

I-Decisions Inc.

An Independent Review Organization

71 Court Street

Belfast, Maine 04915

(207) 338-1141 (phone)

(866) 676-7547 (fax)

Notice of Independent Review Decision

DATE OF REVIEW: 03/15/2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

L5-S1 arthroplasty

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

Board Certified Neurosurgeon with additional training in pediatric neurosurgery

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)

Upon independent review the reviewer finds that the requested L5-S1 arthroplasty is medically unnecessary.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Adverse determination Letters 2/1/08, 2/7/08

ODG Guidelines and Treatment Guidelines

Prior review 1/28/2008

MD, clinic notes, 1/24/08, 1/10/08, 8/14/07

DO, 1/23/08

MD, notes, 1/02/08, 12/05/07, 11/30/07, 11/7/07

MRI of the lumbar spine reports, 1/2/2008, 07/31/2007

CT Spine, 1/21/08
MRI, 7/31/07
Procedure note, ESI, 11/30/07
DC, 10/22/07, 10/17/07, 10/16/07, 10/15/07, 10/10/07, 10/9/07, 10/8/07, 10/4/07,
10/3/07, 09/11/2007
Hospital, 9/10/07

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a female with a date of injury of xx/xx/xxxx while lifting two cases of juice. She has had PT, chiropractic care and a left SI injection. She also had a left foraminal L5-S1 epidural steroid injection, with no relief. Neurological examination reveals 5-/5 EHL weakness on the left. MRI of the lumbar spine 07/31/2007 shows a 4mm central and left paracentral disc protrusion at L5-S1 causing borderline canal stenosis. A repeat MRI of the lumbar spine 01/02/2008 shows a large left paracentral 7mm disc protrusion with possible compression of the left L5 and S1 nerve roots. A discogram showed concordant pain at L5-S1 with no pain at L3-L4 or L4-L5.

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

The surgery is not medically necessary. The Official Disability guidelines do not recommend a lumbar disc arthroplasty (see below). There is nothing specific to this case that warrants an exception to this. Also, it is not completely evident that this patient is not suffering from a radiculopathy. The MRI indicates compression of both the left L5 and S1 nerve roots, and in one report, there is some weakness of the left EHL. She also has unilateral pain of the left buttocks, which can also be a sign of an S1 radiculopathy. A radiculopathy is an exclusion criteria from the FDA for artificial lumbar disc placement (see below).

According to ODG, "Low Back" chapter:

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 \square 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](#)) 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](#)) 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. The anatomic implications of total disc replacement are different from total hip or total knee replacements. The motion segments of the spine are not a single joint as is the case for the hip and knee. Often the source of pain for the spine is not clearly understood, whereas it usually is for the hip and knee. Therefore, the perceived corollary between total disc replacement and total hip or knee replacement is not justified. Furthermore, long-term follow-up repeat surgery rates are unknown for the disc prosthesis. Note: On August 14, 2006, the FDA approved the ProDisc® Total Disc Replacement by Synthes Spine, Inc.

References/Guidelines

2008 *Official Disability Guidelines*, 13th edition

<http://www.fda.gov/cdrh/mda/docs/p050010.html>

**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)