

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. 146586-001

Blue Cross Blue Shield of Michigan,

Respondent.

Issued and entered
this 2nd day of April 2015
by Joseph A. Garcia
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On March 1, 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.* After a preliminary review of the material received, the Director accepted the request on March 9, 2015.

The Petitioner receives health care benefits through a group plan that is underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The Director immediately notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. The Director received BCBSM's response on March 17, 2015.

This case involves medical issues so the Director assigned it to an independent review organization (IRO) which provided its recommendation to the Director on March 23, 2015.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are defined in BCBSM's *Simply Blue Group Benefits Certificate LG*¹ (the certificate).

¹ BCBSM form no. 778E, state approved 10/14, effective 2015.

On October 25, 1983, the Petitioner suffered a traumatic neurological injury as the result of an extradural arteriovenous malformation. The spinal injury, at the thoracic level, left him with no voluntary or sensory function below the injury site.

The Petitioner's physician recommended he use a motorized FES (*functional electrical stimulation*) cycle rehabilitation system called the RT300, made by Restorative Therapies, Inc. The purpose of the device is to strengthen and improve the functioning of the Petitioner's lower extremities.

When the Petitioner's physician requested coverage, BCBSM denied the request, saying it was not medically necessary. 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 January 21, 2015.

The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did BCBSM correctly deny coverage for the Petitioner's RT300 FES?

IV. ANALYSIS

Petitioner's Argument

In an undated "Letter of Medical Necessity," the Petitioner's physician explained the necessity for the device:

I am requesting the RT300 FES cycle rehabilitation system for [the Petitioner]. This rehabilitation system will provide [him] with multiple medical and physical benefits and also help to reduce the burden of care and medical expenses.

[The Petitioner] is a 54 year old male with Level T4 paraplegia. Prior to his injury [he] was an active individual.

Since the time of his injury, [the Petitioner] has pursued various therapy avenues to provide opportunities for strengthening and improving function. [He] also needs to undertake an alternative form of activity therapy since he has lost the ability to do this volitionally. This is medically necessary to maintain his physical condition and to minimize concomitant medical complications which can have serious health consequences and be costly to resolve.

Once a patient has sustained a spinal cord injury and is stabilized, upper and lower extremity mobilization can be achieved by use of a cycle ergometer powered by a patient's own muscle strength evoked by FES. Based on the level

and nature of [Petitioner's] injury, our experience indicates that [he] would benefit from a continued program of lower extremity movement utilizing the RT300 FES cycle rehabilitation system.

The RT300 is an integrated FES system, which provides a complex rehabilitation treatment. [The Petitioner's] peripheral nerve supply is intact allowing him to respond to electrical stimulation. [He] has been evaluated on the RT300 and had an excellent response while trialing it at [REDACTED]. With the electrical stimulation [the Petitioner] is able to achieve strong, coordinated muscle contractions in his legs (including gluteal muscles). This positive lower extremity response to electrical stimulation is supportive of future benefits of an FES home program. Future benefits of FES cycling have been well documented over the last 25 years of research and most recently also been tracked in RT300 home patients.

* * *

Research has shown that the benefits of FES cycling include: increase in muscle cross sectional area, muscle hypertrophy and capillarization, increases in lean body mass with a decrease in whole body fat content, increases in muscle endurance, increases in muscle output, increases in bone density, improved oxygen uptake, improvements in body's utilization of oxygen (typically 20-35%), improvement in heart rate, improved cardiac stroke volume, improved cardiac output during activity and pronounced effect on cardiovascular health at rest, lead to significant positive changes in spasticity and increased in knee flexion range of motion. . . .

BCBSM's Argument

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

. . . After review I confirmed that our initial denial of preauthorization must be maintained. You do not meet the medical necessity criteria required for approval.

You are covered under the *Simply Blue Group Benefits Certificate LG*. As indicated on Pages 159 and 160 of the certificate, a service must be medically necessary to be covered. Further, this requirement necessitates a determination by physicians acting for BCBSM, based on criteria and guidelines developed by physicians for BCBSM who are acting for their respective provider type or medical specialty, that the covered service is accepted as necessary and appropriate for the patient's condition and not mainly for the convenience of the member or physician.

