I. POLICY/CRITERIA

A. BSGI is considered experimental and investigational as an adjunct to mammography for imaging of breast tissue, for the detection of axillary metastases, staging the axillary lymph nodes in members with breast cancer, and to assess response to adjuvant chemotherapy in members with breast cancer and for all other indications because its effectiveness has not been established.

B. BSGI may be covered when part of an Institutional Review Board (IRB) approved clinical trial designed to assess its clinical utility for individuals with initial abnormal screening mammograms compared with other commonly used secondary screening techniques. Individual medical director review required.

II. MEDICAL NECESSITY REVIEW

☐ Required  ☐ Not Required  ☑ Not Applicable

III. APPLICATION TO PRODUCTS

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

- **HMO/EPO**: This policy applies to insured HMO/EPO plans.
- **POS**: This policy applies to insured POS plans.
- **PPO**: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO**: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL**: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE**: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
IV. DESCRIPTION

Breast-specific gamma imaging (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. 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.

Results of the available studies do not provide conclusive evidence that BSGI can be relied on rather than biopsy in women who have suspicious breast lesions. Studies that compared the sensitivity of BSGI with other techniques showed no statistically significant differences in the sensitivity of BSGI, mammography, ultrasonography, and MRI. Although further studies may indicate that BSGI has greater sensitivity than ultrasonography and MRI, BSGI has the disadvantage that it requires radiation exposure. In addition, unlike biopsy, BSGI does not provide a definitive diagnosis since it has a 15% to 40% incidence of false-positive results. Further studies are needed to determine the clinical role of BSGI versus MRI and ultrasonography as adjuncts to mammography and clinical breast exams as well as to validate the impact of BSGI on patient survival.

V. CODING INFORMATION

ICD-10 Codes that are not covered:
- C50.011 - C50.929 Malignant neoplasm of breast
- D05.00 – D05.92 Lobular carcinoma in situ of breast
- R92.0 - R92.8 Abnormal and inconclusive findings on diagnostic imaging of breast
- Z12.31 Encounter for screening mammogram for malignant neoplasm of breast
- Z12.39 Encounter for other screening for malignant neoplasm of breast
- Z40.01 Encounter for prophylactic removal of breast
- Z80.3 Family history of malignant neoplasm of breast
- Z85.3 Personal history of malignant neoplasm of breast
CPT/HCPCS Codes:
*Not covered for any indication*
- S8080 Scintimammography (radioimmunoscintigraphy of the breast), unilateral, including supply of radiopharmaceutical

*Not covered for the diagnoses listed above*
- 78800 Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); limited area
- 78801 Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); multiple areas

VI. REFERENCES