

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. 149562-001

Blue Cross Blue Shield of Michigan  
Respondent

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Issued and entered  
this 28<sup>th</sup> day of September 2015  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

On August 26, 2015, ██████████ (Petitioner) filed with the Department of Insurance and Financial Services a request for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* The Director accepted the request on September 2, 2015.

The Petitioner receives health care benefits through a group plan underwritten by Blue Cross Blue Shield of Michigan Mutual Insurance Company (BCBSM). The Petitioner's health care benefits are described in BCBSM's *Simply Blue HSA Group Benefits Certificate with Prescription Drugs for Large Groups*.

The case involves medical issues so it was assigned to an independent review organization which provided its analysis and recommendation to the Director on September 17, 2015.

**II. FACTUAL BACKGROUND**

The Petitioner was diagnosed with multiple sclerosis in 1997. She has been treated with the drugs Avonex and Copaxone but her condition continued to worsen. Her physician requested that BCBSM provide coverage for an autologous bone marrow transplant. The procedure is known as hematopoietic stem cell therapy, or "HSCT."

BCBSM denied the request, ruling that the requested treatment is investigational in the treatment of the Petitioner's condition. The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM issued a final adverse

determination dated July 27, 2015 affirming its decision. The Petitioner now seeks review of that determination from the Director.

### III. ISSUE

Is an autologous bone marrow transplant investigational for treatment of the Petitioner's condition?

### IV. ANALYSIS

#### BCBSM's Argument

In its July 27, 2015 final adverse determination to the Petitioner, BCBSM representatives explained its denial:

[A] board-certified M.D. in Internal Medicine reviewed your appeal and determined the following:

It is my understanding that your provider, [REDACTED] of [REDACTED] [REDACTED] Hospital, is recommending an autologous stem cell transplant for your secondary progressive multiple sclerosis. When you were initially diagnosed in 1997, Solu-Medrol was prescribed. Since then you have been treated with extended courses of both Avonex and Copaxone according to the submitted medical records. Currently, you are experiencing relapses, and rather than proceed with other drug regimens such as Tysabri or Gilenya, a stem cell transplant is being sought. You were not eligible to participate in the clinical trial "Stem Cell Therapy for Patients with Multiple Sclerosis Failing Alternative Approved Therapy."

The initial request for this procedure was submitted to BCBSM and denied after review of the medical documentation and discussion with [REDACTED]

Additional documentation shared by you, your family, and [REDACTED] was reviewed. The denial is upheld. According to BCBSM medical policy, "BMT-Stem Cell Transplantation for Autoimmune Diseases," an autologous stem cell transplant when used to treat multiple sclerosis regardless of the stage is considered experimental/investigational. There is inadequate published evidence that supports the effectiveness of this treatment with progressive forms of Multiple Sclerosis.

#### Petitioner's Argument

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

I have been denied by BCBSM for HSCT for my Multiple Sclerosis. I need to have this treatment to stop this disease. I want this decision reversed so that I can

have this treatment. The procedure would use chemo to erase my faulty immune system and then rebuild it with my own stem cells.

In an undated letter filed with the request for an external review, the Petitioner further stated:

I am responding to my recent denial for Hematopoietic stem cell transplantation, due to the reason it is considered experimental/investigational. Are you aware it is fully expected that the treatment will be approved by the FDA by the year 2022. If I have to wait until then for this treatment, I will be forced to use one of the DMD drugs to “hopefully” slow the progression of my disease. I can’t wait that long. I will have transitioned fully into Secondary Progressive MS by then.

If I have to use a DMD, I would probably choose Copaxone because it seems to have the least side effects. But in the meantime from now until 2022, the cost of the medication could have better spent on the HSCT. The cost of one month of Copaxone is \$7,964.69 at my local pharmacy. That would mean \$669,033.96 over the next 7 years. According to the document published in January for the HALT-MS Study, 86% of participating remained relapse-free after 3 years and 91% showed no sign of disease activity. Three years of prescriptions would cost \$286,728.84. The HSCT costs around \$140,000. So that would be a savings of about \$146,728.84. If the procedure was only effective for the minimum of three years, I still would have saved the cost of the procedure. In addition, I have spoken to people that have successfully had the treatment and after 3 plus years still show no trace of activity. And that is not adding on any of the other medications related to MS or physical therapy.

There are other countries that also are performing this procedure. Many people are going to other countries because they can’t get approved for it here. Russia in high demand for this because it has the lowest out of pocket cost. But the waiting list for Russia is already into 2018. Why can’t we get it done on our own country? I don’t expect that this procedure will be a miracle and all my current problems will disappear but I am confident that I would not continue to progress. I can’t say that with the DMD medications. If those had been effective, I probably would never have broken my knee cap from a fall. I want to live my life knowing that I have a chance to NOT end up in a wheelchair and needing full time home health care.

Petitioner also provided letters from her family and material from medical publications to support her argument that the procedure is medically necessary.

#### Director’s Review

The *Simply Blue* certificate (page 140) excludes coverage for investigational/experimental services. Section 7 (page 158) of the certificate defines 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 evaluate the question of whether an autologous bone marrow transplant is investigational for treatment of the 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 IRO 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 autologous bone marrow transplant is considered experimental/investigational for the treatment of the enrollee's condition.

Clinical Rationale for the Decision:

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The medical evidence does not demonstrate that the expected benefits of the requested health care services are more likely to be beneficial than any available standard health care services. Autologous stem cell transplantation as treatment for Multiple Sclerosis has been studied for seventeen years. To date, the results of over 600 transplants for multiple sclerosis have been reported.

The issue with the use of autologous transplantation as treatment of MS include:

1. No controlled, comparative studies have been performed. All are case studies, or small phase II clinical trials.
2. There is no standardization of the conditioning regimen for transplant, and a variety have been used.
3. The characteristics of the patients who may most benefit from transplant are unclear; whether it should be attempted early in the course of the disease or later in the course of the disease.
4. Although more intense conditioning regimens may provide better prevention of relapse, more intensive conditioning regimens also produce greater cognitive toxicity in patients with MS.

Given all these unanswered issues, the effect of autologous stem cell transplantation as treatment for MS on health outcomes is unknown. As such, it remains investigational and is the subject of ongoing clinical trials.

The FDA does not oversee autologous hematopoietic stem cell transplant. The drugs used in the transplant procedure are FDA-approved.

The enrollee has multiple sclerosis (MS). She was diagnosed almost twenty years ago, and has continued symptoms. Based on the documentation submitted for review and current medical literature as noted above, the autologous bone marrow transplant is considered experimental/investigational for the treatment of the enrollee's condition. [References omitted.]

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 an autologous bone marrow transplant is experimental/investigational for treatment of the Petitioner's condition and is therefore not a covered benefit.

#### V. ORDER

BCBSM's final adverse determination of July 27, 2015 is upheld.

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



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Randall S. Gregg  
Special Deputy Director