

**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. 147299-001-SF**

**Clinton Township, Plan Sponsor**  
**and**  
**Blue Cross Blue Shield of Michigan, Plan Administrator**  
**Respondents**

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**Issued and entered**  
**this 13<sup>th</sup> day of May 2015**  
**by Randall S. Gregg**  
**Special Deputy Director**

**ORDER**

**I. PROCEDURAL BACKGROUND**

On April 13, 2015, ██████████ (Petitioner) filed a request for external review with the Department of Insurance and Financial Services, appealing a claim denial issued by Blue Cross and Blue Shield of Michigan (BCBSM), the administrator of the Petitioner's health benefit plan which is sponsored by the Clinton Township.

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 plan's benefits are described in BCBSM's *Community Blue Group Benefits Certificate ASC*.

On April 20, 2015, after a preliminary review of the information submitted, the Director accepted the Petitioner's request. The Director notified BCBSM of the appeal and asked BCBSM to provide the information used to make its final adverse determination. BCBSM furnished its response on April 28, 2015.

This case involves medical issues so the Director assigned it to an independent review organization which provided its recommendation to the Director on May 4, 2015.

## II. FACTUAL BACKGROUND

The Petitioner has multiple sclerosis. He uses a cane and ankle/foot orthosis to walk. His physician recommended he use an electronic WalkAide, a neuromuscular electrical stimulator. BCBSM was requested to provide coverage for the device. The cost of this device is \$8,664.00. BCBSM denied the request, saying the device and related supplies were investigational.

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 February 4, 2015. The Petitioner now seeks a review of that final adverse determination from the Director.

## III. ISSUE

Did BCBSM correctly deny coverage for the WalkAide device?

## IV. ANALYSIS

### BCBSM's Argument

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

The Blue Cross Blue Shield of Michigan (BCBSM)/Blue Care Network (BCN) Joint Uniform Medical Policy Committee (JUMP) has determined that functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified (procedure code E0770) and electrical stimulator supplies, 2 lead, per month (procedure code A4595) are considered investigational.

\* \* \*

An investigational status means that the safety and effectiveness of a particular technology has not been definitively determined....Investigational medical policies are reviewed regularly to guarantee that the investigational status continues to be supported by the evidence.

You are covered under the *Community Blue Group Benefits Certificate ASC*. As indicated on page 143 of your certificate, your coverage does not extend to experimental treatments. Page 161 defines experimental as treatment that has not been scientifically proven to be safe and effective for treatment of the patient's conditions as conventional treatment, and is sometimes referred to as "investigational" or "experimental" services. Because the Walk Aide electrical stimulator device has been deemed investigational, it is not covered under your health care plan.

### Petitioner's Argument

In a letter dated December 29, 2014, addressed to BCBSM and submitted with the request for an external review, the Petitioner and his wife wrote:

We are appealing the decision of the Electrical Stimulator Device (walk aide) for [the Petitioner]. The standard walk aide he had been prescribed previously was not working in his everyday life which was discussed at length with his caregiver, who was concerned with the amount of falls he was experiencing and is adamant about maintaining his mobility, to maintain his overall health, which we strongly concur with.

His doctor had again prescribed a device to help him with the foot drop he is experiencing and referred us to the [REDACTED]. Prior to using the Walk Aide device for the 2 week trial, he was experiencing chronic lower back pain, with numerous associated prescriptions and doctor consultations. He also was experiencing numerous falls, which luckily, so far had not involved a head or bone injury. To elaborate, he was experiencing falls on average of a minimum 3 to 4 times a week. However, while on the WalkAide device, he has not experienced the lower back pain, has not had the balance and fall issues and has been able to navigate in a much more independent manner at home and in social settings. This of course, has also meant a better quality of life for him in addition to maintaining a healthier lifestyle, which is huge in his daily life.

His doctor has concurred with the findings above. We are requesting you further research and reconsider your decision based on the above and his doctor's enclosed review of his health before and after the device.

### Director's Review

The *Community Blue* certificate excludes coverage for experimental or investigational treatment including items of durable medical equipment (page 38). The question of whether the electronic WalkAide device is investigational or 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 reviewer is a physician in active practice who is board certified in rehabilitation and physical medicine and is familiar with the medical management of patients with the member's condition. The IRO reviewer's report included the following analysis and recommendation:

[T]he current research literature for functional electrical stimulation and specifically the WalkAide device, does not demonstrate an improvement in speed

with the use of this device for individuals with multiple sclerosis, except for severely affected individuals....The effect of the WalkAide device on endurance has not been studied in the population of patients with multiple sclerosis. [T]he use of functional electrical stimulation for foot drop has been pursued in small feasibility trials, but has not been clearly established as an alternative to an ankle foot orthosis in randomized clinical trials....[T]he current references continue to explore the WalkAide device's role in medical care.

Pursuant to the information set forth above and available documentation...the requested electrical stimulation device (procedure codes E0770 and A4595) (WalkAide device with associated components) is investigational 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. The Director can discern no reason why the IRO's recommendation should be rejected in the present case. In addition, the IRO's recommendation is not contrary to any provision of the Petitioner's certificate of coverage. MCL 550.1911(15).

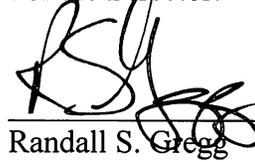
## V. ORDER

The Director upholds BCBSM's adverse determination of February 4, 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:



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Randall S. Gregg  
Special Deputy Director