

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. 150256-001

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 12th day of November 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On October 9, 2015, ██████████ (Petitioner) filed a request for external review with the Department of Insurance and Financial Services (DIFS) for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* On October 16, 2015, after a preliminary review of the information submitted, the Director accepted the request.

The Petitioner receives health care benefits under a group plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The benefits are defined in the *MESSA Account-Based Choices Plan 1 Plan Coverage Guide*. The Director notified BCBSM of the external review request and asked for the information used to make its final adverse determination. The Director received BCBSM's response on October 22, 2015.

This case involves medical issues so the Director assigned it to an independent review organization which provided its recommendation to the Director on October 30, 2015.

II. FACTUAL BACKGROUND

The Petitioner has osteoarthritis of the ankle from an accident in 2012. She has had multiple surgeries, tried various medications and treatment methods to control her pain and improve her ability to walk but with little success. Her orthopedic surgeon recommended use of an Intrepid Dynamic Exoskeletal Orthosis (IDEO) device. The Petitioner requested that BCBSM provide coverage for the device. BCBSM denied the request.

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 August 6, 2015. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did BCBSM correctly deny coverage for the IDEO device?

IV. ANALYSIS

BCBSM's Argument

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

After review, the denial is maintained as the IDEO is considered experimental/investigational.

* * *

Page 45 of your *Plan Coverage Guide*, under subsection **Exclusions and Limitations**, explains that the following exclusion and limitation applies to the MESSA ABC Plan:

- Experimental treatment (including experimental drugs or devices) or services related to experimental treatment except as approved by the BCBSM or MESSA medical director. In addition, we do not pay for administrative costs related to experimental treatment or for research management.

A board-certified D.O. in Physical Medicine and Rehabilitation reviewed your case and determined:

I have reviewed all of the information submitted regarding the Intrepid Dynamic Exoskeleton Orthosis (IDEO) device. This information includes: the medical records regarding the client, the Blue Cross Blue Shield of Michigan policies regarding orthotics and prosthetics and the videos of the device in action. I have had a discussion with the Blue Cross Blue Shield orthotic and prosthetic consultant, [REDACTED], regarding the Intrepid Dynamic Exoskeleton Orthosis (IDEO). After careful consideration, it is my opinion that this device is still considered investigational under the Blue Cross Blue Shield of Michigan medical policy "Orthotic Devices" and the Blue Cross Blue Shield Association policy, "Powered Exoskeleton for Ambulation in Patients with Lower-Limb Disabilities." It is my understanding that the device needs to undergo valid research studies that can be validated and approved by

Centers for Medicare and Medicaid Services (CMS) before Blue Cross Blue Shield could designate it as non experimental or non -investigational for their member population.

The Blue Cross Blue Shield Association Medical Policy Reference Manual titled, *Powered Exoskeleton For Ambulation in Patients with Lower-Limb Disabilities* explains that the use of a powered exoskeleton for ambulation in patients with lower-limb disabilities is considered investigational. Additionally, BCBSM Medical Policy titled, *Orthotic Devices*, excludes coverage for orthotic devices that are investigational, experimental, or research devices or appliances.

As the IDEO is considered experimental/investigational, our denial of prior authorization must be maintained. If you choose to obtain the IDEO, you will be responsible for its cost.

Petitioner's Argument

In a letter to DIFS dated October 3, 2015 submitted with the request for an external review, the Petitioner wrote:

On August 11, I received a letter from Blue Cross Blue Shield of Michigan (BCBS) informing me of their Final Adverse Determination of coverage for my Intrepid Dynamic Exoskeletal Orthosis (IDEO). The IDEO is a prosthetic device prescribed for me as medically necessary that allows me to walk without amputation. I was covered at the date of service, and BCBS made errors when determining that my device is not a covered benefit.

The Final Adverse Determination came after a conference call with my orthopedic surgeon Dr. Christopher Peer, the developer of the IDEO prosthetist Ryan Blank, and an administrative assistant at BCBS. The purpose of the conference call was for the surgeon and prosthetist who are treating me to speak directly to a board-certified DO in Physical Medicine and Rehabilitation working for BCBS. I was informed by the BCBS administrative assistant at the start of the conference call that BCBS made a scheduling error and the DO would not participate in the call. The administrative assistant suggested continuing the call without the DO due to the difficulty in scheduling because of my surgeon's schedule (Eastern time zone) and that of my prosthetist who practices on the West Coast (Pacific time zone). I believe this lack of direct communication between my medical team and BCBS's DO led to errors of fact contained in the DO's 'opinion' as written that led to the denial of coverage for my prosthetic device.

