

MEDICAL CONTESTED CASE HEARING 21006

DECISION

This case is decided pursuant to the Texas Workers' Compensation Act and the Rules of the Texas Department of Insurance, Division of Workers' Compensation. For the reasons discussed herein, the Administrative Law Judge determines the following:

The preponderance of the evidence is not contrary to the decision of the Independent Review Organization (IRO) that Belbuca 600 mcg film, quantity 60 for a 30-day supply with two refills, and ZTLido patch #60 for a 30-day supply is not health care reasonably required for the compensable injury of (Date of Injury).

ISSUE

A contested case hearing was held on March 16, 2021, to decide the following disputed issue:

Is the preponderance of the evidence contrary to the decision of the Independent Review Organization (IRO) that Belbuca 600 mcg film, quantity 60 for a 30-day supply with two refills, and ZTLido patch #60 for a 30-day supply is not health care reasonably required for the compensable injury of (Date of Injury)?

PERSONS PRESENT

The claimant appeared and was represented by TM, attorney. The insurance carrier appeared and was represented by RG, attorney. The hearing was held by teleconference in accordance with Commissioner Cassie Brown's March 24, 2020, memo to system participants regarding workers' compensation operations in light of COVID-19.

EVIDENCE PRESENTED

The following witnesses testified:

For the claimant: The claimant.

For the insurance carrier: None.

The following exhibits were admitted into evidence:

Administrative Law Judge Exhibit: ALJ-1.

The claimant's Exhibits: C-1 through C-14.

The insurance carrier's Exhibits: CR-A through CR-D.

DISCUSSION

The claimant sustained a compensable injury on (Date of Injury), when she was involved in a motor vehicle accident. The compensable injury includes at least an injury to the spine. The claimant is paralyzed from the waist down. According to the claimant she has severe pain and has tried a number of different combinations of pain medications with various success. The claimant stated that the combination of Belbuca and the ZTLido patch are effective in relieving her pain.

To determine if treatment is medically necessary, Texas law requires DWC to use treatment guidelines. These guidelines must be evidence-based, scientifically valid, and outcome-focused. Use of these guidelines ensures that an injured employee will receive reasonable and necessary health care. (See Labor Code §413.011(e) and 413.017(1).) DWC uses the current edition of the *Official Disability Guidelines (ODG)*. If the *ODG* does not address the requested treatment, then other guidelines or generally accepted standards of practice recognized in the medical community are used.

In September 2020, Dr. SM started treating the claimant, and Dr. M noted that the claimant was taking Belbuca 450 mcg in addition to taking Norco. According to Dr. M, she prescribed Belbuca 600 mcg to prevent breakthrough pain and to get the claimant off the Norco and its side effects. Dr. M stated that Belbuca 600 mcg is a safer alternative to Hydrocodone because it is not used as a street drug; therefore, it has no street value.

Dr. M wrote in her January 18, 2021, letter that in addition to Belbuca 600 mcg, she also prescribed ZTLido 1.8% patch for the claimant's hip and chin pain. Dr. M stated that the patches are used to help with nerve pain resulting from the claimant's paraplegia. Dr. M opined that with this type of complicated injury, a doctor has to try several types of medications until the correct one works, even if it is used off label. According to Dr. M, medical records indicated that the claimant was already using Lidocaine patches to control this pain, and the ZTLido 1.8% patch is just an updated version of the Lidocaine patch and it has adherent properties that are superior. Thus, this patch stays in place and better delivers the medications that the claimant needs to control her pain.

Dr. M stated that in her opinion, the ZTLido 1.8% patch and the Belbuca 600 mcg are medically necessary for the reasons explained above, and to allow the claimant to live as close a pain free life as she can with the injuries that she sustained.

On September 25, 2020, physician advisor, Dr. LL, completed a utilization review regarding the medical reasonableness and necessity of the requested Belbuca. In that review, the advisor noted the lack of objective functional gains from ongoing use of medication and treatment, as well as the lack of ongoing assessment of pain and functional outcomes. The physician advisor

attempted a peer-to-peer discussion with Dr. M, which was not successful, and recommended non-authorization of the request.

On September 29, 2020, physician advisor, Dr. CC, provided a utilization review regarding the ZTLido. Dr. C noted that topical Lidocaine was listed as an "N" drug in the Workers' Compensation formulary and was not recommended as a first line treatment for neuropathic pain. The advisor also noted that it was not probable that topical Lidocaine would help with pain from a spinal cord injury. Further, he noted that the *ODG* stated that there needed to be objective improvements in pain and function and decreased use of other medications to justify the continued use of the medication, which had not occurred.

On October 13, 2020, physician advisor, Dr. DB, performed a utilization review of the requested Belbuca increase. Dr. B noted that the claimant had previously used Belbuca at 450 mcg dose and that the requesting physician had failed to specify why the claimant required an increase in the dose of the medication if she was responding favorably to the lower dose of Belbuca previously. The physician advisor stated that the current request for increased dose of Belbuca could not be authorized due to this lack of information. Dr. B also addressed the requested ZTLido, and she noted that the *ODG* did not recommend the use of ZTLido as a first line treatment for neuropathic pain and that the ZTLido patches were approved by the FDA for treatment of post-herpetic neuralgia, which is not among the claimant's clinical conditions. Dr. B also opined that the requesting doctor did not explain why a change in patches was necessary. The denial was upheld.

