

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
OFFICE OF FINANCIAL AND INSURANCE REGULATION
Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXX

Petitioner

File No. 118870-001

v

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 5th day of August 2011
by R. Kevin Clinton
Commissioner

ORDER

I. PROCEDURAL BACKGROUND

On January 4, 2011, XXXXX, authorized representative of XXXXX (Petitioner), filed a request for external review with the Commissioner of Financial and Insurance Regulation. The request was filed under Public Act No. 495 of 2006, MCL 550.1951 *et seq.*, which authorizes the Commissioner to conduct external reviews for state and local government employees who receive health care benefits in a self-funded plan. Under Act 495, reviews are conducted in the same manner as reviews conducted under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives health care benefits through her employer, XXXXX. The XXXXX benefit plan is a self-funded plan whose terms and conditions are described in Blue Cross Blue Shield of Michigan's (BCBSM) *Community Blue* certificate of coverage.

Because this appeal involves a medical question, the Commissioner assigned the case to an independent medical review organization which provided its analysis and recommendation on January 25, 2011.

II. FACTUAL BACKGROUND

The Petitioner has multiple sclerosis (MS), a disorder which affects walking skills. Presently, the Petitioner uses a forearm crutch and cane when walking. In January 2010, the Petitioner received a WalkAide External Functional Neuromuscular Stimulator, a device which

attaches to the lower leg and uses electrical stimulation to counteract “foot drop” which causes walking problems for individuals with MS. The charge for this device was \$4,520. BCBSM denied coverage, ruling that the device is investigational for treatment of the Petitioner’s condition and therefore not a covered benefit.

The Petitioner appealed the denial through BCBSM’s internal grievance process. BCBSM maintained its decision and issued a final adverse determination dated November 22, 2010.

III. ISSUE

Did BCBSM properly deny coverage for the Petitioner’s Walk-Aide device?

IV. ANALYSIS

Petitioner’s Argument

The Petitioner believes that this device allows her to ambulate safely and decreases her fall risk by preventing her foot from dragging during ambulation. In addition, her goal is to decrease her energy expenditure since fatigue is a major factor for MS patients in their daily activities. She contends that with continued bio-mechanical abnormalities she is at risk for joint injury and fall from unstable gait.

In a letter dated April 27, 2010, following Petitioner’s trial use of the WalkAide, Petitioner’s orthotist concluded that “. . . the WalkAide is the most appropriate treatment for [Petitioner] given her current condition.”

BCBSM’s Argument

BCBSM states it does not cover the WalkAide because it considers the device to be investigational for the treatment of Petitioner’s condition. Experimental and investigational medical care is excluded from coverage under BCBSM’s certificates of coverage.

Commissioner’s Review

The BCBSM *Community Blue* certificate of coverage includes the following definition:

Experimental or Investigational

A service that has not been scientifically demonstrated to be as safe and effective for treatment of the patient’s condition as conventional or standard treatment.

Section 6 of the certificate states, “We do not pay for experimental treatment (including experimental drugs or devices). . .”

The question of whether the WalkAide device is experimental or investigational for treatment of the Petitioner's condition was presented to an independent medical review organization (IRO) for analysis as required by section 11(6) of PRIRA, MCL 550.1911(6). The IRO reviewer is a physician in active clinical practice who is certified by the American Board of Psychiatry and Neurology with subspecialty certification in neurology and clinical neurophysiology. The reviewer is certified by the American Board of Electrodiagnostic Medicine, is a fellow of the American Academy of Neurology, and is a clinical professor of pediatrics and neurology at a Midwest children's hospital. The reviewer is also director of an electrophysiology monitoring program and is published in peer-reviewed medical literature. The IRO reviewer's report includes the following analysis and conclusion:

The current standard for treatment in someone who has Multiple Sclerosis includes medication to improve fatigue, improve the course of the disease and physical therapy as needed as well as assistive devices as needed to prevent falls and assist in ambulation. The Walk-Aide Functional Electrical Stimulator is not considered standard of care for the treatment of MS or other upper motor neuron disorders and there is no evidence to support its use for this condition.

* * *

A review of the peer reviewed literature notes that the data reflects that the use of the neuromuscular electrical stimulator is promising; however large randomized controlled studies are warranted.

* * *

The Walk-Aide is designed to offer persons with foot drop increased mobility, functionality and independence. It was cleared by the FDA through the 510(k) process. However, there is currently insufficient evidence in the peer-reviewed published medical literature to support its use for drop foot and other indications. Prospective clinical studies of the Walk-Aide device are necessary to evaluate whether it improves function and reduces disability compared to standard bracing in persons with drop foot. A randomized controlled trial comparing Walk-Aide to AFO is currently underway.

Thus, at this time, the Walk-Aide has not been demonstrated in the current peer-reviewed published medical literature to be safe or effective for the use in the setting of MS. It is therefore considered experimental and its use is not considered to be in keeping with the standard of care for the treatment of foot drop due to MS or other upper motor neuron disorders.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO recommendation is afforded deference by the Commissioner. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principal reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16) (b). The IRO reviewer's analysis is based on expertise and professional judgment and the Commissioner can discern no reason why the recommendation should be rejected in this case.

Therefore, the Commissioner finds that BCBSM's denial of the WalkAide as

investigational for treatment of the Petitioner's condition is consistent with the terms of the certificate.

V. ORDER

The Commissioner upholds BCBSM's November 22, 2010, final adverse determination and BCBSM is not required to provide coverage for the Petitioner's WalkAide device.

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 the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.

R. Kevin Clinton
Commissioner