

Notice of Independent Review Decision

DATE OF REVIEW:

09/08/2009

IRO CASE #:**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE**

L5 artificial disc replacement with three day inpatient stay.

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

Board Certified Orthopaedic Surgeon

REVIEW OUTCOME

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

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.

The requested procedure L5 artificial disc replacement with three day inpatient stay is not medically necessary.

PATIENT CLINICAL HISTORY [SUMMARY]:

The injured individual is a xx year old diabetic who was reported to have sustained a work-related injury on xx/xx/xx. The described mechanism of injury was a low back injury while trying to lift heavy objects with a pallet jack. He was seen by M.D. on 03/04/2009. Dr. noted a similar episode approximately one and one half years ago which responded to lumbar epidural steroid injection and noted a bulging disc at that time. He reported the injured individual to have pain in his back, pain down his leg and numbness of the right leg over the anterolateral thigh on 03/25/2009. His diagnosis was lumbar disc disease. He recommended referral to Dr. a spine surgeon. It is unclear why, but the injured individual is not seen by Dr. until 05/21/2009. Dr. noted that the injured individual had undergone conservative treatment, but there is no record of physical therapy or epidural steroid injection in the recent medical documentation. A MRI was performed on 03/18/2009. It revealed evidence of multi-level degenerative disc disease. The study report documented a disc herniation at L2-L3 on the right with associated degenerative findings. Another herniation is reported on the left at L4-L5 with degenerative change. Finally a moderate disc bulge more to the left is seen at L5-S1. The injured individual is evaluated by Dr. on 05/21/2009. Dr. then recommended on 06/11/2009 L5 Disc replacement surgery. The injured individual has not returned to work since day of injury. There is no information regarding his clinical response to any conservative treatment other than to say it failed. There is no information regarding physical therapy, medication management, or injection therapy.

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

The injured individual is a xx year old diabetic male with multiple level degenerative disc disease. There is insufficient documentation of an adequate trial of conservative treatment as recommended by the evidence-based Official Disability Guidelines (ODG). The Occupational Medicine Practice Guidelines note that the biggest predictor of a future episode of back pain is a prior history of one. The requested procedure does not address the injured individual's multi-level degenerative spine condition. In addition, the reported pathology at L2-L3 and L4-L5 and the injured individual's symptoms are not concordant with the request. The injured individual has evidence of more than a single level of disease present.

The recommendations of the Official Disability Guidelines:

Disc prosthesis: Not recommended in the lumbar spine, but under study in the cervical spine, with recent promising cervical results. See the Neck & Upper Back Chapter for information on use in the cervical spine. Other than spinal fusion, there are currently no direct comparison studies, and artificial disc outcomes in the lumbar spine are about the same as lumbar fusion, but neither results have demonstrated superiority compared with recommended treatments, including nonoperative care. 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 Charité disc replacement prosthesis for use in the United States (on 6/2/2004 an FDA panel recommended approval of the Charité 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) Note: On August 14, 2006, the FDA approved the ProDisc® Total Disc Replacement by Synthes Spine, Inc. 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.

Recent research: A recent high quality meta-analysis/health technology assessment concluded that there is insufficient evidence to draw extensive efficacy/effectiveness conclusions comparing artificial disc replacement (ADR) with a broad range of recommended treatment options, including conservative nonoperative care, since, other than spinal fusion, there are currently no direct comparison studies. **Effectiveness - Lumbar Spine:** With respect to the comparison of lumbar artificial disc replacement (L-ADR) and fusion, overall clinical success was achieved in 56% of patients receiving L-ADR and 48% receiving lumbar fusion. Though the results suggest that 24-month outcomes for L-ADR are similar to lumbar fusion, it should be noted that for the lumbar spine, the efficacy of the comparator treatment, lumbar fusion, for degenerative disc disease remains uncertain, especially when it is compared with nonoperative care. Given what is known about lumbar fusion as a comparator and having evidence that only compares L-ADR with lumbar fusion limits the ability to fully answer the efficacy/effectiveness question. (Zigler, 2007) (Blumenthal, 2005) (Dettori, 2008) Although there is fair evidence that artificial disc replacement is similarly effective compared to fusion for single level degenerative disc disease, insufficient evidence exists to judge long-term benefits or harms. (Chou, 2009)

