

**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. 152426-001-SF**

**Michigan State University, Plan Sponsor**  
**and**  
**BCN Service Company, Plan Administrator**  
**Respondents**

---

**Issued and entered**  
**this 4<sup>th</sup> day of April 2016**  
**by Sarah Wohlford**  
**Special Deputy Director**

**ORDER**

**I. BACKGROUND**

On February 29, 2016, ██████████ (Petitioner) filed a request for external review with the Department of Insurance and Financial Services. The request for review concerns a denial of coverage issued by BCN Service Company (BCNSC) for the prescription drug Prolia. BCNSC is the administrator of the Petitioner's health benefit plan, which is sponsored by Michigan State University.

The request for external review was filed under Public Act No. 495 of 2006 (Act 495), MCL 550.1951 *et seq.* Act 495 requires the Director to provide external reviews to a person covered by a self-funded health plan that is established or maintained by a state or local unit of government. The Director's review is performed "as though that person were a covered person under the Patient's Right to Independent Review Act." (MCL 550.1952) The Petitioner's health benefit plan is a governmental self-funded plan.

The Director notified BCNSC of the appeal and asked it to provide the information used to make its final adverse determination. BCNSC furnished its response on March 7, 2016. On that date, after a preliminary review of the information submitted, the Director accepted the request for review.

This case involves medical issues, so the Director assigned it to an independent review organization which provided its analysis and recommendation to the Director on March 21, 2016.

## II. FACTUAL BACKGROUND

The Petitioner is [REDACTED] years old and has osteoporosis. Her rheumatologist prescribed the drug Prolia for treatment of her condition. BCNSC denied coverage.

The Petitioner appealed the denial through BCNSC's internal grievance process. At the conclusion of that process, BCNSC issued a final adverse determination on February 11, 2016, affirming the denial. The Petitioner now seeks the Director's review of the denial.

## III. ISSUE

Did BCNSC properly deny prescription drug coverage for Prolia?

## IV. ANALYSIS

### Respondent's Argument

In its final adverse determination, BCNSC stated:

We based our decision on the guidelines for coverage of this medication in the BCN Medical Policy. Since you cannot tolerate the oral bisphosphonates, treatment with intravenous bisphosphonates such as Reclast are recommended.

### Petitioner's Argument

In her request for an external review, the Petitioner wrote:

My physician has prescribed Prolia for osteoporosis. BCN has denied this and has recommended Reclast in spite of numerous side effects and against the recommendation of [REDACTED], a rheumatologist who specializes in osteoporosis issues.

The Petitioner's rheumatologist, in a letter dated February 2, 2016, wrote:

Patient has a history of osteopenia and was tried on Fosamax. This medication caused patient to have severe GI distress including nausea, vomiting, and severe heartburn. Since then patient has developed a fracture in the thoracic spine. This is causing severe pain and somewhat limited mobility.

At this time patient's diagnosis is osteoporosis. Patient is unable to tolerate oral medications. Prolia would be the best medication for her at this time. And this is a medical necessity to prevent future fractures.

### Director's Review

The Director assigned an independent review organization (IRO) to evaluate whether Prolia is medically necessary in the treatment of the Petitioner's osteoporosis. Such a review is 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 internal medicine, rheumatology, and allergy and immunology. The IRO reviewer's report included the following analysis and conclusion:

The member has a history of previous wrist and compression fractures with no active fractures at the time of the request for this medication. The member also has a history of gastrointestinal upset from oral bisphosphonates. A DEXA scan performed in October 2015 showed osteoporosis with continued worsening. The member has a history of normal kidney function and no pending dental issues or plans for major dental work. The member is reported to have gastrointestinal reflux and to be unable to take oral bisphosphonates. There is no history of contraindication to bisphosphonates or chronic kidney disease.

[G]iven the member's history, the current guidelines would recommend intravenous bisphosphonates (zoledronic acid) as the preferred agent for her. (Black DM. Clinical Practice. Postmenopausal Osteoporosis. *N Engl J Med*. 2016 Jan 21;374(3):254-62.) ... Reclast (zoledronic acid) is preferred if oral bisphosphonates cannot be tolerated: "In a large randomized trial involving women with low BMD, existing vertebral fractures, or both, a once-per-year infusion ( $\geq 15$  minutes) of 5 mg of zoledronic acid resulted in significantly lower rates of vertebral fractures (by 70%), hip fractures (by 41%), and nonvertebral fractures (by 25%) than the rates with placebo." (Black DM. Clinical Practice. Postmenopausal Osteoporosis. *N Engl J Med*. 2016 Jan 21;374(3):254-62.) ... Prolia is a recommended alternative in the member's case, and is relatively safe, but there are no long term safety data for it at this time as opposed to bisphosphates, which have been used for years. Prolia has the risks of hypocalcemia, osteonecrosis of the jaw, atypical femur fractures and serious infections. The Clinician's Guide to Prevention and Treatment of Osteoporosis states: "Denosumab is an alternative to IV zoledronic acid for women at high risk for fracture, difficulty with the dosing requirements of oral bisphosphonates, prefer to avoid intravenous bisphosphonates due to side effects, or have chronic kidney disease." (Cosman F, et al. Clinician's Guide to Prevention and Treatment of Osteoporosis. *Osteoporos Int*. 2014 Oct; 25(10):2359-81.) ... [D]enosumab (Prolia) is not cost effective and Reclast would be cost effective ... Reclast would be preferred in this member's case given her normal renal function and its efficacy, long term safety profile and cost effectiveness. Therefore ... there is a medical rationale for the use of Reclast rather than the requested Prolia in this member's case.

Pursuant to the information set forth above and available documentation ... Prolia is not medically necessary treatment of the member's condition.

(Lexicomp: denosumab. Black DM, et al. Once-yearly zoledronic acid for treatment of postmenopausal osteoporosis. *N Engl J Med.* 2007;356:1809-1822.)

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. The Director, discerning no reason why the IRO's recommendation should be rejected in the present case, finds that BCNSC's denial of prescription drug coverage for Prolia is consistent with the terms of the plan's coverage.

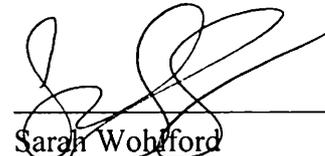
#### V. ORDER

The Director upholds BCN's final adverse determination of February 11, 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 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



---

Sarah Wohlford  
Special Deputy Director