



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

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Subject Mammography

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Hyperlink to Related Coverage Policies

Electrical Impedance Scanning (EIS) and Optical Imaging of the Breast
 Genetic Testing for Susceptibility to Breast and Ovarian Cancer (BRCA1 & BRCA2)
 Magnetic Resonance Imaging (MRI) of the Breast
 Mammary Ductoscopy (MD)
 Nuclear Imaging including Single-Photon Emission Computed Tomography (SPECT)

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2010 CIGNA

Coverage Policy

CIGNA covers an annual mammography for screening or surveillance as medically necessary for ANY of the following indications:

- woman age 40 and over
- woman age 25-39 when ANY of the following criteria are met:
 - history of prior high-dose thoracic irradiation (e.g., prior therapeutic radiation therapy)
 - a strong family history or genetic predisposition for breast cancer including ANY of the following:
 - the individual has a known BRCA mutation
 - a first-degree relative of BRCA carrier, but untested
 - a five-year risk of invasive breast cancer $\geq 1.7\%$ as determined by a risk assessment tool based upon the modified Gail model (e.g., National Cancer Institute risk assessment tool)
 - a lifetime risk of breast cancer $> 20\%$ as determined by a risk assessment tool such as BRCAPRO (i.e., Duke model) or other model that is largely dependent on family history (e.g., BOADICEA [Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm], Gail, Claus, or Tyrer-Cusick model)
 - personal history of or a first-degree relative with Li-Fraumeni syndrome, Cowden syndrome or Bannayan-Riley-Ruvalcaba syndrome

- personal history of breast cancer (including surveillance of the contralateral breast)

CIGNA covers diagnostic mammography in males and females as medically necessary for ANY of the following indications:

- abnormal or inconclusive screening mammography
- signs or symptoms of breast disease
- silicone gel-filled breast implant rupture is suspected

CIGNA covers direct digital image production, for both screening and diagnostic mammography as medically necessary.

CIGNA covers computer-aided detection when used as an adjunct to radiologist's interpretation as medically necessary, for both screening and diagnostic mammography.

CIGNA does not cover digital tomosynthesis for breast imaging because it is considered experimental, investigational or unproven.

General Background

Mammography is a specific type of imaging that uses a low-dose x-ray system for examination of the breasts. The image of the breast is produced as a result of some of the x-rays being absorbed, while others pass through the breast. With standard or conventional mammography (i.e., screen-film mammography [SFM]), x-rays are exposed to a film cassette (conventional mammography) and then placed in a developing machine. With digital mammography (i.e., full-field digital mammography [FFDM]), x-rays are exposed to an electronic x-ray detector, a phosphor screen. The x-ray photons are converted to light, and then passed through a fiberoptic cable to a device that converts the light to a digitized signal for display on a computer monitor. The image is digitally stored on computer. Standard mammography may be digitized with a film digitizer or laser scanner. Computer-aided detection (CAD) and diagnosis involves the use of imaging software to identify suspicious areas on a mammogram for further radiologist review. Software programs for diagnosis are more complex than for detection, with the algorithms continuing to analyze the suspicious areas after detection.

Risks

Radiation: The effective radiation dose from a mammogram is about 0.7 mSv, which is similar to that which the average person receives from background radiation in three months. Federal mammography guidelines require that each unit be checked by a medical physicist every year to ensure that the unit operates correctly.

False-Positive Mammograms: 5–15% of screening mammograms are followed with additional testing. Most of these tests turn out to be normal. If there is an abnormal finding, additional imaging or biopsy may have to be performed. Most of the biopsies confirm that no cancer was present. It is estimated that a woman who has yearly mammograms between ages 40 and 49 has about a 30% chance of having a false-positive mammogram at some point in that decade and about a 7–8% chance of having a breast biopsy within the 10-year period.

