STATE OF MICHIGAN

DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES

Before the Director of Insurance and Financial Services

In the matter of:

[redacted],

Petitioner,

v **File No. 152853-001**

Blue Cross Blue Shield of Michigan,

Respondent.

Issued and entered
this 26th day of April 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. BACKGROUND

On March 24, 2016, [redacted] (Petitioner) filed a request with the Director of Insurance and Financial Services for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq*. On March 31, 2016, after a preliminary review of the material submitted, the Director accepted the request.

The Petitioner receives prescription drug coverage through a group plan underwritten by Blue Cross Blue Shield of Michigan (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 responded on April 4, 2016.

Because the case involves a medical issue, it was assigned to an independent medical review organization which provided its recommendation to the Director on April 14, 2016.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits, including prescription drugs, are described in BCBSM's *Simply Blue Group Benefits Certificate SG* (the certificate).

The Petitioner has osteoporosis. Her physician prescribed the injectable specialty drug Prolia (denosumab) to treat her condition. BCBSM denied coverage for this drug because the Petitioner did not meet its preauthorization requirements.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM issued a March 16, 2016, final adverse determination upholding the denial. The Petitioner now seeks a review of that final adverse determination from the Director.

III. Issue

Did BCBSM properly deny coverage for the specialty drug Prolia?

IV. Analysis

Petitioner's Argument

The notes of the managerial-level grievance conference on February 25, 2016, noted the Petitioner's argument for the drug:

> — The member stated she is 70 years old and didn't want to be on pill regiment for rest of her life; getting shots was recommended by doctor because It would work faster
>
> — She stated she is suffering from achiness and fatigue
>
> — She stated she has not tried an IV, and didn't give any reason why she couldn't

Respondent's Argument

In the final adverse determination, BCBSM representative explained the reason for its denial to the Petitioner:

> . . . After review, I confirmed the denial must be maintained.
>
> * * *
>
> Prolia is a specialty pharmaceutical that requires preauthorization. For this reason, a Clinical Pharmacist, RPh review[ed] the documentation and the notes from your Conference and determined the following:
>
> > The 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) for at least 24 months that did not work, was not tolerated or could not be used. We have record you are unable to take oral bisphosphonates (such as Fosamax), however we have no record you are unable to take intravenous (IV) bisphosphonates (such as Reclast or Boniva) for at least 24 months.
> >
> > AND
> >
> > The Medical Policy for Prolia requires that you have a diagnosis of osteoporosis with chart notes demonstrating a specific bone density testing results (T-score less than or

equal to -2.5 at lumbar spine or total hip). We have no record (chart notes) that you have these required test results at the lumbar spine or total hip.

Therefore, preauthorization could not be approved. . . .

Director's Review

The certificate (p. 78) covers specialty pharmaceuticals such as Prolia if they are preauthorized. BCBSM based its denial on the criteria in its medication use policy "Denosumab (Prolia/Xgeva)." To determine if BCBSM's denial was correct, the case was assigned to an independent review organization (IRO) 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 Obstetrics and Gynecology; is a fellow of the American College of Obstetrics and Gynecology; and is in active clinical practice. The IRO reviewer's 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 prescription drug Prolia is not medically necessary for the treatment of the enrollee's condition.

Review Questions to Answer:

1. **Is BCBSM's medical policy for Prolia consistent with the current standards of medical care?** Yes. The American College of Obstetricians and Gynecologists (ACOG) reports that bisphosphonates have been the leading treatment for osteoporosis since alendronate was approved in 1995 and are generally considered first line therapy. Therefore, BCBSM's policy for Prolia would be consistent with the current standards of medical care requiring first a trial of bisphosphonate therapy before initiating an alternative treatment.
2. **If not, what are the current standards of medical care for the prescription drug Prolia?** N/A
3. **Is Prolia medically necessary for the treatment of the enrollee's condition? Why or why not?** No. There are other standard treatment options available to this enrollee for the treatment of her osteoporosis.
4. **Please comment on BCBSM's conclusion on page two (2) of the March 16, 2016, final adverse determination.** This conclusion is in agreement with the information provided in the documentation submitted for review. There is no documentation that the enrollee was given a trial of intravenous (IV) bisphosphonates for at least twenty four (24) months. There is also no documentation that the enrollee had a T-score of less than or equal to -2.5 at the lumbar spine or hip. Based on BCBSM's medical policy requirements for

preauthorization of Prolia, this enrollee did not meet these requirements and therefore preauthorization could not be approved.

