STATE OF MICHIGAN

DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES

Before the Director of the Department of Insurance and Financial Services

In the matter of:

Electronic Waveform Lab, Inc.
Petitioner **File No. 21-1060**

v

Liberty Mutual Insurance Company
Respondent

Issued and entered
this 20th day of July 2021
by Sarah Wohlford
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On June 4, 2021, Electronic Waveform Lab, Inc. (Petitioner) filed with the Director of the Department of Insurance and Financial Services (Department) a request for an appeal pursuant to Section 3157a of the Insurance Code of 1956 (Code), 1956 PA 218, MCL 500.3157a. The request for an appeal concerns the determination of Liberty Mutual Insurance Company (Respondent) that Petitioner overutilized or otherwise rendered or ordered inappropriate treatment, products, and services under Chapter 31 of the Code, MCL 500.3101 to MCL 500.3179.

The Director accepted the request for an appeal on June 4, 2021. Pursuant to R 500.65, the Director notified the Respondent and the injured person of the Petitioner's request for an appeal on June 9, 2021. Respondent filed a reply to the Petitioner's appeal on June 23, 2021. The Respondent did not submit a request for explanation to the Petitioner.

The Director assigned an independent review organization (IRO) to analyze issues requiring medical knowledge or expertise relevant to this appeal. The IRO submitted its report to the Director on June 30, 2021.

The Petitioner's appeal is made under R 500.65(3), which allows a provider to appeal to the Department from the denial of a provider's bill. The Petitioner seeks reimbursement in the full amount it billed for the date of service at issue.

II. FACTUAL BACKGROUND

The Petitioner appeals the denial of reimbursement for an electrical stimulation (H-Wave) medical device. The H-Wave device was provided to the injured person on February 24, 2021 as a home-care unit, along with conductive gel or paste and electrodes for operating the device.

The Respondent determined that the H-Wave medical device and its accompanying components were not medically necessary.

With its request for appeal, the Petitioner submitted supporting documentation stating that the H-Wave medical device and accompanying gel or paste and electrodes were medically necessary for management of low back pain. In support of the appeal, the Petitioner provided a prescription dated February 1, 2021, from the injured person's treating physician, for the H-Wave homecare unit to be used twice daily for 30 minutes to treat a diagnosis of lumbar intervertebral disc displacement. In support of its appeal, the Petitioner also submitted a "patient delivery evaluation" record dated February 24, 2021, that noted the injured person complained of pain at 7 on a 10-point pain scale prior to the electrical stimulation treatment. In addition, the record noted the following physical complaints: "difficulty walking, lower back is very tight and pain shoots down legs." On the patient delivery evaluation form, the Petitioner noted that after using the H-Wave device, the injured person experienced decreased pain and increased function.

In its Explanation of Payment issued March 16, 2021, the Respondent denied payment on the basis that the treatment was "not medically necessary and/or has extended above the usual range of utilization based on medically accepted standards."

In its reply to the appeal, the Respondent reaffirmed its position that the H-wave device and its components for the date of service at issue were not medically necessary. The Respondent's supporting documentation included a medical reviewer's report from its medical review organization, citing the Official Disability Guidelines, noting that the "ACOEM [American College of Occupational and Environmental Medicine] guidelines had no recommendations for an H-wave unit." The Respondent further stated that the H-Wave device was not recommended by its reviewer "as a first-line therapy or as an isolated intervention due to weak supportive evidence." The Respondent explained in its reply:

> When the home-based modality has been clearly documented to be effective in decreasing reported chronic pain, reducing medication intake and improving function during the 1-month home-based trial, the device may be considered for longer term purchase…A 1-month initial trial requires that the provider evaluate and document effects and benefits, including less reported pain, increased functional improvement and pain medication reduction.
>
> There was a lack of documentation that a 1-month trial had occurred or that an H-wave unit had been effective in decreasing reported chronic pain, reducing medication intake and improving function during a trial. There was a lack of

> documentation of other noninvasive, conservative treatment for chronic pain [having] been unsuccessful including medication, physical therapy, behavioral therapy or TENS unit that would warrant the request.

