

**STATE OF MICHIGAN**  
**DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS**  
**OFFICE OF FINANCIAL AND INSURANCE REGULATION**  
**Before the Commissioner of Financial and Insurance Regulation**

In the matter of

XXXXX

Petitioner

File No. 111247-001

v

Blue Cross Blue Shield of Michigan  
Respondent

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Issued and entered  
this \_\_\_\_ day of April 2011  
by R. Kevin Clinton  
Commissioner

**ORDER**

**I**

**PROCEDURAL BACKGROUND**

On August 3, 2010 XXXXX, authorized representative of XXXXX (Petitioner), filed a request for external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* The Commissioner reviewed the request and accepted it on August 12, 2010.

The Commissioner notified Blue Cross Blue Shield of Michigan (BCBSM) of the external review and requested the information used in making its adverse determination. The Commissioner received BCBSM's response on August 19, 2010.

The contract here is the BCBSM *Community Blue Group Benefits Certificate* (the certificate). Because medical issues were involved, the Commissioner assigned the case to an independent review organization which provided its analysis and recommendations to the Commissioner on August 30, 2010.

## II FACTUAL BACKGROUND

The Petitioner had a diagnostic radiographic procedure known as breast specific gamma imaging (BSGI) on September 2, 2009. Based on the published literature BSGI is performed using recently developed high-resolution gamma cameras, specifically designed to image the breast, offer improved signal-to-noise ratio and improved spatial resolution to produce high-contrast images of small lesions.

BCBSM denied coverage because it believes BSGI to be investigational and therefore excluded under the terms of the certificate. The amount in dispute is \$320.00.

The Petitioner appealed BCBSM's decision. BCBSM did not complete the internal review process within the required thirty-five days; therefore the Petitioner is eligible for an external review.

## III ISSUE

Did BCBSM correctly deny coverage for the Petitioner's BSGI procedure?

## IV ANALYSIS

### Petitioner's Argument

The Petitioner's position was prepared by her authorized representative, XXXXX.

The Petitioner has a family history of breast cancer. She also has a dense breast pattern. Her mammogram yielded a suspicious breast abnormality. The findings were of moderate concern and further evaluations were required before considering sending her for a biopsy. Based on the American College of Radiology (ACR) BIRAD score, the Petitioner meets criteria for BIRAD category 3 or 4. The ACR defines category 3 as probably benign; category 4 as possibly malignant.

To determine whether a breast biopsy was required, Petitioner's physician believed a BSGI was medically necessary. Because her physician believed the test was medically necessary and could avoid an unwarranted breast biopsy, it was scheduled and performed. BCBSM denied payment for the BSGI indicating it was investigational or experimental and not a covered benefit.

The Petitioner argues that this procedure was not investigational for diagnosis of her condition. She provided medical documentation and articles to support her position. She believes this care is medically necessary for her condition and BCBSM is required to provide coverage for the test.

### BCBSM's Argument

BCBSM says that under the terms of the certificate, investigational services are not covered.

The certificate, in "Section 6: General Conditions of Your Contract," has this provision:

#### **Experimental Treatment**

##### **Services That Are Not Payable**

We do not pay for experimental treatment (including experimental drugs or devices) or services related to experimental treatment. . . .

In Section 7, the certificate defines experimental treatment as:

Treatment that has not been scientifically proven to be as safe and effective for treatment of the patient's conditions as conventional treatment.

BCBSM determined that the BSGI is investigational /experimental because it has not been scientifically demonstrated to be as effective as conventional treatment. In its denial of coverage, BCBSM relied on Blue Cross Blue Shield Association medical policy titled, "Scintimammography/Breast-Specific Gamma Imaging," which states in part:

When scintimammography is used as an adjunct to mammography to improve patient selection for biopsy, a key diagnostic statistic is the negative predictive value. Can patients who have negative scintimammography test results reliably forego breast 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 scintimammography would have to be extremely high to influence treatment decisions. The negative predictive value will also vary according to the prevalence of disease. . . .

BCBSM consulted the medical and scientific literature and concluded that the BSGI has not been scientifically demonstrated to be an effective treatment and therefore categorized as experimental.

BCBSM submits that the denial of benefits for the Petitioner's care was correct and in accordance with the terms of the certificate.

Commissioner's Review

The question of whether the Petitioner's BSGI was experimental or investigational was presented to an independent review organization (IRO) for analysis as required by Section 11(6) of Patient's Right to Independent Review Act. The IRO reviewer is board-certified in radiology and has been in active practice for more than fifteen years. The IRO report includes the following analysis:

[T]here are multiple articles in the literature that supported the use of breast specific gamma imaging in the detection of breast cancer. [Citations omitted but are included in the IRO report which is provided to the parties to this appeal.] However . . . some of these studies involved only small groups of patients and many of the studies were retrospective in nature. . . . [T]hese studies found that breast specific gamma imaging had high sensitivity but limited specificity for detection of breast cancer. . . . [P]atients in these studies had equivocal findings within the breast following a complete evaluation including a breast examination, mammography and ultrasound. . . . [T]he literature did not include articles supporting the use of breast specific gamma imaging for screening for breast cancer in patients with dense breast tissue. . . . [T]he National Comprehensive Cancer Network and American College of Radiology guidelines do not include the use of breast specific gamma imaging for breast cancer screening in patients with dense breasts. . . .

[T]he screening mammogram performed on 8/7/09 showed dense breast tissue in the upper outer aspects of both of the [Petitioner's] breasts. . . . [T]he [Petitioner] was referred for breast specific gamma imaging only because of the finding of dense breasts. . . . [T]here was no documentation of equivocal findings within the breast on physical examination, mammogram or breast ultrasound. . . . [A]s there is no support in the literature for the use of breast specific gamma imaging for screening purposes in patients with dense breasts, this testing was investigational for diagnosis and treatment of the [Petitioner's] condition.

While the Commissioner is not required in all instances to accept the IRO's recommendation, it is afforded deference. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principal reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16) (b). The IRO reviewer's analysis is based on extensive expertise and professional

judgment and the Commissioner can discern no reason why that judgment should be rejected in the present case.

The Commissioner accepts the conclusion of the IRO and finds that BCBSM's denial of coverage is consistent with the terms of the certificate and should be upheld.

**V  
ORDER**

BCBSM's final adverse determination that the Petitioner's BSGI is investigational is upheld. BCBSM is not required to provide coverage for the Petitioner's breast specific gamma imaging.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than sixty days from the date of this Order in the circuit court for the county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.

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R. Kevin Clinton  
Commissioner