U.S. Food and Drug Administration (FDA)

Mammographic x-ray systems are classified as Class II devices intended to produce radiographs of the breast. The FDA regulates the marketing of mammography devices and regulates the use of such devices via the Mammography Quality Standards Act (MQSA), which requires that all mammography facilities become accredited and certified to provide mammography services. The FDA has granted pre-market approval to several digital mammography systems (product code MUE) for breast cancer screening and diagnosis. Also, the FDA has approved several computer-aided detection (CAD) systems (product code MYN) for evaluating screening mammograms. FDA approval for CAD states that CAD is to be applied only after the interpreting radiologist has reviewed and interpreted all mammograms for a given patient and that the purpose of CAD is to minimize observational oversights by identifying and calling attention to regions of concern that warrant close attention, or a second look.

Screening Mammography

Screening mammography is a radiological examination performed to detect unsuspected breast cancer in asymptomatic women. Mammography plays a central part in early detection of breast cancers because it can show changes in the breast up to two years before a patient or physician can feel them. Research has shown that annual mammograms lead to early detection of breast cancers, when they are most curable and breast-conservation therapies are available. The American Cancer Society (ACS), American College of Radiology (ACR), American College of Obstetricians and Gynecologists (ACOG), and National Comprehensive Cancer Network (NCCN) recommend annual screening mammography for women age 40 and older. Research has shown that annual mammograms lead to early detection of breast cancers, when they are most curable and breast-conservation therapies are available.

American Cancer Society (ACS): The following recommendations are from the ACS guidelines for breast cancer screening (Smith, et al., 2003) and the ACS guidelines for breast screening with MRI as an adjunct to mammography (Saslow, et al., 2007):

The ACS Recommendations for Early Breast Cancer Detection are as follows:

- Women age 40 and older should have a screening mammogram every year, and should continue to do so for as long as they are in good health.
- Women in their 20s and 30s should have a clinical breast exam (CBE) as part of a periodic (regular) health exam by a health professional preferably every 3 years. After age 40, women should have a breast exam by a health professional every year.
- BSE is an option for women starting in their 20s. Women should be told about the benefits and limitations of BSE. Women should report any breast changes to their health professional right away.
- Women at high risk (greater than 20% lifetime risk) should get an MRI (magnetic resonance imaging) and a mammogram every year. Women at high risk include those who:
 - have a known BRCA1 or BRCA2 gene mutation
 - have a first-degree relative (mother, father, brother, sister, or child) with a BRCA1 or BRCA2 gene mutation, and have not had genetic testing themselves
 - have a lifetime risk of breast cancer of 20%-25% or greater, according to risk assessment tools that are based mainly on family history
 - had radiation therapy to the chest when they were between the ages of 10 and 30 years
 - have a genetic disease such as Li-Fraumeni syndrome, Cowden syndrome, or Bannayan-Riley-Ruvalcaba syndrome, or have one of these syndromes in first-degree relatives
- Women at moderately increased risk (15% to 20% lifetime risk) should talk with their doctors about the benefits and limitations of adding MRI screening to their yearly mammogram. Yearly MRI screening is not recommended for women whose lifetime risk of breast cancer is less than 15%. Women at moderately increased risk include those who:
 - have a lifetime risk of breast cancer of 15%-20%, according to risk assessment tools that are based mainly on family history
 - have a personal history of breast cancer, ductal carcinoma in situ (DCIS), lobular carcinoma in situ (LCIS), atypical ductal hyperplasia (ADH), or atypical lobular hyperplasia (ALH)
 - have extremely dense breasts or unevenly dense breasts when viewed by mammograms
- If MRI is used, it should be in addition to, not instead of, a screening mammogram. This is because while an MRI is a more sensitive test, it may still miss some cancers that a mammogram would detect.
- For most women at high risk, screening with MRI and mammograms should begin at age 30 years and continue for as long as a woman is in good health. But because the evidence is limited regarding the best age at which to start screening, this decision should be based on shared decision making between patients and their health care providers, taking into account personal circumstances and preferences.
- Several risk assessment tools, with names such as BRCAPRO, the Claus model, and the Tyrer-Cuzick model, are available to help health professionals estimate a woman's breast cancer risk. These tools give approximate, rather than precise, estimates of breast cancer risk based on different combinations of risk factors and different data sets. As a result, they may give different risk estimates for the same woman. Their results should be discussed by a woman and her doctor when being used to decide on whether to start MRI screening.
- It is recommended that women who get screening MRI do so at a facility that can do an MRI-guided breast biopsy at the same time if needed. Otherwise, the woman will have to have a second MRI exam at another facility at the time of biopsy.

