STATE OF MICHIGAN

DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES

Before the Director of Insurance and Financial Services

In the matter of:

[redacted]
Petitioner

v **File No. 150242-001**

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 6th day of November 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On October 7, 2015, [redacted] (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 October 14, 2015.

The Petitioner receives health care benefits through a group plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). Her prescription drugs benefits are defined in BCBSM's *Blue Cross Premier Gold Benefits Certificate* and BCBSM's *Custom Select Drug List*.

The Director notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. BCBSM provided its response on October 19, 2015.

The Director assigned an independent medical review organization to analyze the medical issues in the case. The report was submitted to the Director on October 28, 2015.

II. FACTUAL BACKGROUND

The Petitioner, who is [redacted] years old, has a history of menopausal symptoms. She has been taking the prescription drug Vivelle-Dot, a brand name estradiol patch to control vasomotor symptoms. She tried the Mylan estradiol transdermal patch system, a generic equivalent to Vivelle-Dot, but it caused a number of adverse symptoms and was not as effective. As a result,

her physician requested that BCBSM authorize continued prescription drug coverage for Vivelle-Dot. BCBSM denied the request.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM affirmed its denial in a final adverse determination dated August 12, 2015. The Petitioner now seeks a review of that adverse determination from the Director.

III. Issue

Did BCBSM correctly deny coverage for the prescription drug Vivelle-Dot?

IV. Analysis

BCBSM's Argument

In its final adverse determination to the Petitioner, BCBSM wrote:

> A Clinical Pharmacist, RPh, reviewed your claim, your appeal, and your health care plan benefits for Blue Cross Blue Shield of Michigan (BCBSM) and determined the following:
>
> > "Your Custom Select drug plan does not cover brand name drugs when a generic product is available. The requested brand name drug, Vivelle-Dot, has a generic available and is therefore excluded from the prescription benefit. Other covered options include: generic Climara patch, Alora patch, Minivelle patch."

Petitioner's Argument

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

> I have previously submitted an internal review and was denied despite my physician's request for Blue Cross Blue Shield of Michigan to continue supplying the same Vivelle estradiol transdermal system that they had been covering for the last many years. I submitted a prescription and was sent Mylan instead. I tried it for a number of weeks and found the following, as reported by my physician previously:
>
> - Extreme skin irritation. Each spot takes well over a week to calm down. I can email a picture if needed.
> - Sleep interruption. I used to sleep continuously through the night and now awake 2-3 times.
> - I have breakthrough hot flashes.

- I have a low-grade headache often and given my allergy to aspirin, I am not able to take anything for it except Tylenol which does not help.

None of these were present with Vivelle. To have to increase a dosage of an ineffective drug is not an effective or safe solution.

The Petitioner's physician wrote an appeal letter dated July 8, 2015, explaining her need for Vivelle-Dot:

> The generic estradiol patch is not effectively treating her vasomotor symptoms and in addition causes a skin irritation resulting in rash and discomfort. As such, this requires name brand Vivelle-Dot....

Director's Review

BCBSM's *Premier Gold Benefits Certificate* states on page 85: "we do not pay for brand-name drugs with a generic equivalent available...."

The question of whether brand name Vivelle-Dot is a medically necessary and appropriate alternative for treatment of the Petitioner's condition was presented to an independent review organization (IRO) 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 in active clinical practice for more than 12 years who is board certified in obstetrics and gynecology. The reviewer's report included the following analysis and recommendation:

> The member was on Vivelle-Dot estradiol patches for vasomotor symptoms. This was substituted for a generic. The member stated that she developed a skin irritation and rash. The member also stated that she had breakthrough hot flashes on the generic. The Health Plan stated that other patches are available through the member's plan, including generic Climara, Alora and Minivell.
>
> [T]he member had skin irritation from the generic version of Vivelle-Dot and is unable to use this preparation. However...there are other generic hormone replacement therapy options available to the member....[I]t would be reasonable for the member to try these formulary transdermal hormone replacement therapy preparations to relieve her menopausal symptoms.
>
> Pursuant to the information set forth above and available documentation... Vivelle-Dot is not a medically necessary and appropriate alternative for treatment of the member's condition at this time. ([redacted], et al. Preparations for menopausal hormone therapy. UptoDate. Literature review current through September 2015.)

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 recommendation is not contrary to any provision of the Petitioner's certificate of coverage. MCL 550.1911(15). The Director can discern no reason why the IRO's recommendation should be rejected in the present case.

The Director finds that Vivelle-Dot is not a medically necessary and appropriate alternative to generic drugs for which BCBSM does provide coverage.

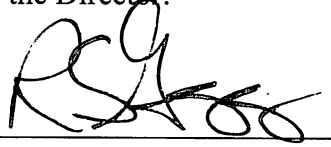
V. ORDER

The Director upholds BCBSM's final adverse determination of August 12, 2015.

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 General Counsel, Post Office Box 30220, Lansing, MI 48909-7720.

Patrick M. McPharlin
Director

For the Director:



Randall S. Gregg
Special Deputy Director