

STATE OF MICHIGAN  
DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES  
Before the Director of Insurance and Financial Services

In the matter of:

██████████

Petitioner,

v

File No. 145159-001

Blue Cross Blue Shield of Michigan,

Respondent.

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Issued and entered  
this 6<sup>th</sup> day of January 2015  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

On December 1, 2014, ██████████ (Petitioner) filed a request with the Director of Insurance and Financial Services for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* The Director reviewed the request and accepted it on December 9, 2014.

The Petitioner receives health care benefits through a group plan that is underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The Director notified BCBSM of the external review request and asked for the information used to make its final adverse determination. BCBSM submitted the material on December 12, 2014.

This case involves medical issues so it was assigned to an independent review organization which submitted its recommendation to the Director on December 23, 2014.

**II. FACTUAL BACKGROUND**

The Petitioner's health care benefits are defined in BCBSM's *Simply Blue Group Benefits Certificate*<sup>1</sup> (the certificate).

On May 7, 2014, the Petitioner had a digital tomosynthesis mammogram, a method of creating a three-dimensional picture of the breast using multiple X-rays. The charge was \$129.00.

BCBSM denied coverage, saying the radiology study was experimental in the treatment of the Petitioner's condition. The Petitioner appealed the denial through BCBSM's internal grievance process.

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<sup>1</sup> BCBSM form no. 787B, approved 10/12.

At the conclusion of that process BCBSM issued a final adverse determination dated November 18, 2014, affirming its denial. The Petitioner now seeks a review of that adverse determination from the Director.

### III. ISSUE

Did BCBSM correctly deny coverage for Petitioner's digital breast tomosynthesis mammogram?

### IV. ANALYSIS

#### BCBSM's Argument

In the final adverse determination BCBSM told the Petitioner:

. . . After review, our denial is maintained. The BCBSM/BCN Joint Uniform Medical Policy has determined that the digital breast mammogram (Procedure 76499) is considered experimental/investigational.

\* \* \*

An investigational status means that the safety and effectiveness of a particular technology has not been definitively determined. An established technology means that the safety and effectiveness have been definitively determined. Investigational medical policies are reviewed regularly to guarantee that the investigational status continues to be supported by the evidence.

You are covered under the *Simply Blue Group Benefits Certificate*. As explained in *Section 6: General Conditions of Your Contract* (Page 6.3), we do not pay for experimental treatment or services including experimental drugs or devices.

In order to give your appeal full consideration, a board-certified M.D. in Internal Medicine and Endocrinology reviewed your claim, your appeal, the medical documentation, and your health care plan benefits for [BCBSM]. The medical consultant concluded that the digital breast tomosynthesis mammogram is considered experimental/investigational. Per BCBSM medical policy titled, *Digital Breast Synthesis*, the benefit of this test in either screening or diagnosis of breast malignancy has not been established. As a result of the medical consultant's review and the provisions of your policy, payment cannot be approved.

#### Petitioner's Argument

In the request for external review, the Petitioner wrote:

After a regular mammogram, my OBGYN and breast surgeon were not satisfied with the findings. There was much concern regarding a lump, calcifications, and other unclear areas. Instead of a follow up in 6 months, both doctors recommended the digital breast

tomosynthesis. Due to doctor recommendations and areas of concern I believe this procedure should be covered.

### Director's Review

BCBSM's medical policy title, "Digital Breast Tomosynthesis," contains this statement:

The clinical utility of digital tomosynthesis in the screening and diagnosis of breast cancer has not been demonstrated. In addition, there is insufficient evidence that the use of digital tomosynthesis improves health outcomes, therefore it is considered experimental/investigational.

The certificate (p. 6.3) has this exclusion for experimental or investigation 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 addition, we do not pay for administrative costs related to experimental treatment or for research management.

"Experimental treatment" is defined (p. 7.10) as

[t]reatment that has not been scientifically proven to be as safe and effective for treatment of the patient's conditions as conventional treatment. Sometimes it is referred to as "investigational" or "experimental services."

The question of whether the digital tomosynthesis mammogram was investigational or experimental in the treatment of Petitioner's condition was presented to an independent review organization (IRO) for analysis and a recommendation as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO physician reviewer is board certified in obstetrics and gynecology and has been in active practice for more than fifteen years. The IRO report included the following analysis and recommendation:

In May 2014, the member presented with a 0.5 cm lump in the right breast. A mammogram revealed heterogeneously dense breast tissue. No masses were seen on mammogram. No masses were seen on tomosynthesis examination or on ultrasound of the area of the palpable abnormality. The results were BIRADS category 2, benign findings with clinical follow-up recommended. The member had previous mammograms that were BIRADS 3, but the reports from those mammograms were not included in the information submitted for review.

The MAXIMUS physician consultant indicated that as the lump was palpable in this case, a biopsy could be performed as needed. The physician consultant also noted that the findings on mammogram and ultrasound are not indeterminate. The consultant explained that tomosynthesis is a promising method of breast imaging that may decrease the call

back for false positives and may increase the detection rate of invasive cancers according to early prospective data. However, the consultant also explained that tomosynthesis remains in the investigational stage. The literature states that further multi-site prospective studies are needed to evaluate the technology.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the digital breast tomosynthesis mammogram (procedure code 76499) that the member underwent was experimental/investigational for diagnosis and treatment of her condition. [Reference omitted]

The Director is not required to accept the IRO's recommendation. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). However, the recommendation is afforded deference by the Director. In a decision to uphold or reverse an adverse determination, the Director must cite "the principal reason or reasons why the [Director] did not follow the assigned independent review organization's recommendation." MCL 550.1911(16)(b). The IRO's analysis is based on extensive experience, expertise, and professional judgment. Further, the IRO's recommendation is not contrary to any provision of the Petitioner's certificate. See MCL 550.1911(15).

The Director, discerning no reason to reject the IRO's recommendation, finds that the digital tomosynthesis mammogram is experimental or investigational for treatment of the Petitioner's condition and is therefore not a benefit under the certificate.

#### V. ORDER

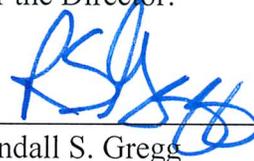
The Director upholds BCBSM's final adverse determination of November 18, 2014.

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 60 days from the date of this order in the circuit court for the Michigan 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 Department of Insurance and Financial Services, Office of General Counsel, Post Office Box 30220, Lansing, MI 48909-7720.

Annette E. Flood  
Director

For the Director:



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Randall S. Gregg  
Special Deputy Director