

**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. 154497-001

Blue Cross Blue Shield of Michigan,  
Respondent.

---

Issued and entered  
this 8<sup>th</sup> day of August 2016  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

██████████ (Petitioner) asked her health insurer, Blue Cross Blue Shield of Michigan (BCBSM), to cover an item of durable medical equipment. BCBSM denied the request.

On July 7, 2016, the Petitioner filed a request with the Director of Insurance and Financial Services for an external review of that denial 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 July 14, 2016.

The Petitioner receives health care benefits through a plan that is underwritten by 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 July 20, 2016.

This case involves medical issues so the Director assigned it to an independent review organization (IRO), which provided its recommendation to the Director on July 28, 2016.

## II. FACTUAL BACKGROUND

The Petitioner's health care benefits are defined in the *Blue Cross Premier Gold Benefits Certificate* (the certificate).

The Petitioner has relapsing remitting multiple sclerosis (RRMS). Her physician recommended she use a motorized functional electrical stimulation (FES) seated elliptical rehabilitation device (the RT200 from Restorative Therapies) to strengthen and improve the functioning of her lower extremities. BCBSM declined to cover the device, 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. 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 RT200?

## IV. ANALYSIS

### Petitioner's Argument

In an October 20, 2015 "Letter of Medical Necessity," the Petitioner's physician explained the need for the device:

I am requesting the RT200 Functional Electrical Stimulation (FES) seated elliptical therapy system for my patient, [the Petitioner]. This rehabilitation system will provide [her] with multiple medical and physical benefits and help to reduce the burden of care and medical expenses.

[The Petitioner] is a 59 year old female who has Multiple Sclerosis with a date of onset of September 2010. Prior to onset, [she] was an active individual. [She] now has reduced volitional motor function to her lower left and right extremities, along with poor balance and gait issues.

Since the onset of her disease, [the Petitioner] has pursued various therapy avenues to provide opportunities for strengthening and improving function. For example, [she] utilizes a standing frame weekly to maintain leg and trunk flexibility as well as reaping the benefits from weight bearing and upright positioning of her body. [She] 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 main 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 therapy system powered by a patient's own muscle strength evoked by functional electrical stimulation (FES). Based on the nature of [the Petitioner's] condition, our experience indicates that [she] would benefit from a continued program of upper and lower extremity movement utilizing the RT200 FES seated elliptical rehabilitation system.

The RT200 FES seated elliptical therapy system works arms and legs simultaneously. It is also fully integrated with FES providing a complex rehabilitation treatment. The RT200 produces a one to one leg to arm motion for natural swing using a smooth continuous elliptical motion. The reciprocal forward and backward movement allows for mass practice of extensor and flexor muscles.

\* \* \*

[The Petitioner's] peripheral nerve supply is intact allowing her to respond to electrical stimulation. The patient has demonstrated a commitment to pursue an FES activity regimen in their home setting.

\* \* \*

Research has shown that the benefits of FES ergometry for individuals with a neurological disorder 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 the final adverse determination, BCBSM's representative told the Petitioner:

. . . After review, I confirmed the denial must be maintained. The criteria for preauthorization for the RT200 FES Cycle Ergometry Rehabilitation Therapy System have not been met.

\* \* \*

... BCBSM only pays for services deemed to be medically necessary. Page 180 of your *Certificate* defines medically necessary as health care services that a professional provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing, or treating an illness, injury, disease, or its symptoms, and that are:

- In accordance with generally accepted standards of medical practice,
- Clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the member's illness, injury, or disease, and
- Not primarily for the convenience of the member, professional provider, or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that member's illness, injury, or disease.

