THIS DECISION HAS BEEN APPEALED. THE FOLLOWING IS THE RELATED SOAH DECISION NUMBER: SOAH DOCKET NO. 453-03-3647.M5

MDR Tracking Number: M5-03-1465-01

Under the provisions of Section 413.031 of the Texas Workers' Compensation Act, Title 5, Subtitle A of the Texas Labor Code, effective January 1, 2002 and Commission Rule 133.305 and 133.308 titled <u>Medical Dispute Resolution by Independent Review Organizations</u>, the Medical Review Division (Division) assigned an IRO to conduct a review of the disputed medical necessity issues between the requestor and the respondent.

The Division has reviewed the enclosed IRO decision and determined that **the requestor did not prevail** on the issues of medical necessity. The IRO agrees with the previous determination that chiropractic treatments and services were not medically necessary. Therefore, the requestor is not entitled to reimbursement of the IRO fee.

Based on review of the disputed issues within the request, the Division has determined that chiropractic treatment and service fees were the only fees involved in the medical dispute to be resolved. As the treatment was not found to be medically necessary, reimbursement for dates of service from 10/20/01 to 10/30/01 is denied and the Division declines to issue an Order in this dispute.

This Decision is hereby issued this 16th day of May 2003.

Noel L. Beavers Medical Dispute Resolution Officer Medical Review Division NLB/nlb

NOTICE OF INDEPENDENT REVIEW DECISION

Date: May 13, 2003

 RE: MDR Tracking #:
 M5-03-1465-01

 IRO Certificate #:
 5242

has been certified by the Texas Department of Insurance (TDI) as an independent review organization (IRO). The Texas Workers' Compensation Commission (TWCC) has assigned the above referenced case to _____ for independent review in accordance with TWCC Rule §133.308 which allows for medical dispute resolution by an IRO.

has performed an independent review of the proposed care to determine if the adverse determination was appropriate. In performing this review, relevant medical records, any documents utilized by the parties referenced above in making the adverse determination, and any documentation and written information submitted in support of the appeal was reviewed.

The independent review was performed by a Chiropractic physician reviewer. The Chiropractic physician reviewer has signed a certification statement stating that no known conflicts of interest exist between him or her and any of the treating physicians or providers or any of the physicians or providers who reviewed the case for a determination prior to the referral to for independent review. In addition, the reviewer has certified that the review was performed without bias for or against any party to this case.

Clinical History

According to the documentation supplied, it appears the claimant was injured on _____. There was not any treatment documentation supplied for the entirety of the case, only the treatment for the dates in question. The chiropractor was the treating chiropractor and on 10/02/2002, 10/08/2002, 10/23/2002, and on 10/30/2002 the claimant had an unlisted procedure of the nervous system performed. The information that was supplied states the therapy utilized was a Synaptic 3400. The documentation ends with several pages describing the Synaptic 3400 and its treatment protocol.

Requested Service(s)

The medical necessity of the chiropractic treatment rendered between 10/02/2001 - 10/30/01.

Decision

I agree with the insurance company that the services rendered between 10/02/2001 - 10/30/2001 was not medically necessary.

Rationale/Basis for Decision

The documentation was reviewed and found no apparent need for the treatment rendered. The machine described appeared to be very similar to an inferential current machine. The Synaptic 3400 appears to be a relatively new medical device on the market. If one goes to the website of the manufacturer, there is no documentation of any literature or even of any studies funded by the manufacturer showing any long-term benefit from the use of this device. The closest category is "Testimonials," and even this is "under construction". A MEDLINE search was performed on this date, and no literature could be found regarding any studies on the Synaptic 3400, much less large, randomized, controlled, double-blinded studies. A search on the FDA website shows that this device came to market with a "510(k) Premarket Notification Database" designation, and was found to be "substantially equivalent" to devices already on the market. It is classified by the FDA as a "Transcutaneous nerve stimulator", and the supplied marketing literature suggests that this is similar to interferential devices already marketed. There is, therefore, no support for the medical necessity of a device, with substantial equivalence to devices already marketed, and with no proven record of efficacy.