

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. 151140-001

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 6th day of January 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On December 3, 2015, ██████████, father and authorized representative of ██████████, 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.* On December 10, 2015, after a preliminary review of the information submitted, the Director accepted the request.

The Petitioner receives health care benefits through a plan underwritten by BCBSM. The benefits are defined in BCBSM's *Blue Cross Premier Gold Benefits Certificate*. The Director notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. BCBSM responded on December 15, 2015.

The case involves medical issues so it was assigned to an independent review organization which submitted its analysis and recommendation on December 21, 2015.

II. FACTUAL BACKGROUND

The Petitioner has Crohn's disease. Since 2006, he has received various treatments without success. His physician recommended that he have a stem cell procedure performed in South Korea as his best option since they are not yet performed in the United States. In July 2015, the Petitioner's requested that BCBSM approve coverage for the surgery. BCBSM denied the request, ruling that the procedure was investigational or experimental for the Petitioner's

condition and therefore is not a covered benefit. The Petitioner proceeded with the surgery in August 2015 and appealed the coverage denial through BCBSM's internal grievance process. At the conclusion of that process BCBSM issued a final adverse determination dated October 29, 2015, affirming its denial. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Was the stem cell procedure experimental or investigational for the treatment of the Petitioner's condition?

IV. ANALYSIS

BCBSM's Argument

In its final adverse determination, BCBSM wrote:

A board certified D.O. in Internal Medicine reviewed this appeal and [Petitioner's] health care plan benefits for [BCBSM] and determined the following:

On Wednesday, October 21, 2015, a managerial-level conference was conducted with ██████████ regarding our member and [Petitioner] who has a diagnosis of refractory Crohn's disease. ██████████ was discussing the denial of prior authorization for a stem cell injection into the fistulous tissue of [Petitioner's] Crohn disease in an attempt to promote healing to the area. ██████████ explained that all standard medical and/or surgical therapies had been tried, failed, and that the disease is progressive, resulting to make a poor quality of life as the result of the disease progression for [Petitioner]. Further, ██████████ compared [Petitioner's] situation to a "cancer diagnosis" in that all therapy is failing to help.

██████████ further explained that the lack of concrete evidence (for stem cell use) does not alleviate the need to try this therapy. He further explained that the cost of injecting stem cells into the tissue is not as costly as a hematopoietic transfusion. Stem cell therapy is not being performed in the United State of America (USA) except in clinical trials and would be performed in another country.

As supporting evidence and documentation, ██████████ submitted multiple studies in relation to stem cell use for refractory Crohn's disease. According to BCBSM interim policy, "Stem Cell Therapy for Crohn's Fistula," the use of stem cell injection therapy for the treatment of Crohn's fistula is considered investigational and/or experimental. There is insufficient evidence in the peer reviewed medical literature demonstrating the safety and effectiveness of this procedure for this condition. Therefore, this service cannot be approved for this therapy.

Further, a board-certified M.D. in Internal Medicine also reviewed this appeal and [Petitioner's] health care plan benefits for [BCBSM] and determined the following:

All the provided information was reviewed, including a research article. [Petitioner] has Crohn's disease, managed with medications and surgery (Ileostomy, Seton placement). His perianal fistula has not healed. Autologous stem cell therapy, as an infusion into the fistula is proposed. Review of literature fails to find any evidence for the long term effectiveness of the proposed treatment. Based on the BCBSM interim policy, "Stem Cell Therapy for Crohn's Fistula" such treatment is considered experimental and/or investigational and the denial for coverage of this service is maintained.

* * *

While we understand your expressed concerns for the request of this service for [Petitioner], BCBSM must administer benefits based on the terms that align with the provisions of his health care coverage. Further, according to our records, we do not have any claims for the dates of service you mention in your letter, August 26, 2015 through August 28, 2015, and October 14, 2015 through October 19, 2015. Please note that if you received this service or are planning to receive this service, you will be liable for all applicable charges incurred.

Petitioner's Argument

In a letter dated July 24, 2015 Petitioner's physician wrote regarding authorization for the services to be performed in South Korea:

I am writing to request preauthorization for stem cell injection into a complex non-healing perianal fistula in my patient. It is my expert opinion that this is medically necessary.

I have been treating [Petitioner] for the past five years for Crohn's colitis. He has refractory perianal disease with complex fistula. He has had a seton in place for more than one year without improvement. He has received escalating doses of Remicade and now is receiving Entyvio infusions every four weeks, along with Methotrexate weekly.

Despite the medical therapies, he has required a diverting loop ileostomy.

Recently I was invited as International speaker at Asian Crohn's and Colitis Meeting held in China where I found that the stem cell injection into Crohn's-related fistulas had a reasonable success rate, and in similarly complex patients.

I am now recommending this procedure for [Petitioner]. Because this is not yet available in the United States, he will need to go to South Korea to have this done.

Petitioner's physician also submitted several medical literature articles supporting the medical necessity of the procedure for the Petitioner since he has failed medication therapy and ileostomy.

Director's Review

The *Blue Cross Premier Gold Benefits Certificate* (page 142) excludes coverage for experimental or investigational treatment which is defined in the certificate as:

[t]reatment that has not been scientifically proven to be as safe and effective for treatment of the patient's condition as conventional treatment. Sometimes it is referred to as "investigational" or "experimental services."

The question of whether the requested procedure was investigational 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 in active practice who is certified by the American Board of Colon and Rectal Surgery and the American Board of Surgery. The reviewer is a member of the American Society of Colon and Rectal Surgeons and the American College of Surgeons and has been published in peer reviewed medical literature. The IRO reviewer's report included the following analysis and recommendation:

Stem cell injection therapy for a Crohn's fistula is an experimental therapy. It has not been proven in the current medical literature to be standard of care for this condition, and it has not been approved by the Food and Drug Administration.

The enrollee's condition is that of refractory Crohn's disease of the colon and perineum. The standard of care was rendered, which includes being treated medically with biologic therapy and undergoing perineal drainage, as well as a diverting ileostomy. The enrollee unfortunately continue to have refractory disease.

This particular enrollee has been evaluated by multiple gastroenterologists who are experts in the field for his medically refractory Crohn's disease. They have determined that the medical therapy they have administered has been ineffective to this point. As such, they recommended stem cell treatment, which the enrollee received in South Korea. However, stem cell treatment remains an experimental treatment and it is neither commonly used nor standard of care.

Therefore, based on the documentation submitted for review, current standards of care in the field, and peer-reviewed medical literature, stem cell injection therapy is experimental/ investigational for the treatment of this enrollee's condition.

It is the recommendation of this reviewer that the denial issued by [BCBSM] for the stem cell injection therapy for a Crohn's fistula (procedure code H2218) be upheld.

The Director is not required to accept the IRO's recommendation. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). However, the 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. Furthermore, it is not contrary to any provision of the Petitioner’s coverage. MCL 550.1911(15).

The Director, discerning no reason why the IRO’s recommendation should be rejected in this case, finds that the Petitioner’s surgery is experimental/investigational for the treatment of the Petitioner’s condition and is therefore, not a benefit under the terms of the *Blue Cross Premier Gold Benefits Certificate*.

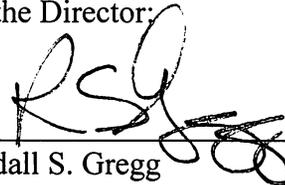
V. ORDER

The Director upholds BCBSM’s final adverse determination of October 29, 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:

A handwritten signature in black ink, appearing to read 'RSG', is written over a horizontal line. The signature is stylized and cursive.

Randall S. Gregg
Special Deputy Director