Clinical Rationale for the Decision:

The current standard of care for treatment of osteoporosis would include generally accepted first line treatment with bisphosphonate therapy for BMD [*bone mineral density*] T-scores of less than or equal to -2.5 at the femoral neck or spine. The World Health Organization has established the following definitions based on BMD measurement at the spine, hip, or forearm by dual-energy X-ray absorptiometry (DXA) devices:

- NORMAL: BMD is within one (1) standard deviation (SD) of a "young normal" adult (T-score at -1.0 and above).
- LOW BONE MASS: BMD is between 1.0 and 2.5 SD below that of a "young normal" adult (T-score between -1.0 and -2.5).
- OSTEOPOROSIS: BMD is -2.5 or more SD below that of a "young normal" adult (Tscore at or below -2.5).

The National Osteoporosis Foundation (NOF) (1) recommends initiation of therapy on those with BMD T-scores less than or equal to -2.5 at the femoral neck or spine by DXA.

Current Food and Drug Administration (FDA) approved pharmacologic options for osteoporosis prevention and / or treatment include bisphosphonates, calcitonin, estrogens, parathyroid hormone, receptor activator of nuclear factor kappa-B (RANK) ligand inhibitor (denosumab / Prolia) and estrogen agonist / antagonist (raloxifene). While all of these medications may be effective in the treatment of osteoporosis, the clinician should assess the potential benefits and risks of therapy in each patient. The American College of Obstetricians and Gynecologists (ACOG) (2) notes that bisphosphonates have been the leading treatment for osteoporosis since the approval of alendronate in 1995.

This enrollee has a T-score of -2.5 of the left forearm and a T-score of -2.4 of the femoral neck. The documentation submitted for review does not provide a BMD score of the lumbar spine and gives no specific reason as to why the spine was not included in this enrollee's evaluation.

Additionally, the record indicates that the enrollee was given a trial of bisphosphonate at the age of fifty (50) and was taken off, but gives no specific reason indicating she was not able to tolerate the medication.

The enrollee does not meet the NOF recommendations for initiation of therapy when BMD Tscores are less than or equal to -2.5 at the femoral neck or spine. An exception to this would be a Fracture Risk Assessment Tool (FRAX) score indicating a 20% or greater risk of any fracture or a 3% or greater risk of a hip fracture, in which case initiation of therapy would be recommended. FRAX scores were not provided in the submitted documentation, so further risk assessment cannot be determined. Therefore, based on the

> clinical information submitted for review and current standards of care, the prescription drug Prolia is not medically necessary for this enrollee.
>
> **Recommendation**:
>
> It is the recommendation of this reviewer that the denial issued by Blue Cross Blue Shield of Michigan for the prescription drug Prolia be upheld.

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 recommendation is not contrary to any provision of the Petitioner's coverage. MCL 550.1911(15). The Director, discerning no reason why the IRO's recommendation should be rejected in this case, finds that Prolia is not medically necessary and therefore is not a covered benefit under the certificate.

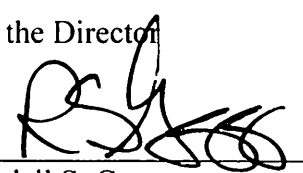
V. ORDER

The Director upholds BCBSM's March 16, 2016, final adverse determination.

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 sixty 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



Randall S. Gregg
Special Deputy Director