- There is no evidence at this time that MRI will be an effective screening tool for women at average risk. While MRI is more sensitive than mammograms, it also has a higher false-positive rate (where the test finds things that turn out to not be cancer), which would result in unneeded biopsies and other tests in a large portion of these women (Smith, et al., 2003; Saslow, et al., 2007).

National Comprehensive Cancer Network® (NCCN®): The NCCN Breast Cancer Screening and Diagnosis Guidelines (v.1.2010) recommend annual mammogram and annual clinical breast examination for normal-risk women age 40 and older, with breast awareness encouraged. The NCCN recommends annual mammogram and clinical breast examination every six to twelve months for:

(1) Women aged 25 years and older who have received prior thoracic irradiation: For these patients, mammogram screening is usually initiated 8 to 10 years after radiation exposure or at age 25 years whichever comes last.

(2) Women aged 35 years or older with a five-year risk of invasive breast carcinoma risk $\geq 1.7\%$ (utilizing the National Cancer Institute on-line risk assessment tool which is based on the modified Gail model).

(3) Women who have a lifetime risk $> 20\%$ as defined by models that are largely dependent on family history (e.g., BRCAPRO, BOADICEA). Note: The Gail model should not be used for women with a predisposing gene mutation or strong family history of breast or ovarian cancers or for those with LCIS.

(3) Women with a strong family history or genetic predisposition: Women with a genetic predisposition for hereditary breast and/or ovarian cancer should have clinical breast exams every 6- 12 months and annual mammograms beginning at age 25. Women 25 years or older with a strong family history or other genetic predisposition for breast cancer should have clinical breast exams every 6-12 months and annual mammograms starting 5-10 years prior to the youngest breast cancer case in the family. Women younger than age 25 with a strong family history or genetic predisposition should have annual clinical breast exams. Breast awareness should be encouraged.

(4) Women with lobular carcinoma in situ (LCIS) or atypical hyperplasia

The NCCN notes that women with prior history of breast cancer should be treated according to the surveillance and follow-up section of the NCCN Breast Cancer Treatment Guidelines. The NCCN Breast Cancer Treatment Guidelines (v.2.2010) mentions mammography throughout the guideline, including noting that mammography should be performed 6-12 months after breast conserving radiation therapy.

American College of Radiology (ACR): The ACR Practice Guideline for the performance of screening and diagnostic mammography (2008) states that asymptomatic women 40 years of age or older should have an annual screening mammogram.

Society of Breast Imaging (SBI)/American College of Radiology (ACR): The SBI with the ACR published recommendations for breast cancer screening with imaging (Lee, et al., 2010). Recommendations specific to mammogram include:

- Women at average risk for breast cancer, annual screening from age 40.
- Women with certain BRCA1 or BRCA2 mutations or who are untested but have first-degree relatives (mothers, sisters, or daughters) who are proved to have BRCA mutations, yearly starting by age 30 (but not before age 25)
- Women with $\geq 20\%$ lifetime risk for breast cancer on the basis of family history (both maternal and paternal), yearly starting by age 30 (but not before age 25), or 10 years earlier than the age of diagnosis of the youngest affected relative, whichever is later
- Women with mothers or sisters with pre-menopausal breast cancer, yearly starting by age 30 (but not before age 25), or 10 years earlier than the age of diagnosis of the youngest affected relative, whichever is later
- Women with histories of mantle radiation (usually for Hodgkin's disease) received between the ages of 10 and 30, yearly starting 8 years after the radiation therapy, but not before age 25
- Women with biopsy-proven lobular neoplasia (lobular carcinoma in situ and atypical lobular hyperplasia), atypical ductal hyperplasia (ADH), ductal carcinoma in situ (DCIS), invasive breast cancer or ovarian cancer, yearly from time of diagnosis, regardless of age.

