

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

In the matter of:

██████████

Petitioner

v

File No. 213194-001

Blue Cross Blue Shield of Michigan  
Respondent

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Issued and entered  
this 8<sup>th</sup> day of February 2023  
by Sarah Wohlford  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

On January 10, 2023, ██████████ (Petitioner) filed with the Director of the Department of Insurance and Financial Services a request for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* The request for review concerns prior authorization for a prescription drug.

The Petitioner receives health care benefits through Blue Cross Blue Shield of Michigan (BCBSM). Their benefits are described in BCBSM's *Simply Blue HSA with Rx Embedded Cost-Sharing Group Benefits Certificate LG*. The Director notified BCBSM of the external review request and asked for the information used to make its final adverse determination. BCBSM responded on January 17, 2023.

The Director assigned an independent review organization to analyze the medical issues in this appeal. The review organization submitted its report to the Director on February 1, 2023.

**II. FACTUAL BACKGROUND**

The Petitioner has osteoporosis (a condition that causes bones to become fragile) with history of fractures, scoliosis (a curved spine), and symptoms of reflux disease, which makes it difficult for her to swallow pills. Her doctor recommended the prescription drug Denosumab (Prolia). BCBSM denied the request on the basis that their medical policy criteria for coverage had not been met.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM issued a final adverse determination dated October 24, 2022, affirming its coverage denial. The Petitioner now seeks the Director's review of that final adverse determination.

### III. ANALYSIS

#### Respondent's Argument

In its final adverse determination, BCBSM wrote:

Our Medical Policy for Denosumab (Prolia) for the treatment of osteoporosis (a condition in which bones become weak and fragile) requires that you have completed 12 months of bisphosphonate therapy (a class of drugs that help prevent or slow down bone thinning) and it was not effective. Bisphosphonates can be given by mouth (such as Fosamax) or in the vein (such as Reclast). If you have a medical reason that prevents the use of a bisphosphonate by mouth, we require that you try a bisphosphonate in the vein. The information we received from your doctor shows that you're unable to take a bisphosphonate by mouth due to heart burn and stomach problems. Additionally, you've submitted information that you have chronic pain and want to avoid bisphosphonate medications because they can cause pain too. But Prolia can also cause pain as a side effect. We did not receive any information showing that you're unable to take a bisphosphonate in the vein. Therefore, we did not approve Prolia for you at this time. This review was performed by the plan Medical Director who is a licensed physician, board-certified in emergency medicine.

#### Petitioner's Argument

In the request for review the Petitioner wrote:

Since 1978, I have suffered with severe, chronic musculoskeletal pain as a result of a spinal fusion and scoliosis. Increased joint and muscle pain is a common side effect of the Bisphosphonate therapy class of drugs that BCBSM is requiring I take to treat my osteoporosis (hereafter "Bisphosphonate drug"). Based upon the concern and advice of my Physicians, this common side effect has prevented me from taking any Bisphosphonate drug.

In my case, my Physicians have recommended the medication Prolia as the preferred and superior alternative to treat my osteoporosis. Prolia is a twice a year injection that is a very effective drug in treating osteoporosis without the common side effects of joint and muscle pain. The Reclast infusion that BCBSM is requiring, is an annual infusion. Consequently, any adverse side effects could have debilitating consequences for the entire year following the infusion...

Reviewed against the specifics of my case, I respectfully request that you grant my appeal and rule that BCBSM should provide coverage for Prolia to treat my osteoporosis.

#### Director's Review

The certificate (page 175) defines covered services:

A health care service that is identified as payable in this certificate. Such services must be medically necessary, as defined in this certificate, and ordered or performed

by a provider that is legally authorized or licensed to order or perform the service. The provider must also be appropriately credentialed or privileged, as determined by BCBSM, to order or perform the service.

For prescription drugs: Drugs or supplies used to treat medical conditions, such as disposable needles and syringes when dispensed with insulin, or chemotherapeutic drugs.

The Director assigned an independent review organization (IRO) to help determine whether the prescription drug Denosumab (Prolia) is medically necessary for treating the Petitioner's condition. This review is required by section 11(7) of the Patient's Right to Independent Review Act, MCL 550.1911(7).

The IRO reviewer is a physician in active practice who is board certified in internal medicine and endocrinology, diabetes, and metabolism. The IRO reviewer's report included the following analysis and recommendation:

*Are the plan's criteria which denied coverage for Denosumab (Prolia) for the treatment of osteoporosis consistent with the standard of care? Please explain.*

No. The Endocrine Society guidelines on the management of osteoporosis recommend initial treatment with Prolia or bisphosphonate therapy [1,2]. Prolia has been shown to be superior to oral bisphosphonates at 12 months for effect on bone mineral density at the lumbar spine and in a second study treatment with Prolia resulted in greater bone mineral density at all measured skeletal sites and greater inhibitor of bone remodeling as compared intravenous bisphosphonates.

This patient is at very high fracture risk given her T-score of -3.1 in her lumbar spine and worsening bone density. Without Prolia, this patient will continue to be at high risk of a fragility fracture. The plan's criteria is not consistent with standard of care as Prolia is an appropriate initial therapy over bisphosphonate therapy for patients such as this one who is at high fracture risk as bisphosphonate therapy is not expected to sufficiently lower fracture risk.

*If they are, does the member meet these criteria for coverage of Denosumab (Prolia)? Please explain.*

Not applicable.

*If the plan's criteria are inconsistent with standard of care criteria, does the member meet standard of care criteria such that Denosumab (Prolia) is medically necessary? Please explain.*

Yes. This patient has post-menopausal osteoporosis and is at high fracture risk. Use of Prolia in this clinical situation is consistent with the Endocrine Society guidelines on the management of osteoporosis and the Prolia prescribing information. Without Prolia, this patient will remain at high fracture risk. The requested Prolia is medically necessary and consistent with standard of care.

The IRO reviewer recommended that the Director reverse BCBSM's denial of coverage.

The Director is not required to accept the IRO's recommendation. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). However, the 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(18)(b). The IRO's review 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(17).

The Director, discerning no reason why the IRO's recommendation should be rejected, finds that the prescription drug Denosumab (Prolia) is medically necessary, therefore, it is a covered benefit under the Petitioner's benefit plan.

#### IV. ORDER

The Director reverses BCBSM's October 24, 2022, final adverse determination. BCBSM shall immediately provide coverage for the prescription drug Denosumab (Prolia). See MCL 550.1911(19). Further, BCBSM shall, within seven days of providing coverage, furnish the Director with proof it has implemented this order.

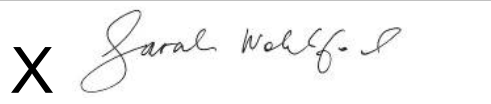
To enforce this order, the Petitioner may report any complaint regarding its implementation to the Department of Insurance and Financial Services, Office of Research, Rules, and Appeals, at this toll-free telephone number: (877) 999-6442.

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 Research, Rules, and Appeals, Post Office Box 30220, Lansing, MI 48909-7720.

Anita G. Fox  
Director

For the Director:

 Recoverable Signature



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Sarah Wohlford  
Special Deputy Director  
Signed by: Sarah Wohlford