

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. 148176-001-SF

██████████, **Plan Sponsor,**

and

Blue Cross Blue Shield of Michigan, Plan Administrator,

Respondents.

Issued and entered
this 8th day of July 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

██████████ (Petitioner) was denied a health care benefit. On June 4, 2015, he filed a request with the Director of Insurance and Financial Service for an external review of that denial under Public Act No. 495 of 2006 (Act 495), MCL 550.1951 *et seq.* After a preliminary review of the information submitted, the Director accepted the request on June 11, 2015.

The Petitioner receives health care benefits through a plan sponsored by the ██████████ (the plan), a self-funded governmental health plan as defined in Act 495. Blue Cross Blue Shield of Michigan (BCBSM) administers the plan. 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 June 17, 2015.

Section 2(2) of Act 495, MCL 550.1952(2), authorizes the Director to conduct this external review as though the Petitioner were a covered person under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

To address the medical issue in this case, the Director assigned it to an independent medical review organization which provided its analysis and recommendation on June 25, 2015.

II. FACTUAL BACKGROUND

The plan's benefits are described in BCBSM's *Community Blue Group Benefits Certificate ASC*¹ (the certificate).

The Petitioner is a paraplegic as the result of a fall in October 2013. His doctor recommended the use of a device called the RT300 FES Cycle Ergometry Rehabilitation Therapy System to strengthen his muscles and improve his function. The device, an item of durable medical equipment, costs \$23,200.00. BCBSM denied authorization for the device, saying it is investigational for treatment of the Petitioner's condition.

The Petitioner appealed the denial through BCBSM's internal grievance process. BCBSM held a managerial-level conference and then issued a final adverse determination dated April 6, 2015, upholding its decision. The Petitioner now seeks a review of that adverse determination from the Director.

III. ISSUE

Did BCBSM correctly deny coverage for the Petitioner's RT 300 FES Cycle Ergometry Rehabilitation Therapy System?

IV. ANALYSIS

Respondent's Argument

In its final adverse determination to the Petitioner, BCBSM explained:

... After review, the denial of prior authorization for this durable medical equipment, procedure code E1399 (durable medical equipment, miscellaneous) is maintained. This durable medical equipment can also be referred to as RT300 FES Cycle Ergometry Rehabilitation System. The BCBSM/BCN Joint Uniform Medical Policy Committee (JUMP) has determined that the durable medical equipment is investigational. Investigational devices and/or equipment are not a benefit of your contract.

* * *

A board-certified M.D. in Family Practice reviewed your claim, your appeal, and your health care plan benefits for [BCBSM] and determined the following:

"All documentation was reviewed. Appeal for denial of RT300 FES Cycle Ergometry Rehabilitation Therapy System. You are a 64 year old male with a level T8 ASIA (American Spinal Injury Association). You became paraplegic as a result of fall that

¹ BCBSM form no. 457F, effective 02/15.

occurred in October 2013. You have no voluntary muscular control below the level of T8. Per medical policy “Neuromuscular Electrical Stimulation (NMES)”, coverage of NMES is considered experimental/investigational to reduce spasticity or facilitate voluntary motor control in individual with spinal cord injury. There is insufficient evidence to conclude that electrical neuromuscular stimulation provides any long term benefit toward the rehabilitation of spinal cord injured patients. Deny E1399.”

Petitioner’s Argument

In a May 11, 2015, sent with the external review request, the Petitioner wrote:

The RT 300 FES Cycle Therapy System is a neuro muscular electrical stimulation device that is a component of a comprehensive rehabilitation program (activating 12 muscles 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 use atrophy, relaxation of muscle spasms, increasing local blood circulation, maintaining or increasing range of motion.

The RT300 system provides a therapeutic intervention that applies patterned electrical activation of the nervous system below the level of my neurologic injury. This therapeutic activity is extremely important as with it I can achieve muscle stimulation below my level of injury which will result in increased blood circulation, decreased in spasms and prevention of muscle atrophy. Able bodied individuals have many physical activity choices in which they can partake with or without the use of equipment. Because an able bodied person has an undamaged nervous system that can routinely achieve a threshold of activity and relatively good health just undertaking their activities of daily living.