U.S. Preventive Services Task Force (USPSTF): The USPSTF previously (2002) recommended screening mammography, with or without clinical breast exam (CBE), every 1-2 years for women aged 40 and older. In December 2009, the recommendations were updated as follows:

- recommend biennial (every two years) screening mammography for women aged 50 to 74 years.
- the decision to start regular, biennial screening mammography before the age of 50 years should be an individual one and take patient context into account, including the patient's values regarding specific benefits and harms.
- the current evidence is insufficient to assess the additional benefits and harms of screening mammography in women 75 years or older.
- recommend against teaching breast self-examination (BSE).
- the current evidence is insufficient to assess the additional benefits and harms of clinical breast examination (CBE) beyond screening mammography in women 40 years or older.
- the current evidence is insufficient to assess the additional benefits and harms of either digital mammography or magnetic resonance imaging (MRI) instead of film mammography as screening modalities for breast cancer.

For biennial screening mammography in women aged 40 to 49 years, there is moderate certainty that the net benefit is small. Although the USPSTF recognizes that the benefit of screening seems equivalent for women aged 40 to 49 years and 50 to 59 years, the incidence of breast cancer and the consequences differ. The USPSTF emphasizes the adverse consequences for most women—who will not develop breast cancer—and therefore use the number needed to screen to save 1 life as its metric. By this metric, the USPSTF concludes that there is moderate evidence that the net benefit is small for women aged 40 to 49 years. For biennial screening mammography in women aged 50 to 74 years, there is moderate certainty that the net benefit is moderate (USPSTF, 2009).

National Cancer Institute (NCI): The Breast Cancer Risk Assessment Tool is an interactive tool based on the modified Gail model, designed for use by health professionals and is available online at the National Cancer Institute,

Diagnostic Mammography

Diagnostic mammography is used to evaluate a patient with abnormal clinical findings such as a breast lump, which have been found by a woman or her doctor. Diagnostic mammography may also be done after an abnormal screening mammography in order to determine the cause of the area of concern on the screening exam (RSNA, 2009).

American College of Radiology (ACR): The ACR Practice Guideline for the performance of screening and diagnostic mammography (2008) states that indications for diagnostic mammography may include:

- specific focus of clinical concern including, but not limited to, mass, induration, axillary lymphadenopathy, some types of nipple discharge, skin changes, or persistent focal areas of pain or tenderness
- possible radiographic abnormalities detected on screening mammography
- short-interval follow-up (e.g., less than one year) for probably benign radiographic concerns as defined by the ACR Breast Imaging Reporting and Data System (BI-RADS[®])
- any patient whose examination requires direct involvement of the radiologist for special views, breast physical examination or consultation
- women who have implants or who have been treated for breast cancer may undergo screening mammography or diagnostic mammography, at the discretion of the facility.

American Society of Clinical Oncology (ASCO): The ASCO Update of the Breast Cancer Follow-up and Management Guidelines in the Adjuvant Setting notes that “for those who have undergone breast-conserving surgery, a post-treatment mammogram should be obtained one year after the initial mammogram and at least six months after completion of radiation therapy. Thereafter, unless otherwise indicated, a yearly mammographic evaluation should be performed” (Khatcheressian, et al., 2006).

