APPENDIX to Scintimammography/Breast-Specific Gamma Imaging/Molecular Breast Imaging Policy

Prior Authorization Requirements

This service (or procedure) is considered **investigational** in all instances. If you would like to submit additional information please forward to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

Evidence Basis for the Policy

Rationale

Breast-specific gamma imaging (BSGI) and molecular breast imaging (MBI) have been suggested for a variety of applications. Much of the research on BSGI and MBI has been conducted at the Mayo Clinic. The Society for Nuclear Medicine (2010) released guidelines for breast scintigraphy with breast-specific gamma cameras. The potential uses are as follows:

- Patients with recently detected breast malignancy, initial staging; detecting multicentric, multifocal, or bilateral disease; and assessing response to neoadjuvant chemotherapy
- Patients at high risk for malignancy, evaluating suspected recurrence or using it when a mammogram is limited or a previous malignancy was occult on mammogram
- Patients with indeterminate breast abnormalities and remaining diagnostic concerns, evaluating lesions identified by other breast imaging techniques, palpable or non-palpable, aiding in biopsy targeting, and a number of others
- Patients with technically difficult breast imaging, such as radiodense breast tissue or implants, free silicone, or paraffin injections

- Patients for whom breast magnetic resonance imaging (MRI) is indicated but contraindicated, e.g., patients with implanted pacemakers or pumps, or as an alternative for patients who meet MRI screening criteria, such as BRCA1, BRCA2 mutations
- Patients undergoing preoperative chemotherapy, for monitoring tumor response in order to determine the impact of therapy or plan for residual disease

The primary radiopharmaceutical used with scintimammography, BSGI or MBI is technetium Tc 99m sestamibi (marketed by Draxis Specialty Pharmaceuticals Inc., Cardinal Health 414, LLC, Mallinckrodt Inc., and Pharmalucence, Inc.). The labeling states technetium-99m sestamibi is "indicated for planar imaging as a second-line diagnostic drug after mammography to assist in the evaluation of breast lesions in patients with an abnormal mammogram or a palpable breast mass. Technetium Tc 99m sestamibi is not indicated for breast cancer screening, to confirm the presence or absence of malignancy, and it is not an alternative to biopsy" (FDA, 2008).

Sestamibi is a chemical complex that principally congregates in the heart, breast tissue, and parathyroid. Technetium is a radioactive metallic element that is a byproduct of uranium decay. It may also be produced by bombarding another metal, molybdenum, with specific atoms. Technetium 99m is a widely used radionuclide with a half-life of approximately six hours, which is long enough to examine metabolic processes, but short enough to minimize the radiation dose received by the patient. It decays by gamma emission, which is measured by scintillation or gamma cameras. Sestamibi is combined with technetium 99m to produce functional and physiological images of the breast, heart, or parathyroid. The radiopharmaceutical is administered by intravenous injection (Ingenix, 2010).

Several scintillation or gamma cameras have general 510(k) marketing clearance from the United Stages Food and Drug Administration (FDA), which indicates they are cleared for "use in imaging the distribution of radionuclides in the human body using planar imaging techniques." Two examples of gamma cameras used in breast-specific gamma imaging or molecular breast imaging are Dilon 6800® (Dilon Technologies®, Newport News, VA) and LumaGEM™ (Gamma Medica, Inc., Northridge, CA).

Interest in scintimammography as an adjunct to mammography has waned over time primarily because of the difficulty in imaging small lesions.

A meta-analysis published in 2006 reviewed retrospective and prospective evidence on 2,424 patients from single-site trials and 3,049 patients from multi-site trials performed since January 1997 on the use of scintimammography for the diagnosis of primary breast cancer (Hussain & Buscombe, 2006). The studies included at least 100 patients, used pathology findings as the reference standard, included planar images, and used Tc-99m-MIBI or Tc-99m-tetrofosmin. The overall sensitivity and specificity were 85% and 84%, respectively, in the single-site trials and 85% and 83%, respectively, in the multi-site trials.

The Agency for Healthcare Research and Quality (AHRQ) published a comparative effectiveness report on the accuracy of non-invasive diagnostic tests in women presenting with breast abnormalities (either by mammography or physical examination), specifically comparing ultrasound (US), positron emission tomography (PET), scintimammography, and magnetic resonance imaging (MRI) (Bruening et al., 2006). The report recommended against using scintimammography to identify women with suspicious mammograms who do not need to go on

for biopsy. This performance is worse (i.e., there are more missed cancers) than PET, US, or MRI. None of these tests met the suggested standard of less than 2% risk of having cancer among women with negative diagnostic results.