III. ANALYSIS

Director's Review

Under MCL 500.3157a(5), a provider may appeal an insurer's determination that the provider overutilized or otherwise rendered inappropriate treatment, products, services, or accommodations, or that the cost of the treatment, products, services, or accommodations was inappropriate under Chapter 31 of the Code. This appeal is a matter of medical necessity.

The Director assigned an IRO to review the case file. The IRO reviewer is board-certified in physical medicine and rehabilitation and pain medicine and is in active practice. In its June 30, 2021 report, the IRO reviewer recommended that the Department uphold the insurer's determination. The IRO reviewer concluded that the treatment, products, and services provided to the injured person on February 24, 2021, were not medically necessary in accordance with medically accepted standards.

The IRO reviewer opined that the medical device and supplies provided on the date of service at issue were not medically necessary in accordance with medically accepted standards as defined by R 500.61(i). The IRO reviewer provided the following explanation:

> The Official Disability Guidelines (ODG) by Milliman Care Guidelines (MCG) note that H-Wave stimulation is not recommended as an isolated intervention but a one-month home-based trial of H-Wave which may be considered as a noninvasive conservative treatment option when conservative treatments for chronic pain have not proven successful, including all of the following: medications, physical therapy, and a TENS unit.

The IRO reviewer explained that Home H-Wave treatment "may be considered only when other noninvasive, conservative treatments for chronic pain have proven to be unsuccessful, including at least 2 of the following: (1) medication (2) physical therapy (i.e., exercise), (3) behavioral therapy (4) TENS." The IRO reviewer stated that a 1-month trial requires a provider to "evaluate and document effects and benefits, including less reported pain, increased functional improvement, and pain medication reduction." Notably, in its review of the Petitioner's submitted documentation, the IRO reviewer did not find medical documentation to show that any other previous or concurrent conservative treatments, services, or medications were utilized by the injured person to manage his low back pain and pain radiating to the legs or improve function.

In addition, the IRO reviewer stated that the documentation submitted by the Petitioner did not include evidence that first-line treatment methods had been utilized, and failed, prior to the use of H-Wave

stimulation treatment for managing the injured person's chronic back pain. The IRO reviewer noted the submitted documentation lacked "clinical progress notes outlining subjective complaints, treatment history, medication list, pain levels, objective findings, diagnostic workup, or current treatment plan." In addition, the IRO reviewer stated the following:

> There is no evidence supporting H-wave stimulation as effective for chronic pain. There is also no documentation that the patient had a full 30-day trial with clear documentation of measurable improvements in pain, increased functional capacity and decreased medication use to support the purchase of H-wave unit and related supplies includ[ing] conductive gel and electrodes. The request is not medically necessary or in accordance with medically accepted standards of care.

Based on the above, the IRO reviewer recommended that the Director uphold the Respondent's determination on the basis that the medical device and medical supplies provided to the injured person on February 24, 2021 were not medically necessary in accordance with medically accepted standards, as defined by R 500.61(i). The Director, therefore, upholds the Respondent's determination dated March 16, 2021.

IV. ORDER

The Director upholds the Respondent's determination dated March 16, 2021.

This is a final decision of an administrative agency. A person aggrieved by this order may seek judicial review in a manner provided under Chapter 6 of the Administrative Procedures Act of 1969, 1969 PA 306, MCL 24.301 to 24.306. MCL 500.244(1); R 500.65(7). A copy of a petition for judicial review should be sent to the Department of Insurance and Financial Services, Office of Research, Rules, and Appeals, Post Office Box 30220, Lansing, MI 48909-7720.

Anita G. Fox
Director
For the Director:

7/20/2021

X Sarah Wohlford

Sarah Wohlford
Special Deputy Director
Signed by: Sarah Wohlford