



IMED, INC.

1819 Firman • Suite 143 • Richardson, Texas 75081
Office 972-381-9282 • Toll Free 1-877-333-7374 • Fax 972-250-4584
e-mail: imeddallas@msn.com

NOTICE OF INDEPENDENT REVIEW

NAME OF EMPLOYEE:
IRO TRACKING NUMBER: M2-06-1620-01
NAME OF REQUESTOR: Injured Employee
NAME OF CARRIER: American Home Assurance
DATE OF REPORT: 09/19/06
IRO CERTIFICATE NUMBER: 5320

TRANSMITTED VIA FAX:

IMED, Inc. has been certified by the Texas Department of Insurance (TDI) as an independent review organization (IRO).

In accordance with the requirement for TDI to randomly assign cases to IROs, TDI has assigned your case to IMED, Inc. for an independent review. The peer reviewer selected has performed an independent review of the proposed care to determine if the adverse determination was appropriate. In performing this review, the peer reviewer reviewed 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.

The independent review was performed by a matched peer with the treating physician. This case was reviewed by a D.O. physician reviewer who is Board Certified in the area of Orthopedic Surgery and is currently listed on the DWC approved doctor list.

I am the Secretary and General Counsel of IMED, Inc., and I certify that the reviewing physician in this case has certified to our organization that there are no known conflicts of interest that exist between him and the provider, the injured employee, injured employee's employer, the injured employee's insurance carrier, the utilization review agent, or any of the treating doctors or insurance carrier health care providers who reviewed the case for decision before referral to the Independent Review Organization. I further certify that no conflicts of interest of any nature exist between any of the aforementioned parties and any director, officer, or employee of IMED, Inc.

REVIEWER REPORT

I have reviewed the records forwarded on the above injured worker and have answered the questions submitted.

Information Provided for Review:

- 11/21/02 – Initial consultation, Dr. Larry Kjeldgaard.
- 11/26/02 – MRI of the lumbar spine.
- 12/11/02 – EMG/NCV report.
- 01/21/03, 01/30/03, 03/12/03 – Follow-up with Dr. Kjeldgaard.
- 04/08/03 – Radiology review, Texas Back Institute.
- 05/29/03 – Quantum Diagnostics in Richardson.
- 11/09/04 – Texas Back Institute.
- 12/19/04, 12/20/04 – CT/discogram of the lumbar spine.
- 12/21/04 – Texas Back Institute.
- 01/18/05 – Texas Back Institute.
- 02/15/05 – Consultation with Dr. Kjeldgaard.
- 10/31/05 – Consultation with Dr. Kjeldgaard.
- 11/03/05 to 03/28/06 – Multiple visits with Dr. Kjeldgaard.
- 01/30/06, 03/13/06, 04/18/06, 05/11/06, 05/15/06 – Follow-up with Dr. Kjeldgaard.

Clinical History Summarized:

The employee was injured on ___ while employed by _____. The employee was lifting a heavy passenger to a wheelchair and began experiencing low back pain and then developed some numbness in the right leg.

The employee's initial treatment was with Dr. Brozek, a chiropractor, with some relief.

The employee was examined by Dr. Larry Kjeldgaard, an orthopedic surgeon, on 11/21/02. The doctor noted symptoms of pain in the low back, but especially in the right lower extremity. The doctor also noted a previous back injury that cleared up without any long-term problems. Physical examination included mildly decreased range of motion. There was diminished light touch around the L4 and L5 dermatomes on the right. Straight leg raising was negative. Reflexes were normal and symmetrical in the bilateral lower extremities. There was mildly decreased strength in the quadriceps on the right, but the remainder of the strength was intact.

Dr. Kjeldgaard noted an MRI from Lone Star Open MRI that reported disc desiccation throughout the lumbar spine, with associated loss of disc height. There was a right paracentral disc protrusion at L3-L4. Dr. Kjeldgaard recommended a repeat MRI.

Tarrant Medical Imaging performed a lumbar MRI on 11/26/02. Dr. Spencer Smith reported significant multilevel degenerative disc disease and spondylosis for his age between L5-S1 and

Case No.: M2-06-1620-01

Page Three

T11-T12. There was generalized annular bulging and intervertebral spurring at all the levels to varying degrees. A small focal left far lateral disc protrusion was found at L3-L4. There was combined congenital and acquired neural foraminal narrowing bilaterally between L3-L4 and L5-S1. There was a conjoined right fifth lumbar and first sacral nerve root.

Dr. Richard Guyer, an orthopedic spine surgeon at Texas Back Institute, recommended a two level disc replacement surgery. This procedure had been repeatedly denied because it did not conform to the F.D.A. authorization for the implant. The employee was still working for on light duty.

Dr. Kjeldgaard considered the employee to be disabled and was apparently off work per Dr. Kjeldgaard.