The BCBS DO therefore (understandably) made his decision by consulting the BCBS Medical Policy titled, *Orthotic Devices*, which designates powered orthotic devices to be investigational, and made the decision that the IDEO is powered by

consulting the BCBS Medical Policy Manual titled, *Powered Exoskeleton for Ambulation in Patients with Lower-Limb Disabilities*. Had he/she been able to attend the conference call as planned, the BCBS DO would have learned that the IDEO IS NOT A POWERED DEVICE. Therefore, the BCBS DO's 'opinion' and 'understanding' is not based on facts relevant to this case. The BCBS Policy Manual designates a powered device as one which has, "A power source that supplies the energy for limb movement." However, my IDEO device has no power source whatsoever of its own. It is a non-powered device.

The BCBS DO continues with this misunderstanding of facts saying that it is his/her 'understanding' that the device must be approved by the Centers for Medicare and Medicaid before it can be designate as "non experimental." However, BCBS of California, Texas, Washington, Oregon, Illinois, Georgia, Vermont, as well as Federal BCBS which covers 5.3 million federal employees, all cover the IDEO device. The IDEO device is also covered for active duty US military and disabled veterans.

I have end-stage post traumatic arthritis in my ankle due to a trimalleolar fracture and dislocation on October 18, 2012. I have already endured 5 surgeries attempting to allow me to walk without debilitating pain. I have exhausted all other options short of below knee amputation. My surgeon has prescribed my IDEO as medically necessary. I can no longer attend to my own activities of daily living without my IDEO device. I cannot live independently without my IDEO device. I am the Coordinator of Behavior Outreach Service and the Social Skills Teaching Program for K-12 students with severe emotional and behavioral disorders for a Michigan Intermediate School District. I am highly qualified as a Special Education Teacher. Each day I run to protect my staff and students from assaults and break up fights, safely restrain students, and I'm often on my feet all day training school teachers in our three county area to manage classroom behavior. I cannot do my job without my IDEO device. Without my IDEO device, I am disabled. With my IDEO device, I am fully functional.

In a progress noted dated January 13, 2015, the Petitioner's surgeon wrote:

I have recommended the IDEO device as her best medical therapy in my professional judgment. This is based on the specific application of the device and its utility compared to other existing devices that are available. It is my opinion that this is the ONLY prosthesis that will restore her mobility to the desired level based on her age, activity level and physical pursuits prior to her injury. I do not believe any other available devices even custom fit orthoses will restore a reasonable level of function for her it is my opinion that she is too young and healthy and fit to consider disability at this point in time. There are no good surgical options available. She has utilized and fully maximized all the benefits of

nonsurgical options including activity modification, medications (including fentanyl patch Lyrica oxycodone and ibuprofen), footwear modification, use of a rocker bottom device, even to the point where she uses a knee scooter in her own home for daily activities. It is my professional judgment that the IDEO device is basically her only rational option at this point in time I advised her to continue to pursue IDEO device.

Director's Review

The *MESSA Account-Based Choices Plan 1 Plan Coverage Guide* (page 45) excludes coverage for items of durable medical equipment that are experimental or investigational. The question of whether the IDEO device is investigational or experimental according to current medical standards of care 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 physical medicine and rehabilitation 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:

The member has been treated with multiple reconstructive surgeries for the trimalleolar fractures that she sustained. The member underwent open reduction internal fixation (ORIF), subsequent hardware removal, open debridement of the ankle joint with removal of bony fragments, arthroscopy with ligament reconstruction and debridement and further hardware removal with manipulation under anesthesia and an intra-articular injection in February 2014. The member has not had an ankle fusion.

* * *

[T]here are no quality studies comparing the efficacy of the requested orthosis against conventional treatments such as use of a properly fitted and designed conventional ankle foot orthosis (AFO)...[A]dvantages of a conventional AFO are its reliability and ease of use....[F]urther research is needed to determine whether the device offers a clinically significant benefit in comparison with conventional treatments.

Pursuant to the information set forth above and available documentation...an Intrepid Dynamic Exoskeletal Orthosis (IDEO) device is experimental/ 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. In addition, the IRO’s recommendation is not contrary to any provision of the Petitioner’s benefit guide. MCL 550.1911(15).

The Director, discerning no reason why the IRO’s recommendation should be rejected in the present case, finds that the IDEO device is experimental or investigational, and is therefore, not a covered benefit.

The Director notes that the Petitioner has argued that BCBSM’s denial of coverage was based on its medical reviewer’s belief that the IDEO was an externally powered device. It appears that BCBSM did rely on that erroneous belief. However, the IRO’s conclusion that the device was experimental did not rely on that error. Rather, the IRO analysis was based on the absence of research showing that the IDEO was superior to other conventional ankle foot orthotics.

V. ORDER

The Director upholds BCBSM’s adverse determination of August 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:



Randall S. Gregg
Special Deputy Director