

# P – IRO

An Independent Review Organization  
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December 28, 2005

TDI-DWC Medical Dispute Resolution  
Fax: (512) 804-4868

Delivered via Fax

Patient / Injured Employee	_____
TDI-DWC #	_____
MDR Tracking #:	M2-06-0278-01
IRO #:	5312

P-IRO, Inc. has been certified by the Texas Department of Insurance as an Independent Review Organization. The TDI-Division of Worker's Compensation (DWC) has assigned this case to P-IRO for independent review in accordance with DWC Rule 133.308 which allows for medical dispute resolution by an IRO.

P-IRO has performed an independent review of the proposed care 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 MD board certified and specialized in Orthopedic Surgery. The reviewer is on the DWC Approved Doctor List (ADL). The P-IRO Panel Member/Reviewer is a health care professional who has signed a certification statement stating that no known conflicts of interest exist between the Reviewer 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 carriers health care providers who reviewed the case for decision before referral to IRO America for independent review. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.

## **RECORDS REVIEWED**

Notification of IRO assignment, information provided by The Requestor, Respondent, and Treating Doctor(s), including:

- Medical dispute paperwork
- Report of injury, 02/12/97
- X-ray lumbar, 02/12/97
- Initial medical report, Dr. Talbert, 02/19/97

- X-ray right hip, 02/22/97
- Office note, Dr. Harris, 03/03/97
- Bone scan 03/06/97
- Office note, Dr. Talbert, 05/01/97
- Neurology consult, Dr. Hooker, 06/10/97
- Incomplete report, Dr. Talbert, 01/02/98
- DDE, Dr. Harris, 01/27/98
- Right sacroiliac joint injection, 04/01/98 and 01/10/99
- Office note, Dr. Herren, 05/05/98, 01/08/99, 02/23/99 12/01/000, 08/20/01, 03/11/02, and 12/20/02
- Office note, Dr. Chapman, 05/27/98
- Epidural steroid injection, right L5, 10/07/98
- Office note, Dr. Vokac, 02/14//00 and 03/15/00,
- Letter, Dr. Vokac, 03/15/00
- Massage therapy note, 01/24/01
- Work status report, Dr. Herren, 02/16/01, 05/21/01, and 06/05/02
- Chiropractic note, Dr. Doering, 03/02/02 and 11/08/02
- Office note, Dr. Parkey, 04/20/04, 05/28/04, 07/20/04, 08/31/04, 11/20/04, 11/30/04, 02/05/05, 05/02/05, 06/17/05, 07/19/05, and 10/03/05
- Phone note, Dr. Parkey, 05/20/04 and 09/01/05
- Denial for surgery, 08/19/05
- Notice of dispute for refusal to pay benefits, 08/31/05
- Dispute for Charite disc, 09/26/05
- Handwritten office notes, Dr. Parkey, 10/27/05 and 11/02/05
- Letter from Attorney, 11/10/05 and 11/22/05

### **CLINICAL HISTORY**

The Patient is a 40 year-old female who sustained a low back injury on \_\_\_ when she fell from a loading dock and a fifty pound package fell on her. She complained of low back and right hip pain. Lumbar and hip radiographs, as well as bone scan, were normal. She treated with medications and chiropractic modalities. A lumbar MRI in 1997 was reportedly within normal limits. She treated for long term complaints of right sacroiliitis with medications, physical therapy with massage, chiropractic, and sacroiliac joint injection. The Patient underwent epidural steroid injection on 10/07/98. In 2000 she was treated for narcotic addiction due to long term OxyContin use. The Patient had ongoing treatment for myofascial pain, fibromyalgia, and depression as well. In 2004 she noted increased lumbar pain with bilateral radicular symptomatology however there were essentially normal examination findings. A repeat MRI in August of 2004 noted a left L5-S1 disc herniation. She has ongoing complaints of right lower extremity pain and numbness. A Charite artificial disc replacement has been recommended.