The use of gamma camera systems has increased interest in breast-specific imaging as a primary screening technique. Rhodes and colleagues (2005) reported on a study that used a dedicated gamma camera for breast imaging which permitted cranial-caudal images with compression. Scintimammography, which would now be called breast-specific gamma imaging, was performed on 40 women with small mammographic abnormalities (< 2 centimeters (cm)) scheduled to undergo biopsy. Thirty-three of the 36 malignant lesions confirmed at biopsy were identified on BSGI images. The authors concluded this preliminary study suggested an important role for BSGI in women with dense breasts in whom the sensitivity of mammography is decreased. The high prevalence of malignant lesions suggested this study recruited a highly selected population of patients.

Brem and colleagues (2005) also used a breast-specific gamma camera to evaluate 94 women considered at high risk of breast cancer with normal mammographic findings. High risk was defined as a calculated five-year risk of developing breast cancer of 1.66%, as determined by the Gail model. Of the 94 women in the study, 35 had a prior history of some type of breast cancer or atypical hyperplasia. The results of the scintimammography were categorized from 1 to 5, similar to the BI-RADS scoring system developed for mammographic evaluation. A total of 16 of the 94 women (17%) had abnormal scintimammograms. Follow-up US in 11 of these 16 identified a hypoechoic lesion that was biopsied. The five remaining patients had normal US results and were followed up with a repeat scintimammogram at six months, which was normal. Of the 11 who underwent US-guided biopsy, two invasive cancers (12%) were identified; the cancers measured less than 8 millimeter (mm) in diameter.

Brem and colleagues (2008) examined the performance of BSGI in a retrospective study of 146 consecutive patients, who had a mixed set of indications, including palpable lesions with no mammographic correlation, diagnosis of multicentricity or multifocality in women with known breast cancer, or screening of women at high risk of breast cancer. The analysis was performed per lesion (n = 167). The overall prevalence of disease was 49.7%. The sensitivity of BSGI was 96.4% (95% confidence interval (CI): 92% to 99%), and the specificity was 59.5% (95% CI: 49% to 70%). The positive predictive value was 68.8% (95% CI: 60% to 78%), and the negative predictive value was 94.3% (95% CI: 88% to 99%). However, the sensitivity in detecting invasive cancer was 100% for lesions larger than 10 mm, 87.5% (95% CI: 45% to 99%; n = 8) for lesions 6 mm to 10 mm, and 83.3% (95% CI: 35% to 99%; n = 6) for tumors 0 to 5 mm; the sensitivity differed for ductal carcinoma in situ (DCIS) and the number of cases was smaller. The performance of BSGI in detecting smaller tumors in particular requires further investigation. As the authors pointed out, additional larger studies are needed to confirm or modify these findings.

In another study, 150 patients with BI-RADS 4 or 5 lesions smaller than 2 cm who were scheduled for biopsy underwent scintimammography using a dual-head, breast-specific gamma camera; the results from three blinded readers were averaged (Hruska et al., 2008). In 88 patients, 128 cancers were found. The per-lesion sensitivity with the dual-head camera was 90% (115 out of 128) for all lesions and 82% (50 out of 61) for lesions 1 cm or smaller.

In a retrospective study on BSGI, Brem et al., (2010) examined the detection of occult foci of breast cancer among 159 women with recently diagnosed breast cancer (77%) or a clinically suspicious lesion among women who were ultimately proven to have breast cancer (23%). Twelve percent of the women had personal histories of breast cancer, and 43% had family histories of breast cancer. Breast-specific guided imaging identified 56 potential, additional cancers among 46 women. “Second look” US was performed to evaluate 53 of the lesions and MRI for 14 of the lesions. Biopsies were performed on 46 of the 56 lesions, using US, stereotactic, or MRI guidance. Biopsy or surgery revealed 14 cancerous lesions (25%) and 35 benign lesions (63%). Five lesions initially identified as benign were subsequently found to be cancerous. Of the 159 women overall, additional cancerous lesions were identified using BSGI in 9%; 3% of the 9% were in the contralateral breast.

