

WellCare Health Plans, Inc.

The WellCare Group of Companies

Clinical Coverage Guideline



WellCare Prescription Insurance, Inc.

*'Ohana Health Plan, a plan offered by
WellCare Health Insurance of Arizona, Inc.*

WellCare Health Insurance of Illinois, Inc.

WellCare Health Insurance of New York, Inc.

Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

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WellCare Health Plans of New Jersey, Inc.

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WellCare of Connecticut, Inc.

WellCare of Georgia, Inc.

Harmony Health Plan of Illinois, Inc.

WellCare of Ohio, Inc.



Electrical Impedance Scanning (for Breast Cancer)

Guideline Number: HS-054

Original Effective Date: 10/2/2008

Revision Date: 10/16/2009

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

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DISCLAIMER

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APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

CLINICAL COVERAGE GUIDELINE

Electrical Impedance Scanning (EIS) is considered experimental and investigational and NOT a covered benefit as an adjunct to mammography for the detection of breast cancer.

BACKGROUND

According to a recent estimate, 13% of women in the United States will develop breast cancer during their lifetimes. Since early detection improves survival, the United States Preventive Services Task Force recommends that women aged 40 and older be screened for breast cancer every 1 to 2 years. Mammography is considered the gold standard for breast cancer screening and the most effective means for detecting breast cancer when combined with breast self-examination. However, mammography has a large number of false-positive results. When biopsies are done on lesions identified by mammography, approximately three fourths of the lesions are benign. A better method of detecting breast cancer would prevent many women from having unnecessary biopsies.

Electrical impedance scanning (EIS) was developed as a confirmatory test to be used in conjunction with mammography. This device detects abnormal breast tissue using small electrical currents, since malignant tissue tends to conduct more electricity than normal tissue. During EIS with the Mirabel T-Scan device, the patient holds a metal cylinder in one hand, while a probe is applied to numerous predefined sites on each breast to complete the electric circuit. Each time the probe touches the breast, an integrated computer system applies a 0.1- to 2.5-volt alternating current at 7 different frequencies, ranging from 100 to 2 million cycles per second. The electric current is too small to be felt by the patient. Based on the electric currents recorded at the differing frequencies, the integrated computer system creates a conductivity map of the breast and automatically identifies sites that appear suspicious. In most cases, the EIS exam is completed in 5 minutes. EIS is typically performed on an outpatient basis by a radiology technologist, with results interpreted by a radiologist.

The literature search identified five studies of EIS that evaluated the T-Scan 2000 or TS2000 devices as an adjunct to mammography. Results of these studies provide evidence that EIS can detect malignant breast tissue in some patients; however, this technique does not seem to be an adequate substitute for biopsy when there is uncertainty about whether tissue is cancerous or benign. Two key measures of the accuracy of EIS are its sensitivity and negative predictive value

(NPV). These measures can be as high as 100%, but they decrease as inability to detect cancer increases. In the reviewed studies, the sensitivity of EIS ranged from 17% to 95%, and NPV ranged from 67% to 97%. It is not clear whether these variations were due to differences in the types of patients enrolled in the studies or differences in the computer software installed in the EIS devices. Regardless of the source of the variability, until EIS consistently provides high sensitivity and high NPV as an adjunct to mammography, EIS is unlikely to become a reliable substitute for breast biopsy. Further studies of EIS are needed to assess its effectiveness as an adjunct to mammography in women who meet all criteria specified by the Food and Drug Administration for use of EIS (from Hayes, 2008).

Professional Statements

The Society of Breast Imaging (2008) stated: “Techniques employing computer analysis of different signals transmitted through or emitted from the breast and focusing on various portions of the electromagnetic spectrum, or metabolic consequences of cancer have been the basis for other physiologic imaging techniques. 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 reduce mortality among tested women in randomized controlled trials”.

The National Cancer Institute (2002) stated: “The scanner is not approved as a screening device for breast cancer, and is not used when mammography or other findings clearly indicate the need for a biopsy. This device has not been studied with patients who have implanted electronic devices, such as pacemakers. It is not recommended for use on such patients”.

CODING

Non-Covered CPT* Codes

76499+ Unlisted diagnostic radiographic procedure
+Note: Not covered when used to report optical imaging of the breast.

Non-Covered CPT Level III Code

0060T - has been deleted from CPT 2009 and is not longer valid

ICD-9-CM Procedure Codes

No applicable codes

HCPCS Codes

No applicable codes

ICD-9-CM Diagnosis Codes – This list may not be all inclusive

217 Benign neoplasm of breast
610.0 - 611.9 Disorders of breast

*Current Procedural Terminology (CPT®) ©2009 American Medical Association: Chicago, IL.

REFERENCES

1. Hayes Brief. Electrical Impedance Scanning (EIS) for Detection of Breast Cancer. August 22, 2008.
2. National Cancer Institute: Improving Methods for Breast Cancer Detection and Diagnosis. 2002.
3. Society of Breast Imaging. Use of Alternative Approaches to Detection of Breast Cancer. 2008.