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Notice of Independent Review Decision

DATE OF REVIEW: 06/16/10

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

The item in dispute is the prospective medical necessity of an artificial disc replacement at L4-5 and L5-S1.

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

The reviewer is a Medical Doctor who is board certified in Orthopedic Surgery. This reviewer has been practicing for greater than 15 years.

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 reviewer agrees with the previous adverse determination regarding the prospective medical necessity of an artificial disc replacement at L4-5 and L5-S1.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Records were received and reviewed from the following parties:
Back Institute and Ins. Co.

These records consist of the following (duplicate records are only listed from one source): Records reviewed from Institute: COPE report – 3/23/10, Surgery Scheduling Slip/Checklist – 2/19/10, Injured Worker Info – Follow-up Notes – 12/18/09-2/19/10, Consultation Notes – 8/14/09, Radiology Review – 8/14/09; Spine Institute, PA Follow-up Notes – 7/16/08-2/17/10, Operative Report – 2/4/2010; MRI CT Scan Report – 2/4/10; MRI Central MRI report – 7/27/09; Therapy Initial Eval – 8/27/09; MD Note – 7/23/09.

Records reviewed from Ins. Co.: Denial letter – 4/1/10 & 4/16/10, ODG Low Back Chapter regarding Disc Prosthesis.

A copy of the ODG was provided by the Carrier/URA for this review.

PATIENT CLINICAL HISTORY [SUMMARY]:

The male was noted to have low back pain with radiation into the lower extremities, resistant to non-op. treatment. There has been a consideration for a 2-level (L4-S1) lumbar disc replacement. The psychosocial screen was non-problematic and dated 3/23/10. The 2/19/10 discussion of the CT-discogram “concordant” pain at the proposed level of L4-5 and pain to the left leg was noted when L5-S1 was injected. The 2/4/10 dated discogram report denoted “concordant pain” at L4-5 only although a “central fissure” was noted at L5-S1. Prior AP records discussed the failure of ESIs, medications and therapy along with a normal neurological exam despite a +SLR, left-sided. The 7/27/09 dated MRI denoted only a central protrusion at L5-S1. The 4/1/10 dated denial letter’s rationale included the lack of nerve root compression or disc herniation at L4-5 along with the lack of long-term studies documenting efficacy for back pain. The use of this device at two levels is not considered standard of care.

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

The reviewer states that as per applicable guidelines, artificial disc replacement is “Not recommended in the lumbar spine...” In addition, a single artificial disc replacement would be the only guideline-associated consideration, in any event. Finally, “long term” safety and efficacy has not yet been documented in the medical literature with regards to the lumbar artificial disc replacement.

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. 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.” At the current time radiculopathy is an exclusion criterion for the FDA studies on lumbar disc replacement. Even though medical device manufacturers expect this to be a very large market, 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. Furthermore, despite FDA approval, the disc prosthesis is not generally covered by non workers' comp health plans or by some workers' comp jurisdictions. 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. 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. 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. 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. 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. 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. 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. Discography (and not merely the fusion) may actually be the cause of adjacent segment disc degeneration. This study suggested that the phenomenon of accelerated adjacent segment degeneration adjacent to fusion levels may be, in part, explained by previous disc puncture if discography was used in segments adjacent to the fusion.

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. (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.

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. **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. 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. Blue Cross/Blue Shield: Coverage is not recommended. 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. Harvard Pilgrim does not cover artificial disc replacement for DDD as an alternative to spinal fusion. Washington State Department of Labor and Industries: Efficacy: Data insufficient to draw conclusions, L-ADR should be considered experimental only. In March of 2009, based on the 2008 Washington Technology Assessment, 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).

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)**