



review organization which provided its analysis and recommendation on April 12, 2016.

## II. FACTUAL BACKGROUND

The benefits are described in BCBSM's *Community Blue Group Benefits Certificate ASC*<sup>1</sup> (the certificate).

The Petitioner has a history of dense breast tissue. On September 26, 2015, she had routine screening mammograms as well as digital breast tomosynthesis (DBT)<sup>2</sup> of both breasts. The plan covered the routine screening mammograms but denied coverage for the DBT, saying it was experimental or investigational for treatment of her condition. The charge was \$30.00.

The Petitioner appealed the denial through the plan's internal grievance process. At the conclusion of that process, BCBSM issued a final adverse determination on March 3, 2016, affirming the denial. The Petitioner now seeks the Director's review of that final adverse determination.

## III. ISSUE

Was DBT experimental or investigational for the treatment of the Petitioner's condition?

## IV. ANALYSIS

### Petitioner's Argument

In a letter submitted with her external review request the Petitioner wrote:

I am a City of Detroit Employee. I am seeking to appeal the rejection of my claim filed to have full charges paid. The service provided is an annual part of my physical examination process. It was recommended that the 2D / 3D Mammography may assist my physician in further assist and confirm the status of my diagnosis of extremely dense breast tissue. Annually my mammograms are performed and manual exams are performed to assure that the lumps have not advanced in size over time.

This exam will be performed annually as part of my Annual GYN physical. My insurance covers physical exams at 100%. Why is the 2D Mammogram not included in that cost? I challenge the protocol that the cost of this exam should fall on the patient at each annual exam.

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<sup>1</sup> BCBSM form no. 457F, effective 08/15.

<sup>2</sup> DBT, also called 3-D mammography, creates a three-dimensional picture of the breasts using x-rays (CPT code 77063).

I am requesting that the added cost of this exam be reimbursed to me for this is not an investigative matter, it is a matter of a patient's right to take control of her health without financial penalty of additional costs for taking precautions.

### BCBSM's Argument

In the final adverse determination to the Petitioner, BCBSM's representative told the Petitioner:

An associate medical director, board-certified D.O. in Internal Medicine reviewed your claim, your appeal, and your health care plan benefits for Blue Cross Blue Shield of Michigan (BCBSM). Based on that review, you had a digital breast tomosynthesis mammogram as part of a routine screening mammogram. The digital breast tomosynthesis is considered experimental and investigational per BCBSM medical policy, "Digital Breast Tomosynthesis" as the benefit of this test in either screening or diagnosis of breast malignancy has not been established. Therefore, we cannot approve the digital tomosynthesis service you received and you remain responsible for the noncovered charges.

### Director's Review

Diagnostic radiology services, including "medically necessary mammography," are benefits under the certificate (see p. 83). But the certificate (p. 125) also has this exclusion:

#### ***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. . . .

"Experimental treatment" is defined in the certificate (p. 141) 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."

To determine if DBT is experimental in this case, the Director presented the issue to an independent review organization (IRO) 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 radiology, has been in active practice for more than 10 years, and is familiar with the medical management of patients with the Petitioner's condition. The IRO report included this analysis and recommendation:

**Recommended Decision:**

The MAXIMUS physician consultant determined that the digital breast tomosynthesis performed on 9/26/15 was not investigational for diagnosis and treatment of the member's condition.

**Rationale:**

\* \* \*

Tomosynthesis was approved by the Food and Drug Administration for clinical use in 2011 and by the Centers for Medicare and Medicaid Services (CMS) for reimbursement in 2014. The American College of Radiology (ACR) urged that this technique be removed from the investigational category in 2014 due to the advantages that it offers to radiologists in the interpretation of mammograms. The MAXIMUS physician consultant explained that in cases of extremely or heterogeneously dense tissue, as in this member's case, the tomographic qualities of this new technique often allows radiologists to differentiate dense glandular elements of the breast from underlying mass / architectural distortion, resulting in a decrease in callbacks and an increase in detection of small cancers. The physician consultant indicated that for this reason, 3D breast tomosynthesis is no longer considered experimental or investigational.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the digital breast tomosynthesis performed on 9/26/15 was not investigational for diagnosis and treatment of the member's condition. [References 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. In addition, the IRO's recommendation is not contrary to any provision of the certificate. MCL 550.1911(15). The Director, discerning no reason why the IRO's recommendation should be rejected in this case, finds that the Petitioner's September 26, 2015, digital breast tomosynthesis was not experimental and therefore is a covered benefit.

**V. ORDER**

The Director reverses the plan's March 3, 2016, final adverse determination.

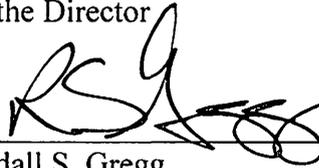
The plan shall immediately cover the Petitioner's September 26, 2015, digital breast tomosynthesis, and shall, within seven days of providing coverage, furnish the Director with proof it has implemented this Order.

To enforce this Order, the Petitioner may report any complaint regarding its implementation to the Department of Insurance and Financial Services, Health Care Appeals Section, at this toll free number: (877) 999-6442.

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.

Patrick M. McPharlin  
Director

For the Director

A handwritten signature in black ink, appearing to read 'RS Gregg', is written over a horizontal line.

Randall S. Gregg  
Special Deputy Director