On 02/28/06, Dr. Kjeldgaard reexamined the employee. Dr. Kjeldgaard and Dr. Guyer had now recommended a combination treatment. The doctors were suggesting a disc replacement arthroplasty at L4-L5 and an anterior discectomy and interbody fusion at L5-S1, with a posterior spinous process plate at L5-S1 for additional stabilization. Dr. Kjeldgaard noted the extensive conservative care had not improved the employee's situation. The employee had received epidural steroid injections that helped temporarily, oral medications, activity modification, and extensive physical therapy. The employee also had undergone a discogram that documented internal disc disruption at L4-L5. There was also an anecdotal report of a discogram at L5-S1.

Disputed Services:

Item in Dispute: Denial of total disc replacement at L4 to S1.

Decision:

Denial upheld.

Rationale/Basis for Decision:

There were several areas of concern with this requested procedure. The first was the problematic nature of results of a lumbar arthrodesis in a employee who was injured four years ago. At the time of his injury, this employee already had multilevel degenerative disc disease, including foraminal compromise bilaterally between L3-L4 and L5-S1. It is unlikely that the work incident exacerbated the previous conditions enough to justify the extensive surgery. There were no indications in the diagnostic studies of any acute injury.

Case No.: M2-06-1620-01

Page Four

The second area of concern has to do with the combination treatment recommended. This was a solution looking for a diagnosis. All of those procedures are expensive and dangerous. The success rate of the individual procedures has not been remarkably high. When the anterior and posterior approaches are combined, especially with two completely different procedures, the chances for success are minimal.

The third area of concern deals with the F.D.A. approved package insert for the Synthis Spine Prodisc-L total disc replacement system. The medical records reviewed did not reflect the specific implant planned by Dr. Guyer. However, the Prodisc-L implant has been used as an example of the difficulty with this procedure. Page 4 of the insert stated that the safety and effectiveness of the device has not been established in patients with more than one vertebral level with degenerative disc disease, with facet joint disease or degeneration, or prior to fusion surgery at intervertebral levels. Those doctors are not operating on prior fusion, however, they are proposing a combination treatment that essentially creates a prior fusion situation. Page 5 of the packet insert stated that Prodisc-L total disc replacement component should not be used with components of spinal systems from other manufacturers. While Synthis is certainly referring to other disc replacement systems, one could interpret this line as recommending that the disc replacement not be used with any other arthrodesis techniques. Dr. Guyer was proposing a combination treatment with the disc replacement at L4-L5 and an anterior interbody fusion at L5-S1. This proposal would seem to be proscribed by the F.D.A. information.

Page 8 of the package insert referred to the exclusion of any patient that has more than one level of degenerative disc disease. This employee had an entire spine that contains degenerative disc disease. This is the principle reason that I believe this procedure should not be approved. Page 12 of the package insert detailed an overall success rate of 53% to 63%. This compared to an overall success rate of a standard arthrodesis of 40%-45%. While this may be slightly increased, those results do not rise to a level of recommendation to ignore all the exclusionary factors, as illustrated above.

Therefore, after a comprehensive review of the medical records and after a review of the F.D.A. recommendations for implantation, it is my conclusion that the requested two level disc replacement arthrodesis not be approved. In addition, it is my conclusion that the combination of the disc implant with an anterior arthrodesis should not be approved.

The rationale for the opinion stated in this report is based on the record review, as well as the broadly accepted literature to include numerous textbooks, professional journals, nationally recognized treatment guidelines and peer consensus.

This review was conducted on the basis of medical and administrative records provided with the assumption that the material is true and correct.

This decision by the reviewing physician with IMED, Inc. is deemed to be a DWC decision and order.

YOUR RIGHT TO REQUEST A HEARING

If you are unhappy with all or part of this decision, you have the right to appeal the decision. The decision of the Independent Review Organization is binding during the appeal process.

If you are disputing the decision (other than a spinal surgery prospective decision), the appeal must be made directly to a district court in Travis County (see Texas Labor Code §413.031). An appeal to District Court must be filed not later than thirty (30) days after the date on which the decision that is the subject of the appeal is final and appealable.

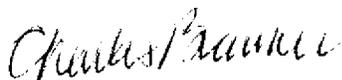
If you are disputing a spinal surgery prospective decision, a request for a hearing must be in writing, and it must be received by the Division of Workers' Compensation, Chief Clerk of Proceedings, within ten (10) days of your receipt of this decision. A request for a hearing should be faxed to 512-804-4011 or sent to:

Chief Clerk of Proceedings/Appeals Clerk
TDI-Division of Workers' Compensation
P.O. Box 17787
Austin, TX 78744

A copy of this decision should be attached to the request. The party appealing the decision shall deliver a copy of its written request for a hearing to all other parties involved in this dispute.

I hereby verify that a copy of this Independent Review Organization's decision was sent to the respondent, the requestor, DWC, and the injured worker via facsimile or U.S. Postal Service this 22nd day of September, 2006 from the office of IMED, Inc.

Sincerely,



Charles Brawner
Secretary/General Counsel