

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. 153518-001

Blue Cross Blue Shield of Michigan
Respondent

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

ORDER

I. PROCEDURAL BACKGROUND

On May 3, 2016, ██████████ (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 May 10, 2016.

The Petitioner receives health care benefits through a plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The benefits are defined in BCBSM's *Community Blue Group Benefits Certificate SG*.

The Director notified BCBSM of the external review request and asked for the information used to make its final adverse determination. BCBSM provided its response on May 17, 2016. To address the medical issue in the case, the Director assigned it to an independent medical review organization which provided its analysis and recommendation on May 25, 2016.

II. FACTUAL BACKGROUND

The Petitioner is 54 years old and has multiple sclerosis. Her doctor recommended she use an item of durable medical equipment known as an RT200 Functional Electrical Stimulation seated elliptical therapy system. BCBSM denied coverage, ruling that it is not medically necessary for the Petitioner.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM affirmed its decision in a final adverse determination dated March 22, 2016. The Petitioner now seeks the Director's review of that adverse determination.

III. ISSUE

Did BCBSM correctly deny coverage for the RT200 system for the Petitioner?

IV. ANALYSIS

BCBSM's Argument

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

The DME you received is not a covered benefit under the terms of your Plan, as it does not meet the necessary medical criteria. Therefore, you remain responsible for the non-covered charge of \$22,400.00.

* * *

To ensure all consideration was given, an associate medical director, a board-certified D.O. in Internal Medicine, reviewed your claim, your appeal, and your health care plan benefits for BCBSM. Our medical consultant determined:

...According to the [BCBSM] medical policy, "Neuromuscular Electrostimulation (NMES)," the approval of these devices requires an intact nervous system or a non-neurologic reason for disuse atrophy or for individuals with spinal cord injury as an aid for walking. In your case, these criteria for approval are not met....

Based on the medical consultant's determination that the DME provided does not meet criteria to be considered medically necessary to treat your condition....

Petitioner's Argument

In the request for external review, the Petitioner wrote:

The RT 200 FES Cycle Therapy System is a neuromuscular electrical stimulation device that is a component of a comprehensive rehabilitation program (activating up to 12 muscle groups with stimulation during a single therapy session) and has been cleared by the FDA as safe and effective as a class II medical device for the prevention and retardation of muscle disuse atrophy, relaxation of muscle spasms, increasing local blood circulation, maintaining or increasing range of motion.

* * *

The RT 200 can prevent many side effects and secondary complications of quadriplegia and paraplegia that can be life-threatening; Side effects and secondary complications that would create unnecessarily painful and traumatic experiences for me in the future (as they have in the recent past) and would be so much more expensive to treat as compared to the cost of the RT200.

In a "letter of medical necessity" Petitioner's physician wrote:

[Petitioner] is a 53 year old female who has Multiple Sclerosis with a date of onset of 1982. Prior to onset [Petitioner] was an active individual. [Petitioner]

now has reduction of volitional motor function to her lower extremities and her light touch sensation and proprioception is absent below spinal level bilaterally.

Since the onset of her disease, [Petitioner] has pursued various therapy avenues to provide opportunities for strengthening and improving function. For example, [Petitioner] utilizes a Thera cycle daily to maintain leg and trunk flexibility as well as reaping the benefits from light weight lifting and stretching. [Petitioner] also needs to undertake an alternative form of activity therapy since she has lost the ability to do this volitionally. This is medically necessary to maintain her physical condition and to minimize concomitant medical complications that can have serious health consequences and be costly to resolve.

Once a patient with neurological impairment is stabilized, upper and lower extremity mobilization can be achieved by use of a therapy system powered by a patient's own muscle strength evoked by functional electrical stimulation (FES). Based on the nature of [Petitioner's] condition, our experience indicates that [Petitioner] would benefit from a continued program of upper and lower extremity movement utilizing the RT200 FES seated elliptical rehabilitation system.

Director's Review

The *Community Blue* certificate (pages 156 and 157) requires that a service must be medically necessary in order to be covered. The question of whether the RT 200 system is medically necessary for the Petitioner 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 Psychiatry and Neurology with a specialty in neurology and a subspecialty in neuro-oncology. The reviewer is a clinical professor of neurology at a university-based school of medicine and is published in the peer reviewed literature. The IRO report included the following analysis and recommendation:

Treatment for a patient such as this enrollee consists of disease-modifying therapy for multiple sclerosis (if a relapsing form of disease), physical therapy when necessary, and a home exercise program, including range of motion exercises to prevent contractures and to improve and maintain muscle tone. In the treatment of the neurological complications of spinal cord injury, including spinal cord injury from multiple sclerosis, there is no evidence that functional electrical stimulation (FES) has been shown to result in superior outcomes compared with conservative therapy, including physical therapy and an exercise program. While non-controlled studies suggest that FES cycles improve the progression of disability, there is no evidence based on randomized clinical trials that this is the case. There is no evidence that FES utilizing the RT 200 cycle therapy improves functional outcomes including activities of daily living, the ability to transfer or the ability to ambulate.

[Description of research studies omitted.]

This enrollee has multiple sclerosis and evidence of spinal cord disease resulting in a myelopathy and loss of motor function and sensation in the lower extremities. There is no evidence that outcomes in patients utilizing FES on a regular basis are superior to those who undergo a standard home exercise program including a range of motion in the lower extremities and upper extremity exercises. As there is no evidence that FES improves outcomes in patients with multiple sclerosis, its use would not be considered medically necessary for this enrollee....

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. The Director, discerning no reason why that analysis should be rejected in the present case, adopts the IRO analysis and finds that the RT200 system is not medically necessary to treat the Petitioner.

V. ORDER

The Director upholds BCBSM's March 22, 2016 final adverse determination. BCBSM is not required to provide the Petitioner with coverage for the RT200 FES system.

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