

**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. 145213-001-SF**

**State of Michigan, Plan Sponsor,**

**and**

**Blue Cross Blue Shield of Michigan, Plan Administrator,**

**Respondents.**

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**Issued and entered**  
**this 8<sup>th</sup> day of January 2015**  
**by Randall S. Gregg**  
**Special Deputy Director**

**ORDER**

**I. PROCEDURAL BACKGROUND**

On December 4, 2014, ██████████ (Petitioner) filed a request with the Director of Insurance and Financial Services for an external review under Public Act No. 495 of 2006 (Act 495), MCL 550.1951 *et seq.* On December 11, 2014, after a preliminary review of the information submitted, the Director accepted the Petitioner's request.

The Petitioner receives health care benefits through a plan sponsored by the State of Michigan (the plan), a self-funded governmental health plan subject to 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 its final adverse determination. The Director received BCBSM's response on December 17, 2014.

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 issue in the case, the Director assigned it to an independent medical review organization which provided its analysis and recommendation on December 24, 2014.

## II. FACTUAL BACKGROUND

The Petitioner's benefits are described in the plan's *Your Benefit Guide*<sup>1</sup> (the benefit guide).

On August 15, 2014, the Petitioner received a collagen cross links test as part of the medical management of her osteoporosis. BCBSM denied coverage, saying the test was experimental or investigational and therefore not a covered benefit under the plan.

The Petitioner appealed the denial through the plan's internal grievance process. Following a managerial level conference, BCBSM issued a final adverse determination dated November 3, 2014, upholding its decision. The Petitioner now seeks a review of that adverse determination from the Director.

## III. ISSUE

Did BCBSM correctly deny coverage for the Petitioner's collagen cross links laboratory test?

## IV. ANALYSIS

### Respondents' Argument

In its final adverse determination, BCBSM told the Petitioner:

A board-certified D.O. in Internal Medicine reviewed your claim, your appeal, and your health plan benefits for [BCBSM]. The current BCBSM Medical Policy "Bone Turnover Markers for Diagnosis and Management of Osteoporosis and Diseases Associated with High Bone Turnover" effective 08/01/2014 indicates the measurement of serum osteocalcin and collagen crosslinks (serum or urine) bone turnover markers in the diagnosis and management of osteoporosis is experimental/investigational. The peer reviewed medical literature has not demonstrated the clinical utility of these laboratory tests of bone turnover for improving patient clinical outcomes.

Although we approved the cross links laboratory test (procedure code 82523 in the past, the service is now considered experimental/investigational. We must maintain the denial for the service you received on August 15, 2014.

### Petitioner's Argument

In a November 28, 2014, letter filed with the external review request the Petitioner said:

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<sup>1</sup> Version for employees hired prior to April 1, 2010, published January 1, 2013.

. . . Because of my osteoporosis, [my doctor] has been checking my bone turnover markers for a number of years. Because a bone density test is just one measure of bone health and does not always portray an accurate picture of bone health, [the collagen cross links] test has been used as an additional measure of my bone health. Results of this blood test along with other lab tests help determine the course of treatment for my condition. This test has been fully covered in past years.

This year I was told by [BCBSM] that, as of August 1, 2014, this test is now considered to be experimental/investigational. I do not understand how this previously covered test can be determined experimental in the middle of a benefit year without notification to enrollees. This test has been used by Endocrinologists for many years, including those at esteemed medical clinics such as Mayo Clinic, to help determine treatment decisions for osteoporosis. Osteoporosis has primary or secondary causes and a bone density test does not show anything but how dense or porous a bone is. Osteoporosis could be caused by a number of other conditions. If a patient is not adequately tested by lab tests other than just a bone density test, the condition of osteoporosis can be treated in a way that is harmful to the patient.

### Director's Review

The benefit guide (p. 47) has this exclusion:

#### **What is not covered**

In addition to the exclusions listed with the benefit, the following services aren't covered under the [State Health Plan] PPO:

\* \* \*

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

“Experimental or investigative” is defined in the benefit guide (p. 59) as

a service, procedure, treatment, device or supply that has not been scientifically demonstrated to be safe and effective for treatment of the patient's condition. BCBSM makes this determination based on a review of established criteria such as:

- Opinions of local and national medical societies, organizations, committees or governmental bodies
- Accepted national standards of practice in the medical profession
- Scientific data such as controlled studies in peer review journals or literature
- Opinions of the Blue Cross and Blue Shield Association or other local or national bodies

To determine if the collagen cross links test is experimental or investigational for the treatment of the Petitioner's condition, 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 certified by the American Board of Internal Medicine with a subspecialty in endocrinology, diabetes, and metabolism. The IRO report included the following analysis and recommendation:

**Reviewer's Decision and Principal Reasons for the Decision:**

It is the determination of this reviewer that the collagen cross links test (Procedure code 82523) was considered experimental/investigational for the treatment of the enrollee's condition.

**Clinical Rationale for the Decision:**

UpToDate summarizes when the crosslinks are useful:

“While the use of biochemical BTMs [bone turnover markers] in clinical trials has been helpful in understanding the mechanism of action of therapeutic agents, their role in the case of individual patients is not well established. The measurement of BTMs is complicated by large random within-patient variability, biologic variability (age, gender, body mass index [BMI], circadian, and menstrual variation), and poor standardization of most assays. These issues have confounded their widespread use in clinical practice.

- BTMs are predictive of the rate of bone loss and in some studies risk of fracture. However, there is no role for BTMs in selecting candidates for bone density testing or for osteoporosis therapy
- We do not routinely measure BTMs in patients initiating osteoporosis therapy. However, for individual patients (e.g., patients with conditions that might interfere with drug absorption or efficacy or patients who are reluctant to take anti-osteoporosis medications regularly), we sometimes measure fasting urinary NTX, serum CTX, or serum P1NP before and three to six months after starting bisphosphonates or other antiresorptive therapy. A 50 or 30 percent reduction in urinary NTX excretion or serum CTX, respectively, provides evidence of compliance and drug efficacy. This approach (with markers of bone resorption) is only useful with antiresorptive therapy, not with recombinant parathyroid hormone (rhPTH) (markers would increase).
- If BTMs are used to monitor osteoporosis therapy, we suggest using BTMs that can be measured using automated technology and that have relatively small spontaneous variability, such as serum P1NP, CTX, or urinary NTX.
- There are insufficient data to support the use of BTMs for deciding

whether or when to discontinue bisphosphonate therapy or whether or when to restart it, or the assessment of risk (osteonecrosis of jaw [ONJ]) on bisphosphonate-treated patients undergoing invasive dental procedures.”

The medical or scientific evidence does not demonstrate that the expected benefits of the requested health service are more likely to be beneficial to the enrollee than any available standard health care service. Therefore, the collagen cross links test . . . is considered experimental in the treatment of the enrollee’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 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 collagen cross links test is experimental or investigational for the treatment of the Petitioner’s condition and therefore not a covered benefit under the plan.

#### V. ORDER

BCBSM’s final adverse determination of November 3, 2014, is upheld.

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