

**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. 152090-001**

**Blue Cross Blue Shield of Michigan**

**Respondent**

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**Issued and entered**  
this 9<sup>th</sup> day of March 2016  
by **Randall S. Gregg**  
**Special Deputy Director**

**ORDER**

**I. PROCEDURAL BACKGROUND**

On February 5, 2016, ██████████ (Petitioner) filed a request with the Department of Insurance and Financial Services for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* On February 12, 2016, after a preliminary review of the information submitted, the Director accepted the request.

The Petitioner receives health care benefits through a group plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The benefits are described in BCBSM's *Community Blue Group Benefits Certificate LG*.

The medical issues in this case were evaluated by an independent review organization which provided its analysis and recommendation to the Director on February 26, 2016.

**II. FACTUAL BACKGROUND**

The Petitioner is ██████████ years old and has osteoporosis. On June 1, 2015 she had a blood test which her doctor ordered to determine the rate of her bone turnover and its influence on bone health, and to ensure that her vitamin D toxicity and osteoporosis could be managed appropriately. The test is known as a serum N-telopeptide test or a collagen crosslink test. BCBSM denied coverage for the test as experimental /investigational.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of the grievance process, BCBSM issued a final adverse determination on January 11, 2016. The Petitioner now seeks the Director's review of that determination.

### III. ISSUE

Was the blood test performed on June 1, 2015 experimental or investigational in the treatment of the Petitioner's condition?

### IV. ANALYSIS

#### BCBSM's Argument

In its final adverse determination, BCBSM wrote:

The service performed, procedure code 85253 (collagen cross links, any method), has been determined to be experimental/investigational by the BCBSM/Blue Care Network Joint Uniform Medical Policy Committee. Your health care plan does not cover experimental or investigational services. Therefore, payment cannot be approved for the \$134.00 in non-covered charges for these services.

\* \* \*

To give your appeal every consideration, a board-certified M.D. in Internal Medicine reviewed your claim, your appeal, and your health care plan benefits for BCBSM. The medical consultant concluded:

Additional documentation reviewed. The member has osteoporosis and is under treatment. Response to treatment will be determined by semi-annual serum measurements of collagen cross links/N-telopeptide. According to BCBSM medical policy "Bone Turnover Markers for Diagnosis and Management of Osteoporosis and Diseases Associated with High Bone Turnover," measurement of this bone turnover marker to monitor treatment response in osteoporosis, or any other condition except Paget's Disease, lacks clinical utility. The results of this test do not lead to improved health outcomes for osteoporosis or other conditions other than Paget's Disease.

#### Petitioner's Argument

The Petitioner's request for external review included a letter dated November 6, 2015, from the Petitioner's physician, who wrote:

As a certified clinical Densitometrist and a Board Certified Internal Medicine Specialist, I can assure you that the serum N-telopeptide is not an investigational lab test. The roots of this type of testing started back in the 1980s when it was investigational. However "almost all of the osteoporosis medical literature has included serum N-telopeptide as a prominent Important marker regarding bone turnover and its influence regarding bone health".

For this patient in particular, she has documented osteoporosis per DXA scan with a lumbar t-score of -2,8 performed on 10/16/2013. In addition, she had vitamin D toxicity with a 25-OH vitamin D level of >96 that was performed on her on 6/18/2015 at St. Mary's of Michigan-Standish Hospital. In addition, she had an elevated alkaline phosphatase of 97 (32-82) performed on that same date, same place. This would indicate to me that with an elevated alkaline phosphatase (and normal liver function test) that she has very reactive bone turnover.

The patient was on no medication to treat her osteoporosis at that time. The N-telopeptide level was necessary to make certain that her vitamin D toxicity and her osteoporosis could be managed appropriately in order to place her health in a lower area of risk. Without the N-telopeptide level, her health would be in jeopardy. I am using the N-telopeptide to determine bone turnover. I have initiated her on a bone antiresorptive agent (Alendronate) and intend to repeat her serum N-telopeptide in approximately 6 months to document efficacy in decrease in bone turnover. If her N-telopeptide remains high, then that indicates that other bone diseases may be at play that the Alendronate is not taking care of.

Therefore, I am challenging your decision making in not covering the cost of the serum N-telopeptides that are being used as a tool to help with the health and well-being of this patient. Without these tools, the patient may have another sinister disease that can be left undiagnosed that can be of a disastrous consequence. If that consequence occurs, I am afraid the insurance company would be liable for not providing the standard of care that is necessary in cases such as this. I certainly hope medical-legal doesn't get involved with this and you can see the wisdom of providing coverage for the cost of this lab test.

### Director's Review

The Petitioner's health benefit plan excludes coverage for experimental and investigational medical services. The *Community Blue Group Benefits Certificate LG*, page 133, states:

#### Services That Are Not Payable

We do not pay for experimental treatment (including experimental drugs or devices) or services related to experimental treatment....

The *Community Blue* certificate, on page 150, defines experimental treatment:

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 the Petitioner's blood test is investigational/experimental for 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 reviewer is a physician who is board certified in internal medicine, has been in active practice for more than 20 years, and is familiar with the medical management of patients with the Petitioner's condition. The reviewer's report included the following analysis and recommendation:

The Centers for Medicare and Medicaid Services (CMS) established a national policy (NCD) for reimbursement of collagen crosslink testing, as of 1/25/02. The Medicare NCD for urine based collagen crosslink tests (CPT 82523) lists three uses under 'Indications', to identify individuals with elevated bone resorption, who have osteoporosis in whom response to treatment is being monitored, to predict response (as assessed by bone mass measurements) to Food and Drug Administration (FDA) approved anti-resorptive therapy in postmenopausal women, and to assess response to treatment of patients with osteoporosis, Paget's disease of the bone, or risk of osteoporosis where

treatment may include FDA approved anti-resorptive agents, anti-estrogens or selective estrogen receptor moderators....[T]he best use of bone markers is in classifying patients with low or moderately low bone density into 'high risk' and 'low risk' categories based on bone marker measurements.

[T]here is no indication for assessing bone markers prior to therapy with a bisphosphonate (Alendronate)....[M]easurement of bone turnover marker performed to monitor treatment response in osteoporosis, as in this case, or any other condition except Paget's disease, lacks clinical utility....[T]he literature does not demonstrate that the results of this testing leads to improved health outcomes for conditions other than Paget's disease.

Pursuant to the information set forth above and available documentation...CPT code 82523 (collagen cross links, any method) performed on 6/1/15 was experimental/investigational for diagnosis and treatment of the member's condition. (Talwar SA. Bone Markers in Osteoporosis. Medscape Internal Medicine, 2014.)

While the Director is not required in all instances to accept the IRO's recommendation, the recommendation is afforded deference by the Director. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). 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. See MCL 550.1911(15).

The Director, discerning no reason why the IRO's recommendation should be rejected in the present case, finds that the blood test performed on June 1, 2015, is experimental/ investigational in the treatment of Petitioner's condition and, therefore, is not a covered benefit.

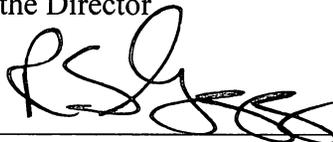
#### V. ORDER

The Director upholds BCBSM's final adverse determination of January 11, 2016.

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



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Randall S. Gregg  
Special Deputy Director