

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. 151576-001-SF

University of Michigan, Plan Sponsor,

and

Blue Cross Blue Shield of Michigan, Plan Administrator,

Respondents.

Issued and entered
this 3rd day of February 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

██████████ (Petitioner) was denied coverage for a 3D mammogram by her health plan.

On January 5, 2016, she filed a request with the Director of Insurance and Financial Services for an external review of that denial under Public Act No. 495 of 2006 (Act 495), MCL 550.1951 *et seq.* On January 12, 2016, after a preliminary review of the information submitted, the Director accepted the Petitioner's request.

The Petitioner receives group health care benefits through a plan sponsored by the University of Michigan (the plan), a self-funded governmental health plan as defined in Act 495. Blue Cross Blue Shield of Michigan (BCBSM) administers the plan. The Director immediately notified BCBSM of the external review request and asked for the information it used to make the plan's final adverse determination. The Director received BCBSM's response on January 15, 2016.

Section 2(2) of Act 495, MCL 550.1952(2), authorizes the Director to conduct this external review as though the Petitioner were a covered person under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

To address the medical issues in the case, the Director assigned it to an independent medical review organization which provided its analysis and recommendation on January 26, 2016.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are described in BCBSM's *Comprehensive Health Care Certificate Series CMM ASC*¹ (the certificate).

The Petitioner has a history of metastatic epithelioid angiosarcoma. On June 15, 2015, she had a digital tomosynthesis mammogram, known as a 3D mammogram. The charge for the digital tomosynthesis was \$83.00. BCBSM denied coverage, saying the procedure is investigational for the diagnosis and treatment of the Petitioner's condition.

The Petitioner appealed the denial through the plan's internal grievance process. At the conclusion of that process BCBSM issued a final adverse determination dated December 8, 2015, upholding the plan's decision. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

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

IV. ANALYSIS

Petitioner's Argument

The Petitioner explained her argument in an undated letter submitted with her external review request:

I am writing this letter to appeal a denied charge for the 3D mammogram that I recently received.

I understand that the use of this technology, in addition to the traditional 2D mammography has resulted in an increase in early cancer detection and a decrease in recall rates and additional expensive testing. Also, 3D mammography is covered under Medicare.

2D mammography provides only a two-dimensional picture of the breast. Since the breast is a three-dimensional object, 3D technology can detect overlapping objects that might be missed when viewing a two-dimensional, flat image. Breast tissue is composed of different structures, such as blood vessels, ducts, fat, and

¹ Form No. 452F, effective date 02/15.

ligaments. All of these structures are located at different heights within the breast. They can overlap and cause confusion when viewed as two-dimensional, flat images. This is how small breast cancers are missed or may appear "abnormal" leading to unnecessary call backs for additional testing.

The initial charge for 3D mammography may be more expensive than a 2D mammogram; however the cost of additional diagnostic mammogram films, ultrasounds, biopsies and MRI's could be avoided through the use of 3D mammography. Furthermore, I challenge you to put yourself in the shoes of the patient who has received the results of an "abnormal" 2D mammogram and who will now require additional testing. Technology that can accurately detect cancerous lesions at the time of testing and avoid delayed additional testing should be embraced and paid for by insurance companies. Furthermore, I have to believe that it is less expensive to treat early detected cancers than it is to treat advanced lesions.

Annual screening preventative mammography technology is a covered benefit. The use of 3D mammography as a screening treatment should reduce unnecessary patient recalls and avoid later-stage cancer treatments. Both should significantly reduce insurer costs. Reducing unnecessary testing or treatment and the associated psychosocial experience of a false-positive 2D mammogram benefits everyone involved in the process.

I offer this information as an appeal in hopes that my 3D mammogram testing will be covered.

BCBSM's Argument

In the final adverse determination, BCBSM explained the plan's decision to the Petitioner:

. . . The BCBSM/BCN Joint Uniform Medical Policy Committee (JUMP) has determined that the service is investigational.

* * *

A board-certified M.D. in Internal Medicine reviewed your claim, your appeal regarding the denial of coverage of your 3D mammogram (also known as digital tomosynthesis), and your health care plan benefits for [BCBSM]. Based on that review and current BCBSM Medical Policy titled, "Digital Breast Tomosynthesis," digital tomosynthesis, is considered experimental / investigational. This is because there is insufficient evidence that the use of digital tomosynthesis improves health outcomes. Therefore, we are unable to approve the digital tomosynthesis service you received and you remain responsible for the non-covered charge.

Director's Review

Radiology services, including mammography, are a benefit under the plan (certificate, p. 79). But the certificate (pp. 119-121) excludes coverage for experimental treatment. "Experimental treatment" is defined in the certificate (p. 134) 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 answer the question of whether digital tomosynthesis is experimental or investigational for use in treating the Petitioner, the Director presented the issue to an independent review organization (IRO) for analysis, 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 the following analysis and recommendation:

Recommended Decision:

The MAXIMUS physician consultant determined that the 3D (digital tomosynthesis) mammogram performed on 6/15/15 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 these advantages relate to the associated ability to separate dense glandular elements from underlying architectural distortion, thereby reducing callback rates and increasing detection of smaller cancers. The physician consultant indicated that the use of digital breast tomosynthesis has gained worldwide support among radiologists for these reasons. The consultant also indicated that while there are no long term studies showing an increase in survival rates when tomosynthesis has been added to the usual 2D imaging protocols commonly used in breast cancer screening, the use of tomosynthesis is rapidly becoming the norm at centers where this technique is available.

Pursuant to the information set forth above and available documentation, the

MAXIMUS physician consultant determined that the 3D (digital tomosynthesis) mammogram performed on 6/15/15 was not investigational for diagnosis and treatment of the member's condition. [Citations omitted.]

The Director is not required to accept the IRO's recommendation. 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 recommendation is based on extensive expertise and professional judgment. In addition, the IRO's recommendation is not contrary to any provision of the Petitioner's coverage. MCL 550.1911(15).

The Director, discerning no reason why the IRO's analysis should be rejected in this case, finds that the digital tomosynthesis performed on June 15, 2015, was not investigational and is therefore a covered benefit under the terms of the certificate.

V. ORDER

The Director reverses the plan's final adverse determination of December 8, 2015. The plan shall immediately cover the Petitioner's digital tomosynthesis performed on June 15, 2015, and shall, within seven days of providing coverage, furnish the Director with proof it has implemented this Order.

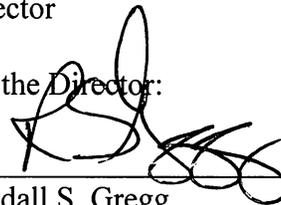
To enforce this Order, the Petitioner may report any complaint regarding its implementation to the Department of Insurance and Financial Services, Health Care Appeals Sections, at this toll free telephone number: (877) 999-6442.

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:



Randall S. Gregg
Special Deputy Director