#### MEDICAL CONTESTED CASE HEARING NO. 20002

## **DECISION AND ORDER**

This case is decided pursuant to Chapter 410 of the Texas Workers' Compensation Act and Rules of the Division of Workers' Compensation adopted thereunder. For the reasons discussed herein, the Administrative Law Judge (ALJ) determines that: Claimant is not entitled to the requested authorization and coverage for RT300 FES Ergometer for legs for home use for the compensable injury of (Date of Injury).

#### STATEMENT OF THE CASE

Contested case hearings were held on October 7, 2019, and December 10, 2019, with the record closing on January 13, 2020 to decide the following disputed issue:

Is the preponderance of the evidence contrary to the decision of the IRO that Claimant is not entitled to authorization and coverage for RT300 FES Ergometer for legs is not reasonably required health care for the compensable injury of (Date of Injury)?

The record was held open after the October 7, 2019, hearing as there was insufficient time to hear all witnesses, and another session was held on December 10, 2019. The record continued to be held open for the submission of an exhibit and additional legal authority. The record was closed on January 13, 2020.

### PARTIES PRESENT

Petitioner/Claimant (Claimant) was present, and represented by LE, attorney. Respondent/Carrier (Carrier) appeared and was represented by HA, attorney.

#### EVIDENCE PRESENTED

The following witnesses testified at the October 7, 2019, hearing:

For Claimant: GC.

For Carrier: Dr. BB.

The following exhibits were admitted into evidence at the October 7, 2019, hearing:

Administrative Law Judge's Exhibits: ALJ-1 and ALJ-2.

Claimant's Exhibits: C-1 through C-11.

Carrier's Exhibits: CR-A through CR-H.

The following witnesses testified at the December 10, 2019, hearing:

For Claimant: SS.

Dr. NS.

For Carrier: None.

The following Exhibits were admitted in evidence at the December 10, 2019, hearing:

Administrative Law Judge's Exhibits: ALJ-3.

Claimant's Exhibits: None.

Carrier's Exhibits: None.

#### **DISCUSSION**

Claimant sustained a compensable injury on (Date of Injury). Claimant testified that he was working on a road crew, and that a large temporary road sign fell and struck him on the top left side of his head. The parties stipulated that the compensable injury extends to and includes at least a concussion, cervical sprain/strain, and C5-C6 disc herniation. Claimant underwent surgery on his neck and there were complications that required two more surgeries. After the second surgery he was paralyzed on his left side. The third surgery improved his condition and he started physical therapy including the use of the RT300 FES Ergometer (RT300) for legs. Claimant testified that the first time he used the machine he saw improvement and he uses it at a rehabilitation facility on Wednesdays. He testified that the physical therapists confirmed to him that he was improving as a result.

During his rehabilitation therapy following surgery Claimant used an RT300 at least 3 times prior to applying for authorization for the home use of the RT300. It is noted that the issue does not indicate that the request was for home use of the RT300. The request for approval stated "The RT300 FES Therapy System was determined to be the most medically appropriate system of Claimant's home FES active physical therapy program." The evidence and arguments of the parties in litigating this matter on the medical necessity for the use of the RT300 was for its use at home. This would presumably require the purchase of the machine or for Carrier to otherwise provide this device to Claimant for his use at home. The ALJ treated the issue as litigated as "Is the preponderance of the evidence contrary to the decision of the IRO that Claimant is not entitled to authorization and coverage for RT300 FES Ergometer for legs for home use is not reasonably required health care for the compensable injury of (Date of Injury)."

The first utilization review of the request for the RT300 for legs was performed by Dr. BB and his recommendation was reflected in request complete dated letter of April 8, 2019. This letter stated that Carrier found that the services or treatment described were not medically necessary or appropriate. The denial indicated that the RT300 for legs is not specifically addressed by the Official Disability Guidelines (ODG). The denial noted it is unclear if the long-term use is needed or that Claimant would use the equipment without direct supervision and that medical necessity is not established. Dr. B testified and stated that in his opinion home use was not appropriate for Claimant as he had comorbidities. He testified Claimant had diabetes, heart disease, was obese, had a smoking history, and hypertension. He opined that the use of the devise in a physical therapy setting with supervision would be safer and that there was risk in using the RT300 at home because of Claimant's comorbidity conditions. Claimant testified that he did not have any health problems while using the machine at the rehabilitation facility.

