



CIGNA MEDICAL COVERAGE POLICY

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

Subject Electrical Impedance Scanning (EIS) and Optical Imaging of the Breast

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Coverage Policy

CIGNA does not cover electrical impedance scanning (EIS) or optical imaging of the breast, because they are considered experimental, investigational or unproven.

General Background

Mammography continues to be considered the gold standard screening tool for breast cancer detection and diagnosis, with a high sensitivity and specificity for detecting abnormal masses and microcalcifications. In order to detect potential breast cancers in their earliest stages, researchers have proposed the use of several additional screening and diagnostic techniques, including electrical impedance scanning (EIS) and optical imaging of the breast.

Electrical Impedance Scanning (EIS)

Electrical impedance imaging scans the breast for electrical conductivity, based on the idea that breast cancer cells conduct electricity in a different way than do normal cells. The test passes a very small electrical current through the body and then detects it on the skin of the breast with a small probe (much like an ultrasound probe). It does not use radiation or compress the breasts. This test is FDA-approved as a diagnostic aid in helping classify tumors found on mammogram. But it has not had enough clinical testing to be used in breast cancer screening (American Cancer Society [ACS], 2010).

Optical imaging

This test either passes light through the breast or reflects light off it and then measures the light that returns. The technique does not use radiation and does not require breast compression. Optical imaging might be useful at some point for detecting tumors or the blood vessels that supply them. One example of optical imaging is computed tomography laser mammography (CTLM). This test passes a harmless laser light through the breast tissue and detects large areas of blood vessels that could be a sign of breast tumors. CTLM is being studied for use along with mammogram to reduce the number of false-positive tests. It has not yet been approved by the FDA. Other experimental techniques now being studied include optoacoustic tomography (sending laser light pulses through the breast and detecting the sound waves they cause) and microwave imaging. These techniques are still in the earliest stages of research (ACS, 2010). Optical breast imaging may also be referred to as transillumination of the breast, optical mammography or dynamic optical breast imaging (DOBI).

U.S. Food and Drug Administration (FDA): The TransScan or T-Scan 2000™ device (Mirabel Medical Systems Inc., Austin, TX) was approved by the FDA under the Premarket Approval Process in April 1999 as an adjunct to mammography in patients whose lesions are American College of Radiology (ACR) Breast Index Reporting Data System (BI-RADS™) category III or IV, based on mammography and not for cases with clear mammographic or non-mammographic indications for biopsy. This device provides the radiologist with additional information to guide a biopsy recommendation.

In August 2006, the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee considered the pre-market approval application (PMA P050003) from Mirabel Medical Systems, Inc. for the T-Scan™ 2000 ED and determined at that time that it was “not approvable”. The proposed indication for this device is “for use as a complement to clinical breast examination (CBE) in asymptomatic women who are 30 to 39 years of age with a negative clinical breast exam and a negative family history for breast cancer. The device detects electrical impedance changes in breast tissue that are associated with an increased risk of breast cancer. A positive T-Scan™ result provides physicians with additional information to guide a recommendation regarding further breast examination, e.g., mammography or ultrasound. The T-Scan evaluates women’s risk of breast cancer at the time of the exam (current risk) and not lifetime risk”.

Literature Review

There is insufficient evidence in the published peer-reviewed scientific literature to support the diagnostic utility of electrical impedance scanning (EIS) of the breast or optical imaging of the breast. The incremental diagnostic value of these alternative breast imaging procedures as an adjunct to mammography has not yet been established, and the impact of the use of these systems on meaningful health outcomes remains unknown.

Electrical Impedance Scanning: In a prospective multicenter study, 583 women (age 25-45) scheduled for mammary biopsy underwent EIS and ultrasound (Wang, et al., 2010). The sensitivities, specificities and the risks in the detective abilities of EIS, ultrasound and the combination method were calculated. Pathological results from biopsy were regarded as a definite diagnosis. Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) for EIS alone was 86.7%, 72.9%, 51.2%, and 94.1% for an overall accuracy of 76.3%. Combined with US, EIS accuracy was 71.4%.

Stojadinovic et al. (2008) conducted a prospective, controlled cohort study, enrolling two subsets of women: one study cohort was used to estimate T-Scan specificity (n=1751) and the other to estimate T-Scan sensitivity (n=390). The Sensitivity cohort consisted of an enriched population of women scheduled to undergo breast biopsy for a suspicious finding during prior diagnostic work-up. The age range was expanded from 30–39 to 30–45 years old and also included women with palpable breast masses. Expansion of the age range to include women ages 39–45 was required due to the low frequency of breast cancer in women under 40. In the Specificity cohort, data were obtained from a consecutive series of examinations of average-risk, asymptomatic women ages 30–39 undergoing a one-time T-Scan procedure after a confirmed negative CBE. There was no mandated follow-up of women with positive EIS findings. All women included in this study cohort continued with

