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. 148186-001**

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 9th day of July 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On June 4, 2015, , authorized representative of , (Petitioner) filed a request with the Department of Insurance and Financial Services for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et* seq. On June 11, 2015, after a preliminary review of the information submitted, the Director accepted the request.

The Petitioner receives health care benefits through an individual plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The Petitioner's health care benefits in 2013 were described in BCBSM's *Flexible Blue II Individual Market Certificate* which became effective on May 15, 2013. Subsequently, the Petitioner had coverage under BCBSM's *Blue Cross Premier Silver Benefits Certificate* which became effective on January 1, 2014. She had no break in coverage between the two benefit plans.

The medical issues in this case were evaluated by an independent review organization which provided its analysis and recommendation to the Director on June 25, 2015.

II. FACTUAL BACKGROUND

The Petitioner has been diagnosed with recurrent glioblastoma multiforme (GBM), an aggressive form of brain cancer. Her oncologist prescribed treatment with a device known as the Novo-TTF 100A System, manufactured by Novocure, Inc., a New Hampshire Company.

The Petitioner's treatment began October 25, 2013 and continued through March 25, 2015. In total, 19 treatments were performed at a cost of $359,500.00.

BCBSM denied coverage, ruling that the four treatments in 2013 were ineligible for coverage because of the pre-existing treatment exclusion in the *Flexible Blue II* certificate of coverage. BCBSM also asserted that the Novo-TTF program is experimental/ investigational and, for that reason, is not covered under either certificate of coverage.

The Petitioner appealed BCBSM's denial of coverage through BCBSM's internal grievance process. On May 4, 2015, at the conclusion of that process, BCBSM issued a final adverse determination affirming its denial. The Petitioner now seeks review of that determination from the Director.

III. Issue

1. Was the 2013 treatment of the Petitioner's GBM, ineligible for coverage as treatment of a pre-existing condition?
2. Is the Novo-TTF treatment program experimental or investigational for treatment of the Petitioner's condition?

IV. Analysis

BCBSM's Argument

In its May 4, 2015 final adverse determination to the Petitioner, BCBSM stated its reasons for denial:

> A board-certified M.D. in Internal Medicine reviewed the claims, your appeal including the medical records and literature submitted with the appeal; and [the Petitioner's] health care plan benefits for [BCBSM]. The services provided in 2013 were denied because the criteria for a waiver of the pre-existing conditions were not met.
>
> In addition, the denial of payment for the services provided in 2014 is maintained because the service is deemed experimental/investigational....
>
> In 2013, [redacted] was covered under the *Flexible Blue II Individual Market Certificate*. As explained in **Section 1: Information About Your Contract**, on page 1.6; Contract dates:
>
> > **When Your Benefits Begin**
> >
> > Unless noted otherwise, all covered services and benefits are subject to a 180-day waiting period for pre-existing condition. This 180-day waiting period begins on the first day your coverage become effective, not on the date your applicable was submitted.
>
> In this instance, the effective date of [Petitioner's] Flexible Blue II health care plan on May 15, 2013. [Petitioner] had a consultation on May 13, 2013 for a diagnosis of glioblastoma. [Petitioner's] treatment with the Novo-TTF 100A System plus transducers

> began on October 25, 2013 within the 180-day waiting period and as a result it is not a benefit under the health care plan.
>
> In addition, the BCBSM/BCN Joint Uniform Medical Policy Committee (JUMP) has determined that the service is investigational.
>
> * * *
>
> An investigational status means that the safety and effectiveness of a particular technology has not been definitively determined. An established technology means that the safety and effectiveness has been definitively determined. Investigational medical policies are reviewed regularly to guarantee that the investigational status continues to be supported by the evidence.
>
> In 2014 [Petitioner's] health care plan changed. As of January 1, 2014 she was covered under the *Blue Cross Premium Silver Benefits Certificate*. As explained on page 140 of the certificate we do not pay for experimental treatment (including experimental drugs or devices) or services related to experimental treatment.
>
> A board-certified M.D. in Internal Medicine reviewed the claims, your appeal including the medical and literature submitted with the appeal...and [Petitioner's] health care plan benefits for BCBSM.
>
> After review, the medical consultant determined according to BCBSM medical policy titled "Tumor-Treatment Fields Therapy for Glioblastoma" tumor-treatment fields for treatment of glioblastoma is not an established therapy. The effectiveness in this clinical indication has not been established. As a result the service is considered experimental/investigational.

Petitioner's Argument

The Petitioner's authorized representative argues that the Novo-TTF treatment is not experimental or investigational. It has been approved by the U.S. Food and Drug Administration. She states that the National Comprehensive Cancer Network supports its use in patients like the Petitioner.

The Petitioner's oncologist submitted a letter dated March 17, 2015 explaining why he believes the treatment should be covered:

- The Petitioner's GBM is an orphan disease and there is a lack of treatment options;
- Many other insurers do provide coverage for the requested treatment;
- The Novo TTF-100A is the most promising treatment option for the Petitioner;
- Since the treatment began, the Petitioner has experienced a striking decrease in the size of her tumor.