Safety & Complications: There is moderate evidence that L-ADR is as safe as lumbar anterior or circumferential fusion. The studies primarily reflect outcomes measured up to 24 months and therefore questions remain regarding the long-term safety and efficacy of L-ADR compared with fusion. This is an important matter, particularly in workers' comp patients who may be younger. Since these are mechanical devices, future failure is a possibility and may influence complication rates and costs in the longer-term. (Dettori, 2008) We do not know the long-term failure rate or impact of particular wear on these devices, and the theoretical position that symptomatic adjacent segment disease leads to more surgery after fusion compared to less aggressive treatment is poorly founded, plus these devices appear at best to yield results equal to or only incrementally better than fusion for the same indications. (Resnick, 2007)

Indications: Indications - Lumbar Spine: Indications for L-ADR include, among other factors, primary back pain and/or leg pain in the absence of nerve root compression. This group of patients is different than those undergoing cervical ADR and results from one group should not be inferred to the other. Cervical ADR is performed in patients with radiculopathy (cervical nerve root compression) causing arm pain and possibly motor weakness, or even myelopathy (compression of the spinal cord that could affect upper extremities, lower extremities, bowel, and bladder function). Consolidating cervical and lumbar disc replacements into a single assessment defeats the purpose of an evidence-based review by too broadly defining the topic area. The problem of identifying those likely to respond to treatment is of concern for L-ADR in that the surgical procedure is designed to treat degenerative disc disease that is thought to be the origin of the patient's pain, but certainty around the diagnosis as the cause of low back symptoms varies. Though L-ADR for degenerative disc disease has been compared with lumbar fusion, not all patients who get a fusion are candidates for L-ADR, including patients with nerve root compression, spondylolisthesis, stenosis and osteoporosis. In fact, the proportion of patients who have an indication for L-ADR make up only about 5% of those who might undergo lumbar fusion. The investigators found that surgeons and institutions with a high volume of

L-ADR cases have reduced key perioperative and postoperative negative outcomes that provide a clinical and/or economic benefit. (Dettori, 2008)

Current US treatment coverage recommendations: Variations exist in coverage policies for ADR for CMS and selected bell-weather payers. Medicare: The Centers for Medicare and Medicaid Services (CMS) will not cover lumbar ADR for patients older than 60 years of age and decisions regarding coverage of patients younger than 60 years of age are at the discretion of local CMS contractors. (Medicare, 2007) Aetna considers FDA-approved prosthetic intervertebral discs medically necessary for spinal arthroplasty in skeletally mature person with lumbosacral degenerative disc disease at one level from L3 to S1, and who have failed at least 6 months of conservative management. (Aetna, 2007) Blue Cross/Blue Shield: Coverage is not recommended. (Blue Cross/Blue Shield, 2007) Cigna covers the implantation of a SB Charité or Prodisc-L lumbar intervertebral disc prosthesis for chronic, unremitting, discogenic low back pain and disability secondary to single-level degenerative disc disease (DDD) as medically necessary in a skeletally mature patient when ALL of the following criteria are met: The unremitting low back pain and disability described has been refractory to at least six consecutive months of standard medical and surgical management (eg, exercise, analgesics, physical therapy, spinal education); Single-level disc degeneration has been confirmed on complex imaging studies (ie, computerized tomography [CT] scan, magnetic resonance imaging [MRI]); & The planned implant will be used in the L4-S1 region if Charité or the L3-S1 region if Prodisc-L. (Cigna, 2007) Harvard Pilgrim does not cover artificial disc replacement for DDD as an alternative to spinal fusion. (Harvard Pilgrim, 2006) Washington State Department of Labor and Industries: Efficacy: Data insufficient to draw conclusions, L-ADR should be considered experimental only. (Washington LNI, 2004) In March of 2009, based on the 2008 Washington Technology Assessment (Dettori, 2008), Washington LNI released an official Coverage Determination stating that Lumbar ADR would be covered under these conditions: (1) Post-completion of a multi-disciplinary pain program; (2) Age 60 or less; (3) Consistent with FDA approved indications (i.e., failure of 6-months non-operative treatment, skeletally mature patient, single disc only, no infection, no sensitivity to implant materials, no osteoporosis or spondylosis). (Washington, 2009)

The injured individual does not have single level disease. There is no medical documentation regarding an adequate trial of conservative treatment as noted above.

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

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

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

The Occupational Medicine Practice Guidelines