

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. 154112-001

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 13th day of July 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

██████████ (Petitioner) was denied coverage for a prescription drug by her health insurer, Blue Cross Blue Shield of Michigan (BCBSM).

On June 14, 2016, the Petitioner filed a request with the Director of Insurance and Financial Services for an external review of that denial under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* After a preliminary review of the material submitted, the Director accepted the request on June 21, 2016.

The Petitioner receives prescription drug benefits through a plan underwritten by BCBSM. The benefits are described in BCBSM's *Simply Blue Group Benefits Certificate SG*. The Director notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. BCBSM responded on June 28, 2016.

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 July 5, 2016.

II. FACTUAL BACKGROUND

The Petitioner has breast cancer. Her physician prescribed Prolia (denosumab), a drug that treat osteoporosis in postmenopausal women at high risk for

bone fractures caused by certain forms of cancer treatment. BCBSM denied coverage for the drug.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM affirmed its decision in a final adverse determination issued May 23, 2016. The Petitioner now seeks the Director's review of that final adverse determination.

III. ISSUE

Did BCBSM correctly deny coverage for the prescription drug Prolia?

IV. ANALYSIS

Petitioner's Argument

In a May 20, 2016 letter BCBSM, the Petitioner's physician explained why Prolia was prescribed:

[Petitioner] is a 63-year-old female diagnosed with ductal carcinoma in situ breast cancer. She was treated with a lumpectomy and radiation therapy. Currently, she is taking Arimidex, which is aromatase inhibitor.

Aromatase inhibitors are hormonal therapies often used in the treatment plan for postmenopausal women diagnosed with either early or advanced breast cancer that is hormone-receptor positive. Hot flashes, night sweats, and joint pain are common side effects of aromatase inhibitors. These medicines can also weaken bones over time and increase the chances of breaking a bone. So it makes sense to use treatment and other steps to strengthen bones while taking aromatase inhibitors.

A DEXA scan (bone densitometry study) in March 2016 showed osteopenia at multiple locations. She will need to be started on Prolia to correct this problem.

Denosumab (brand name: Prolia) is a targeted therapy that is already approved by the U.S. Food and Drug Administration (FDA) for several uses in women. In September 2011, denosumab was FDA-approved to treat bone loss in women taking aromatase inhibitors as part of their breast cancer treatment. Branded as Prolia, denosumab has been approved to treat postmenopausal women diagnosed with osteoporosis at high risk of breaking a bone, or who haven't gotten any benefits from other osteoporosis treatments. Prolia is given as an injection under the skin twice a

year. And now, Prolia is approved to help improve bone health in women taking aromatase inhibitors who are at high risk for breaking a bone.

I am requesting approval for Prolia based on the above information attached.

BCBSM's Argument

In its final adverse determination, BCBSM's representative wrote:

The Medical Policy for Prolia requires a documented osteoporosis-related high risk of breaking bones (3% or higher 10 year likelihood of hip fracture or 20% OR higher 10 year likelihood of a major osteoporosis-related fracture). We have no record documenting high risk of breaking bones as stated above.

AND

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 no record that you have received a bisphosphonate.

Because the criteria have not been met, preauthorization could not be approved ...

Director's Review

The *Simply Blue* certificate (p. 78) covers specialty drugs such as Prolia if they are preauthorized by BCBSM. BCBSM based its denial on the criteria in its medication use policy titled, "Denosumab (Prolia/Xgeva)".

To evaluate BCBSM's criteria for approving coverage for Prolia and to determine if the drug is medically necessary to treat the Petitioner's condition, the Director submitted those issues 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 reviewer is a physician in active practice who certified by the American Osteopathic Board of Internal Medicine with a subcertification in medical oncology and hematology. The reviewer is familiar with the medical management of patients with the Petitioner's condition. The IRO report included the following analysis and recommendation:

Reviewer's Decision and Principal Reasons for the Decision:

Is BCBSM's medical policy for the prescription drug Prolia consistent with current standards of medical care?

No. BCBSM's medical policy for the prescription drug Prolia is not consistent with current standards of medical care.

Does the enrollee meet BCBSM's criteria for the prescription drug Prolia?

No. The enrollee does not meet BCBSM's criteria for the prescription drug Prolia.

Is Prolia medically necessary for treatment of the enrollee's condition?

No. Prolia is not medically necessary for treatment of the enrollee's condition.

Clinical Rationale for the Decision:

The National Comprehensive Cancer Network (NCCN) Guidelines and the peer-reviewed literature do not support the use of denosumab (Prolia) in this clinical scenario.

Adjuvant endocrine therapy with an AI [aromatase inhibitor] is associated with loss of bone mineral density (BMD), and interventions to preserve bone mass in the setting of AI therapy, including bisphosphonates and the anti-RANK-ligand denosumab, may be indicated for many of these women. The adjuvant denosumab in breast cancer (ABCSG)-18 trial demonstrated that denosumab also significantly reduces AI-associated fractures in postmenopausal patients with invasive breast cancer with low rates of toxicity. The ABCSG-18 trial assessed disease free survival (DFS) in 3400 postmenopausal women on AIs for hormone receptor-positive breast cancer, randomly assigned to denosumab or placebo. The primary endpoint of the study was clinical fracture. Secondary endpoints of this study include disease-related outcomes. As presented at the 2015 San Antonio Breast Cancer Symposium, at a median follow-up of four years, denosumab was associated with a trend towards improved DFS (167 versus 203 DFS events, HR 0.82, $p = 0.051$). In subset analyses, the benefit from denosumab was observed in tumors that were larger than two centimeters (HR 0.66, $p = 0.016$), those that were both estrogen receptor (ER) positive and progesterone receptor (PR)-positive (HR 0.75, $p = 0.013$), and those with ductal histology (HR 0.79, $p = 0.048$).

However, this enrollee did not have invasive breast cancer and the benefit of denosumab in the setting of patients receiving an AI as adjuvant therapy of DCIS is unknown. Given the lack of supporting

data for the use of denosumab in this clinical scenario, medical necessity has not been established. Therefore, the prescription drug Prolia is not medically necessary for the treatment of this enrollee.

Recommendation:

It is the recommendation of this reviewer that the denial issued by Blue Cross Blue Shield of Michigan for 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 IRO's 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, adopts the IRO analysis and finds that Prolia is not medically necessary to treat the Petitioner's condition; therefore, it is not a covered benefit.

V. ORDER

The Director upholds BCBSM's final adverse determination of May 23, 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:



Randall S. Gregg
Special Deputy Director