Digital Mammography

Digital mammography, also known as full-field digital mammography (FFDM) is a mammography system in which the x-ray film is replaced by solid-state detectors that convert x-rays into electrical signals. These detectors are similar to those found in digital cameras. Results from the Digital Mammographic Imaging Screening Trial (DMIST) trial indicated that the diagnostic accuracy of digital mammography was significantly higher than that of film mammography among women under the age of 50 (digital sensitivity, 78%, compared to film sensitivity of 51%); women with heterogeneously dense or extremely dense breasts on mammography (digital sensitivity, 70%, compared to film sensitivity of 55%); and premenopausal or perimenopausal women (digital sensitivity, 72%, compared to film sensitivity, 51%) (Pisano, et al., 2005). In a retrospective study of DMIST population subgroups using biopsy results or follow-up information as the reference standard, Pisano et al. (2008) noted that the only population subgroup for which digital mammography was significantly better than film was pre- or perimenopausal women younger than 50 years who had dense breasts at film mammography (areas under the receiver operating characteristic curve [AUCs], 0.79 vs 0.54; P = .0015). Pisano et al. stated that AUCs were not significantly different in any of the other subgroups (defined by combinations of age, menopausal status, and breast density). Results from the Oslo II trial support the use of digital mammography (Skaane, et al., 2007a).

American College of Radiology (ACR): The ACR Practice Guideline for the performance of screening and diagnostic mammography (2008) states “Digital mammography has been shown to be at least equivalent in accuracy to screen-film mammography (Pisano, et al., 2005). In some patient subgroups, digital mammography may have improved accuracy compared to screen-film mammography.”

Computer-Aided Detection (CAD)

Computer-aided detection (CAD) systems use a digitized mammographic image that can be obtained from either a conventional film mammogram or a digitally acquired mammogram. The computer software then searches for abnormal areas of density, mass, or calcification that may indicate the presence of cancer. The CAD system highlights these areas on the images, alerting the radiologist to the need for further analysis (RSNA, 2007). FDA approval for CAD states that CAD is to be applied only after the interpreting radiologist has reviewed and interpreted all mammograms for a given patient. Three studies (n = 347324) reported sensitivity and specificity (or data to calculate it) for women who had screening mammograms read by a single reader plus CAD, with reference to cancer diagnosis one year later (Gromet, et al., 2008; Georgian-Smith, et al., 2007; Fenton, et al., 2007). Noble et al. (2009) combined the results of the three studies in meta-analysis, and determined that for routine screening of asymptomatic women, the sensitivity of a single reading plus CAD reading was 86.0%, and the specificity was 88.2%. Per 100,000 women screened, a second mammography reading with CAD yields an estimated 50 additional cancer diagnoses, 1,190 additional recalls of healthy women, and 80 additional biopsies of healthy women. There is sufficient evidence in the published, peer-reviewed scientific literature to support the use of computer-aided detection systems as an adjunct to radiologist's interpretation (Gilbert, et al., 2008; Skaane, et al., 2007b; Ko, et al., 2006; Cupples, et al., 2005; Freer, et al., 2001).

American Cancer Society (ACS): The ACS breast cancer screening guidelines (Smith, et al., 2003) state that for digital mammography and CAD there is “some clinical evidence for effectiveness or equivalence to screen-film mammography for screening”.

American College of Radiology (ACR): The ACR Practice Guideline for the performance of screening and diagnostic mammography (2008) states “Double reading and computer-aided detection (CAD) may slightly increase the sensitivity of mammographic interpretation, and may be used. However, this sensitivity is at the expense of decreased specificity with increased recall and, at this time, they are not considered standards of care.”