In a study of 145 consecutive patients scheduled for breast biopsy with an 86% prevalence of disease, the sensitivity of BSGI was 97.6% per patient (100% for tumors larger than 10 mm and 91.1% for tumors 10 mm or smaller) (Spanu et al., 2008). The per-lesion specificity was 86.4% (four cancers were missed, three of which were detected by mammography). The authors suggested using BSGI for surgical planning or to avoid biopsy, but the negative predictive value, calculated to be 83%, was not high enough to forgo biopsy. Given the relative ease and diagnostic accuracy of the gold standard of biopsy coupled with the adverse consequences of missing breast cancer, the negative predictive value of BSGI would have to be extremely high to influence treatment decisions. The negative predictive value was determined by the sensitivity of the test as well as the prevalence of disease. Among a population of patients with mammographic abnormalities highly suggestive of breast cancer, the negative predictive value would be lower than in a population of patients with mammographic abnormalities not suggestive of breast cancer. Therefore, the clinical utility of BSGI as an adjunct to mammography may vary according to the type of mammographic abnormalities included in the studies.

To evaluate how BSGI might be used in the diagnosis of breast cancer, it must be compared to other breast-imaging modalities, such as traditional mammography, US, or MRI. Although some comparative studies have been published, they are limited by the retrospective nature of most study designs, small sample sizes, patient populations with mixed indications for imaging, and a high prevalence of cancer. Brem and another set of coauthors (2007) compared the performance of BSGI, mammography, and MRI in 20 of 290 women undergoing BSGI who had pathologically confirmed DCIS. In this review, MRI was performed on only seven patients. Because the study design excluded women without DCIS, it could only address the sensitivity of these tests. It reported the sensitivity of BSGI to be 91%; for MRI, 88%; and for mammography, 82%. The difference was not statistically significant and presumably did not include the same patients (since MRI results were only available for a subset). Spanu et al., (2009) compared BSGI with mammography in the detection of multifocal/multicentric disease in breast cancer patients; they found BSGI was more sensitive than mammography for this purpose. However, the relevant comparison in this context would probably be between BSGI and another modality such as MRI.

A retrospective study compared BSGI, mammography, US, and MRI among 21 women with histologically confirmed lobular cancer, which can be more difficult to detect early than other breast cancers (Brem et al., 2007). No statistically significant difference was found between the

sensitivity of BSGI (93%; n = 26) and mammography (79%; n = 26), US (68%, n=25), or MRI (83%; n=12). However, only some women received US or MRI, as clinically indicated, so sensitivity was being compared for different subsets of patients. In a small study (n = 23) comparing BSGI and MRI in women with indeterminate lesions, there was no difference between the two modalities in sensitivity; the specificity of BSGI was greater than for MRI (Brem et al., 2007). Another study prospectively compared BSGI using technetium Tc-99m tetrofosmin and SPECT/computed tomography (CT) among 157 women with suspicious breast lesion on clinical examination, mammography, or ultrasonography (Spanu et al., 2009). Using surgery or biopsy, 127 women were found to have cancer (140 carcinomas), and 30 women had 33 benign lesions. Breast-specific gamma imaging identified 95.7% of the carcinomas; SPECT/CT identified 90.7% ($p < 0.01$). The specificity for both was 87.9%. Among cancerous lesions < 10 mm, BSGI was more sensitive than SPECT/CT (89.1% versus 78.3%; $p < 0.05$). On the other hand, SPECT/CT identified 36 of 46 axillary lymph node metastases.

Another factor that should be taken into account is the radiation dose associated with BSGI. According to one study, the radiation dose to the breast from the 20 mCi [740 MBq] technetium Tc99m sestamibi used for BSGI is 0.13 roentgen absorbed dose or 1.3 milligray (mGy). This is less than the 0.75 radiation absorbed dose (rad) the authors reported for mammography, except that the dose is given to the entire body (Hruska et al., 2008). The authors asserted this dose posed an “extremely low risk of harmful effects to the patient,” but that it should be reduced by a factor of 5 to 10 if BSGI were to be used as a regular screening technique. The authors also estimated the cost of BSGI is three to four times that of mammography.

An article published by Hendrick (2010) calculated mean glandular doses, and from those, lifetime attributable risk of cancer (LAR) for film mammography, digital mammography, BSGI, and positron emission mammography (PEM). The author, who is a member of the medical advisory boards of Koning Corporation (who are working on dedicated breast CT) and Bracco Diagnostics, Inc. (magnetic resonance (MR) contrast agents), used BEIR VII Group risk estimates to gauge the risks of radiation-induced cancer incidence and mortality from breast imaging studies (National Research Council on the National Academies, 2006).

