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. 149272-001**

Blue Care Network of Michigan
Respondent

Issued and entered
this 10th day of September 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On August 10, 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*. After a preliminary review of the material submitted, the Director accepted the request on August 17, 2015.

The Petitioner receives health care benefits from Blue Care Network of Michigan (BCN), a health maintenance organization. The Petitioner's health care benefits are defined in BCN's *Certificate of Coverage BCN Classic for Large Groups*.

The Director notified BCN of the external review request and asked for the information it used to make its final adverse determination. The Director received BCN's response on August 19, 2015.

This case involves a medical issue so the Director assigned it to an independent review organization which submitted its recommendation on September 1, 2015.

II. FACTUAL BACKGROUND

In 2014, the Petitioner found a lump in her left breast that was tender and causing discomfort. Over the next year, the lump grew in size and became more painful. Her physician recommended that the lump be removed and biopsied. The Petitioner requested that BCN provide coverage for the outpatient procedure. BCN denied the request on April 7, 2015. The Petitioner proceeded with the surgery on April 8, 2015.

The Petitioner appealed the denial through BCN's internal appeal process. BCN held a Step Two grievance conference with the Petitioner in July 2015. At the conclusion of that process BCN issued a final adverse determination, dated July 16, 2015, affirming its denial. The Petitioner now seeks a review of that adverse determination from the Director.

III. Issue

Did BCN correctly deny coverage for the Petitioner's April 8, 2015 outpatient surgery?

IV. Analysis

Respondent's Argument

In its July 16, 2015 final adverse determination, BCN wrote to the Petitioner:

> Our Step Two grievance panel, which consisted of our Senior Medical Director, who is Board Certified in Psychiatry and the Director of the [redacted] Call Center, reviewed your request for retro authorization and reimbursement for surgery you had on 4/8/15, and upheld the previous denial. We based our decision on you not meeting the criteria for coverage for the stated surgery and prior notification you received that the authorization was denied.

In BCN's notes from the Step Two grievance conference, the BCN representative wrote that section 9.1 of the certificate specifies that

> BCN will only cover services that are provided by participating providers and are pre-authorized by BCN for selected services. In addition, this service was not considered medically necessary at the time of the request as it does not meet medical policy guidelines and, under Section 9.3, services that are not medically necessary are not covered....

Petitioner's Argument

In her request for external review, the Petitioner wrote:

> On April 8th, 2015, I had surgery on my left breast to remove a large lump. Before that, on April 7th; I was notified by my surgeon's office that my insurance had denied the procedure with no reasoning as to why. I ended up going ahead and paying out of pocket for the procedure due to the short notice of the denial and that I had been suffering for long enough not to wait another 60-180 day period for the insurance company to make a decision.
>
> The lump in my left breast had started out as a nickel sized lump near my armpit and I discovered it last March. I immediately went to my family doctor and he sent me for mammogram and ultrasound. Those all came back with results of

> dense breast tissue and to return in a few years' time when mammograms became a part of my yearly physicals.
>
> Over the last year, that lump grew into a painful large lump that took up a good third of my left breast and caused significant daily pain.
>
> * * *
>
> I went to see the breast surgeon for a consult....[S]he informed me that I could have a surgical procedure to remove the majority of the lump that caused the pain and she could do a biopsy to confirm it was fibrocystic and not anything cancerous.
>
> I waited for a few days, and decided to go ahead and schedule the procedure through the surgeon's office for April 8th based on the knowledge I had.
>
> Then the insurance company denied me, stating that the reason on my sheet was breast pain and that was not an acceptable reason....I went ahead with the surgery because I was tired of waiting and waiting in pain trying all the alternatives to surgery and worrying that I might have something cancerous or worse growing in my body.

Director's Review

Under BCN's *Classic for Large Groups* certificate of coverage, outpatient surgical treatment is a covered benefit when medically necessary and preauthorized by a member's treating physician and BCN. (Page 32.) The certificate also provides that services that are not medically necessary are not covered. (Page 52.)

In this case, the request for authorization was denied the day before the surgery. BCN stated in the final adverse determination that the Petitioner did not meet the criteria for coverage. The final adverse determination did not specify those criteria nor did it identify where the criteria could be found. In the notes of the Step Two grievance conference BCN staff did list eleven factors which BCN seemed to indicate would support the need for the surgery. BCN indicated that the criteria were to be found in its "Medical Policy criteria for Excision of Breast Lesions." BCN did submit to the Director a copy of a document titled "Excision of Breast Lesions" but that document did not include any factors BCN listed in its grievance conference notes. In fact, the "Excision of Breast Lesions" document explicitly states that there are no inclusionary or exclusionary guidelines that "support individual consideration and pre-authorization decisions." Further, the document includes a "Medical Policy Statement" which provides:

> The safety and effectiveness of excision of breast cysts or lesions have been established. It can be a useful diagnostic and/or therapeutic measure when the nature (pathology) of a lesion cannot be determined by less invasive means.
>
> **Rationale:**
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> Breast pathology including cancer can be detected as a well-defined mass by physical exam or with imaging studies. There can also be "suspicious" lesions

> that can present diagnostic dilemmas. In the above situations an attending physician may determine that it is necessary to excise the lesion for diagnostic and/or therapeutic reasons. This decision is supported by the current standard of medical care.

