

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. 153238-001

Blue Cross Blue Shield of Michigan,

Respondent.

Issued and entered
this 12th day of July 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

Corey Zielinski (Petitioner), a paraplegic, receives health care benefits through a group plan that is underwritten by respondent Blue Cross Blue Shield of Michigan (BCBSM). His health care benefits are described in BCBSM's *Simply Blue Group Benefits Certificate LG* (the certificate).

In July 2015, the Petitioner's physician asked BCBSM to authorize coverage for a ReWalk brand "powered exoskeleton" for his use, an item of durable medical equipment that is described as a

device that is composed of an external, powered, motorized orthosis used for medical purposes that is placed over a person's paralyzed or weakened limbs for the purpose of providing ambulation.¹

In a July 24, 2015 letter, BCBSM denied the request on the basis that the device is investigational:

The safety and effectiveness of this device has not been established. Further studies are needed. [Y]our covered benefits do not include investigational devices.

¹ U. S. Department of Health & Human Services letter to Argo Medical Technologies, Inc., dated June 26, 2014, included in the record.

In October 2015, the Petitioner appealed BSBCM's denial through its internal grievance process. BCBSM held a managerial-level conference on November 3, 2015 and at the conclusion of the process issued a final adverse determination, dated November 5, 2015, upholding its denial. BCBSM said "the denial must be maintained; this device is considered investigational / experimental."

On April 14, 2016, the Petitioner filed a request with the Director of Insurance and Financial Services for an external review of BCBSM's final adverse determination under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* After a preliminary review of the material submitted, the Director accepted the request on April 21, 2016.²

The Director immediately notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. BCBSM responded on April 29, 2016.

To address the medical issue in this case, the Director assigned it to an independent medical review organization, whose amended analysis and recommendation was received on July 5, 2016.³

III. ISSUE

Did BCBSM correctly deny coverage for the powered exoskeleton?

III. ANALYSIS

BCBSM's Argument

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

This letter is in response to your appeal and will inform you of the outcome of your Managerial-Level Conference conducted on November 3, 2015. The purpose of the Conference was to discuss the denial of preauthorization for the ReWalk Exoskeletal Device ... After review, I confirmed the denial must be maintained; this device is considered investigational / experimental.

² Rejecting a challenge from BCBSM, the Director concluded that the request was timely. A request for an external review of an insurer's final adverse determination under the Patient's Right to Independent Review Act must be filed "[n]ot later than 60 days after the date of receipt ..." MCL 550.1911. The Petitioner said he did not receive the November 5, 2015, final adverse determination until April 13, 2016, and noted that it had been sent to an incorrect address.

³ The independent review organization (IRO) submitted its initial report on May 13, 2016. However, during the pendency of this review the Petitioner authorized another person to represent him and was given time to allow his representative to submit additional documentation. The IRO reviewed the additional information and submitted an amended report on July 5, 2016. Both IRO reports contained the same recommendation.

* * *

To ensure all consideration was given, a board-certified M.D. in Internal Medicine reviewed the submitted documentation and determined the following:

This is an appeal request for the preauthorization of a ReWalk Exoskeletal Device. The ReWalk Exoskeletal Device was requested (to assist with walking) for you, a 45 year-old Male, with a diagnosis of paraplegia. According to the Blue Cross Blue Shield Association ... medical policy titled "Powered Exoskeleton for Ambulation in Patients with Lower-Limb Disabilities," use of a powered exoskeleton for ambulation in patients with lower-limb disabilities is considered investigational. The safety and efficacy of the device has not been established. The Blue Cross Blue Shield of Michigan Medical Policy "Durable Medical Equipment" states that devices considered experimental and investigational do not meet the required definition of Durable Medical Equipment. Therefore we are not able to approve the ReWalk Exoskeletal Device.

BCBSM based its denial on this exclusion in the certificate (p. 130):

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 ...⁴

Petitioner's Argument

For BCBSM's internal appeal process, the Petitioner's physical medicine and rehabilitation physician wrote on his behalf in an undated letter:

I am writing in appeal for the [Petitioner] regarding the request for prior approval of ReWalk Exoskeleton Device, which you had denied. Your basic reason for denial was that it is considered investigational. That is incorrect. The FDA approved the power exoskeleton / ReWalk as of June 2014 ... The FDA approval is for spinal cord injury at levels T7-L5. This patient is the perfect candidate with a T12 SCI. The medical necessity is for him to be weight bearing on both lower extremities. That will improve his muscle tone, his bone density, and his ability to perform reciprocal walking, not sitting. In the long run, having [him] on his feet using the ReWalk will prevent costly hospitalizations regarding decubitus ulcers, pneumonias, osteoporotic fractures, etc.

