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**DATE OF REVIEW:** JULY 12, 2007

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE**

L5- SI disc replacement - 3 day length of stay

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

Board certified in Orthopaedic Surgery, licensed in the State of Texas, and DWC ADL approved.

**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)

Health Care Service(s) in Dispute	CPT Codes	Date of Service(s)	Outcome of Independent Review
L5- SI disc replacement - 3 day length of stay	22857, 22851, 22845, 63077, 69990	Upon approval	Adverse determination upheld

**INFORMATION PROVIDED TO THE IRO FOR REVIEW**

Record Description	Record Date
MRI Lumbar Spine – Center	11/27/06
MRI Lumbar Spine – Center	04/16/07
MRI Lumbar Spine – Center	04/21/07
EMG and Nerve Conduction Study – Dr.	05/02/07
Office visit – Dr.	05/07/07
UR findings on L5-SI disc replacement – adverse determination –	05/11/07
UR findings on L5-SI disc replacement appeal – adverse determination –	05/23/07
Letter concurring with recommended surgery – Dr.	05/29/07
Letter and support documentation to IRO Medical Director regarding UR request – Dr.	07/06/07
Journal of Spinal Disorders & Techniques May 2007 – Article on Long Term Flexion-Extension Range of Motion of the total disc replacement	05/07
Spine. October 2003 – Article on Pro Disc literature	10/03
Journal of Spinal Disorders & Techniques 2003 – Article on Lumbar Spine Arthroplasty	2003

Journal of Spinal Disorders & Techniques 2003 – Article on Lumbar disc replacement	2003
Eur Spine J 2002 – Article on Indications for full prosthetic disc arthropasty	2002
J Bone Joint Surgery Am. 2005 – Article on Lumbar total disc replacement 7 to 11 year follow-up	2005
Clinical Biomech May 2005 – Article on The impact of the total lumbar replacement on segmental and total lumbar lordosis	05/05

**PATIENT CLINICAL HISTORY [SUMMARY]:**

Claimant is a male who was injured on the job on xx/xx/xx while lifting. He complained of radiculopathy to the right lower extremity including the dorsum of the right foot. He ascribed his pain as 70% back pain, and 30% right lower extremity pain. He was given the diagnosis of lumbar disc displacement. He complained of his pain being constant, severe, sharp, burning pain aggravated by standing/walking and relieved by medication (Methadone, Dilaudid and Lyrica) and lying flat. Claimant had an MRI done which showed an HNP at L5S1. He was prescribed physical therapy and underwent epidural steroid injections without relief.

Dr. is requesting an IRO for artificial disc replacement and a three day length of hospital stay. He does not feel that a laminectomy and discectomy procedure would be sufficient because of the great amount of axial pain present in the patient.

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

Artificial disc replacement may be indicated in a very select population. Of those carefully selected positions for lumbar surgery, only 5% have no contraindications to artificial disc replacement (ADR). This patient has at least one contraindication to ADR because he has radiculopathy which is an exclusion criterion. Also, the state of the facet joints is not clarified in the clinical history. There is decreased L5-S1 disc space on the MRI report. Usually associated with this condition is facet arthrosis. This would be another exclusion criterion.

In a recent article by Leary, et al (Spine, Vol 32, (9), 4/20/2007 pgs 1001-1010 stated that one of the major reasons for disc prosthesis failure is a facet arthrosis which was missed on pre-operative evaluation. They recommended a CT scan with bone windows as being superior to MRI to evaluate facet arthrosis. Additionally, the diagnosis of discogenic low back pain is elusive and controversial. Provocative discography is believed to increase accuracy in this regard (although discography itself is controversial) and is a pre-requisite before doing an ADR per FDA criteria (Spine Journal, Nov/Dec 2004, Vol 4, pgs 177-S -179-S). The discography should be preceded by a psychological evaluation to include psychometric testing (ACOEM, Chapter 12, pgs 303-304, 2004). Therefore the request is not medically necessary based on evidenced based medicine and the fact that the patient has radiculopathy (an exclusion criteria per FDA criteria), and the condition of the facet joints is unknown and inadequate work up (a discogram has not been done to include a control disc, exact concordant pain and psychological pre-screening for discography).

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

The most recent online version of ODG suggests:

Not recommended at this time for either degenerative disc disease or mechanical low back pain. 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 (2004), or by some workers' comp jurisdictions. (Wang, 2004) 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