The determination by the Petitioner's physician that excision was the appropriate medical treatment was evaluated by an independent medical organization (IRO) as required by MCL 550.1911(6). The IRO physician reviewer is a physician in active practice who is certified by the American Board of Surgery and is an assistant professor of surgery at a university based hospital. The IRO reviewer's report included the following analysis and recommendation:

> It is the determination of this reviewer that the breast biopsy on April 8, 2015 was medically necessary for the treatment of the enrollee's condition.
>
> **Clinical Rationale for the Decision:**
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> In the past, the gold standard for diagnosing a palpable or non-palpable breast mass was to fully excise it out. Core needle biopsy (CNB) has now become the standard of care for *diagnostic purposes*. As noted by guidelines by The American Society of Breast Surgeons (ASBS), CNBs [are] sufficient for the diagnosis of most benign breast lesions and more than 90% of breast cancers. The ASBS goes on to state that diagnostic excisional biopsies should be the exception and not the rule.
>
> The ASBS states the current indications for excisional breast biopsy include:
>
> 1. Discordance between imaging characteristics (mammographic/ sonographic/magnetic resonance image) and core biopsy histology
> 2. Nondiagnostic specimen from core biopsy (i.e., insufficient material, lack of calcifications, hemorrhage)
> 3. Lesion anatomically unsuitable for core biopsy (lesion too far anterior, too far posterior, too close to breast implant)
> 4. Patient anatomically unsuitable (breast tissue too thin, patient too large for biopsy table)
> 5. Suspicious interval changes in a lesion previously diagnosed benign by core biopsy
> 6. Atypical hyperplasia (duct or lobular) or LCIS [lobular carcinoma in situ] on core biopsy
> 7. Papillary and/or sclerosing lesion on core biopsy
> 8. "Fibroepithelial lesion" (i.e., fibroadenoma vs. benign phyllodes tumor) on core biopsy
> 9. Suspicious nipple discharge with normal breast imaging
>
> The ASBS also makes it clear that guidelines are just guidelines. Excisional biopsy may be appropriate without the need for CNB as a preceding step based on the following:

1. clinical circumstances
2. physician judgment
3. patient preference
4. scientific evidence as it evolves

The enrollee had noted in her letters that she had felt a lump in her left breast. [redacted] also documented dense tissue in the LUOQ of the breast in her history and physical note. Though the surgeon did not use the term mass, she did note dense tissue in the area of concern of the left breast corresponding to the patient's feel of a lump. It was documented by [redacted] that various modalities were tried over a year's time and no resolution of the area of concern and its concomitant symptoms were noted.

The persistence of the mass felt by the enrollee, the documented long period of tenderness of the site in question, the lack of findings on imaging studies and yet the palpability of a density or thickening would not have changed the need for excisional biopsy. To make the matter even more clear, most women do not want to feel a mass in their breast, so excision of a *palpable* mass is almost always done even if fine needle aspiration biopsy (FNAB) or CNB had been done. However, regarding non-palpable breast masses, almost all surgeons would agree that CNB or FNAB should be done *prior* to excision.

In other words, excision was being done *therapeutically* as well as diagnostically. Do most women with a palpable breast lump want to leave it even if it was benign? Common sense dictates that most women would want the mass removed, especially one that is tender and been present for a long time.

The omission of performing a CNB in this case does not diminish the indication to proceeding with excisional biopsy. Though some would disagree with not performing a CNB first, in this particular case, reasonable disagreement about the approach would not be out of the norm.

* * *

In this case, the enrollee is premenopausal and had very dense breasts noted on mammography along with a mass or density felt by the patient for almost one year and a density noted by her surgeon. Furthermore, there was no corresponding mass noted on imaging studies to perform image-guided FNAB or CNB. Excision of the mass was done for diagnostic and therapeutic reasons.

Recommendation:

It is the recommendation of this reviewer that the denial issued by Blue Care Network of Michigan for the breast biopsy on April 8, 2015 be overturned. [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 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 this case, finds that the breast biopsy was medically necessary to treat the Petitioner's condition and is a covered benefit.

V. ORDER

The Director reverses BCN's July 16, 2015 final adverse determination. BCN shall immediately provide coverage for the Petitioner's April 8, 2015 excision breast biopsy and related services. See MCL 550.1911(17). BCN shall, within seven days of providing coverage, submit to the Director 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, Health Care Plans Section, toll free 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 sixty 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 General Counsel, Post Office Box 30220, Lansing, MI 48909-7720.

Patrick M. McPharlin
Director

For the Director:

Randall S. Gregg
Special Deputy Director