The claimant then requested an Independent Review Organization (IRO) review of the denial. On November 4, 2020, the IRO upheld the previous denials of the requested medications. The claimant is now appealing the IRO decision.

In this dispute, the claimant has the burden of showing by a preponderance of the medical evidence that the IRO decision is wrong. The claimant relied on her testimony and the medical records in evidence to support her position of entitlement to the disputed treatment. The insurance carrier relied on the medical records and the IRO decision in evidence to support its position that the claimant is not entitled to the requested medical services.

According to the IRO reviewer, ZTLido is not FDA approved for the treatment of neuropathic pain due to spinal cord injury and is listed as an "N" drug on the Workers' Compensation formulary. Additionally, the IRO reviewer stated that since the claimant's lower extremity pain is, in all medical probability centrally mediated due to the spinal cord injury, application of local anesthetic patches such as ZTLido, would be, more medically likely than not, not likely to provide significant pain relief. The IRO reviewer opined that the request for ZTLido patches is not reasonable medically necessary, or in accordance with the *ODG* guidelines. The IRO reviewer upheld the prior physician advisor recommendations for non-authorization for this medication,

The IRO reviewer added that there is no justification provided by the requesting physician for the increase in Belbuca from 450 mcg every twelve hours to 600 mcg every twelve hours nor is there any documentation of significant pain relief or functional improvement from the use of Belbuca. Since the *ODG* guidelines require that there be evidence of improved functional outcome and decreased use of medication, it does not appear that the use of Belbuca is providing significant pain relief at all. Moreover, there has not been any decrease in the use of other medications concurrent with the ongoing use of Belbuca, further casting doubt upon its effectiveness and medical necessity, according to the *ODG*. According to the IRO reviewer, no urine drug screens have apparently been performed on this patient during the time she has been taking both Belbuca and an opioid (Hydrocodone), which is a requirement for physicians to continue prescribing opioids. Therefore, there is no documented medical reason, medical necessity, or indication for increasing the patient's dose of Belbuca to 600 mcg every twelve hours from the current 450 mcg every twelve hours nor any *ODG* support for such.

The IRO reviewer determined that the requested prescription for Belbuca 600 mcg, quantity 60 for a 30 day supply with 2 refills and the prescription for ZTLido 1.8% patch, quantity 60 for a 30 day supply are not appropriate, medically necessary, or in accordance with the *ODG*; therefore, the prior adverse determinations are upheld at this time.

In summary, the evidence offered, does not provide a persuasive explanation using evidence-based medicine of how the disputed treatment is necessary.

The ALJ considered all the evidence admitted. The Findings of Fact and Conclusions of Law are based on an assessment of all the evidence, whether or not the evidence is specifically discussed in this Decision.

FINDINGS OF FACT

1. The parties stipulated to the following facts:
 - A. Venue is proper in the (City) Field Office of the Texas Department of Insurance, Division of Workers' Compensation.
 - B. On (Date of Injury), the claimant was the employee of (Employer), the employer.
 - C. On (Date of Injury), the employer provided workers' compensation insurance through self-insurance.
 - D. On (Date of Injury), the claimant sustained a compensable injury.
 - E. The (Date of Injury), compensable injury includes at least injury to the lumbar spine.

- F. The Independent Review Organization decision upheld the insurance carrier's denial of Belbuca 600 mcg film, quantity 60 for a 30-day supply with two refills, and ZTLido patch #60 for a 30-day supply.
2. The insurance carrier delivered to the claimant a document stating the insurance carrier's true corporate name and the registered agent's name. This document was admitted into evidence as the insurance carrier's exhibit: CR-B.
 3. The Independent Review Organization decision was sent to the parties on September 29, 2020.
 4. On October 14, 2020, the claimant filed this appeal of the Independent Review Organization decision with the Division of Workers' Compensation. The appeal was filed within twenty days from the date the Independent Review Organization decision was sent to the parties.
 5. The decision of the Independent Review Organization has not become final because the Division of Workers' Compensation timely received the request for appeal.
 6. The preponderance of the evidence-based medical evidence does not support that Belbuca 600mcg film, quantity 60 for a 30-day supply with two refills, and ZTLido patch #60 for a 30-day supply is medically necessary for the compensable injury of (Date of Injury).

CONCLUSIONS OF LAW

1. The Texas Department of Insurance, Division of Workers' Compensation, has jurisdiction to hear this case.
2. The preponderance of the evidence is not contrary to the decision of the Independent Review Organization (IRO) that Belbuca 600 mcg film, quantity 60 for a 30-day supply with two refills, and ZTLido patch #60 for a 30-day supply is not health care reasonably required for the compensable injury of (Date of Injury).

ORDER

The insurance carrier is not liable for the benefits in dispute in this hearing. The claimant remains entitled to medical benefits for the compensable injury in accordance with Texas Labor Code §408.021.

The true corporate name of the insurance carrier is **(Self-Insured), (SELF-INSURED)**. The name and address of its registered agent for service of process is:

(NAME)
(ADDRESS)
(CITY, STATE, ZIPCODE)

Signed on 18th day of March, 2021.

Early Moyer
Administrative Law Judge