

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. 150434-001

Blue Cross Blue Shield of Michigan,
Respondent.

Issued and entered
this 16th day of November 2015
by Joseph A. Garcia
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

██████████ (Petitioner) was denied coverage for the prescription drug Prolia by her health insurance carrier, Blue Cross Blue Shield of Michigan (BCBSM).

On October 20, 2015, she filed a request with the Director of Insurance and Financial Services for an external review of BCBSM's denial under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* The Director accepted the request on October 27, 2015, after a preliminary review of the material submitted.

The Petitioner receives prescription drug benefits through an individual plan underwritten by BCBSM. The Director immediately notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. BCBSM provided its response on November 5, 2015.

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 November 10, 2015.

II. FACTUAL BACKGROUND

The Petitioner's prescription drug benefits are defined in the *Blue Cross Premier Silver Benefits Certificate*¹ (the certificate).

The Petitioner has osteoporosis and gastroesophageal reflux disease (GERD). She has also had

¹ BCBSM form no. 603F, effective 08/2015.

bariatric surgery. Because she cannot take oral bisphosphonates, which are commonly used to treat osteoporosis, her physician asked to BCBSM authorize the specialty drug Prolia. BCBSM denied the request.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM affirmed its denial in a final adverse determination dated October 13, 2015. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Is BCBSM required to authorize the prescription drug Prolia to treat the Petitioner's osteoporosis?

IV. ANALYSIS

Petitioner's Argument

This justification was contained on the external review request form submitted by the Petitioner:

This patient is a ■ year old female with history of malabsorption secondary to bariatric surgery. Patient has a history of GERD. [She] had a bone density with an MRI that revealed significant loss in disc height. It is my belief, this [the Petitioner] cannot take oral bisphosphonates. That is contraindicated due to bariatric surgery and history of GERD.

BCBSM's Argument

In its final adverse determination, BCBSM explained the reasons for its denial of preauthorization to the Petitioner:

. . . After review, the denial of prior authorization for Prolia is maintained because you do not meet the medical criterion for approval of Prolia. Therefore, prior authorization cannot be approved.

You are covered under the *Blue Cross Premier Silver Benefits Certificate*. In **Section 3: What BCBSM Pays For, under Prescription Drugs: Prior Authorization for Specialty Pharmaceuticals**, on page 88 of the certificate, it explains the following:

- Prior authorization is required for select specialty pharmaceuticals. Only FDA-approved medications are eligible for prior authorization and of those drugs, only the specialty pharmaceuticals that meet BCBSM's medical policy criteria for treatment of the condition will be preauthorized.

A Clinical Pharmacist, RPh, reviewed your claim, your appeal, and your health care plan benefits for Blue Cross Blue Shield of Michigan (BCBSM) and determined the following:

The BCBSM Medical Policy for Prolia requires that you have a diagnosis of osteoporosis with specific bone density testing results (T-score less than or equal to -

2.5 at lumbar spine or total hip). We have no record that you have these required test results.

Further, the BCBSM Medical Policy for Prolia requires that you have been treated with at least one drug from a group called bisphosphonates (such as Fosamax, Actonel, Boniva or Reclast) that did not work, was not tolerated, or could not be used. While we have record that you are unable to tolerate oral bisphosphonates, we have no record that you have received any intravenous bisphosphonates or a reason why they cannot be used.

We understand that you feel this prior authorization request is based on your medical need; however, BCBSM must administer your prescription drug benefits based on the provisions that align with your health care coverage.

Director's Review

BCBSM declined to cover Prolia, saying that the Petitioner does not meet the criteria of its medical policy² for its use.

To review BCBSM's decision, the case was assigned to an independent review organization (IRO). The IRO physician reviewer is board certified in internal medicine who has been in practice for more than 18 years and is familiar with the medical management of patients with the Petitioner's condition. The IRO reviewer's report included the following analysis and recommendation:

Rationale:

Medical care for osteoporosis includes administration of adequate calcium, vitamin D, and anti-osteoporotic medication, such as bisphosphonates, parathyroid hormone, raloxifene and estrogen. Additionally, potential treatable underlying causes of osteoporosis such as hyperparathyroidism and hyperthyroidism should be ruled out or treated if detected. Currently, no treatment can completely reverse established osteoporosis. Early intervention can prevent osteoporosis in most people and medical intervention can halt progression for patients with established osteoporosis. Therapy should be individualized based on each patient's clinical scenario. Pharmacologic therapy for osteoporosis includes the use of antiresorptive agents to decrease bone resorption, such as bisphosphonates, the selective estrogen-receptor modulator raloxifene, calcitonin and denosumab. In addition, there are anabolic steroids that promote bone formation in patients with osteoporosis, such as teriparatide (Forteo). Monoclonal antibodies such as Prolia (denosumab) inhibit osteoclast formation, decrease bone resorption, increase bone mass density and reduce the risk of fracture.

The MAXIMUS physician consultant indicated that the member has a diagnosis of osteoporosis that requires medical therapy. The member has a diagnosis of

2 Medical use policy, "Denosumab (Prolia/Xgeva)," effective 08/14/2014.

gastroesophageal reflux disease and is status post bariatric surgery and is therefore not an optimal candidate for oral bisphosphonate therapy. However, the physician consultant indicated that there is no contraindication to the use of intravenous bisphosphonate therapy with Reclast. The consultant also indicated that the member does not meet the Health Plan's criteria for coverage of Prolia because while there is a reason why she would be unable to tolerate oral bisphosphonates, there were no records documenting that she has received intravenous bisphosphonate therapy which was not tolerated or did not work and no reason why intravenous bisphosphonate therapy could not be used.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that Prolia is not a medically necessary and appropriate alternative for 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 IRO's 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 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, finds that the Petitioner does not meet BCBSM's criteria for the use of Prolia and therefore BCBSM does not have to authorize its use.

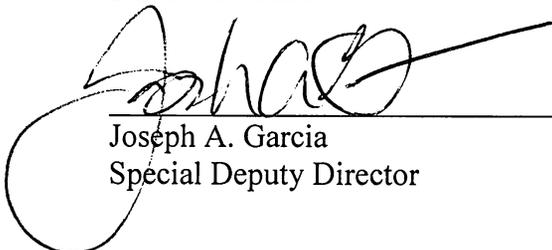
V. ORDER

The Director upholds BCBSM's final adverse determination of October 13, 2015.

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:



Joseph A. Garcia
Special Deputy Director