



IRO REPORT

DATE OF REVIEW: 7/24/07

IRO CASE #:

NAME:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Determine the medical necessity for the previously denied lumbar artificial disc replacement L5-S1

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION

Texas licensed orthopedic surgeon.

REVIEW OUTCOME

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

The previously denied request for lumbar artificial disc replacement L5-S1

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- Document Note dated 7/24/07.
- Notice to INC. of Case Assignment dated 7/24/07.
- Notice of Assignment of Independent Review Organization dated 7/24/07.
- Confirmation of Receipt of a Request for a Review by an Independent Review Organization (IRO) dated 7/20/07.
- Request for a Review by an Independent Review Organization dated 7/13/07.
- Determination Notification Letter dated 7/11/07, 6/26/07.
- Surgery Pre-op / Admission Orders dated 7/7/07.
- Office Visit dated 6/7/07, 5/10/07, 4/12/07, 3/29/07, 2/10/07, 11/16/06, 10/26/06, 8/1/06, 7/6/06.

- Prescription dated 3/23/07.
- MRI Lumbar dated 11/13/06.
- Notes dated 7/31/06.
- Examination dated 7/6/06.
- Lumbar Epidural Steroid Injection dated 6/9/06.
- Progress Report
- Authorization Request dated (unspecified).

PATIENT CLINICAL HISTORY [SUMMARY]:

Age:

Gender: Male

Date of Injury:

Mechanism of Injury: Motor vehicle accident.

Diagnosis: Low back pain, status post epidural steroid injection (ESI).

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION

This is a male machine operator who flipped over his truck. Following the accident, the claimant complained of low back pain. The claimant underwent ESI on 5/26/06 and 6/9/06 with no relief. The 5/9/06 MRI of the lumbar spine showed slight degenerative retrolisthesis at L4 relative to L5 with a 5 millimeter broad based posterior disc protrusion and posterior annular fissuring. There was minimal bilateral facet arthrosis. Dr. evaluated the claimant on 7/6/06 for persistent low back pain radiating to his knee. Exam findings revealed a normal gait, no weakness or decreased sensation. The diagnosis was lumbar disc herniation at L4-5 associated with peripheral annular tear. Dr. recommended physical therapy for truncal strengthening. The claimant saw Dr. again on 10/26/06. The claimant reported numbness going down his right leg. Dr. noted that a required medical examination by Dr. documented degenerative disc disease at L4-5 with a superimposed strain and chronic back pain. Dr. recommended a repeat lumbar MRI and physical therapy. The 11/13/06 MRI of the lumbar spine showed subtle retrolisthesis of L5 relative to S1 with associated bulging and a small focal central disc herniation, which mildly effaced the ventral thecal sac. Dr. noted on 11/16/06 that the radiologist has previously noted pathology at L4-5 and now it was at L5-S1. Dr. felt that the claimant was symptomatic from a central disc herniation at L5-S1 with a possible annular tear. On 3/10/07, Dr. recommended the artificial disc replacement. On 3/23/07, physical therapy was prescribed. The claimant saw Dr. on 3/29/07 and reported significant low back pain. Straight leg raise was negative bilaterally. There was decreased sensation at L2, L3, L4 and L5. On 6/7/07, Dr. saw the claimant. Dr. documented that the claimant had been seen by Dr. for a second opinion. Dr. recommended a central decompression of the disc or lumbar disc replacement. Dr. again recommended the artificial disc. Based on the information reviewed, there is no medical necessity for the artificial disc replacement. This claimant has been diagnosed with discogenic pain with a failure to respond to physical therapy and ESI. There were no changes in motor or reflexes. The claimant's appears to have primarily low back pain. Dr. has recommended an artificial disc replacement. Dr. has recommended either a central decompression or an artificial disc. Physician discussion did not occur for this review. The FDA has approved the artificial disc as safe for use for single level degenerative disc disease without spondylolisthesis; however, there are no long term studies to support the efficacy of this procedure. As noted by the Official Disability Guidelines, "the artificial disc is not recommended for either degenerative disc disease or mechanical low back pain. While disc replacement as a

