neoplasm of upper-outer quadrant of breast, female (code range)
	C50.511-C50.519	Malignant neoplasm of lower-outer quadrant of breast, female (code range)
	C50.611-C50.619	Malignant neoplasm of axillary tail of breast, female (code range)
	C50.811-C50.819	Malignant neoplasm of overlapping sites of breast, female (code range)
	C50.911-C50.919	Malignant neoplasm of breast of unspecified site, female (code range)
	C79.81	Secondary malignant neoplasm of breast

C79.89	Secondary malignant neoplasm of other specified sites
C79.9	Secondary malignant neoplasm of unspecified site
D05.00-D05.92	Lobular carcinoma in situ of breast (code range)
D48.60-D48.62	Neoplasm of uncertain behavior of other and unspecified sites (code range)
D49.3	Neoplasm of unspecified behavior of breast
R92.8	Other abnormal and inconclusive findings on diagnostic imaging of breast
Z12.31	Encounter for screening mammogram for malignant neoplasm of breast
Z12.39	Encounter for other screening for malignant neoplasm of breast
Z80.3	Family history of malignant neoplasm of breast
Z85.3	Personal history of malignant neoplasm of breast

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KEY WORDS:

Digital mammography, Full-field digital mammography, Digital breast tomosynthesis.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for full-field digital mammography.