

**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. 153574-001-SF**

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

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**Issued and entered**  
**this 6<sup>th</sup> day of June 2016**  
**by Randall S. Gregg**  
**Special Deputy Director**

**ORDER**

**I. PROCEDURAL BACKGROUND**

On May 6, 2016, ██████████ (Petitioner), filed a request for external review with the Department of Insurance and Financial Services, appealing a claim denial issued by Blue Cross Blue Shield of Michigan (BCBSM), the administrator of the Petitioner's health benefit plan which is sponsored by the State of Michigan.

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." See MCL 550.1952(2). The Petitioner's health benefit plan is such a governmental self-funded plan. The plan's benefits are described in BCBSM's *Your Benefit Guide State Health Plan PPO*.

On May 13, 2016, after a preliminary review of the information submitted, the Director accepted the Petitioner's request. The Director notified BCBSM of the appeal and asked BCBSM to provide the information used to make its final adverse determination. BCBSM submitted its response on May 19, 2016.

The case was assigned to an independent review organization to analyze the medical issues in the case. The review organization submitted its report to the Director on May 27, 2016.

## II. FACTUAL BACKGROUND

On September 14, 2015, the Petitioner had a screening mammography at a Dickinson County Healthcare System facility. The mammogram detected calcifications in her right breast. A second mammogram was obtained on September 22 which determined that the Petitioner had dense breast tissue that prevented accurate localization of the calcifications. The radiologist then recommended an MRI be performed or a follow-up mammogram be obtained in six months. The Petitioner opted for the MRI which was performed on October 9, 2015.

BCBSM provided coverage for the MRI but not for the radiologist's use of computer-aided detection analysis of the MRI image, which BCBSM considered to be investigational/ experimental.

The Petitioner appealed the claim decision through BCBSM's internal grievance process. At the conclusion of that process, on March 22, 2016, BCBSM issued a final adverse determination affirming its decision. The Petitioner now seeks the Director's review of that adverse determination.

## III. ISSUE

Was the use of computer-aided detection analysis of the MRI image an experimental or investigational service?

## IV. ANALYSIS

### Petitioner's Argument

In the request for external review, the Petitioner stated:

After two mammograms, there was [a] question about a spot in breast due to dense breast tissue. Per radiologist recommendation, [my] primary doctor...requested MRI. MRI images evaluated to determine spot was calcification and not cancer. MRI interpretation was not covered as it is considered investigational. My argument is an MRI has no value without professional interpretation. If MRI procedure is not investigational, how can the evaluation of MRI images be investigational?

### BCBSM's Argument

In its final adverse determination, BCBSM stated that it denied coverage for the computer-aided detection analysis of the MRI image because it is considered investigational:

You are covered under the *State Health Plan*. As explained on page 38 of *Your Benefit Guide*; the following services are not covered under the State Health Plan PPO:

- Services, care, devices or supplies considered experimental or investigative

An associate medical director, board-certified D.O. in Internal Medicine reviewed your claim, the medical records provided by Dr. [REDACTED], your appeal, and your health care plan benefits for Blue Cross Blue Shield of Michigan (BCBSM). After review, the medical consultant determined according to BCBSM medical policy "Computer Aided

Evaluation of Malignancy with MRI of the Breast” the use of computer-aided evaluation for interpretation of contrast-enhanced magnetic resonance imaging (MRI) of the breast is considered investigational because its effectiveness has not been proven. As a result, the service is considered experimental/investigational and payment cannot be approved.

### Director’s Review

The question of whether computer-aided detection analysis of the Petitioner’s MRI was experimental or investigational was presented 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 who is certified by the American Board of Family Medicine with a subspecialty in geriatric medicine. The IRO report included the following analysis and recommendation:

#### Clinical Rationale for the Decision:

The standard of care in this clinical scenario is to perform follow-up mammography in six (6) months or use a different imaging method, such as an MRI to further characterize the findings. (1, 2) CAD [computer-aided detection] is currently becoming standard of care with standard mammography. Screening mammography is frequently used with CAD and is considered mainstream. Despite the lack of proven evidence for CAD with MRI, this technology is not experimental, but an enhancement to the radiologist interpretation, based on its prior use with other modalities (mammography).

Breast MRI is indicated as an adjunct to mammography by current guidelines. (1, 2) CAD with MRI is Food and Drug Administration (FDA) approved and increasingly used by radiologists. The FDA has approved the sale of several algorithms for CAD with MRI.

The enrollee’s condition was healthy, and the mammography was a screening procedure. The cluster of calcifications warranted further imaging. Therefore, for the reasons noted above, the MRI of the breast with CAD is a procedure that is not considered experimental/investigational for this enrollee.

#### Recommendation:

It is the recommendation of this reviewer that the denial issued by Blue Cross Blue Shield of Michigan for the MRI/radiology services performed on October 9, 2015 be overturned.

#### References:

1. Mainiero MB, Lourenco A, Mahoney MC, et al. ACR Appropriateness Criteria breast cancer screening. American College of Radiology. JACR. 2013 Jan; 10(1): 11-14.
2. ACR Practice Parameter for the performance of contrast enhanced magnetic resonance imaging (MRI) of the breast. Amended 2014. American College of Radiology. <http://www.acr.org/~media/2a0eb28eb59041e2825179afb72ef624.pdf>
3. Fenton JJ, Xing G, Elmore JG, et al. Short-Term Outcomes of Screening Mammography Using Computer-Aided Detection: A Population-Based Study of Medicare Enrollees. Ann Intern Med. 2013;158(8):580-587.

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 Petitioner’s certificate of coverage. MCL 550.1911(15).

The Director, discerning no reason why the IRO’s recommendation should be rejected in this case, finds that the computer-aided detection analysis of the breast MRI on October 9, 2015 was not experimental/investigational for treatment of the Petitioner’s condition and is therefore a covered benefit under the State Health Plan *Benefit Guide*.

#### V. ORDER

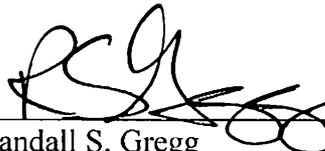
The Director reverses BCBSM’s final adverse determination of March 22, 2016. BCBSM shall immediately provide coverage for the Petitioner’s October 9, 2015 computer-aided detection interpretation of the MRI. See MCL 550.1911(17). BCBSM shall, within seven days of providing coverage, furnish the Director with proof it 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 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:

  
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Randall S. Gregg  
Special Deputy Director