THIS DECISION HAS BEEN APPEALED. THE FOLLOWING IS THE RELATED SOAH DECISION NUMBER:

SOAH DOCKET NO. 453-04-1330.M5

MDR Tracking Number: M5-03-3107-01

Under the provisions of Section 413.031 of the Texas Workers' Compensation Act, Title 5, Subtitle A of the Texas Labor Code, effective June 17, 2001 and Commission Rule 133.305 titled Medical Dispute Resolution - General and 133.308 titled Medical Dispute Resolution by Independent Review Organizations, the Medical Review Division assigned an IRO to conduct a review of the disputed medical necessity issues between the requestor and the respondent. The dispute was received on 7-28-03.

The Medical Review 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 the management, refill, and reprogramming of a synchromed infusion pump to include (office visits, daily hospital management, injection myelography/CT, spinal puncture, contrast x-rays, fluoroscopy, management daily drug, pump refilling and hospital discharge) 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 Medical Review Division has determined that fees were the only fees involved in the medical dispute to be resolved. As the services listed above were not found to be medically necessary, reimbursement for dates of service from to is denied and the Medical Review Division declines to issue an Order in this dispute.

This Decision is hereby issued this 23rd day of October 2003.

Dee Z. Torres
Medical Dispute Resolution Officer
Medical Review Division
DZT/dzt

September 30, 2003
Amended October 20, 2003

David Martinez
TWCC Medical Dispute Resolution
4000 IH 35 South, MS 48
Austin, TX 78704

MDR Tracking #:	M5-03-3107-01
IRO #:	5251

___ has been certified by the Texas Department of Insurance as an Independent Review Organization. The Texas Worker's Compensation Commission has assigned this 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 care rendered to determine if the adverse determination was appropriate. In performing this review, all relevant medical records and documentation utilized to make the adverse determination, along with any documentation and written information submitted, was reviewed.

The independent review was performed by a matched peer with the treating doctor. This case was reviewed by a licensed Doctor of Osteopathy board certified and specialized in Anesthesiology. The reviewer is on the TWCC Approved Doctor List (ADL). The ___ health care professional has signed a certification statement stating that no known conflicts of interest exist between the reviewer and any of the treating doctors or providers or any of the doctors 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 the dispute.

CLINICAL HISTORY

___was injured on ___ when she fell down stairs at work, sustaining a sesamoid fracture of her right foot. She subsequently underwent two surgeries on her right ankle and was diagnosed with reflex sympathetic dystrophy in 1993.

She has been followed by ___since 6/22/94 when he initially evaluated her. Her physical examination at that time demonstrated slight discoloration and moderate hypersensitivity of the skin of the right ankle. Her skin was dry and the temperature was slightly cooler on the right than the left. No color changes, trophic changes of the skin or abnormal hair growth were noted. ___recommended a diagnostic lumbar sympathetic block, but there is no documentation of whether that was ever done.

Eventually, ___had an intrathecal morphine pump system implanted for treatment of her RSD. A review of ___notes form 8/15/02 through 1/2/03 reveals that there is no documentation of whether the intrathecal narcotic pump is providing any relief, no documentation of what other medications, if any, the patient was taking, no documentation of functional improvement, and generally extremely poor superficial and sketchy physical examination findings.

The pump has continued to b refilled with Fentanyl, Marcaine and Sufentanyl on a regular basis, with increasing doses. There have been at least two revisions of the pump system made necessary by disconnects of the catheter from the pump, once on 8/21/02 and then again on 9/26/02.

There was another episode of pump malfunction documented on 12/11/02 necessitating a dye study of the intrathecal pump. That dye study was performed on 12/18/02 with documentation of full visualization of the spinal cord and nerve roots and no evidence of disconnection of the catheter from the pump itself. The question has been raised as to the medical necessity for removal and re-implantation of the intrathecal pump and catheter on 8/21/02 and 9/25/02, refilling and/or maintenance of the implanted pump on 8/16/02, 10/8/02, 11/5/02 and 1/2/032, hospital discharge management on 9/26/02 and office visits on 9/20/02, 11/5/02 and 12/11/02. The carrier has asserted that the disputed medical services above are not medically necessary based on a physician advisor report by ___ as well as according to a Clinical Practice Guideline (second edition) for the diagnosis, treatment and management of reflex sympathetic dystrophy published by the National Guideline Clearing House, a division of the Department of Health and Human Services.

DISPUTED SERVICES

Under dispute is the medical necessity of management, refill and reprogramming of a synchromed infusion pump. (Office visits, daily hospital management, inj. Myelography/CT, spinal puncture, contrast x-rays, fluoroscopy, management daily drug, pump refilling and discharge)

DECISION

The reviewer agrees with the prior adverse determination.

BASIS FOR THE DECISION

___ progress notes present no valid medical evidence of clinical benefit from ongoing use of the intrathecal pump. Moreover, the medications that he continues to place into the pump (Fentanyl, Bupivacaine and Sufentanyl) are not FDA approved or indicated for intrathecal administration.

There are no peer reviewed scientific studies demonstrating either efficacy of use of these medications for prolonged intrathecal use, safety of these agents for prolonged intrathecal use, or lack of long-term side-effects regarding long-term intrathecal administration of these agents. The only medications that are FDA approved for intrathecal administration through the intrathecal pump are Morphine and Baclofen, neither of which is being utilized here.

There is no medical necessity for the continued use of intrathecal medications that are not documented as being effective, especially when those medications are not indicated or FDA approved for intrathecal use. There is, therefore, no medical reason or necessity for continued refills of the pump, revisions of the pump system, or any of the office visits related to refills of the pump or postoperative evaluation following revision.

Regarding the services performed on 12/18/02, it is indicated that the patient had a “diagnostic spinal tap” and “fluoroscopic needle localization of the side port of the pump.” In fact, the patient did not have a diagnostic spinal tap, she only had the pump side port accessed by a needle and subsequent injection of contrast dye through the pump

and catheter system to perform the myelogram. This would not be appropriately considered as a diagnostic spinal tap, as there was no needle penetration of the lumbar spine or the dura. Moreover, there is no medical necessity for flouroscopic needle localization of the side port of the pump, as that port can be adequately located by simple manual palpation, just as the refill port of the pump can be located. Spine x-rays performed on 12/18/02 were also not medically reasonable or necessary, as there was no question raised as to the integrity of the patient's lumbosacral spine or any disease process thereof.

Finally, there is certainly question as to the necessity of performing the dye study on 12/18/02 when there is, as previously mentioned, no documentation by ___or his clinical assistants that the pump system was providing significant, or for that matter, any clinical benefit for this patient's clinical condition. Certainly there is no physical examination documentation that could be considered medically appropriate regarding the patient's lower extremity as related to the injury or subsequent development of reflex sympathetic dystrophy. For all of these reasons, therefore, the reviewer finds that the carrier has appropriately denied reimbursement for service dates from 8/16/02 through 1/2/03.

___ has performed an independent review solely to determine the medical necessity of the health services that are the subject of the review. ___ has made no determinations regarding benefits available under the injured employee's policy

As an officer of ___, I certify that there is no known conflict between the reviewer, ___ and/or any officer/employee of the IRO with any person or entity that is a party to the dispute.

___ is forwarding this finding by US Postal Service to the TWCC.

Sincerely,