STATE OF MICHIGAN

DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES

Before the Director of the Department of Insurance and Financial Services

In the matter of:	
Zynex Medical	
Petitioner	File No. 21-1209
V	
Progressive Michigan Insurance Company Respondent	

Issued and entered this 7th day of October 2021 by Sarah Wohlford Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On August 3, 2021, Zynex Medical (Petitioner) filed with 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 Progressive Michigan Insurance Company (Respondent) that the Petitioner overutilized or otherwise rendered or ordered inappropriate treatment, products, services, or accommodations under Chapter 31 of the Code, MCL 500.3101 to MCL 500.3179.

The Petitioner's appeal is based on the denial of a bill pursuant to R 500.64(3), which allows a provider to appeal to the Department from the denial of a provider's bill. The Respondent issued the Petitioner a bill denial on June 8, 2021. The Petitioner now seeks reimbursement in the full amount it billed for the date of service at issue.

The Department accepted the request for an appeal on August 17, 2021. Pursuant to R 500.65, the Department notified the Respondent and the injured person of the Petitioner's request for an appeal on August 19, 2021 and provided the Respondent with a copy of the Petitioner's submitted documents. The Respondent filed a reply to the Petitioner's appeal on September 3, 2021.

The Department assigned an independent review organization (IRO) to analyze issues requiring medical knowledge or expertise relevant to this appeal. The IRO submitted its report and recommendation to the Department on September 20, 2021.

II. FACTUAL BACKGROUND

This appeal concerns the denial of payment for a spinal orthosis device provided to the injured person on April 15, 2021, under procedure code L0650, which is described as a lumbar-sacral orthosis. In its *Explanation of Review* letter, the Respondent denied payment for the device on the basis that it exceeded the period of care for either utilization or relatedness.

With its appeal request, the Petitioner submitted documentation indicating that the injured person's diagnoses included subluxation of the lumbar at L4-L5 and of the vertebra at T6-T7; other intervertebral disc displacement, lumbar region; dislocation of sacroiliac and sacrococcygeal joint; myalgia; dislocation of other parts of lumbar spine and pelvis; and muscle spasm of back. Additionally, the Petitioner provided a prescription for the spinal orthosis device. The Petitioner's request for an appeal stated that it "offers quality [durable medical equipment] treatment and focuses on providing excellent pain management and rehabilitative treatment without the use of opioids."

In its reply, the Respondent reaffirmed its initial denial of payment for the device, in accordance with the American College of Environmental Medicine (ACOEM) practice guidelines. Specifically, the Respondent stated:

A lumbar support is not recommended for the prevention or treatment of low back pain. The medical records do not support this request, as the lumbosacral orthosis was prescribed for low back pain.

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 involves a dispute regarding inappropriate product.

The Director assigned an IRO to review the case file. In its report, the IRO reviewer concluded that, based on the submitted documentation, medical necessity was not supported on the date of service at issue for the durable medical equipment provided based on medically accepted standards.

The IRO reviewer is a physician, who is familiar with the medical management of patients with the injured person's condition, has examined the medical record and the arguments presented by the parties. In its report, the IRO reviewer referenced R 500.61(i), which defines "medically accepted standards" as the most appropriate practice guidelines for the treatment provided. These may include generally accepted practice guidelines, evidence-based practice guidelines, or any other practice guidelines developed by the federal government or national or professional medical societies, board, and associations. The IRO

reviewer relied on Milliman Care Guidelines, as well as peer-reviewed journal articles related to the treatment of back pain for its recommendation.

The IRO reviewer opined that the lumbar sacral orthosis device provided to the injured person on April 14, 2021 was not medically necessary in accordance with medically accepted standards as defined by R 500.61(i). The IRO reviewer explained that "management of chronic benign musculoskeletal pains affecting body regions such as the neck and back due to injury can include pharmacological agents, rehabilitation, psychological treatment, complementary or alternative medicine, and invasive approaches."

The IRO reviewer explained further that:

[T]he aim of rehabilitation in this clinical setting is to reduce pain, reduce impairment or disability, and improve quality of life ... [and] formal rehabilitative interventions are rendered in conjunction with education towards a goal of self-management, independent exercise, and remaining active...[and] exercise and physical activity have low risk for adverse effects and are generally encourage in the setting of these types of chronic pains.

Based on the documentation provided, the IRO reviewer opined:

[T]hat the use of any type of lumbar orthosis is not a generally accepted standard of medical practice for the injured person's condition ... [and] there is no indication for this type of intervention absent an unstable bony spine such as a fracture or significant spondylolisthesis or recent destabilizing spinal surgery ... [and] this type of intervention does not improve or otherwise treat mechanical low back pain.

In addition, the IRO reviewer noted:

[T]here are no high-grade published data that this type of intervention favorably impacts the natural history of the patient's conditions in a clinically meaningful manner ... [and] back orthoses, whether off the shelf or custom fitted, are generally considered contraindicated in the injured person's clinical setting because they can promote core weakness which is the opposite of appropriate treatment.

The IRO reviewer opined further that "lumbar orthoses are not recognized in any generally accepted practice guideline, evidence-based practice guidelines, or other guidelines developed by the federal government or national or professional medical societies, boards or associations, as appropriate management with respect to back or spinal pain or other type of persistent or chronic pain."

Based on the above, the IRO reviewer recommended that the Director uphold the Respondent's determination that the durable medical equipment provided to the injured person on April 14, 2021 was not medically necessary in accordance with medically accepted standards, as defined by R 500.61(i).

IV. ORDER

The Director upholds the Respondent's determination dated June 8, 2021.

This order applies only to the treatment and dates of service discussed herein and may not be relied upon by either party to determine the injured person's eligibility for future treatment or as a basis for action on other treatment or dates of service not addressed in this order.

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:

Recoverable Signature

Jarah Wohlford

Sarah Wohlford Special Deputy Director Signed by: Sarah Wohlford