Digital Tomosynthesis

Digital tomosynthesis systems are being studied as an adjunct and alternative to x-ray mammography for the screening and diagnosis of breast cancer. Digital tomosynthesis techniques are also in development for orthopedic, lung, and radiotherapy imaging applications. Unlike conventional mammography units, a tomosynthesis system's x-ray tube sweeps along an arc around the breast to acquire between 60 and 70 2-dimensional (2-D) projections from slightly different angles in about 10 to 20 seconds. The resulting 2-D images are digitally manipulated to create tomograms (i.e., slices) in any plane, thus allowing for 3-D reconstruction that reveals depth. The number of tomograms that can be created depends on the number of 2-D projections captured during the x-ray sweep. The slices can be displayed individually (resembling conventional

mammograms with sharper details) or in a dynamic "movie" mode. Providing a 3-D reconstruction of the breast eliminates the problem of overlying tissue that might be mistaken for lesions or that might obscure small cancers, according to technology developers.

Currently, there is no FDA-approved digital tomosynthesis for breast imaging; however Hologic, Inc. (Bedford, MA) submitted a Premarket Approval (PMA) application in 2007 for its Selenia Dimensions digital breast tomosynthesis (DBT) system. The FDA is still reviewing the PMA (ECRI, 2010).

Comparative data (accuracy, clinical utility) for digital tomosynthesis versus other breast imaging modalities are lacking. The published feasibility and experimental studies do not clarify what role digital tomosynthesis should provide in lieu of or in conjunction with other breast imaging modalities; including if it should be utilized for screening, diagnostic or surveillance purposes. There is insufficient evidence in the published peer-reviewed scientific literature supporting the accuracy and clinical utility of digital tomosynthesis for breast imaging.

Summary

Mammography: Women of any age who think they may be at an increased risk for breast cancer should consult with their physicians about a personalized screening mammography schedule. Numerous professional societies and government organizations recommend an annual screening mammography for average-risk women age 40 and over and certain groups of women with specific risk factors. Diagnostic mammography is indicated for any persons with an abnormal screening mammography, signs or symptoms of breast disease, or if silicone gel-filled breast implant rupture is suspected.

Full-field Digital Mammography (FFDM): Results of the DMIST trial indicate that, although the diagnostic accuracy of digital and film mammography as a means of screening for breast cancer was similar across the general population, there were subsets of the population in which the accuracy of digital mammography was significantly higher than that of film mammography.

Computer-Aided Detection (CAD): CAD systems have been developed to help radiologists detect suspicious abnormalities on mammograms. The standard of care appears to have shifted towards routine use of these technologies in large radiology practices. CAD systems are effective in identifying regions of interest after initial mammographic interpretation has been completed by the radiologist.

Digital Tomosynthesis: The published peer-reviewed scientific literature does not demonstrate the accuracy and clinical utility of digital tomosynthesis for breast imaging.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT®* Codes	Description
77051	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 (List separately in addition to code for primary procedure)
77052	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 (List separately in addition to code for primary procedure)
77055	Mammography; unilateral
77056	Mammography; bilateral
77057	Screening mammography, bilateral (two view film study of each breast)

HCPCS Codes	Description
G0202	Screening mammography, producing direct digital image, bilateral, all views
G0204	Diagnostic mammography, direct digital image, bilateral, all views
G0206	Diagnostic mammography, producing direct digital image, unilateral, all views

ICD-9-CM Diagnosis Codes	Description
610.0-610.9	Benign mammary dysplasia
611.0	Inflammatory disease of breast
611.1	Hypertrophy of breast
611.6	Galactorrhea not associated with childbirth
611.71	Mastodynia
611.72	Lump or mass in breast
611.79	Other signs and symptoms in breast
611.83	Capsular contracture of breast implant
611.9	Unspecified breast disorder
793.80	Unspecified abnormal mammogram
793.82	Inconclusive mammogram
793.89	Other (abnormal) findings on radiological and other examinations
V10.3	Personal history of malignant neoplasm of breast
V15.3	Personal history of irradiation
V76.11	Screening mammogram for high-risk patient
V76.12	Other screening mammogram
V84.01	Genetic susceptibility to malignant neoplasm of breast

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
	No specific codes

HCPCS Codes	Description
	No specific codes

***Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.**

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	10/15/2008	0123	Mammography

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