their standard course of clinical care. Negative T-Scan results were not taken into consideration in the clinical management of women in either study cohort. The authors used ascertained sensitivity and specificity levels, along with published data on prevalence of breast cancer in the intended use population to estimate the relative probability (likelihood ratio) that a woman who is positive on EIS examination actually has breast cancer and assessed that estimate in the context of a woman randomly selected from the population at large. In the specificity cohort, 93 of 1751 women were T-Scan positive (specificity = 94.7%). In the sensitivity cohort, 23 of 87 biopsy-proven cancers were T-Scan positive (sensitivity = 26.4%). The authors calculated using a prevalence of 1.5 cancers/1,000 women (ages 30–39), the relative probability of a T-Scan positive woman having breast cancer is 4.95. Limitations of this study noted by the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee included the sensitivity arm of the study included women aged 30-45 years, rather than the 30-39 target age group included in the specificity arm. Also, both arms included clinical sites in Israel, where the population differs from that of the United States in ethnic makeup, body mass index, and possibly other factors.

In a prospective case series, Fuchsjaeger et al. (2005) performed EIS on 128 BI-RADS category IV lesions in 121 women. Histopathological results were obtained for each lesion. EIS was true positive in 35 of 37 malignancies and true negative in 68 of 91 benign lesions. The sensitivity, specificity, accuracy, positive predictive value and negative predictive value of the EIS exam were 94.6%, 74.7%, 80.5%, 60.3% and 97.1%, respectively. In a prospective case series, Malich et al. (2003) compared EIS finding to either histology or a follow-up of at least two years. Included in the series of patients with abnormal mammogram findings were 387 lesions (129 malignant and 258 benign). Using EIS, 103 of 129 malignant lesions and 165 of 258 benign lesions were correctly detected, for a sensitivity of 79.8%, specificity of 64.0%, and an accuracy of 71.9%. Malich et al. (2001) conducted a prospective case series of 100 equivocal mammographic abnormalities in 94 patients. All lesions that were found to be suspicious by mammogram were biopsied for histological confirmation. EIS scanning located 64 bright-spot lesions but missed 36 others. Based upon histopathological findings, EIS demonstrated a sensitivity and specificity of 81% (50/62) and 63% (24/38) respectively.

TransScan conducted an international multicenter, prospective, blinded rereading study from May 1995 to March 1997 to determine the accuracy of their T-Scan 2000 unit. Mammograms and T-Scans were collected prospectively, blindly reread, and the diagnostic accuracy of the mammogram films was then compared to the adjunctive combination of mammography and T-Scan readings. A total of 481 patients were enrolled in the study and underwent breast biopsy procedures. Two hundred and seventy-three equivocal mammograms revealed the following when combined with T-Scan readings: sensitivity improved from 60% to 82% (n=50 cases), while specificity improved from 41% to 57% (n=223 cases). The statistical significance of these results was not reported. Due to the radiographic readings being done blindly and not as the intended application of the T-Scan, an additional study was conducted. At two centers, the T-Scan examiner had knowledge of the mammography readings or clinical exam findings at the time of the T-Scan. A total of 657 scans were conducted and accuracy of the readings was recorded as 150 malignancies, 507 benign lesions, for a sensitivity of 78% and specificity of 67%, when the readings were done in combination with mammography or clinical exam findings (FDA, 1999).

Optical Imaging: In a prospective cohort trial, Fournier et al. (2008) prospectively determined the diagnostic accuracy of dynamic optical breast imaging (DOBI) compared to pathology in 46 women with BI-RADS 3–5 classification lesions. DOBI was conducted immediately prior to biopsy. Twelve lesions (26%) were diagnosed as benign and 35 (74%) as malignant. Results demonstrated a sensitivity of 74%, a specificity of 92%, a positive predictive value of 93%, a negative predictive value of 55% and a diagnostic accuracy of 79%. The authors noted that further evaluation will be required to optimize the technique, evaluate its sensitivity and specificity in a wider range of patients, and explore its potential role in patient management.

Professional Societies/Organizations

Society of Breast Imaging (SBI): The SBI Position Statement ‘Use of Alternative Imaging Approaches to Detection of Breast Cancer’ states that “often predicated on the increased vascularity associated with cancer, techniques to detect increased heat production, oxygen consumption, electrical impedance, light absorption, microwave transmission, and nitrous oxide production have indicated changes in the breast containing cancer that may assist in detection or diagnosis. While many of these approaches have received FDA approval for safety, such techniques remain either experimental or investigational, given the lack of standard techniques that can be uniformly applied and paucity of sufficient research to substantiate reliability of results. None of these tests have been shown to reduce mortality among tested women in randomized controlled trials.”