The appeal of this denial was upheld in a letter with an April 17, 2019, complete date, wherein Carrier stated "we reviewed the appeal of the UR denial determination that was received on April 10, 2019, and it was determined that the request still does not meet medical necessity guidelines. This appeal review noted that the Claimant only had 3 sessions of use of the RT300 for legs and according to guidelines the Claimant would need a completion of a training program to include 32 sessions with the device every 3 months. Therefore, the RT300 is non-certified. This appeal determination cited the ODG treatment index for Ankle and Foot chapter that is for a functional electrical stimulation (FES) state that it is recommended for foot drop to help patients with spinal cord injury (SCI) to improve ambulation. FES cycling may be considered as an adjunct to spinal cord injury motor recovery during supervised office physical therapy but is not recommended alone or for home use. It set out the criteria for the FES which included at least 6-months post recovery of spinal cord injury and restorative surgery. It was noted that Claimant's surgery on February 20, 2019, and the request for authorization for the RT300 was dated March 28, 2019. Claimant appealed this determination.

Maximus Federal Services, Inc was appointed by the Texas Department of Insurance as the Independent Review Organization to conduct the independent review. The review was conducted by an MD who was board certified in Physical Medicine and Rehabilitation/Pain Management. The IRO Review upheld the prior reviews of April 8, 2019, and April 17, 2019, that denied the request for the RT300 for lower legs for home use. Notice to all parties was provided by the IRO on June 13, 2019.

The IRO review acknowledged that Claimant has an incomplete C5 AIS D spinal cord injury. It also noted that after a spinal cord injury, most recovery occurs in the first six to 12 months and can extend beyond one year. It also noted that Claimant was less than two months status post-surgery when the request for the RT300 was made. The denial stated that in terms of functional abilities, Claimant should be able to use adapted conventional equipment for strengthening and an upper extremity or wheelchair ergometer for cardiovascular exercise as he is currently using a

manual wheelchair and there is already a plan to use a standing frame. The denial indicated Claimant's use of the RT300 due to his condition would carry risk of autonomic dysreflexia, postural hypotension, and skin pressure ulceration. The review also indicated that comorbid conditions include type II diabetes, which would also increase his risk of pressure ulcer formation and that Claimant's history of myocardial infarction and obesity would be relative contraindication to using the electrical stimulation versus volitional exercises. The denial stated that the RT300 FES cycle system would not treat the Claimant's spinal cord injury and was being requested as a preventive measure and means of exercise. The review noted although exercise is beneficial and highly recommended, it is considered no more medically necessary in this case than for any other individual. The review also cited that the FES cycling is addressed by ODG in the Foot and Ankle chapter.

With regard to functional electrical stimulation (FES), the ODG provides as follows:

Recommended for foot drop to help patients with spinal cord injury (SCI) to ambulate as indicated below. Functional electrical stimulation (FES) reduces foot drop and improves walking speed. (Springer, 2012) (Marsden, 2012) Therapy combining FES and a conventional rehab program is superior to a conventional rehab program alone, in terms of reducing spasticity, improving dorsiflexor strength and lower extremity motor recovery. (Sabut, 2011) Peroneal FES seems to be superior to an AFO with regard to obstacle avoidance ability in community-dwelling people with stroke. The observed gains in obstacle avoidance ability appear to be clinically most relevant in the people with relatively low leg muscle strength. (van Swigchem, 2012) See also Foot drop treatment.

Criteria for use of functional electrical stimulation (FES):

- Diagnosis of spinal cord injury with intact lower motor units (L1 and below); &
- Can bear weight on upper and lower extremities to maintain an upright posture independently; &
- Shows muscle contraction to neuromuscular electrical stimulation and sensory perception of electrical stimulation sufficient for muscle contraction; &
- Patient is highly motivated and has the cognitive ability to use such devices for walking; &
- Can transfer independently and stand for at least 3 minutes; &
- Has hand and finger function to manipulate the controls; &
- At least 6 months post recovery of spinal cord injury and restorative surgery; &
- No hip or knee degenerative disease and has no history of long bone fracture secondary to osteoporosis; &
- Completion of a training program, 32 PT sessions with the device over a 3 months period; &

 Using devices, such as Parastep I, that are FDA approved for this treatment, but not devices approved as exercise equipment, such as the FES Power Trainer, ERGYS, REGYS, NeuroEDUCATOR, STimMaster Galaxy, RT300 motorized FES ergometer, and SpectraSTIM.

Both parties acknowledged at the CCH that the Foot and Ankle chapter was not technically applicable here. The ALJ did not treat these guidelines under which such treatment is presumed to be health care reasonably required.

Claimant's evidence established that the RT300 is a Functional Electrical Stimulator Ergometer that uses electrical stimulation to the nerves and muscles. The RT300 has been approved by the FDA for relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, maintaining or increasing range of motion and muscle re-education.