For this reason, a board-certified M.D. in Emergency Medicine reviewed the submitted documentation to determine if the criteria for medical necessity were met and determined the following:

All documentation was reviewed. You are appealing the denial of preapproval to purchase the RT200 FES Cycle Ergometry Rehabilitation Therapy System (procedure code E1399) to treat your Multiple Sclerosis, which was recommended by your doctor. Per the Blue Cross Blue Shield of Michigan medical policy "Neuromuscular Electrical Stimulation" (NMES) these devices may be approved for cases of disuse atrophy that is the result of a non-neurologic condition. The documentation does not support the inclusion criteria.

Therefore, preauthorization for the RT200 FES Cycle Ergometry Rehabilitation Therapy System could not be approved. If this equipment is purchased / rented, you will be liable for all charges.

#### Director's Review

The certificate (p. 22) covers only services that are medically necessary. BCBSM determined that the RT200 device was not medically necessary on the basis that the Petitioner did not meet its criteria, noting specifically, "these devices may be approved for cases of disuse atrophy that is the result of a non-neurologic condition. The documentation does not support the inclusion criteria."

The questions of whether Petitioner met BCBSM's medical criteria and whether the RT200 device is medically necessary to treat her condition were 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 board certified in physical medicine and rehabilitation, is familiar with the medical management of patients with the member's condition, and is in active practice. The IRO report included the following analysis and recommendation:

**Rationale:**

\* \* \*

The member was seen for an initial evaluation by the requesting provider on 10/13/14 and had symptoms beginning in September 2010. Over the prior year, the member had a gradual decline in balance and worsening strength in her left leg more than her right leg. The member was having urinary and bowel symptoms and had complaints of fatigue. Copaxone and Provigil were started. By November 2014, the member's fatigue had improved with Provigil. The member had a six second 25 foot walking time documented in November 2015. In September 2015, the member reported that her right leg had been turning in when walking and that she had felt progressive left leg weakness over the prior 3 months. The member had 2 to 3 episodes of positional vertigo in the past, which was not active at the time of that office visit. The member reported that she had a throbbing in the right temporal/occipital region over the prior 2 to 3 weeks. There was no change in left lower extremity numbness or tingling. Provigil continued to control the member's fatigue. At an office visit in October 2015, the member had significant improvement in her energy after a course of Solu-Medrol, which lasted for one week. The member also reported that she felt her strength, balance and gait had remained improved. The member's examination was not significantly changed from September 2015.

\* \* \*

The MAXIMUS physician consultant noted that the requested RT200 FES System is being requested as a preventive measure and a means of exercise. The physician consultant explained that although exercise is beneficial and highly recommended, it is considered no more medically necessary in this member's case than for any other individual. The consultant also explained that there is no evidence that the member would

not be able to use conventional or adapted exercise equipment for strengthening and cardiovascular conditioning. The member has lower extremity impairments without reported upper extremity impairment. There were no reports of assistive device use or bracing of the lower extremities in the records provided for review. The physician consultant noted that assistive device use or conventional bracing are part of the standard of care for treatment of gait dysfunction due to neuromuscular disease. The member is able to use a standing frame. The consultant indicated that there are also other available treatments for spasticity, improving circulation and maintaining or increasing range of motion. The physician consultant explained that the requested RT200 system does not address as specific activity of daily living limitation. The consultant also explained that this system would be considered investigational for treatment of the member's condition and is not medically necessary. The consultant indicated that the Health Plan's criteria for the RT200 FES Cycle Ergometry Rehabilitation Therapy System are consistent with current standards of care and that the member does not meet these criteria.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that a RT200 FES cycle 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, discerning no reason why the IRO's recommendation should be rejected in this case, finds that BCBSM's denial of coverage of the RT200 FES device was consistent with the terms of the certificate.

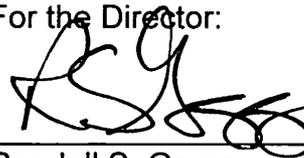
**V. ORDER**

The Director upholds BCBSM's adverse determination.

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.

Patrick M. McPharlin  
Director

For the Director:



---

Randall S. Gregg  
Special Deputy Director