

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. 146894-001

Priority Health,
Respondent.

Issued and entered
this 15th day of April 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On March 19, 2015, ██████████ (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 group health care benefits through Priority Health, a health maintenance organization. The Director immediately notified Priority Health of the external review request and asked for the information it used to make its final adverse determination. Priority Health provided its response on March 19, 2015. On March 26, 2015, after a preliminary review of the material submitted, the Director accepted the external review request.

This case involves medical issues so the Director assigned it to an independent review organization which submitted its recommendation on April 7, 2015.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are defined in a Priority Health document called *MyPriority POS Agreement*.

The Petitioner has osteopenia, a condition in which bone mineral density is lower than normal. She treated the condition with Fosamax for three years but had no improvement and the drug caused side effects.

When her physician asked Priority Health to authorize the injectable prescription drug Prolia to treat her condition, the request was denied on the basis that the Petitioner did not meet the criteria for coverage.

The Petitioner appealed the denial through Priority Health's internal grievance process. When the internal grievance process concluded, Priority Health maintained its denial and issued a final adverse determination letter dated February 27, 2015. The Petitioner now seeks a review of that adverse determination from the Director.

III. ISSUE

Did Priority Health correctly deny coverage for Prolia?

IV. ANALYSIS

Petitioner's Argument

On the request for external review form, the Petitioner wrote:

. . . I have used Fosamax for 3 yrs with no improvement in bone density. Also did not tolerate it well resulting in muscle and joint pain, GI side effects exacerbating my celiac disease and decreased absorption of nutrients resulting in 20 lb wt. loss. The requirement to take Reclast which acts the same as Fosamax would not be beneficial to me and delay any efforts to improve my bones. My doctor does NOT advise Reclast!

In a separate letter included with the external review request, the Petitioner submitted additional comments:

I would like to outline my case in addition to the comments I included on the review form.

1. Treatment with Fosamax did not improve my bone density
2. Treatment with Fosamax exacerbated my celiac condition
3. Treatment with the same type of drug as Fosamax such as Reclast which is required by my insurance company would continue to damage the health issues I have that result from Celiac disease. The weight loss I have experienced and the intestinal intolerances as a result of the disease.
4. Treatment with Reclast would increase chance of fracture to areas that I already show significant bone loss, femur and lower back.
5. Prolia as my doctor prescribed is shown to improve bone strength significantly over the aforementioned drugs with little side effects.

6. My physician understands my health issues. The diet and intestinal intolerances I have experienced that caused my significant weight loss and muscle loss. This makes her much more qualified to direct my care.
7. Priority Health is not my doctor and therefore should not prescribe my medication which is essentially what they are doing by requiring me to take Reclast which will be harmful to my overall health and not improve my bone density and more importantly NOT what my doctor has prescribed. She knows that Prolia is the better drug for me.
8. Prolia is a covered drug by Priority Health
9. Paying \$700 a month for health insurance and then getting refused a drug prescribed by my doctor, that they do include in their covered drugs, is in my opinion unconscionable practice.

Respondent's Argument

In its final adverse determination to the Petitioner, Priority Health's appeals committee said:

Uphold denial – requested coverage will not be provided. [The Petitioner] does not currently meet the medical criteria for coverage of Prolia Injections. Specifically, medical records reviewed from the DXA Scan on October 30, 2014, indicate that [she] has osteopenia in the lumbar spine and osteopenia in the femoral neck.

The Appeal Committee noted that [the Petitioner] has spent a great amount of time researching her condition and the committee understands that [she] believes Prolia injections are her best treatment option. The Committee also questioned if Prolia is the most appropriate course of treatment for [her] and based on her most recent bone density study, the committee did not feel it was appropriate to make an exception at this time.

Director's Review

Priority Health will cover Prolia if precertification requirements are met:

Before this drug is covered, the patient must meet all of the following requirements:

1. Must have osteoporosis (males or postmenopausal females), be at high risk of fracture, and must first try: one formulary oral bisphosphonate (alendronate, Actonel, or ibandronate), and zoledronic acid (generic Reclast).
...

The question of whether the Petitioner meets the plan's criteria for injectable Prolia was presented to an independent review organization (IRO) for a recommendation 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 with a specialty in maternal and fetal medicine and is in active clinical practice. The IRO report included the following analysis and recommendation:

The enrollee does not have osteoporosis. She has osteopenia in both the lumbar and hip regions. It is important to recognize that the enrollee does not have osteoporosis. The provider in this case is focusing on the Ward's (Ward's Triangle) measurement of bone mineral density (BMD), which is not a true anatomic area but is generated by the DEXA, as the area of lowest bone mineral density in the femoral head. This area is not utilized in making a diagnosis of osteoporosis and is never included in the diagnosis of this condition according to the current standards of care. The femoral neck BMD, trochanter BMD, or total hip BMD as determined by the DEXA scan are used to diagnose osteoporosis. All of these measures are greater than -2.5 and would be considered osteopenia. The report from the enrollee's DEXA scan on [REDACTED] 2014 correctly identifies the enrollee's diagnosis as osteopenia in the spine and hip. There is no diagnosis of osteoporosis. The WHO recommends that the international standard for diagnosis of osteoporosis be made using the T-score measured by DXA at the femoral neck. However, the National Osteoporosis Foundation (NOF) and the International Society for Clinical Densitometry (ISCD) suggest that the diagnosis of osteoporosis in clinical practice be made by DXA using the lowest T-score of the lumbar spine (L1-L4), total proximal femur, or femoral neck. In the hip, Ward's area, trochanter, and other regions of interest (ROIs) should not be used for diagnosis. Prolia is approved by the Food and Drug Administration (FDA) for the treatment of osteoporosis and is NOT indicated or approved for osteopenia. Given the absence of long-term safety data and the availability of other agents, Prolia (denosumab) is not recommended for osteoporosis prevention. The United States FDA and the European Medicines Agency approved denosumab for the treatment of postmenopausal women with osteoporosis at high risk for fracture (history of osteoporotic fracture, multiple risk factors for fracture) or patients who have failed or are intolerant of other available osteoporosis therapies. In this case, Prolia is not indicated in this enrollee as she does not have osteoporosis, but rather has osteopenia for which this agent is not approved for use in treating.

* * *

In summary, the enrollee in this case has a diagnosis of osteopenia at the spine and femur. There is no evidence of osteoporosis and Prolia is not medically necessary for osteopenia.

Recommendation:

It is the recommendation of this reviewer that the denial issued by Priority Health for Prolia injections provided be upheld. [References omitted]

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 certificate of coverage. MCL 550.1911(15).

The Director, discerning no reason why the IRO's recommendation should be rejected in the present case, finds that Prolia injections are not medically necessary and therefore are not a covered benefit under the Petitioner's plan.

V. ORDER

The Director upholds Priority Health's February 27, 2015, final adverse determination. Priority Health is not required to prior authorize and cover the Petitioner's proposed Prolia injections.

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 Director of Insurance and Financial Services, Health Care Appeals Section, Post Office Box 30220, Lansing, MI 48909-7720.

Annette E. Flood
Director

For the Director:



Randall S. Gregg
Special Deputy Director