

STATE OF MICHIGAN
DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES
Before the Director of Insurance and Financial Services

In the matter of:

██████████
Petitioner

v
Health Alliance Plan of Michigan
Respondent

File No. 153601-001

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

ORDER

I. BACKGROUND

On May 10, 2016, ██████████ (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.*

The Petitioner receives prescription drug coverage from Health Alliance Plan of Michigan (HAP), a health maintenance organization. The Petitioner's benefits are defined in HAP's *HMO Subscriber Contract*.

The Director notified HAP of the external review request and asked for the information used to make its final adverse determination. HAP provided its response on May 12, 2016. On May 17, 2016, after a preliminary review of the material submitted, the Director accepted the request.

Because the case involves medical issues, it was assigned to an independent medical review organization, which provided its analysis and recommendation to the Director on May 31, 2016.

II. FACTUAL BACKGROUND

The Petitioner is 53 years old and has a history of breast cancer. As part of her care, her physician prescribed the drug Prolia (denosumab) and requested that HAP approve coverage. HAP denied the request stating that the Petitioner did not meet its criteria for coverage of the drug.

The Petitioner appealed the denial through HAP's internal grievance process. HAP issued a final adverse determination dated April 29, 2016, upholding the denial. The Petitioner now seeks the Director's review of the denial.

III. ISSUE

Did HAP properly deny coverage for the prescription drug Prolia?

IV. ANALYSIS

Respondent's Argument

In its final adverse determination to the Petitioner, HAP stated:

The original request was denied because criteria were not satisfied. According to the reviewed documentation you have not used an oral or IV Bisphosphonate product. The appeal letter addressed the prescribing information for Prolia which indicates "treatment of bone loss in women receiving Adjuvant Aromatase Inhibitor therapy for breast Cancer"; however, the appeal does not address why Bisphosphonates, which can also be used in this scenario have not been tried. The National Comprehensive Cancer Network (NCCN) guidelines indicate that the use of a Bisphosphonate or Denosumab is acceptable to improve bone mineral density for women taking Adjuvant Aromatase Inhibitor. NCCN does not prefer Prolia over Reclast or Fosamax. Additionally, your bone mineral density results were not submitted (a criteria requirement). However, office visit notes submitted indicate a "normal bone density."

Although you are at risk for bone fracture due to Aromatase Inhibitor therapy (Anastrozole); based on medical records, you do not have Osteopenia or Osteoporosis or other risk factors for bone fracture. The coverage criteria for use of Prolia require an indication of Osteopenia or Osteoporosis. The formulary provides coverage for oral Bisphosphonates of Alendronate and Ibandronate without a prior authorization. If there is intolerance to oral Bisphosphonates, IV formulations of Zoledronic Acid and Ibandronate are covered under the medical benefit with no prior authorization required. Therefore, our Pharmacy Care Management upholds the original denial because failure of oral or IV Bisphosphonates has not occurred, medical necessity for using Prolia over Bisphosphonate therapy has not been demonstrated, and a diagnosis of Osteopenia or Osteoporosis has not been demonstrated.

Petitioner's Argument

In her request for an external review, the Petitioner stated that her oncologist, Dr. [REDACTED], prescribed Prolia, not for bone density problems, but to prevent cancer. Petitioner also says that Dr. [REDACTED] told her that Prolia is showing great results in preventing cancer.

In a letter to HAP dated April 27, 2016, Dr. Dul stated that the Petitioner “is currently on Arimidex therapy daily.” (Arimidex is in a category of drugs known as aromatase inhibitors that stop estrogen production. Estrogen stimulates the growth of certain breast cancer cells.) According to Dr. [REDACTED] “Prolia is the only FDA approved medication for patients receiving Aromatase inhibitors with a high risk for bone loss.”

Director’s Review

The Food and Drug Administration has approved Prolia as a treatment for bone loss in postmenopausal women and women taking aromatase inhibitors who are at high risk for breaking a bone.¹ It is not a drug used for cancer prevention as the Petitioner asserts. In her April 27, 2016 letter, Dr. [REDACTED] does not claim that Prolia is a cancer treatment.

The use of Prolia as a part of the Petitioner’s treatment was evaluated by an independent medical 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 for more than 15 years who is board certified in oncology. The IRO reviewer’s report included the following analysis and conclusion:

[A]lthough the member is on an aromatase inhibitor, she is not at high risk for fracture as evidenced by normal bone density. According to the package insert, Prolia is indicated for treatment to increase bone mass in women at high risk for fracture who are receiving adjuvant aromatase inhibitor therapy for breast cancer...[T]he member is not at high risk for fracture as she had a normal bone density according to the records provided for review.

...Prolia is not medically necessary 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’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 the present case, finds the prescription drug Prolia is not medically necessary for treatment of the Petitioner’s condition and is, therefore, not a covered benefit.

1. <http://www.breastcancer.org/research-news/20110919>

V. ORDER

The Director upholds HAP's April 29, 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 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