Director's Review

Issue 1 – Pre-existing Conditions

The *Flexible Blue II* certificate that was in effect in 2013 included a 180-day waiting period for pre-existing conditions. A pre-existing condition is defined in the certificate as:

> A condition for which medical advice, diagnosis, care or treatment was recommended or received within the 180-day period ending on the enrollment date.

The *Flexible Blue II* certificate, on page 1.6, explains the waiting period:

> **When Your Benefits Begin**
>
> Unless noted otherwise, all covered services and benefits are subject to a 180-day waiting period for pre-existing conditions. This 180-day waiting period begins on the first day your coverage becomes effective, **not** on the date your application was submitted. **This 180-day waiting period does not apply to covered members who are less than 19 years of age.**
>
> For members over the age of 19, the 180-day pre-existing condition waiting period will not apply if:
>
> - You have creditable coverage and meet the following:
> - There was no more than a 62-day break in your prior coverage
> - You did not lose your prior coverage because of nonpayment of your premium or for fraud
> - Your most recent coverage was with a group (even if the coverage was only for one day)
>
> **Note**: If you were eligible for COBRA when your prior group coverage ended, you must have elected and exhausted COBRA coverage in order for your creditable coverage to eliminate the pre-existing waiting period.
> - You transferred from a prior BCBSM nongroup or group conversion certificate to this certificate with no lapse in coverage **and** your prior certificate did not include a waiting period.

No information was submitted concerning any insurance the Petitioner may have had prior to her *Flexible Blue II* coverage. In the Petitioner's case, then, the waiting period began May 15, 2013 and ended November 11, 2013.

The Petitioner had received medical advice and treatment for her GBM in the 180 day period before her *Flexible Blue II* certificate became effective. Therefore, her GBM treatment was excluded until November 11, 2013. The Petitioner's October 25, 2013 treatment is excluded from coverage as treatment of a pre-existing condition. The other 2013 treatments were not subject to the pre-existing condition exclusion. However, coverage for all the Novo-TTF treatments is determined by the experimental/investigational exclusion discussed below.

Issue 2 – Experimental/Investigational Treatment

Both of the Petitioner's health benefit plans exclude coverage for experimental and investigational medical services. Section 7 of the *Flexible Blue II* and Section 6 of the *Blue Cross Premium Silver* certificates of coverage provide:

> Services That Are Not Payable
>
> We do not pay for experimental treatment....

Both certificates define experimental treatment as:

> Treatment that has not been scientifically proven to be as safe and effective for treatment of the patient's conditions as conventional treatment. Sometimes it is referred to as "investigational" or "experimental services."

To determine whether the Novo-TTF 100A System is experimental/investigational for the treatment of Petitioner's condition, the Director presented the issue 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 in active practice who is certified by the American Board of Internal Medicine with a subspecialty in medical oncology. The reviewer is an assistant professor at a university based school of medicine, has been a principal investigator of clinical trials, and is published in peer reviewed medical literature. The reviewer's report included the following analysis and recommendation:

> **Reviewer's Decision and Principal Reasons for the Decision**:
>
> It is the determination of this reviewer that the Novo TTF-100A System is considered experimental/investigational for the treatment of the enrollee's condition.
>
> **Clinical Rationale for the Decision**
>
> The Novo TTF-100A system has not been shown to be effective for the treatment of GBM. The enrollee has GBM that has progressed after resection, Chemo radiation and treatment with Temozolomide. The standard of care for this clinical situation is treatment with Bevacizumab, Bevacizumab+Chemotherapy (Irinotecan, Carmustine/Lomustine), Lomustine or Carmustine, combination chemotherapy with PCV or platinum-based regimens.
>
> The Novo TTF-100A is FDA approved for treatment of recurrent GBM. However, the medical or scientific evidence does not demonstrate that the expected benefits of the requested health care services are more likely to be beneficial to the enrollee than any available standard health care service.
>
> * * *
>
> The National Comprehensive Cancer Network (NCCN) is an organization formed by the nation's NCI-designated comprehensive cancer centers. The NCCN publishes guidelines

> for the treatments of most cancers. Guidelines are evidence-based and are written by panel experts drawn from the member institutions....
>
> There is no consensus within the NCCN panel that this device is effective for GBM.
>
> * * *
>
> **Recommendation**
>
> It is the recommendation of this reviewer that the denial issued by [BCBSM] for the Novo-100A System be upheld.

While the Director is not required in all instances to accept the IRO's recommendation, the recommendation is afforded deference by the Director. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). 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. See MCL 550.1911(15).

The Director, discerning no reason why the IRO's recommendation should be rejected in the present case, finds that the Novo-TTF 100A System is experimental/investigational for the treatment of the Petitioner's condition and, for that reason, is not a covered benefit.

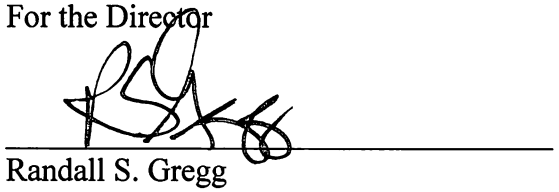
V. ORDER

BCBSM's final adverse determination of May 4, 2015 is upheld. BCBSM is not required to provide coverage for the Petitioner's Novo TTF-100A treatment.

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 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