The RT300 FES cycle rehabilitation therapy system is NOT investigational; in fact FES has been studied for over 40 years and resulted in hundreds of peer-reviewed scientific journal articles and as a result is being utilized as a standard clinical practice and is a home-based therapy option. The RT 300 has been cleared by the FDA as safe and effective for the following indications: prevention or retardation of disuse atrophy, relaxation of muscle spasms, maintaining or increasing range of motion and increasing local blood circulation. Those indications are exactly what I struggle with on a daily basis.

The Petitioner’s physician and physical therapist wrote a joint letter of medical necessity dated September 9, 2014, that said:

. . . RT300 will provide [the Petitioner] with multiple medical and physical benefits and also help to reduce the burden of care and medical expenses.

. . . Prior to his injury [the Petitioner] was an active individual. He now has loss of volitional motor function below T6 in bilateral lower extremities and trunk, and his light touch sensation and proprioception is absent below T8 spinal level bilaterally.

Since the time of his injury, [he] has pursued various therapy avenues to provide opportunities for strengthening and improving function. For example, [he] participates in a daily self-stretching and strengthening program to maintain positioning of his body and appropriate strength for transfers and wheelchair mobility. [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 [his] injury, our experience indicates that he would benefit from a continued program of lower extremity movement utilizing RT300.

[The Petitioner] has been evaluated on RT300 and had an excellent response while trialing it at the [REDACTED] [His] peripheral nerve supply is intact allowing him to respond to RT300's electrical stimulation.

[The Petitioner] has cycled 7 sessions and was able to tolerate 20 minutes of treatment without fatigue limitations. During a session, 1.96 miles of FES cycling were accomplished at 30-35 revolutions per minute. [He] has demonstrated a commitment to pursue an FES activity regimen in his home setting.

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. Since starting electrical stimulation using the RT300 [the Petitioner] has also had reduced abdominal and lower extremity muscle spasms. 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.

Director's Review

“Experimental treatment” is defined in the certificate (p. 142) as

[t]reatment 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.”

The certificate has this general exclusion for experimental or investigational treatment (p. 127):

Experimental Treatment

Services That Are Not Payable

We do not pay for experimental treatment (including experimental drugs or devices) or services related to experimental treatment. . . .² In addition, we do not pay for administrative costs related to experimental treatment or for research management.

Durable medical equipment is a benefit under the plan (see “Section 3: What BCBSM Pays For,” pp. 34-35). But the certificate (p. 35) does not cover all durable medical equipment:

We do not pay for:

* * *

- Experimental equipment

To answer the question of whether the RT300 FES Cycle Ergometry Rehabilitation System is investigational or experimental for the treatment of the Petitioner’s condition, the Director assigned the case 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 with a subspecialty in pain medicine and is in active practice. The IRO 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 RT 300 FES cycle therapy system is considered experimental /investigational for the treatment of the enrollee’s condition.

Clinical Rationale for the Decision:

The evidence for decreasing fracture or improving exercise capacity is scarce and there are no large volume trials supporting use of this device or other FES cycles. Most trials also use significantly younger participants as compared to the enrollee who is 64 years old. Use of a hand cycle has been shown to be equally effective in these studies.

* * *

The RT RES cycle therapy system is [FDA] approved. It has a 510(k) number of K090750. “Commercial FES cycling systems first became available in the mid 1980’s and has since been adapted and deployed for home use. Habitual use of these devices is necessary to achieve discernable health benefits, but exercise compliance in the general population is often poor, even when exercise is medically prescribed for life-threatening conditions. Given the poor adherence to exercise in general, a detailed look at usage patterns for home FES cycling seems warranted.”

There is no evidence that the FES cycling system can prevent muscle loss any better than exercise with a cycle ergometer which is more cost effective. Overall use of the FES cycle

2 The certificate lists some exceptions to this exclusion but none apply in the Petitioner’s case.

over time has been shown to be poor. The research has not shown that users of the cycle are able to generate sufficient forces or use the device as frequently as necessary to achieve minimum exercise goals. Based on the above data the FES cycling system is felt to be experimental/investigational for the enrollee's condition and therefore not medically necessary.

Recommendation:

It is the recommendation of this reviewer that the denial issued by [BCBSM] for the RT 300 FES cycle therapy system 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 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 to reject the IRO's recommendation, finds that the RT300 FES Cycle Therapy System is experimental or investigational to treat the Petitioner's condition and therefore is not a covered benefit under the terms of the certificate.

V. ORDER

The Director upholds BCBSM and the plan's final adverse determination of April 6, 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:



Randall S. Gregg
Special Deputy Director