

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. 151575-001-SF

University of Michigan, Plan Sponsor
and
BCN Service Company, Plan Administrator
Respondents

Issued and entered
this 4th day of February 2016
by **Randall S. Gregg**
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On January 5, 2016, ██████████, authorized representative of his son ██████████ (Petitioner), filed a request for external review with the Director of Insurance and Financial Services. The request for review concerns a denial of coverage for physical therapy equipment. The denial was issued by BCN Service Company (BCNSC), the administrator of the Petitioner's health benefit plan which is sponsored by the University of Michigan.

The request for external review was filed under Public Act No. 495 of 2006 (Act 495), MCL 550.1951 *et seq.* Act 495 requires the Director to provide external reviews to a person covered by a self-funded health plan that is established or maintained by a state or local unit of government. The Director's review is performed "as though that person were a covered person under the Patient's Right to Independent Review Act." (MCL 550.1952) The Petitioner's health benefit plan is such a governmental self-funded plan. The benefits are described in the *U-M Premier Care Benefit Document*.

The Director notified BCNSC of the external review request and asked for the information used to make its final adverse determination. The Director received BCNSC's response on January 7, 2016. After a preliminary review, the Director accepted the request on January 12, 2016. BCNSC provided additional information on January 12, 2016.

This case involves medical issues so the Director assigned it to an independent review organization which provided its recommendation to the Director on January 26, 2016.

II. FACTUAL BACKGROUND

The Petitioner, who is [REDACTED] years-old, suffered a spinal cord injury in October 2014 and is now a quadriplegic. After his initial inpatient rehabilitation, his physician recommended he use a functional electrical stimulation (FES) cycle rehabilitation system called the RT300 to aid in his outpatient rehabilitation. The Petitioner requested that his benefit plan provide coverage.

BCNSC, as the plan administrator, denied the request, ruling that the RT300 was experimental. The Petitioner appealed the denial through BCNSC's internal grievance process. At the conclusion of that process, BCNSC affirmed its denial in a final adverse determination issued November 6, 2015.

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

III. ISSUE

Did BCNSC correctly deny coverage for the Petitioner's RT300 system?

IV. ANALYSIS

Petitioner's Argument

In a March 12, 2015 letter the Petitioner's physician wrote:

[Petitioner] is a patient under my care related to tetraplegia from a traumatic cervical spinal cord injury. Use of the neuro-muscular electrical stimulation is indicated for [Petitioner] for treatment and prevention of disuse atrophy and to maintain musculature to decrease long term risk of metabolic diseases associated with muscle wasting including diabetes and hyperlipidemia....

In the request for external review, the Petitioner's father describes the benefits his son has received from using the RT300 system:

The continued use of the FES bike was highly recommended by his initial rehab provider, [REDACTED] in [REDACTED] – a highly acclaimed and nationally recognized rehab Institute in the [REDACTED] area. His rehab intervention at the [REDACTED] [REDACTED] in [REDACTED] also employs this equipment in an aggressive manner....

[Petitioner] has regained the use of both biceps and shoulder and arms rotation movements dramatically since his accident and discharge from [REDACTED]. Still today, he has no movement with his triceps and no feelings in his wrist, hands, and

fingers - nor can he move his legs. The initial use of the FES bike was principally applied to his legs but over the last year, he has adopted its use for his arms to a greater degree and application. Based on his progress to date, the FES may in the long run have a greater impact and result in a more positive return on investment for his arms. However, research (see attached documented references) clearly indicates that for patients similar to [Petitioner's] condition there are a multitude of benefits from use of a FES system on a regular basis.

Director's Review

BCNSC asserts that the RT300 FES system is experimental and, for that reason, not a covered benefit. The *U-M Premier Care Benefit Document*, on page 53, defines an experimental or investigational service as "a service that has not been scientifically demonstrated to be as safe and effective for treatment of the Member's condition as conventional or standard treatment in the United States." The question of whether the RT300 FES cycle therapy system is experimental in the treatment of 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 board certified 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:

[T]he RT300 FES Cycle Ergometry Rehabilitation Therapy System is considered experimental for treatment of the member's condition....[T]he indications for use of this system are limited to the treatment of disuse atrophy (muscle wasting) where the nerve supply, including brain, spinal cord and peripheral nerves, to the muscle remains intact....[T]he use of this system for patients with spinal cord injury, such as this member, and for the treatment of denervated muscles is experimental/investigational.

