

Independent Resolutions Inc.

An Independent Review Organization

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Notice of Independent Review Decision

DATE OF REVIEW:

AUGUST 17, 2007

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Lumbar artificial disc replacement L4/5 Charite artificial disc lumbar anterior

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

Board Certified 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)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Initial Management Consult, 04/03/06

Lumbar spine x-rays, 04/12/06

Lumbar MRI, 04/12/06 and 11/16/06

EMG/NCV, 04/26/06

Pain Management office notes, 05/01/06, 06/08/06, 06/12/06, 07/10/06, 08/25/06 and 10/03/06

Decision and order noted, 05/10/07

Epidural steroid injections noted, 05/19/06

Office notes, Dr., 07/07/06, 08/03/06, 11/04/06 and 12/16/06

Discogram noted, 07/25/06

Post discogram CT scan, 07/26/06

Lumbar CT scan, 09/12/06

Hospital discharge summary, 09/14/06 bone scan, 11/27/06

Gallium bone scan, 11/29/06

Peer review, 02/17/07
Non-authorization for surgery noted, 06/26/07
Appeal, 07/11/07

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a female with chronic low back pain. The medical records provided for review indicate that the claimant was injured on xx/xx/xx while pulling on a stove ventilation filter. She treated conservatively but continued to have low back pain with radiation into the buttocks.

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

The reviewer agrees with the determination of the insurance carrier in this case.

The proposed L4-5 Charite disc replacement surgery is not recommended for this claimant. The use of artificial discs remains investigational. The FDA literature specifically states that although artificial discs are approved for use, further investigation is necessary and in fact was specifically stipulated in the approval notification. Furthermore, although the body of literature continues to grow regarding these implants, a number of questions remain, particularly as it pertains to its longevity as well as deterioration at adjacent levels. As such, the artificial disc, while FDA approved for use, remains investigational as outlined in the FDA language and further long-term study is needed. Based on the information provided, the reviewer cannot recommend this procedure as being medically necessary.

The proposed L3-4 anterior interbody fusion surgery is also not recommended for this claimant. The medical records do not provide documentation of spondylolisthesis or instability on imaging. The claimant is only years-old and it may be more reasonable to pursue extended conservative treatment prior to undertaking such an operation in a person this young in the absence of neurologic compromise, radicular pathology or instability. Fusion for discogenic pain does not reliably relieve pain or lead to increased function when performed in the absence of instability.

Official Disability Guidelines Treatment in Workers' Comp 2007 Updates: Low Back – Disc Prosthesis

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 ([BlueCross BlueShield, 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](#)) 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. The studies quoted above have failed to demonstrate a superiority of disc replacement over simple fusion for the limited indications for surgical treatment of lower back pain. 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.

Official Disability Guidelines Treatment in Workers' Comp 2007 Updates: Low Back – Fusion

Not recommended for patients who have less than six months of failed conservative care unless there is severe structural instability and or acute or progressive neurologic dysfunction, but recommended as an option for spinal fracture, dislocation, spondylolisthesis or frank neurogenic compromise, subject to the selection criteria outlined in the section below entitled, "Patient Selection Criteria for Lumbar Spinal Fusion." After screening for psychosocial variables, outcomes are improved and fusion may be recommended for degenerative disc disease with spinal segment collapse with or without neurologic compromise after 6 months of recommended [conservative therapy](#). For complete references, see separate document with all studies focusing on [Fusion \(spinal\)](#). There is limited scientific evidence about the long-term effectiveness of fusion for degenerative disc disease compared with natural history, placebo, or conservative treatment, but studies conducted in order to compare different surgical techniques have shown success for fusion in carefully selected patients. ([Gibson-Cochrane, 2000](#)) ([Savolainen, 1998](#)) ([Wetzel, 2001](#)) ([Molinari, 2001](#)) ([Bigos, 1999](#)) ([Washington, 1995](#)) ([DeBarard-Spine, 2001](#)) ([Fritzell-Spine, 2001](#)) ([Fritzell-Spine, 2002](#)) ([Deyo-NEJM, 2004](#)) ([Gibson-Cochrane/Spine, 2005](#)) ([Soegaard, 2005](#)) ([Glassman, 2006](#)) ([Atlas, 2006](#)) According to the recently released AANS/NASS Guidelines, lumbar fusion is recommended as a treatment for carefully selected patients with disabling low back pain due to one- or two-level degenerative disc disease after failure of an appropriate period of conservative care. This recommendation was based on one study that contained numerous flaws, including a lack of standardization of conservative care in the control group. At the time of the 2-year follow up it appeared that pain had significantly increased in the surgical group from year 1 to 2. Follow-up post study is still pending publication. In addition, there remains no direction regarding how to define the "carefully selected patient." ([Resnick, 2005](#)) ([Fritzell, 2004](#)) Until further research is conducted