A major difference in the impact of radiation between mammography and BSGI or PEM, is for mammography the substantial radiation dose is limited to the breast. With BSGI and PEM, all organs are irradiated. Furthermore, as one ages, the risk of cancer induction from radiation exposure decreases more rapidly for the breast than for other radiosensitive organs. Hendrick (2010) concluded:

> The results reported herein indicate the BSGI and PEM are not good candidate procedures for breast cancer screening because of the associated higher risks for cancer induction per study compared with the risks associated with existing modalities such as mammography, breast US, and breast MR imaging. The benefit-to-risk ratio for BSCI and PEM may be different in women known to have breast cancer, in which additional information about the extent of disease may better guide treatment.

Hendrick estimated the breast radiation dose for digital breast tomosynthesis is one to two times that for 2-view mammography (depending on whether it is one- or 2-view

tomosynthesis), while dedicated breast CT doses aim to be close to 2-view mammography; neither of these tests have received FDA approval yet. A lower dose version of MBI has been developed and is currently being tested at the Mayo Clinic among 1000 women with dense breast tissue on mammography who are at increased risk of cancer (O'Connor et al., 2009). According to the authors, all of whom are from the Mayo Clinic, this new approach will “make MBI comparable with screening mammography in terms of radiation exposure.” It is not clear whether this statement refers to breast exposure or whole body exposure.

Since the use of BSGI or MBI has been proposed for women at high risk of breast cancer, it should be mentioned that there is controversy and speculation over whether some women, such as those with breast cancer (BRCA) mutations, have a heightened radiosensitivity (Berrington et al., 2009; Ernestos et al., 2010). Of course, if women with BRCA mutations are more radiosensitive than the population as a whole, the above numbers may underestimate the risks they face from breast imaging with ionizing radiation (i.e., mammography, BSGI, MBI, PEM, SPECT/CT, breast-specific CT, and tomosynthesis; US and MRI do not involve the use of radiation). More research is needed to resolve this issue. Also, the risk associated with radiation exposure will be greater for women at high risk of breast cancer, whether or not they are more radiosensitive, because they start screening at a younger age when the risks associated with radiation exposure are larger.

Several uses have been currently proposed for BSGI: to screen or diagnose women with dense breasts; to identify women with suspicious findings suggestive of possible breast cancer who could avoid biopsy (Spanu et al., 2008); to evaluate the extent of disease in a newly diagnosed patient (Zhou et al., 2009; Killelea et al., 2009); to gauge the effectiveness of neoadjuvant therapy (Spanu et al., 2008); and to identify possible spread of cancer to lymph nodes.

In the use of scintimammography to detect axillary metastases, studies using different radiopharmaceuticals have shown sensitivities in the high 80% to 90% range (Spanu et al., 2001; Schillaci et al., 2002). Scintimammography is still not accurate enough to replace surgical nodal dissection. Studies have not examined patient outcomes comparing the strategy of using scintimammography to aid in decision making regarding nodal dissection versus standard nodal dissection. Current research focuses on technical issues only (Werner et al., 2009; Jones et al., 2010).

In summary, the evidence to date does not provide sufficient support for any of the uses discussed above. However, these imaging approaches are an active field of research.

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of

service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

Type	Number	Description
CPT	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
	78803	Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); tomographic (SPECT)
HCPC	A4641	Radiopharmaceutical, diagnostic, not otherwise classified
	A9500	Technetium tc-99m sestamibi, diagnostic, per study dose
	S8080	Scintimammography (radioimmunoscintigraphy of the breast), unilateral, including supply of radiopharmaceutical
ICD9 Procedure	None	
ICD9 Diagnosis	All Diagnoses	
Place of Service	All Places of Service	

Tables

N/A

Definitions

N/A

Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

- Radioimmunoscintigraphy for Prostate Cancer
- Positron Emission Tomography (PET)

Key / Related Searchable Words

N/A

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Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
2/25/1998	Adopted policy from BCBSA TEC	Medical Policy Committee
11/2/2002	Coding Update	Administrative Change

Effective Date	Action	Reason
1/7/2011	Policy title change from Scintimammography Policy revision with no position change	Medical Policy Committee

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

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