MEDICAL REVIEW OF TEXAS

[IRO #5259]

10817 W. Hwy. 71 **Austin, Texas 78735**
Phone: 512-288-3300 **FAX: 512-288-3356**

NOTICE OF INDEPENDENT REVIEW DETERMINATION

TDI-WC Case Number:	
MDR Tracking Number:	M2-06-1415-01
Name of Patient:	___
Name of URA/Payer:	Insurance Company of the State of PA
Name of Provider: (ER, Hospital, or Other Facility)	Orthofix, Inc.
Name of Physician: (Treating or Requesting)	John Milani, MD

June 30, 2006

An independent review of the above-referenced case has been completed by a physician board certified in orthopedic surgery. The appropriateness of setting and medical necessity of proposed or rendered services is determined by the application of medical screening criteria published by Texas Medical Foundation, or by the application of medical screening criteria and protocols formally established by practicing physicians. All available clinical information, the medical necessity guidelines and the special circumstances of said case was considered in making the determination.

The independent review determination and reasons for the determination, including the clinical basis for the determination, is as follows:

See Attached Physician Determination

Medical Review of Texas (MRT) hereby certifies that the reviewing physician is on the Division of Workers' Compensation Approved Doctor List (ADL). Additionally, said physician has certified that no known conflicts of interest exist between him and any of the treating physicians or providers or any of the physicians or providers who reviewed the case for determination prior to referral to MRT.

Sincerely,

Michael S. Lifshen, MD
Medical Director

cc:
Orthofix, Inc.
John Milani, MD
Division of Workers' Compensation

DOCUMENTS REVIEWED

- Tanya Rhodes, RN, AD notes from 4/10/06 and 4/17/06;
- James R. Sheffield, III an attorney's letter written 6/8/06;
- Bill Kissentaner, BS, RN, AD notes from 3/22/06;
- Patricia Fowler, Orthofix patient advocate letter 4/7/06;
- John E. Milani, MD clinical notes from 2/1/06, an addendum from 2/21/06, clinical notes from 3/9/06, an operative report from 3/13/06, a discharge summary from hospitalization 3/13 through 3/16/06, office notes from 3/28/06 and 5/9/06, a prescription for an Orthofix external bone growth stimulator from 3/15/06, and a 3/23/06 prescription stating that the bone growth stimulator was medically necessary;
- Pine Crest Medical Center chest x-ray report from 3/10/06; and
- "Pulse Electromagnetic Fields: An adjunct to interbody spinal fusion surgery in high risk patients", an article written by Vert Mooney, MD *Orthopedic and Spine Surgery Surgical Technology International*.

CLINICAL HISTORY

This 46-year-old man was injured on ___ when his foot got caught on a conveyor belt. He fell backwards. He felt a pop in his low back and has had ongoing low back pain.

An MRI obtained 4/5/05 of the lumbar spine reportedly showed disc desiccation and bulging at the L4-5 level. Flexion and extension x-rays showed mobility at that level. EMG and nerve conduction studies were normal.

The patient was initially treated with therapy commencing in February 2005 for approximately one year. He also had two epidural steroid injections. He did not get better.

Because of ongoing symptomatology John C. Milani, MD took the patient to the operating room on 3/13/06. The preoperative diagnosis was L4-L5 disc disruption with central protrusion and concomitant severe low back and left leg pain. The operation performed included

laminectomy and discectomy at L3-L4 and L4-L5, posterior lumbar interbody fusions using 12mm carbon fiber cages at L3-L4 and L4-L5 and an L3 through L5 posterior fusion using an Expedium titanium rod and screw system bilaterally with posterolateral fusion using iliac crest autograft as well as allograft and autologus bone marrow. The rationale for operating on the L3-L4 level was not provided in the records submitted for review.

REQUESTED SERVICE(S)
Orthofix spinal stimulator (external) – bone growth stimulator

DECISION
Denied.

RATIONALE/BASIS FOR DECISION
This 46-year-old man is skinny, being 5'4" tall weighing 150 pounds. He is a non-smoker. He does not drink alcohol. He exercises regularly. He has no other medical problems. Further, there should be no instability at the fusion site as both anterior as well as posterior instrumentation has been inserted. The only risk factor that this patient has for developing a non-union of his lumbar fusion is that the fusion involved two levels instead of one.

The study by Vert Mooney, MD entitled "Pulse Electromagnetic Fields: An adjunct to intervetebral spinal fusion in the high risk patient" discussed patients who underwent interbody fusions who are deemed to be at high risk. Mr. ___ had both an interbody fusion as well as a posterolateral fusion bilaterally. This included both anterior and posterior instrumentation as well as autograft, allograft and autologus bone marrow. His situation is not comparable to patients in Dr. Mooney's study who were fused only anteriorly with or without instrumentation and had other risk factors being present.

In conclusion, the documents submitted do not reflect that this individual has a sufficient risk of non-union to warrant the use of a bone growth stimulator. His only risk factor is that he has had a 2-level fusion. This is mitigated by the fact that he has undergone both anterior and posterior fusions with instrumentations and the use of autologus iliac crest and autologus bone marrow grafting material.

Certification of Independence of Reviewer

As the reviewer of this independent review case, I do hereby certify that I have no known conflicts of interest between the provider and the injured employee, the 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 IRO.

YOUR RIGHT TO APPEAL

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 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.

Chief Clerk of Proceedings
Division of Workers' Compensation
P.O. Box 17787
Austin, Texas 78744

Or fax the request to (512) 804-4011. A copy of this decision must be attached to the request.

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

In accordance with Rule 102.4(h), I hereby verify that a copy of this Independent Review Organization (IRO) Decision was sent to the carrier, the requestor and claimant via facsimile or U.S. Postal Service from the office of the IRO on this 3rd day of July 2006.

Signature of IRO Employee: _____

Printed Name of IRO Employee: Cindy Mitchell