[T]here is no consistent evidence that long term FES use decreases spasticity. One article claimed that no definitive statement can be made regarding the type, the magnitude, or even the direction of the effect of electrical stimulation on the spasticity of patients with spinal cord injury. (Yarkony GM, et al. Neuromuscular stimulation in spinal cord injury II: Prevention of secondary complications. *Arch Phys Med Rehabil.* 1992;73(2):195-200.)...[S]tandard treatment for this condition includes physical therapy, oral medications, intrathecal infusions of medication, motor point or nerve blocks or destructive neurosurgical procedures. (Merritt JL. Management of spasticity in spinal cord injury. *Mayo Clin Proc.* 1981;56(10):614-22.)...[F]atigue of electrically stimulated muscles is a principal limiting factor in the applications of FES. One article stated that more research is needed to ascertain the mechanisms of fatigue of this type of peripherally induced exercise, and to substantiate the potential fitness and health benefits of FES exercise training. (Glaser RM. Physiologic aspects of spinal cord injury and functional neuromuscular stimulation. *Cent Nerv Syst Trauma.* 1986;3(1):49-62.)

Another study examined FES bicycle ergometry and stated that future studies should include a placebo control group. (Sipski ML, et al. Functional electrical stimulation bicycle ergometry: Patient perceptions. *Am J Phys Med Rehabil.* 1989;68(3):147-9.) This study involved a small number of patients with a history of neurogenic pain who reported an increase in this pain which caused them to drop out of the training program. The cause of this intensification of pain was unclear. One article stated that more research is needed to document the benefits, if any, of the use of bicycle ergometry to justify the use of this equipment. (Sipski ML, et al. Long-term use of computerized bicycle ergometry for spinal cord injured subjects. *Arch Phys Med Rehabil.* 1993;74(3):238-41.) Another study reported that bone mineral density did not increase in quadriplegic men who had undergone 6 months of FES cycle ergometry training. (Leeds EM, et al. Bone mineral density after bicycle ergometry training. *Arch Phys Med Rehabil.* 1990;71(3):207-9.) One article concluded that much more research in FES techniques and treatment protocols is needed before this approach can be used widely as a means to provide cardiorespiratory fitness for quadriplegics. Pentland B. Rehabilitation. Quadriplegia and cardiorespiratory fitness. *Lancet.* 1993;341(8842):413-4.) A recent study stated that there was no clear effects of FES cycling on urine output, swelling and spasticity even though all point estimates of treatment effects favored FES cycling and participants perceived therapeutic effects. (Ralston KE, et al. Functional electrical stimulation cycling has no clear effect on urine output, lower limb swelling, and spasticity in people with spinal cord injury: a randomised cross-over trial. *J Physiother.* 2013 Dec;59(4):237-43.) Another study suggested that NMES [Neuromuscular Electrical Stimulation] may increase muscle mass in some spinal cord injury patients with disuse atrophy, however the literature does not demonstrate that this led to improved health outcomes such as reduced fracture risk from increase in bone density. (Baldi J, et al. Muscle atrophy is prevented in patients with acute spinal cord injury using functional electric stimulation. *Spinal Cord.* 36(1998):463-9. Limb blood flow has been shown to increase via neuromuscular electrical stimulation in one study. (Nash M, et al. Evaluation of a training program for persons with SCI paraplegia using the Parastep 1 Ambulation System: Part 5. Lower extremity blood flow and hyperemic responses to occlusion are augmented by ambulation training. *Arch Phys Med Rehabil.* 78(1997):808-14.) However...it has not been clearly linked with a health outcome....[F]or these reasons, NMES is not proven to be clinically effective long term for the treatment of disuse atrophy in spinal cord injury patients.

Pursuant to the information set forth above and available documentation...a RT300 FES cycle therapy system is experimental for treatment of the member's condition.

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 the present case, finds that BCNSC's denial of coverage for the RT300 system was consistent with the terms of the benefit document.

V. ORDER

The Director upholds BCNSC's adverse determination of November 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 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:

A handwritten signature in black ink, appearing to read 'R. S. Gregg', is written over a horizontal line.

Randall S. Gregg
Special Deputy Director