To ensure all possible consideration was given, a board-certified M.D. in Internal Medicine reviewed the documentation received, your appeal and your health care plan benefits for [BCBSM] and determined the following:

All documentation was reviewed. Member is appealing the October 10, 2014 denial of payment for a RT300 FES Cycle Ergometry Rehabilitation Therapy System. The member is a 54 year old male with T4 level paraplegia. The RT300 FES Cycle has been requested to, "Maintain his physical condition and to minimize concomitant complications which can have serious health consequences." In response to the member's appeal letter:

1. According to the BCBSM medical policy titled "Neuromuscular Electrical Stimulation (NMES)," coverage of NMES is limited to treatment of disuse atrophy where nerve supply (including peripheral nerves, brain, and spinal cord) to the muscle remain intact. There is insufficient evidence to conclude that electrical neuromuscular stimulation provides any long-term benefit toward the rehabilitation of spinal cord injured patients.
2. Available peer reviewed literature has not established evidence of sufficient quality to allow definitive conclusions regarding the effectiveness of FES cycling in improving various measures of physical function, overall functional status and long-term health outcomes.

Therefore, because the RT300 FES Cycle Ergometry Rehabilitation Therapy System is not considered medically necessary in your case, the denial of preauthorization must be maintained. BCBSM must administer your benefits according to the terms and conditions of your group's plan.

Director's Review

BCBSM denied coverage for the RT300 device on the basis that it was not medically necessary because it has not been shown to be effective or provide any long-term benefit. The certificate (pp. 158-159) says that "a service must be medically necessary to be covered." The certificate further says that medical necessity is a

[d]etermination by physicians acting for BCBSM, based on criteria and guidelines developed by physicians for BCBSM who are acting for their respective provider type or medical specialty, that:

- The covered service is accepted as necessary and appropriate for the patient's condition. It is not mainly for the convenience of the member or physician.

The question of whether the RT300 device is medically necessary to treat 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 physician reviewer is certified by the American Board of Physical Medicine and Rehabilitation, is familiar with the medical management of patients with the member's condition, and is in active practice. The IRO reviewer's report included the following analysis and recommendation:

Rationale:

The results of the consultant's review indicate that this case involves a 54 year-old male who has a history of T4 paraplegia secondary to arteriovenous malformation rupture. At issue in this appeal is whether a RT300 FES Cycle Ergometry Rehabilitation Therapy System is medically necessary for treatment of the member's condition.

There are multiple studies in the literature that find that repetitive passive movement of the lower extremities of chronic spinal cord injury patients via functional electrical stimulation may be beneficial for spasticity, vascular perfusion and even neurologic impairment. These studies show that functional electrical stimulation can reverse disuse atrophy and increase muscle bulk in muscles below the level of an injury. However, the MAXIMUS physician consultant explained that long-term benefits and effect on health outcome from functional electrical stimulation in patients with spinal cord injuries remains unclear at this time. The physician consultant also explained that any benefits are lost if the functional electrical stimulation activity is discontinued. The consultant indicated that there is no definitive evidence that functional electrical stimulation cycle ergometry will lead to better health outcomes or functional improvement than other types of conservative treatments such as functional electrical stimulation and/or passive range of motion of the extremities. Therefore, the medical necessity of functional electrical stimulation via the RT300 system remains unproven at this time.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that a RT300 FES Cycle Ergometry Rehabilitation Therapy System is not medically necessary for treatment of the member's condition. [References omitted]

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 experience, expertise, and professional judgment. In addition, the IRO’s 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 therefore finds that BCBSM’s denial of coverage of the RT300 device was consistent with the terms of the certificate.

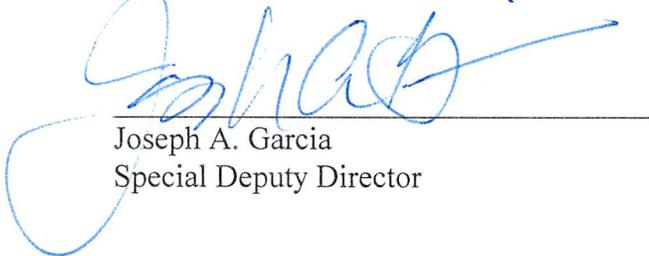
V. ORDER

The Director upholds BCBSM’s adverse determination of January 21, 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 sixty 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.

Annette E. flood
Director

For the Director:



Joseph A. Garcia
Special Deputy Director