



# 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 BreastCare™/BreastAlert™  
Differential Temperature  
Sensor**

**Effective Date ..... 2/15/2011  
Next Review Date ..... 2/15/2012  
Coverage Policy Number ..... 0286**

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## Hyperlink to Related Coverage Policies

Electrical Impedance Scanning (EIS) and  
Optical Imaging of the Breast  
Magnetic Resonance Imaging (MRI) of the  
Breast  
Mammary Ductal Lavage (DL)  
Mammary Ductoscopy (MD)  
Mammography  
Nuclear Imaging including Single-Photon  
Emission Computed Tomography  
(SPECT)  
Thermography/Temperature Gradient  
Studies

## INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer'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 customer'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 customer'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 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 ©2011 CIGNA

## Coverage Policy

**CIGNA does not cover the BreastCare™/BreastAlert™ Differential Temperature Sensor (DST) test for any indication including the diagnosis or management of breast disease because it is considered experimental, investigational or unproven.**

## General Background

With the exception of nonmelanoma skin cancers, breast cancer is the most common cancer among women. Self-breast examination, clinical breast examination and mammography are considered standard techniques for the screening and early detection of changes in breast tissue that may be indicative of cancer.

To provide an additional tool that may assist in the early detection of cellular changes that can occur within the breast, researchers developed a thermal sensor device that detects varying degrees of heat in breast tissue. It is proposed that testing with the BreastCare DTS™ device (Life Medical Technologies, Fishkill, NY) previously known as BreastAlert™ (HumaScan, Inc., Cranford, NJ) may detect an abnormal change in breast tissue (e.g.,

lumps, masses, cancer) before it would be identified by self-examination, clinical examination or mammography. The device is intended to be used by clinicians as an adjunct to established clinical procedures (e.g., examination, ultrasound, mammography).

BreastCare includes two round disposable pads containing columns of heat sensitive chemical sensors reflecting an 8.5-degree temperature range between 90 and 98.5 degrees Fahrenheit. The pads are placed on each breast under the bra for 15 minutes and temperature variations are digitally recorded by color changes. The color changes (i.e., blue, green, yellow) are visually reviewed and recorded. An asymmetrical temperature difference between the two breasts of two-degrees Fahrenheit is considered “significant” and as an adjunct to other clinical assessments may be indicative of the need for further evaluation for breast disease. Because the results rely on mirror image comparison of quadrants of both breasts, the pads are not recommended for women with a history of a mastectomy or lumpectomy, or in women with breasts that are not symmetrical. It was also determined that the presence of mastitis, sclerosing adenosis, or other heat-generating infectious processes could produce false-positive readings.

According to the manufacturer, BreastCare has been reported to have a sensitivity of 83.0%–88.1%, specificity of 86.5%, false negative rates of 3%–13%, a positive predictive value of 98% and a negative predictive value of 93%–94% (Scantek Medical, 2010). These findings need to be validated through well-designed large population clinical trials published in peer-reviewed scientific journals.

### **U.S. Food and Drug Administration (FDA)**

This Class I device was originally 510(k) approved by the FDA in 1984 as a liquid crystal thermographic system under the name of Breast Thermal Activity Indicator (BCSI Laboratories, Inc., New York, NY) “to be used by physicians as an adjunct to routine physical examination including palpation, mammography and other established procedures for the detection of breast disease”. Later, the device was distributed as the BreastAlert™ Differential Temperature Sensor (HumaScan Inc., Cranford, NJ) (FDA, 1998; FDA, 1984).

### **Literature Review**

Evidence in the published peer-reviewed scientific literature investigating the clinical utility of BreastCare/BreastAlert and its impact on health outcomes is limited. There is a paucity of studies comparing BreastAlert to mammography and other established diagnostic tools. The accuracy of the device has not been established.

### **Professional Societies/Organizations**

**American Cancer Society (ACS):** In their discussion of thermography, ACS (2010b) stated that “no study has ever shown that it is an effective screening tool for finding breast cancer early.”

**American College of Obstetricians and Gynecologists (ACOG):** ACOG (2003, reaffirmed 2006) considered thermography as a screening technique in their 2003 Breast Cancer Screening guidelines, but did not recommend its use.

### **Summary**

There is insufficient evidence in the published peer-reviewed scientific literature to support the clinical utility of the BreastCare™/BreastAlert™ Differential Temperature Sensor (DTS) for the early detection and management of breast disease. Well-designed, published clinical trials comparing BreastCare/BreastAlert to established breast cancer screening methods (e.g., mammography) are needed before the role of this technology in patient management can be determined. The impact of this test on meaningful net health outcomes, such as patient survival, has not been established.

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## **Coding/Billing Information**

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

**Experimental/Investigational/Unproven/Not Covered when used to report BreastAlert™ /BreastCare™ for any indication, including the diagnosis and management of breast disease:**

| CPT* Codes | Description                  |
|------------|------------------------------|
| 93740      | Temperature gradient studies |

| HCPCS Codes | Description  |
|-------------|--|
| A9279       | Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified |

| ICD-9-CM Diagnosis Codes | Description                            |
|--------------------------|--|
| 174.0-174.9              | Malignant neoplasm of female breast    |
| 198.81                   | Secondary malignant neoplasm of breast |
| 217                      | Benign neoplasm of breast              |
| 233.0                    | Carcinoma in situ of breast            |
| 610.0-610.9              | Benign mammary dysplasias              |
| 611.0-611.9              | Other disorders of breast              |
|                          | All other codes                        |

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

## References

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13. U.S. Food and Drug Administration (FDA). Breast thermal activity indicator. K832989. 1984 Accessed Jan 8, 2011. Available at URL address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/PMNSimpleSearch.cfm?db=PMN&ID=K832989>

## Policy History

| <b>Pre-Merger Organizations</b> | <b>Last Review Date</b> | <b>Policy Number</b> | <b>Title</b>  |
|---------------------------------|-------------------------|----------------------|---|
| CIGNA HealthCare                | 2/15/2007               | 0286                 | BreastCare™/BreastAlert™<br>Differential Temperature Sensor |

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