Claimant presented the testimony of Dr. NS, who was the Claimant's treating surgeon. Dr. S acknowledged that he has never recommended or prescribed the RT300 before and has no experience with it, and that he usually does not do the recommendations he relies on other doctors and physical therapist. He testified that Claimant had cervical disc herniations with neuralgic compromise and a spinal cord injury. He testified that Claimant used the RT300 at the rehabilitation center and made progress and that Claimant worked harder than any other person to achieve rehabilitation. However, Dr. S did not cite or explain any evidence based medicine that supported his recommendation or prescription of this device or that addressed and overcame the basis of denial by the IRO. Dr. S testified that he prescribed this device for Claimant. The medical records in evidence do not support that Dr. S prescribed the RT300.

Claimant also presented the testimony of SS, the (title) of (company), the manufacturer of the RT300. Mr. S testified about the uses and benefits of RT300. Mr. S indicated that most of their sales are for use at home customers. However, Mr. S did not persuasively provide any evidence based medicine to overcome the finding by the IRO that the device was not medically necessary for home use.

The party disputing the IRO has the burden of proof to overcome the decision by a preponderance of the evidence-based medical evidence. Evidence based medicine must involve the opinion of a qualified expert. Texas Labor Code § 401.011 (22-a) provides: Health care reasonably required means health care that is clinically appropriate and considered effective for the injury and provided in accordance with best practices consistent with (A) evidence based medicine; or (b) if that evidence is not available, generally accepted standards of medical practice recognized in the medical community. DWC has adopted the Official Disability Guidelines and the medical care provided in accordance with the ODG is presumed reasonable.

The evidence reveals that it was Dr. MR that prescribed the RT300 and provided a letter of medical necessity. Dr. R stated that Claimant has partial loss of volitional motor function below

L1 spinal level in his left lower extremity his pin prick and light touch sensation is impaired or absent below C5 spinal level bilaterally. She noted that once a patient has sustained a spinal cord injury and is stabilized, lower extremity mobilization can be achieved by an ergometer powered by a Claimant's own muscle strength evoked by FES. She noted that Claimant's peripheral nerve supply is intact allowing him to respond to the RT300's electrical stimulation. She stated the RT300 FES therapy system was determined to be the most medically appropriate system for Claimant's at home FES active physical therapy program. She noted that Clinicians are able to monitor, and control Claimant's use of the RT300 from a satellite facility using HIPAA compliant internet database to provide on demand home supervision to ensure Claimant's safety, therapy effectiveness and compliance. She did not cite any ODG guidelines to support her opinion. Since it was agreed that no ODG Guidelines existed for use of the RT300 for Claimant's condition it was the Claimant's burden to introduce evidence that is consistent with evidence based medicine and if none exist by generally accepted standards of medical practice recognized in the medical community.

In her letter of medical necessity, Dr. R noted that the injury to the spinal cord causes profound immobility and inactivity and can lead to several physical and metabolic damages to Claimant health. The changes include a decrease in muscle mass, muscle atrophy, decreased muscle endurance and other conditions. She stated these changes can lead to further complications such a skin breakdown, thromboembolic disease, recurrent urinary tract infections, and other conditions. She opined that all of these factors can lead to frequent and lengthy hospitalization expensive medical cost and need for greater care. Dr. R stated that:

there were 70 peer reviewed and established journals such as the Spinal Cord, Archives of Physical Medicine and Rehabilitation, American Journal of Physiology, Neurosurgery and Clinical Orthopedics that has demonstrated that the use of lower extremity FES ergometry, the RT300, has been proven as a safe and effective tool for the management and prevention of these changes for individuals with a spinal cord injury."

Dr. R provided a list of 40 articles as references in an appendix at the end of her letter. The list provided titles of the articles or studies, the author, date and where they were published. However, Dr. R did not provide any findings of these articles, any summary of the articles, or explain why or how they were relevant to Claimant and the RT300.

Dr. R also did not cite any evidence based medicine that supports any opinion that the home use of a RT300 is clinically appropriate or medically necessary. She also did not persuasively address the Carrier's position that the home use created risk to the Claimant because of his comorbidity conditions as stated by the utilization review and the appeal denial upheld by the IRO. It is also noted that Claimant did not establish the expertise and experience of Dr. R with

the RT300 or other Functional Electrical Stimulation devices. The only evidence about Dr. R was her title of DO, MS, CLCP and Medical Director of (Provider).

