



BREAST SPECIFIC GAMMA IMAGING (BSGI) HS-129



Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

Harmony Health Plan of Illinois, Inc.

HealthEase of Florida, 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.

WellCare Health Plans of New Jersey, Inc.

WellCare of Florida, Inc.

WellCare of Connecticut, Inc.

WellCare of Georgia, Inc.

WellCare of Kentucky, Inc.

WellCare of Louisiana, Inc.

WellCare of New York, Inc.

WellCare of Ohio, Inc.

WellCare of Texas, Inc.

WellCare Prescription Insurance, Inc.

Breast Specific Gamma Imaging (BSGI)

Policy Number: HS-129

Original Effective Date: 9/3/2009

Revised Date(s): 9/3/2010; 9/1/2011

DISCLAIMER

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.

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.

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 U.S. Preventive Services Task Force has recommended that women aged 40 and older be screened for breast cancer every 1 to 2 years. Mammography is considered the reference 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.

BSGI was developed as a confirmatory test used after mammography and a clinical breast exam. This technique detects abnormal breast tissue based on uptake of technetium-99m sestamibi, a radioactive agent that emits gamma rays and that tends to accumulate in cancerous breast tissue. Approximately 5 to 10 minutes after intravenous injection of the radioactive agent, each breast undergoes two 10-minute sessions of imaging. One image is taken with the gamma camera continuously pressed against the bottom of the breast and the other image is taken with the camera continuously pressed against the side of the breast. This technique uses the specially designed Dilon 6800 Gamma Camera, which has a small field of view and greater ability to detect fine detail than typical gamma cameras. BSGI is typically performed on an outpatient basis by a nuclear medicine technician with results interpreted by a radiologist or physician specializing in nuclear medicine. Hayes (2010) gives BSGI using the Dilon gamma camera a D rating based on insufficient evidence of its efficacy and for minor safety issues including an increased risk of cancer due to repeated exposure to radiation - "BSGI has been estimated to cause a 20- to 30-fold increase in lifetime-adjusted risk of fatal cancer compared with digital mammography."

The literature search identified 5 comparative studies that evaluated BSGI for detection of breast cancer. Results of these studies do not provide conclusive evidence that BSGI can be relied on rather than biopsy in women who have suspicious breast lesions. In the 2 largest reviewed studies, BSGI detected some cancerous lesions that were not detected by mammography; however, these studies did not report whether the increased detection corresponded to a statistically significant increase in the sensitivity of BSGI compared with mammography. Moreover, in 2 small studies that compared the sensitivity of BSGI with other techniques, there were no statistically significant differences in the sensitivity of BSGI, mammography, magnetic resonance imaging (MRI), and ultrasonography. Although further studies may indicate that BSGI has greater sensitivity than ultrasonography and MRI, BSGI has the disadvantage that it exposes the patient to radiation. In addition, unlike biopsy, BSGI does not provide a definitive diagnosis since it incorrectly indicates that 15% to 40% of benign lesions are cancerous. Further studies are needed to determine the clinical role of BSGI versus MRI and ultrasonography as supplements to mammography and clinical breast exams (Hayes, 2009).

POSITION STATEMENT

Breast Specific Gamma Imaging (BSGI) **is considered experimental and investigational** for the diagnosis or confirmation of breast cancer.

CODING

Non-Covered CPT® Codes

78800 Tumor localization - limited area, i.e. breast
78801 Tumor localization - multiple areas, i.e. breast

ICD-9-CM Procedure Codes

92.19 Radioisotope scan of other sites (e.g., Breast)

Non-Covered HCPCS Level II Code

A9500 Imaging agent; Technetium TC 99M sodium gluceptate, diagnostic, per study dose up to 25 millicurie (Included in S8080, do not report separately with S8080)

S8080+ Scintimammography (radioimmunoscinigraphy of the breast, unilateral), including supply of radiopharmaceutical
+S-Codes are NON COVERED FOR MEDICARE– Refer to HCPCS Level II Temporary National Codes
For Medicare, bill the appropriate CPT code listed above.

Non-Covered ICD-9-CM Diagnosis Codes

701.4 Keloid Scar; hypertrophic scar; trunk

793.80 Abnormal Mammogram, unspecified

793.81 Mammographic Microcalcification

793.89 Other abnormal findings on radiological examination of breast, i.e. Calcification, Calculus

V10.3 Personal History of Breast Cancer

V16.3 Family History of Breast Cancer

*Current Procedural Terminology (CPT®) ©2011 American Medical Association: Chicago, IL.

REFERENCES

Peer Reviewed

1. Hayes Directory. (2010, November 23). Breast-specific gamma imaging (BSGI) using the Dilon 6800® gamma camera. Retrieved from <http://www.hayesinc.com>
2. Hayes Directory. (2009, March 17). Breast-specific gamma imaging (BSGI). Retrieved from <http://www.hayesinc.com>

Government Agencies, Professional and Medical Organizations

N/A

HISTORY AND REVISIONS

Date	Action
12/1/2011	• New template design approved by MPC.
9/1/2011	• Approved by MPC.