### **DISPUTED SERVICE (S)**

Under dispute is the prospective and/or concurrent medical necessity of Charite Artificial Disc Replacement.

### **DETERMINATION / DECISION**

The Reviewer agrees with the determination of the insurance carrier.

## **RATIONALE/BASIS FOR THE DECISION**

Physician discussion was not requested for this case. Based on the records provided for review the requested artificial disc replacement would not be recommended as medically necessary. The Patient has been treating for low back pain and right sacroiliitis since 1997. Recent complaints of worsening low back and right lower extremity pain with numbness were reported in 2004. The Patient treated at the Texas Back Institute without records provided for review. The records provided indicate a relatively normal examination with reference to MRI findings of L5-S1 disc herniation. There are no diagnostic findings identifying a degenerative process.

The Patient does not meet the FDA guidelines for the Charite disc as there is no documentation of degenerative disc disease. The Patient's physical examination fails to indicate painful motion or radicular findings. While the FDA has approved use of the Charite artificial disc as no longer experimental, it remains investigational pending long term peer reviewed studies. The long term safety, efficacy, or superiority of the device over other treatments continues to require evaluation. While a small group of physicians do utilize the device with initial favorable results, ongoing assessment is still required prior to the procedure being considered a main stream Orthopedic intervention.

### **Screening Criteria**

#### 1. Specific:

Tropiano P, Huang RC, Girardi FP, Cammisa FP, Marnay T: Lumbar Total Disc Replacement: Seven to Eleven Year Follow-Up. The Journal of Bone and Joint Surgery, Volume 87-A, Number 3, March 2005

#### 2. General:

In making his determination, the Reviewer had reviewed medically acceptable screening criteria relevant to the case, which may include but is not limited to any of the following: Evidence Based Medicine Guidelines (Helsinki, Finland); Texas Medical Foundation: Screening Criteria Manual (Austin, Texas); Texas Chiropractic Association: Texas Guidelines to Quality Assurance (Austin Texas); Texas Medical Foundation: Screening Criteria Manual (Austin, Texas); Mercy Center Guidelines of Quality Assurance; any and all guidelines issued by DWC or other State of Texas Agencies; standards contained in Medicare Coverage Database; ACOEM Guidelines; peer-reviewed literature and scientific studies that meet nationally recognized standards; standard references compendia; and findings; studies conducted under the auspices of federal government agencies and research institutes; the findings of any national board recognized by the National Institutes of Health; peer reviewed abstracts submitted for presentation at major medical associates meetings; any other recognized authorities and systems of evaluation that are relevant.

## **CERTIFICATION BY OFFICER**

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

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

P-IRO is forwarding by mail or facsimile, a copy of this finding to the DWC, the Injured Employee, the Respondent, the Requestor, and the Treating Doctor.

Sincerely,  
**P-IRO Inc.**



Ashton Prejean

**President & Chief Resolutions Officer**

Cc: Protective Ins. Co. / Downs & Stanford PC  
Attn: W. Jongrove  
Fax: 214-748-4530

William Bradley  
Fax: 940-483-8933

### **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.

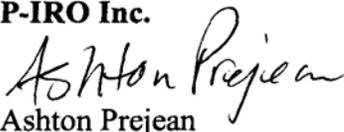
If you are disputing the decision (other than a spinal surgery prospective decision), the appeal must be made directly to a district court in Travis County (see Texas Labor Code §413.031). An appeal to District Court must be filed not later than 30 days after the date on which the decision that is the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

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

**I hereby certify, in accordance with DWC Rule 102.4 (h), that a copy of this Independent Review Organization decision was sent to the carrier, requestor, patient (and/or the patient's representative) and the DWC via facsimile, U.S. Postal Service or both on this 28<sup>th</sup> day of December 2005.**

**Name and Signature of P-IRO Representative:**

Sincerely,  
**P-IRO Inc.**



Ashton Prejean

**President & Chief Resolutions Officer**