strategy for treating degenerative disc disease has gained substantial attention, it is not currently possible to draw any conclusions concerning disc replacement's effect on improving patient outcomes.” Based on the review of the records alone, the artificial disc replacement is not recommended as medically necessary.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- ACOEM – AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE.
- AHCPR – AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES.
- DWC – DIVISION OF WORKERS’ COMPENSATION POLICIES OR GUIDELINES.
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN.
- INTERQUAL CRITERIA.
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS.
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES.
- MILLIMAN CARE GUIDELINES.

X ODG – OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES.

Official Disability Guidelines 2007 Updates: Low back

Not recommended at this time for either degenerative disc disease or mechanical low back pain. See separate document with all studies focusing on Disc prosthesis. Studies have concluded that outcomes in patients with disc disease are similar to spinal fusion. (Cinotti-*Spine*, 1996) (Klara-*Spine*, 2002) (Zeegers, 1999) (Blumenthal, 2003) (Zigler, 2003) (McAfee, 2003) (Anderson-*Spine*, 2004) (Gamradt-*Spine*, 2005) (Gibson-*Cochrane*, 2005) A recent meta-analysis, published prior to the release of the Charite disc replacement prosthesis for use in the United States (on 6/2/2004 an FDA panel recommended approval of the Charite® disc from Johnson & Johnson DePuy), even concluded, “Total disc replacements should be considered experimental procedures and should only be used in strict clinical trials.” (deKleuver, 2003) At the current time radiculopathy is an exclusion criteria for the FDA studies on lumbar disc replacement. (McAfee-*Spine*, 2004) Even though medical device manufacturers expect this to be a very large market (Viscogliosi, 2005), the role of total disc replacement in the lumbar spine remains unclear and predictions that total disc replacement (TDR) will replace fusion are premature. One recent study indicates that only a small percentage (5%) of the patients currently indicated for lumbar surgery has no contraindications to TDR. (Huang-*Spine*, 2004) Furthermore, despite FDA approval, the disc prosthesis is not generally covered by non workers' comp health plans (Blue Cross Blue Shield, 2004), or by some

workers' comp jurisdictions. (Wang, 2004) Because of significantly varying outcomes, indications for disc replacement need to be defined precisely. In this study better functional outcome was obtained in younger patients under 40 years of age and patients with degenerative disc disease in association with disc herniation. Multilevel disc replacement had significantly higher complication rate and inferior outcome. (Siepe, 2006) With an implementation date of October 1, 2006, the Centers for Medicare & Medicaid Services (CMS), upon completion of a national coverage analysis (NCA) for Lumbar Artificial Disc Replacement (LADR), determined that LADR with the Charite lumbar artificial disc is not reasonable and necessary for Medicare patients. (CMS-coverage, 2006) (CMS-review, 2006) The U.S. Medicare insurance program said on May 28, 2007 in a draft proposal that it was rejecting coverage of artificial spinal disc replacement surgery no matter which disc was used. (CMS, 2007) This study reporting on the long-term results of one-level lumbar arthroplasty reported that after a minimum 10-year follow-up, 90% of patients had returned to work, including 78% of patients with hard labor level employment returning to the same level of work. (David, 2007) According to this prospective, randomized, multicenter FDA IDE study, the ProDisc-L has been shown to be superior to circumferential fusion by multiple clinical criteria. (Zigler, 2007) Thus disc replacement is considered a controversial and unproven alternative to fusion surgery. Note: On August 14, 2006, the FDA approved the ProDisc® Total Disc Replacement by Synthes Spine, Inc.

- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR.
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE AND PRACTICE PARAMETERS.
- TEXAS TACADA GUIDELINES.
- TMF SCREENING CRITERIA MANUAL.
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION).

X OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION).

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

Orthopedic Knowledge Update 7, Spine, pages 477-478
