

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. 151725-001-SF

State of Michigan, Plan Sponsor
and
Blue Cross Blue Shield of Michigan, Plan Administrator
Respondents

Issued and entered
this 17th day of February 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On January, 2016, Tom George, authorized representative of his wife Sandra George (Petitioner), filed a request for external review with the Department of Insurance and Financial Services. The request for review concerns a denial of coverage issued by Blue Cross Blue Shield of Michigan (BCBSM) for an August 19, 2015 medical test. BCBSM is the administrator of the Petitioner's health benefit plan which is sponsored by the State of Michigan. The benefits are described in BCBSM's *Community Blue Group Benefits Certificate LG*.

The request for external review was filed under Public Act No. 495 of 2006 (Act 495), MCL 550.1951 *et seq.* Act 495 requires the Director to provide external reviews to a person covered by a self-funded health plan that is established or maintained by a state or local unit of government. The Director's review is performed "as though that person were a covered person under the Patient's Right to Independent Review Act." (MCL 550.1952) The Petitioner's health benefit plan is such a governmental self-funded plan.

On January 25, 2016, after a preliminary review of the information submitted, the Director accepted the request for review. The Director notified BCBSM of the appeal and asked it to provide the information used to make its final adverse determination. BCBSM furnished its response on January 29, 2016.

This case involves medical issues so the Director assigned it to an independent review organization which provided its analysis and recommendation to the Director on February 8, 2016.

II. FACTUAL BACKGROUND

The Petitioner has a history of breast cancer, surgery, chemotherapy and radiation treatment. On August 19, 2015, the Petitioner had a mammogram with digital tomosynthesis on both breasts. Digital tomosynthesis, also called 3-D mammography, is used to detect breast cancer and creates a three-dimensional picture of the breasts using X-rays. BCBSM denied coverage for the service, saying it was experimental or investigational and therefore not a covered benefit.

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 December 9, 2015, affirming the denial. The Petitioner now seeks the Director's review of that final adverse determination.

III. ISSUE

Was the Petitioner's digital tomosynthesis experimental or investigational for treatment of her condition?

IV. ANALYSIS

BCBSM's Argument

In the final adverse determination to the Petitioner, a BCBSM representative wrote:

[A] board-certified M.D. in Internal Medicine reviewed [Petitioner's] claims, your appeal, and your health care plan benefits for Blue Cross Blue Shield of Michigan (BCBSM). Our medical consultant determined:

We have reviewed your appeal regarding the denial of coverage for [Petitioner's] 3D mammogram (also known as digital breast tomosynthesis). This test was performed in conjunction with her routine 2D mammogram. Per the current Blue Cross Blue Shield of Michigan Medical Policy "Digital Breast Tomosynthesis," digital tomosynthesis is considered experimental/ investigational. This is because there is insufficient evidence that the use of 3D mammography improves health outcomes. Therefore, we cannot approve this request.

Petitioner's Argument

In his request for external review, the Petitioner's husband wrote:

BCBSM continues to consider the service, breast tomosynthesis, “investigational” despite new evidence and determinations by Medicare and the American College of Radiology that it is no longer investigational.

Director’s Review

The *Community Blue Group Benefits Certificate* has this exclusion on page 131:

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 *Community Blue Group Benefits Certificate* (page 148) as:

Treatment 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 evaluate the question of whether digital breast tomosynthesis is experimental, 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 reviewer is a physician in active practice for more than 15 years who is board certified in radiology and is familiar with the medical management of patients with the Petitioner’s condition. The IRO report included this following analysis and recommendation:

Tomosynthesis was approved by the Food and Drug Administration for clinical use in 2011 and by the Centers for Medicare and Medicaid Services for reimbursement in 2014. Due to the advantages the technique brings to radiologists in the interpretation of mammograms the American College of Radiology urged that the technique be removed from the investigational category in 2014. (www.acr.org ACR statement on breast tomosynthesis. 2014 Nov.)...[T]his technique is particularly valuable in cases where there is very dense or heterogeneously dense tissue, as in this member’s situation....[T]he literature notes a decrease in callbacks and increase in detection of small cancers when tomosynthesis has been added to the usual 2D imaging protocol. (Freidewald SM, et al. Breast cancer screening using tomosynthesis in combination with digital mammography. *JAMA*. 2014 Jun;311(24):2497-507. Rose SL, et al. Implementation of breast tomosynthesis in a routine screening practice: an observational study. *AJR*. 2013;200:1401-8.)...[W]hile there are no long term studies proving an increased survival rate when tomosynthesis has been added to the usual 2D mammographic views, the technique is no longer considered investigational.

Pursuant to the information set forth above and available documentation...the digital breast tomosynthesis service performed on 8/19/15 was not experimental/investigational for diagnosis and treatment of the member's condition.

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 August 19, 2015, digital breast tomosynthesis was not experimental and therefore is a covered benefit.

V. ORDER

The Director reverses the plan's December 9, 2015, final adverse determination.

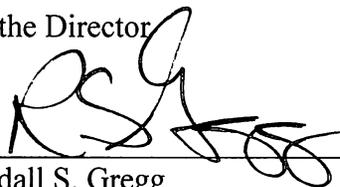
The plan shall immediately provide coverage for the Petitioner's August 19, 2015, screening digital breast tomosynthesis and related facility fees and shall, within seven days of providing coverage, furnish the Director with proof it has implemented this order.

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 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