Texas Labor Code Section 408.021 provides that an employee who sustains a compensable injury is entitled to all health care reasonably required by the nature of the injury as and when needed. Health care reasonably required is further defined in Texas Labor Code Section 401.011 (22a) as health care that is clinically appropriate and considered effective for the injured employee's injury and provided in accordance with best practices consistent with evidence based medicine or, if evidence based medicine is not available, then generally accepted standards of medical practice recognized in the medical community. Health care under the Texas Workers' Compensation system must be consistent with evidence based medicine if that evidence is available. Evidence based medicine is further defined in Texas Labor Code Section 401.011 (18a) to be the use of the current best quality scientific and medical evidence formulated from credible scientific studies, including peer-reviewed medical literature and other current scientifically based texts and treatment and practice guidelines. The Commissioner of the Division of Workers' Compensation is required to adopt treatment guidelines that are evidencebased, scientifically valid, outcome-focused, and designed to reduce excessive or inappropriate medical care while safeguarding necessary medical care. Texas Labor Code Section 413.011(e). Medical services consistent with the medical policies and fee guidelines adopted by the commissioner are presumed reasonable in accordance with Texas Labor Code Section 413.017(1).

In accordance with the above statutory guidance, the Division of Workers' Compensation has adopted treatment guidelines by Division Rule 137.100. This rule directs health care providers to provide treatment in accordance with the current edition of the Official Disability Guidelines (ODG), and such treatment is presumed to be health care reasonably required as defined in the Texas Labor Code. Thus, the focus of any health care dispute starts with the health care set out in the ODG. Also, in accordance with Division Rule 133.308(s), "A decision issued by an IRO is not considered an agency decision and neither the Department nor the Division are considered parties to an appeal. In a Contested Case Hearing (CCH), the party appealing the IRO decision has the burden of overcoming the decision issued by an IRO by a preponderance of evidence-based medical evidence."

Based on the evidence presented, Claimant did not meet his burden of proof to overcome the decision of the IRO by the preponderance of evidence-based medical evidence. Claimant's evidence discussed the recommendation of two physicians and an executive from the manufacturer of the RT300 for the proposed home use of the RT300, however, Claimant did not present persuasive evidence-based medical evidence to support his position. As a preponderance of the evidence is found not to be contrary to the decision of the IRO that the home use of the RT300 is not health care reasonable required for the compensable injury of (Date of Injury).

Even though all the evidence presented was not discussed, it was considered. The Findings of Fact and Conclusions of Law are based on all of the evidence presented.

#### FINDINGS OF FACT

- 1. The parties stipulated to the following facts:
  - A. The Texas Department of Insurance, Division of Workers' Compensation has jurisdiction to hear this matter.
  - B. Venue is proper in the (City) Field Office of the Texas Department of Insurance, Division of Workers' Compensation.
  - C. On (Date of Injury), Claimant was the employee of (Employer), Employer.
  - D. On (Date of Injury), Employer provided workers' compensation insurance coverage with Travelers Casualty & Surety Company, Carrier.
  - E. Claimant sustained a compensable injury on (Date of Injury).
  - F. The compensable injury of (Date of Injury), extends to and includes at least a concussion, cervical sprain/strain and C-5-C6 disc herniation.
  - G. Carrier denied preauthorization for the requested authorization and coverage for RT300 FES Ergometer for legs.
  - H. The Texas Department of Insurance appointed Maximus Federal Services Inc. as the Independent Review Organization.
  - I. The Independent Review Organization upheld Carrier's denial of preauthorization for authorization and coverage for RT300 FES Ergometer for legs for home use.
- 2. Carrier delivered to Claimant a single document stating the true corporate name of Carrier, and the name and street address of Carrier's registered agent, which document was admitted into evidence as Administrative Law Judge's Exhibit Number 2.
- 3. The preponderance of the evidence is not contrary to the decision of the Independent Review Organization that Claimant is not entitled to the requested authorization and coverage for RT300 FES Ergometer for legs for home use 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. Venue is proper in the (City) Field Office.
- 3. Claimant is not entitled to the requested authorization and coverage for RT300 FES Ergometer for legs for home use for the compensable injury of (Date of Injury).

#### **DECISION**

Claimant is not entitled to the requested authorization and coverage for RT300 FES Ergometer for legs for home use for the compensable injury of (Date of Injury).

# **ORDER**

Carrier is not liable for the benefits at issue in this hearing. Claimant remains entitled to medical benefits for the compensable injury in accordance with §408.021.

The true corporate name of the insurance carrier is **TRAVELERS CASUALTY & SURETY COMPANY** and the name and address of its registered agent for service of process is:

CORPORATION SERVICE CO. D/B/A
CSC-LAWYERS INCORPORATING SERVICE CO.
211 EAST 7TH STREET STE. 620
AUSTIN, TX 78701-3218

Signed this 16<sup>th</sup> day of January, 2020.

Christopher M. Maisel Administrative Law Judge