NOTICE OF INDEPENDENT REVIEW DECISION

Date: July 29, 2004

MDR Tracking #: M2-04-1521-01-SS
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 an Orthopedic Surgeon reviewer (who is board certified in Orthopedic Surgery) who has an ADL certification. The 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.

Submitted by Requester:

- Similar documentation as supplied by the respondent.

Submitted by Respondent:

- Peer review analysis on 3/24/04 and 4/5/04
- Treatment record clinic notes by ___, neurosurgeon, on 1/21/04
- Clinic notes by ___ on 7/9/03
- 6/25/03 lumbar steroid injections performed by ___
- 10/31/03 lumbar discogram showing symptomatic discogram at L5/S1 and no pain response at L3/4 or L4/5. There was no evidence of localized extravasation.
- Clinic notes from ___ from 11/25/03, 3/2/04. ___ initially recommended an L4/5 and L5/S1 fusion. However, in review of the lumbar discogram, ___ recommended an IDET procedure at L5/S1.
- 5/6/03 MRI of the lumbar spine showed 3 level lumbar spondylosis. At L3/4 there was mild annular bulge and a posterior osteophyte formation with no central canal or foraminal stenosis. At L4/5 there was a small central and paracentral disc bulge with anterior indentation of the thecal sac and no significant central canal neuroforaminal that was patent. At L5/S1 there was a broad based degenerative bulge and posterior osteophyte formation with 4mm retrolisthesis at L5 on S1 with patent neural foramina.

Clinical History
On ___ ___ noted the claimant is a 39 year old gentleman who works for ___ and incurred injury to his low back in ___. The claimant had physical therapy and was able to return to work regular duty. The claimant had a re-injury to his lower back in ___ and was treated with physical therapy, epidural steroid injections and continued to have low back pain. ___ felt the claimant would benefit from surgery at the L4/5 level in addition to L5/S1. However, the discogram results showed the L4/5 disc level to not have concordant pain. Following review of the lumbar discogram, ___ recommended an IDET procedure at L5/S1. No post-discogram CT is provided, and there is no documentation of extravasation of dye through an annular tear at L5/S1.

Requested Service(s)
The medical necessity of the proposed IDET procedure at L5/S1

Decision
I agree with the insurance carrier and feel that the services in dispute are not medically necessary.

Rationale/Basis for Decision
Saal and Saal, the originators of the IDET procedure, have, amongst their criteria, that concordant pain, at the time of discography, should be low volume and low pressure. Pressures were not recorded. Low volume is defined, per Saal and Saal, as ≤1.25 cc. In this particular case, the discogram documents that 3 cc was used. Using strict Saal and Saal criteria, we know that IDET is a highly effective procedure, with a success rate of 75-80% after 2 years. Studies which have expanded those criteria do not report such good results. In fact, assuming a 50/50 mix of patients meeting Saal criteria and those not meeting these criteria, the data suggests that the success rate is well below 50%, when Saal criteria are not strictly used. While certainly IDET represents an attractive alternative to fusion, if it isn't effective, it only represents a delay of effective treatment. This case does not meet Saal and Saal criteria. It is also of concern that there is no documentation of an annular tear, which generally is required for a diagnosis of discogenic pain. This case also demonstrates a spondylolisthesis of 4 mm of L5 on S1. While IDET has not been demonstrated to produce instability in a normal disc space, there are no studies, that I can find, that have specifically looked at IDET and spondylolisthesis, both with worsening of the spondylolisthesis, and whether effective pain relief is achieved.

The literature, therefore, supports that Saal and Saal criteria should be strictly followed, and this case does not meet all the criteria. There was not low volume and, since pressures were not measured, it is unknown if it was low-pressure. There was no annular tear documented. Finally, there was a spondylolisthesis. For these reasons, IDET at L5-S1 is not considered an appropriate procedure. I feel that claimant would be better served with fusion at this level.

YOUR RIGHT TO REQUEST A HEARING

Either party to this medical dispute may disagree with all or part of the decision and has a right to request a hearing.

If disputing a spinal surgery prospective decision, a request for a hearing must be in writing, and it must be received by the TWCC Chief Clerk of Proceedings within **10** (ten) calendar days of your receipt of this decision (28 Tex. Admin. Code 142.5(c)).

If disputing other prospective medical necessity (preauthorization) decisions, a request for a hearing must be in writing, and it must be received by the TWCC Chief Clerk of Proceedings within **20** (twenty) calendar days of your receipt of this decision (28 Tex. Admin. Code 142.5(c)).

This decision is deemed received by you 5 (five) days after it was mailed or the date of fax (28 Tex. Admin. Code 102.5(d)). A request for a hearing and a **copy of this decision** must be sent to:

Chief Clerk of Proceedings / Appeals Clerk
P.O. Box 17787
Austin, Texas 78744
Fax: 512-804-4011

The party appealing this decision shall deliver a copy of its written request for a hearing to other party involved in this dispute.

In accordance with Commission Rule 102.4 (h), I hereby verify that a copy of this Independent Review Organization (IRO) Decision was sent to the patient, the requestor, the insurance carrier, and TWCC via facsimile or U.S. Postal Service from the office of the IRO on this 3rd day of July 2004.