Summary

There is a lack of evidence in the published peer-reviewed literature to support the use of electrical impedance scanning (EIS) or optical imaging of the breast to detect or confirm lesion(s) or malignancies. It is unclear whether the data obtained from EIS or optical imaging adds meaningful clinical information beyond that provided by standard breast imaging techniques, thus clinical utility has not been established. Studies evaluating EIS and optical imaging have failed to demonstrate that these technologies can:

- improve the detection of breast cancer over conventional screening tools for any age group
- decrease the need for breast biopsies (e.g., surgical or core-needle) to confirm the presence of cancer within an identified lesion
- accurately detect lesions adjacent to the areola and proximal to the skin surface or lesions that are adjacent to the chest wall (i.e., depth greater than three millimeters [mm])
- distinguish a benign skin lesion or interstitial fluid from a malignant mass.

Coding/Billing Information

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

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
76499 [†]	Unlisted diagnostic radiographic procedure

[†]**Note: Experimental/Investigational/Unproven/Not Covered when used to report electrical impedance scanning (EIS) or optical imaging of the breast**

ICD-9-CM Diagnosis Codes	Description
174.0-174.9	Malignant neoplasm of female breast
175.0-175.9	Malignant neoplasm of male breast
198.81	Secondary malignant neoplasm of other specified sites, Other specified sites, Breast
217	Benign neoplasm of breast
233.0	Carcinoma in situ of breast and genitourinary system, Breast
238.3	Neoplasm of uncertain behavior of other and unspecified sites and tissues, Breast
239.3	Neoplasms of unspecified nature, Breast
611.0-611.89	Other disorders of breast
612.0-612.1	Deformity and disproportion of reconstructed breast
	All other codes

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

References

1. American Cancer Society. Newer and experimental breast imaging methods. Revised 10/26/2010. Accessed December 2010. Available at URL address: <http://www.cancer.org/Healthy/FindCancerEarly/ExamandTestDescriptions/MammogramsandOtherBreastImagingProcedures/index>
2. Fournier LS, Vanel D, Athanasiou A, Gatzemeier W, Masuykov IV, Padhani AR, et al. Dynamic optical breast imaging: A novel technique to detect and characterize tumor vessels. Eur J Radiol. 2009 Jan;69(1):43-9. Epub 2008 Sep 30.

3. Fuchsjaeger MH, Flory D, Reiner CS, Rudas M, Riedl CC, Helbich TH. The negative predictive value of electrical impedance scanning in BI-RADS category IV breast lesions. *Invest Radiol.* 2005;40:478-85.
4. Hope TA, Iles SE. Technology review: the use of electrical impedance scanning in the detection of breast cancer. *Breast Cancer Res.* 2004;6(2):69-74.
5. Imaginis Corporation. Introduction Updated October 31, 2000. Accessed December 2010. Available at URL address: <http://www.imaginis.com/t-scan#introduction>
6. Leff DR, Warren OJ, Enfield LC, Gibson A, Athanasiou T, Patten DK, et al. Diffuse optical imaging of the healthy and diseased breast: a systematic review. *Breast Cancer Res Treat.* 2008 Mar;108(1):9-22. Epub 2007 Apr 28.
7. Malich A, Boehm T, Facius M, Freesmeyer MG, Fleck M, Anderson R, Kaiser WA. Differentiation of mammographically suspicious lesions: evaluation of breast ultrasound, MRI mammography and electrical impedance scanning as adjunctive technologies in breast cancer detection. *Clin Radiol.* 2001 Apr;56:278-83.
8. Malich A, Facius M, Anderson R, Bottcher J, Sauner D, Hansch A, et al. Influence of size and depth on accuracy of electrical impedance scanning. *Eur Radiol.* 2003 Jul;13:2441-6.
9. Society of Breast Imaging. Position Statement. Use of alternative imaging approaches to detection of breast cancer. Not dated. Accessed December 2010. Available at URL address: <http://www.sbi-online.org/displaycommon.cfm?an=4>
10. Stojadinovic A, Nissan A, Shriver CD, Mittendorf EA, Akin MD, Dickerson V, et al. Electrical impedance scanning as a new breast cancer risk stratification tool for young women. *J Surg Oncol.* 2008 Feb 1;97(2):112-20.
11. U.S. Food and Drug Administration. Device Approvals and Clearances. Updated April 24, 2002. Accessed December 2010. Available at URL address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=p970033>
12. U.S. Food and Drug Administration. Advisory Committees, Medical Devices. PMA P050003. August 29, 2006. Accessed December 2010. Available at URL address: http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4231b1_01_Sponsor%20Panel%20Pack.pdf
<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/ucm125145.htm>
13. Wang T, Wang K, Yao Q, Chen JH, Ling R, Zhang JL, et al. Prospective study on combination of electrical impedance scanning and ultrasound in estimating risk of development of breast cancer in young women. *Cancer Invest.* 2010 Mar;28(3):295-303.

Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	1/15/2008	0260	Electrical Impedance Scanning (EIS) and Transillumination of the Breast

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