STATE OF MICHIGAN

DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES

Before the Director of Insurance and Financial Services

In the matter of:

Petitioner

v

Blue Care Network

Respondent

File No. 148913-001

Issued and entered
this 21st day of August 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. BACKGROUND

On July 22, 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 prescription drug coverage from Blue Care Network (BCN), a health maintenance organization (HMO). The benefits are described in BCN's *High Deductible Health Plan for Individuals Certificate of Coverage*. The Petitioner's coverage became effective on March 1, 2015.

The Director notified BCN of the external review request and asked for the information it used to make its final adverse determination. BCN provided its response on July 23, 2015. On July 29, 2015, 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. The IRO provided its analysis and recommendation to the Director on August 12, 2015.

II. FACTUAL BACKGROUND

Prior to her enrollment with BCN, the Petitioner's health benefits were provided by Blue Cross Blue Shield of Michigan (BCBSM). While the BCBSM coverage was in effect, the

Petitioner was treated for menopausal symptoms with the Vivelle-Dot patch. BCBSM provided coverage for this drug.

The Petitioner's physician requested that BCN provide coverage for the continued use of the Vivelle-Dot patch. BCN denied the request, ruling that the drug was excluded under its *Custom Select Drug List*. The Petitioner's physician then prescribed an alternative drug, the estradiol transdermal patch, which BCN does cover. The Petitioner found that she experienced several side effects and found it to be ineffective.

At that point, the Petitioner appealed, through BCN's internal grievance process, the denial of coverage for the Vivelle-Dot patch. At the conclusion of the grievance process, BCN issued a final adverse determination on June 15, 2015, affirming its denial. The Petitioner now seeks a review of the final determination from the Director.

III. Issue

Did BCN properly deny prescription drug coverage for the Vivelle-Dot patch?

IV. Analysis

On her external review request form, the Petitioner explained why she was seeking coverage for the brand name prescription drug Vivelle-Dot patch:

> Prior to Jan. 2015, I had BCBS. They covered the Vivelle-Dot patch I was on for years with no problems....In Jan. 2015 BCN said they only approve the generic patch. I used it and have been getting my period every 2 weeks.
>
> The pharmacist, the doctor, and I all say it's the generic and I need to get back on Vivelle-Dot. I even had an ultrasound which was normal. (The pharmacist and doctor have or rather know of others experiencing the same problems as I, because of the switch.)
>
> Please OK the Vivelle-Dot patch so BCN will at least pay something....

In a letter dated July 20, 2015, Petitioner's physician explained why the brand name Vivelle-Dot patch is medically necessary:

> The above named patient is under my care here at Age Management of West Michigan. She was previously on Vivelle patch (brand name) and had great management of her menopausal symptoms.
>
> She was then switched to the generic version which caused multiple problems and was not effective. She since has had a pelvic ultrasound that resulted normally.

> The brand name Vivelle patch is much more effective for treating her menopausal symptoms and she has not had the side effects that she is currently experiencing with the generic version of the patch.

BCN denied authorization for Vivelle-Dot since it was not listed as a covered drug on its *Custom Select Drug List* for the Petitioner's benefit plan. However, section 3406o of the Michigan Insurance Code, MCL 500.3406o, requires insurers and HMOs offering prescription drug coverage to provide an exception from the formulary limitation when a nonformulary alternative is a medically necessary and appropriate alternative.

The question of whether Vivelle-Dot is medically necessary for treatment of the Petitioner's condition was presented to an independent review organization (IRO) for analysis 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 who has been in active practice for more than 15 years and who is board certified in obstetrics and gynecology. The reviewer is familiar with the medical management of patients with the member's condition. The IRO reviewer's report included the following analysis and conclusion:

> The member is using Vivelle-Dot patches for menopausal symptoms. The member tried the estradiol transdermal patch that is covered by the Health Plan and had abnormal bleeding as well as difficulty with the patch sticking. The Health Plan stated that Climara and Alora patches are alternatives that are covered by the member's plan.
>
> The member had side-effects from a generic version of the transdermal patch. However…the member has not tried other covered transdermal preparations to see if they are effective without side-effects. [T]herefore, brand name Vivelle-Dot is not medically necessary at this time.

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 can discern no reason why the IRO's recommendation should be rejected in the present case. The Director finds that BCN's denial of coverage for Vivelle-Dot is consistent with the terms of the certificate and Michigan law.

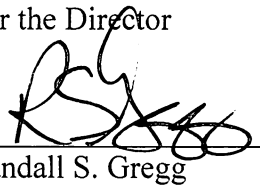
V. ORDER

The Director upholds BCN's June 15, 2015 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