there remains insufficient evidence to recommend fusion for chronic low back pain in the absence of stenosis and spondylolisthesis, and this treatment for this condition remains “under study.” It appears that workers’ compensation populations require particular scrutiny when being considered for fusion for chronic low back pain, as there is evidence of poorer outcomes in subgroups of patients who were receiving compensation or involved in litigation. ([Fritzell-Spine, 2001](#)) ([Harris-JAMA, 2005](#)) ([Atlas, 2006](#)) Despite poorer outcomes in workers’ compensation patients, utilization is much higher in this population than in group health. ([Texas, 2001](#)) ([NCCI, 2006](#)) A recently published well respected international guideline, the “European Guidelines,” concluded that fusion surgery for nonspecific chronic LBP cannot be recommended unless 2 years of all other recommended conservative treatments – including multidisciplinary approaches with combined programs of cognitive intervention and exercises – have failed, or such combined programs are not available, and only then in carefully selected patients with maximum 2-level degenerative disc disease. ([Airaksinen, 2006](#)) For chronic LBP, exercise and cognitive intervention may be equivalent to lumbar fusion without the potentially high surgical complication rates. ([Ivar Brox-Spine, 2003](#)) ([Keller-Spine, 2004](#)) ([Fairbank-BMJ, 2005](#)) ([Brox, 2006](#)) Patients with increased instability of the spine after surgical decompression at the level of degenerative spondylolisthesis may be candidates for fusion. ([Eckman, 2005](#)) In acute spinal cord injury (SCI), if the spine is unstable following injury, surgical fusion and bracing may be necessary. ([Bagnall-Cochrane, 2004](#)) ([Siebenga, 2006](#)) A study on improving quality through identifying inappropriate care found that use of guideline-based Utilization Review (UR) protocols resulted in a denial rate for lumbar fusion 59 times as high as denial rates using non-guideline based UR. ([Wickizer, 2004](#)) The profit motive and market medicine have had a significant impact on clinical practice and research in the field of spine surgery. ([Weiner-Spine, 2004](#)) ([Shah-Spine, 2005](#)) ([Abelson, 2006](#)) Data on geographic variations in medical procedure rates suggest that there is significant variability in spine fusion rates, which may be interpreted to suggest a poor professional consensus on the appropriate indications for performing spinal fusion. ([Devo-Spine, 2005](#)) ([Weinstein, 2006](#)) Outcomes from demanding surgical fusion techniques (with internal fixation) may be no better than the traditional posterolateral fusion. ([van Tulder, 2006](#)) ([Maghout, 2006](#)) Presurgical biopsychosocial variables predict patient outcomes from lumbar fusion, which may help improve patient selection. Workers’ compensation status, smoking, depression, and litigation were the most consistent presurgical predictors of poorer patient outcomes. Also predictors were number of prior low back operations, low household income, and older age. ([DeBerard-Spine, 2001](#)) ([DeBerard, 2003](#)) ([Devo, 2005](#)) ([LaCaille, 2005](#)) ([Trief-Spine, 2006](#)) A recent study found only a 27% success from spinal fusion in patients with low back pain and a positive single-level low-pressure provocative discogram, versus a 72% success in patients having a well-accepted single-level lumbar pathology of unstable spondylolisthesis. ([Carragee, 2006](#)) According to the recent Medicare Coverage Advisory Committee Technology Assessment, the evidence for lumbar spinal fusion does not conclusively demonstrate short-term or long-term benefits compared with nonsurgical treatment for elderly patients. ([CMS, 2006](#)) Lumbar spinal fusion surgeries use bone grafts, and are sometimes combined with metal devices, to produce a rigid connection between two or more adjacent vertebrae. The therapeutic objective of spinal fusion surgery for patients with low back problems is to prevent any movement in the intervertebral spaces between the fused vertebrae, thereby reducing pain and any neurological deficits.

Patient Selection Criteria for Lumbar Spinal Fusion:

For chronic low back problems, fusion should not be considered within the first 6 months of symptoms, except for fracture, dislocation or progressive neurologic loss. Indications

for spinal fusion may include: (1) Neural Arch Defect - Spondylolytic spondylolisthesis, congenital unilateral neural arch hypoplasia. (2) Segmental Instability - Excessive motion, as in degenerative spondylolisthesis, surgically induced segmental instability and mechanical intervertebral collapse of the motion segment and advanced degenerative changes after surgical discectomy. (3) Primary Mechanical Back Pain/Functional Spinal Unit Failure, including one or two level segmental failure with progressive degenerative changes, loss of height, disc loading capability, with and without neurogenic compromise. In cases of workers' compensation, patient outcomes related to fusion may have other confounding variables that may affect overall success of the procedure, which should be considered. (4) Revision Surgery for failed previous operation(s) if significant functional gains are anticipated. Revision surgery for purposes of pain relief must be approached with extreme caution due to the less than 50% success rate reported in medical literature. (5) Infection, Tumor, or Deformity of the lumbosacral spine that cause intractable pain, neurological deficit and/or functional disability.

Pre-Operative Surgical Indications Recommended: Pre-operative clinical surgical indications for spinal fusion include all of the following: (1) All pain generators are identified and treated; & (2) All physical medicine and manual therapy interventions are completed; & (3) X-ray demonstrating spinal instability and/or MRI, Mylogram or CT discography demonstrating disc pathology; & (4) Spine pathology limited to two levels; & (5) Psychosocial screen with

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**

- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR**
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS**
- TEXAS TACADA GUIDELINES**
- TMF SCREENING CRITERIA MANUAL**
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)**
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**