⁴ "Experimental treatment" is also defined in the certificate (p. 148): "Treatment 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.'"

Again, the ReWalk was FDA approved in June of 2014 as a Class II orthotic, powered exoskeleton. Please approve this for insurance coverage of the orthosis ...

The Petitioner and his authorized representative also submitted documentation to support his request. That information is listed in the independent review organization's July 5, 2016 report.

Director's Review

The question of whether BCBSM correctly denied coverage for the powered exoskeleton as experimental or investigational was presented to an independent review organization (IRO) for analysis 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 (Diplomate) and the American Board of Independent Medical Examiners; is a member of the American Paraplegia Society, the Association of Academic Physiatrists, and the International Spinal Cord Society; is published in peer-reviewed medical literature; and is in active practice.

The IRO report contained the following analysis and recommendation:

Reviewer's Decision and Principal Reasons for the Decision:

Is the ReWalk Exoskeletal Device (procedure code E1399) considered experimental / investigational for treatment of the enrollee's condition?

Yes. It is the determination of this reviewer that the ReWalk Exoskeletal Device (procedure code E1399) is experimental / investigational for the treatment of the enrollee's condition.

Clinical Rationale for the Decision:

The standard of care in this clinical scenario is promoting physical activity using volitionally active musculature, including regular propulsion of a manual wheelchair, wheelchair sports and other adaptive sports / exercise activities. Compared to these standard activities, the physical activity promoted by powered exoskeleton-aided ambulation with the ReWalk Exoskeletal device is very modest.

The device in question is Food and Drug Administration (FDA) approved as an option for use as a mobility device in persons with selected levels of paraplegia. It is not, however, an efficient or reliable means of mobility in comparison to standard mobility devices such as wheelchairs. Recent evidence, notably, suggests that these type of exoskeletal ambulation

devices have high feasibility challenges and have not met users' high expectations of benefits.

There is, more importantly, no expected significant health benefit of walking using an externally powered exoskeleton to power the lower limbs. There is no expected marginally significant health benefit of this requested service over standard care. The alleged health benefits suggested by papers supported by the industry are subjective in nature and have not been demonstrated in a scientifically rigorous manner. The type of device in question, in addition, puts users at risk of injury.

The device, overall, is experimental / investigational. FDA approval allows the sale and use of this device by the public with a physician's prescription. Its benefits with respect to health and mobility in the setting of this condition, however, have not been established. The available, published data are scarce and low quality. The device in question is an adjunctive mobility device that is significantly less efficient and much less reliable than standard mobility devices, and has no proven health benefits. The medical and scientific evidence does not demonstrate that the requested device is more likely to be beneficial to the enrollee than other available standard health care service. Therefore, based on the above information, the ReWalk Exoskeletal device is experimental / investigational for treatment of the enrollee's condition.

Recommendation:

It is the recommendation of this reviewer that the denial issued by Blue Cross Blue Shield of Michigan for the ReWalk Exoskeletal Device (procedure code E1399) be upheld.

* * *

Addendum:

The enrollee sustained a spinal cord injury due to a fall from a tree. He has paraplegia and uses a manual wheelchair for mobility. He has been undergoing physical therapy which has included ambulation using a ReWalk exoskeletal device. He has completed training with this device. The device has been prescribed for routine home and community use. A letter from his physician . . . indicated that the enrollee has had "serious secondary clinical complications" due to his spinal cord injury. He was noted to have met inclusion criteria for use of the device at a therapy center. Although the ReWalk device has been FDA approved, the medical and scientific evidence does not demonstrate that the requested device is more likely to be beneficial to the enrollee than other available standard health care service. The additional documentation does not change the reviewer's determination. The ReWalk Exoskeletal device is experimental/investigational for treatment of the enrollee'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 a final 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 recommendation is based on experience, expertise, and professional judgment and the Director can discern no reason why it should be rejected in this case. Therefore, the Director accepts the IRO recommendation and finds that the powered exoskeleton is investigational / experimental for the Petitioner's condition and therefore not a benefit under the certificate.

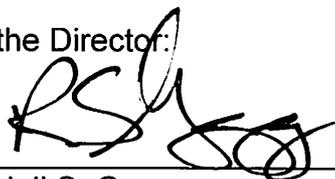
V. ORDER

The Director upholds BCBSM's final adverse determination of November 5, 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