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Notice of Independent Review Decision

DATE OF REVIEW: March 2, 2009

IRO CASE #:

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

This case was reviewed by a neurosurgeon, Licensed in Texas and board certified. The reviewer has signed a certification statement stating that no known conflicts of interest exist between the reviewer and the injured employee, the injured employee's employer, the injured employee's insurance carrier, the utilization review agent (URA), any of the treating doctors or other health care providers who provided care to the injured employee, or the URA or insurance carrier health care providers who reviewed the case for a decision regarding medical necessity before referral to the IRO. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Two days inpatient for total disc arthroplasty at L4-5 and L5-S1 at Medical Center

REVIEW OUTCOME

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

Upheld (Agree)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- o Submitted medical records were reviewed in their entirety.
- o Treatment guidelines were provided to the IRO.
- o December 21, 2007 Lumbar MRI as read by Dr.
- o January 14, 2008 Letter to Dr. from Dr.
- o July 2, 2008 Notice of IRO decision
- o September 23, 2008 Letter to Dr. from Dr.
- o December 31, 2008 Summary of approval and denial decisions - 2pp.
- o January 12, 2009 Encounter report from Dr.
- o January 16, 2009 Fax note
- o January 20, 2009 Denial letter for outpatient artificial lumbar discectomy
- o February 4, 2009 Reviewer note regarding denial rationale
- o February 5, 2009 Denial letter for reconsideration 2 days inpatient
- o February 14, 2009 Designated Doctor Report from Dr.
- o February 20, 2009 Request for IRO - Surgery, artificial lumbar disc (Synthes prodisc L)

PATIENT CLINICAL HISTORY [SUMMARY]:

According to the medical records submitted for review, the patient is an employee who sustained an industrial injury to the low back on xx/xx/xx when lifting his gear onto the truck.

The patient underwent lumbar MRI on December 21, 2007 which shows, "a small posterior annular tear at the L4-5 disc with no significant disc protrusion or herniation. Degenerative disc disease L5-S1 with mild diffuse annular bulge but no nerve root involvement. Otherwise unremarkable MRI of the lumbar spine."

A neurosurgical note of January 12, 2009 indicates the patient has failed maximal conservative treatment including therapy and interventional pain management and is on chronic narcotic pain medication. His MRI shows an annular tear at L4-5 and diffuse

annular bulge at L5-S1. Recommendation is for an artificial lumbar disc (Synthes prodisc L).

The patient was examined neurosurgically on January 14, 2008. The patient has had physical therapy without improvement. Initially he had bilateral radicular pain. Now he has occasional left lower extremity radicular pain. He is using Ultram, Soma and codeine. He has not smoked for 10 years. On examination he has full lower extremity motor strength and full sensory and reflex function. Straight leg raise is negative. Surgery is not recommended. He could benefit from additional conservative treatment.

An Independent Review was performed on July 2, 2008 by an anesthesiology/pain management specialist to consider if denial for outpatient lumbar discogram at L3-4, L4-5, L5-S1 was appropriate. The review noted the patient has participated in conservative treatment of physical therapy, medication management, and lumbar transforaminal steroid injections at bilateral L4. The injections provided 100% pain relief. The patient's only medication appears to be Darvocet. MRI showed no nerve root involvement. The patient was seen by a neurosurgeon and considered for artificial disc replacement (ADR), however he did not want to take an extended period of time off work and pursued a repeat lumbar epidural steroid injection. The denial was upheld with rationale that there was lack of indication for surgery and therefore lack of indication for discography that has already been denied multiple times per ODG criteria. There was no rationale from the provider refuting The Official Disability Guidelines. It was noted that the surgery requested was disc arthroplasty which remains investigational and unproven at this time. Additionally a psychosocial screening is required and the patient appears to have issues of depression and stress.

The patient returned for neurosurgical reevaluation on September 23, 2008. He has only had temporary benefit from injections and he is using Kadian, Lyrica and bupropion on a chronic basis. On examination, his back inspection is normal. Heel and toe walk are normal. He has full motor strength. His MRI shows a likely annular tear at L4-5 and some disc changes at L4-5 and L5-S1. Recommendation is for a discogram to see if he is a candidate for artificial disc replacement.

Request for outpatient lumbar discectomy and artificial disc replacement (ADR) was not certified in review on January 29, 2009 with rationale that the patient does not have the guideline criteria for fusion let alone artificial disc replacement which is also not supported by The Official Disability Guidelines. The patient was noted to have minimal disc disease per his age and no demonstrable neurologic or mechanical findings. Additionally, the medical records fails to document psyche clearance as required by guidelines.

Request for reconsideration for two days inpatient stay for total disc arthroplasty at L4-S1 was also not certified in review with rationale that the patient does not have the criteria necessary for disc replacement. He is normal clinically and has no herniated nucleus pulposus, but only annular bulges, at L4-5 and L5-S1. He has also not had psychological clearance including Minnesota Multiphasic Personality Inventory.

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

Per MRI, there is a small posterior annular tear at the L4-5 disc with no significant disc protrusion or herniation. Degenerative disc disease L5-S1 with mild diffuse annular bulge but no nerve root involvement. Otherwise unremarkable MRI of the lumbar spine. These are findings not including a neurocompressive lesion. On examination, the patient consistently demonstrates full motor strength, intact sensation and normal reflexes. Even straight leg raise is not documented to elicit back or radicular pain. The patient could benefit from weaning narcotic medications. His self-management measures have not been clarified. The patient appears to be working. The medical records fail to document criteria that would indicate a need for surgery, especially a two level surgery. ODG does not support artificial disc replacement as studies on this treatment have failed to demonstrate a superiority of disc replacement over simple fusion for the limited indications for surgical treatment of lower back. Given the patient does not have the criteria for lumbar surgery and guidelines do not support ADR, the requested intervention must be considered not medically appropriate or necessary. Therefore, my recommendation is to agree with the previous non-certification of the request for two days inpatient for total disc arthroplasty at L4-5 and L5-S1 at Covenant Medical Center.

The IRO's decision is consistent with the following guidelines:

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

___X___ 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

The Official Disability Guidelines: Lumbar - Disc Prosthesis - Updated February 19, 2008:

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)

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) At the beginning of 2009, based on the 9/19/08 Washington Technology Assessment (Dettori, 2008), Washington LNI released a Draft Coverage Determination stating that both Cervical and Lumbar ADR would be covered under these conditions: (1) Post-completion of a multi-disciplinary pain program; (2) Consistent with FDA approved indications (i.e., failure of non-operative treatment, skeletally mature patient, single disc only, no infection, no sensitivity to implant materials, no osteoporosis or spondylosis); (3) For lumbar, age 60 or less. (Washington, 2009).