



Specialty Independent Review Organization, Inc.

December 5, 2005

DWC Medical Dispute Resolution
7551 Metro Center Suite 100
Austin, TX 78744

Patient: ____
DWC #: ____
MDR Tracking #: M2-06-0325-01
IRO #: 5284

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

Specialty 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.

This case was reviewed by a licensed Doctor of Osteopathy with a specialty in Orthopedics. The reviewer is on the DWC ADL. The Specialty IRO 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 Specialty IRO 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

This 47 year old female injured her low back on _____. She was moving cabinets, tripped and fell. Patient was treated with numerous epidural injections and physical therapy which did not give her relief. Eventually, she underwent surgery at L4-5 in September 2003.

Following the surgery, the patient redeveloped pain in her low back and right leg. The EMG of 11/04/2004 revealed a right L5 radiculopathy.

The patient continued to have increasing low back pain. She has marked limitation of movement and is unable to tolerate bending, prolonged standing, or prolonged sitting. There is some relief by straightening up and going into extension. The physical examination reveals a small midline scar at L4-5. Forward bending is limited to 25 degrees, extension is 10 degrees. Straight leg

raise is negative and no radicular pain. There is no motor weakness, but there is decreased sensation over the dorsum of the right foot and lateral border of the foot.

The X-rays reveal narrowing of the disc space at L4-5. There is no abnormal translation or rotation noted with flexion and extension X-rays. There is evidence of a previous laminectomy at L4-5. The MRI of 03/24/2004 revealed degenerative changes at L4-5.

Conservative measures have been exhausted with physical therapy over an extremely extended period of time and numerous epidural steroid injections.

RECORDS REVIEWED

R Francis MD, Reports: 5/4/04 to 9/10/05.

J Keepers MD, Report: 7/23/04.

Imaging Institute of TX, MRI: 3/24/2004.

Records from Carrier:

Harris & Harris, Letter: 11/28/05.

Additional Records/Doctor Facility:

W Kowalski DC, Reports: 6/28/05 to 11/01/05.

REQUESTED SERVICE

The items in dispute are the prospective medical necessity of a lumbar artificial disc replacement L4-5, Charite artificial disc, and a 10 day rental of a cryo unit.

DECISION

The reviewer disagrees with the previous adverse determination.

BASIS FOR THE DECISION

The reviewer states that this patient fits the criteria for artificial disc replacement. She has a degenerated disc at one level and has failed at least six months of conservative care. There is diagnostic imaging of a lesion and her clinical findings also indicate a lesion.

The FDA approved the Charite artificial disc on 10/26/2004. It is approved for degenerative disc disease at L4-5 and 5-S1.

Following surgery it is important to control swelling and pain. The use of a continuous cooling device may provide this control of swelling and pain. The use of a cryo unit with a 10 day rental is certified.

Tropiano P, Huang R, et al: LUMBAR TOTAL DISC REPLACEMENT, JBJS 2005; 85-A (3): 490-496.

Shuff and An: ARTIFICIAL DISC REPLACEMENT: The New Solution for Discogenic Low Back Pain? American Journal of Orthopedics, January 2005, 8-12.

Griffith, Shelokov, Buttner-Janz: A MULTICENTER RETROSPECTIVE STUDY OF THE CLINICAL RESULTS OF THE LINK SB CHARITE INTERVERTEBRAL PROSTHESIS. The initial European experience. Spine. 1994;19:1842-1849.

Cinnotti, Postacchini: RESULTS OF DISC PROSTHESIS AFTER A MINIMUM FOLLOW-UP PERIOD OF 2 YEARS. SPINE. 1996,21:995-1000.

Guyer, McAfee, Hochschuler, et al: PROSPECTIVE RANDOMIZED STUDY OF THE CHARITE ARTIFICIAL DISC: Data from two investigational centers. Spine J. 2004;4:S252-259.

Mayer, Wiechert, Korge, et al: Minimally invasive total disc replacement surgical technique and preliminary clinical results, Eur Spine J.2002;11:S124-130.

US Department of Health and Human Services. Charite Artificial Disc Report 10/26/2004.

DePuy Spine: Technical Monograph 4/13/2005.

Specialty IRO has performed an independent review solely to determine the medical necessity of the health services that are the subject of the review. Specialty IRO has made no determinations regarding benefits available under the injured employee's policy. Specialty IRO believes it has made a reasonable attempt to obtain all medical records for this review and afforded the requestor, respondent and treating doctor an opportunity to provide additional information in a convenient and timely manner.

As an officer of Specialty IRO, Inc, dba Specialty IRO, I certify that the reviewing provider has no known conflicts of interest between that 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.

Sincerely,

Wendy Perelli, CEO

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.

Sincerely,

Wendy Perelli, CEO

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, claimant (and/or the claimant's representative) and the via facsimile, U.S. Postal Service or both on this 5th day of December 2005

Signature of Specialty IRO Representative:

Name of Specialty IRO Representative: Wendy Perelli