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IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

360 Fusion at L5-S1 with Disk Displacement Arthroplasty at L4-5

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

Orthopaedic Surgeon; Board Certified; 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
360 Fusion at L5-S1 with Disk Displacement Arthroplasty at L4-5	22224, 22558, 22612, 63047, 22851, 76000, 22840, 64999, 20937, 20930	N/A	Upheld

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Record Description	Record Date	Pages
1. Nerve Conduction and Electromyography Study	12/15/05	2
2. MRI of the Lumbar Spine	01/09/06	2
3. Initial Orthopaedic Consultation; M.D.	06/06/06	4
4. Initial Evaluation; M.D.	10/02/06	4
5. CT Discography of the Lumbar	10/16/06	1
6. Operative Report; M.D.	10/16/06	4
7. Subsequent Medical Report; M.D.	11/14/06	4
8. Subsequent Medical Report, M.D.	01/09/07	3
9. Initial Outpatient Non-Authorization Recommendation	01/24/07	3
10. Initial Outpatient Non-Authorization Recommendation	04/13/07	3
11. Outpatient Reconsideration Decision: Non-Authorization	04/13/07	2

PATIENT CLINICAL HISTORY (SUMMARY):

Medical records were reviewed for a work injury regarding this patient. The work injury occurred .There is reference in the medical notes reviewed that this patient was treated initially by. Surgery was recommended, but the patient deferred. In 2004 an MRI was performed of the lumbar spine. It revealed 2-

level degenerative changes. This patient continued non-operative treatment, found other work capacities when he was discharged from his present employ. On 6/6/06 Dr. suggests he was working as a waiter. Dr. saw and evaluated this patient initially on 6/6/06 and he described a listhesis of L4 on 5 and recommended a discography. Ultimately Dr. became involved. He notes that the patient has considerable low back and right greater than left leg pain. Dr. describes this as a radiculopathy and further notes that there is litigation involved. The patient was out of work and the patient is a one pack per day smoker. The evaluation shows that the patient has excellent flexion with arms outstretched to what appears to be to the ankles. He does not comment upon the listhesis. On 10/6/06 a CT discogram was performed. The only medical information provided suggests the morphology on CT is normal at L3-4 and abnormal at both L4-5 and L5-S1. Further review of the discography procedure itself performed on 10/16/06 by Dr. notes that it was done in a non-blinded fashion. Dr. was aware of the MRI findings and the clinical situation. Only 1 cc of contrast was injected in any of the disc levels. No pressure data was noted and only the L5-S1 level was "concordant" with 10/10 pain. There is no mention of what intensity of sedation was provided. No drug dosages were provided. Based upon this information, Dr. again consulted the patient on 1/9/07 and is now recommending an L5-S1 fusion with a concomitantly performed L4-5 total disc replacement. He does not comment upon the listhesis he previously noted. No flexion extension studies are performed.

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

Based on current medical thinking and evidence based medicine, the requested procedures are not medically warranted. Guidelines recently to be adopted by the State of Texas as promulgated by the Texas Department of Insurance, reference ODG as indicating disc replacement surgery is not warranted at this time. Certainly as a combined procedure atop a fusion procedure, this has little or no evidence based support and no clinical studies I am aware of that this has even been proclaimed as a reasonable treatment alternative. Adjacent segment level degeneration is moot and is a poorly understood phenomena. The best medical literature to date suggests that the incidence of this to the degree that would require additional surgery is small and probably less than 20% over 7-10 years. In brief, this patient has multi-level degenerative spondylosis. Fusion surgery and, for that matter, disc replacement surgery is a moot therapeutic intervention. Most evidence based literature and current thinking suggest these patients are better served long term with a cognitive behavioral rehabilitative course and not multi-level surgical intervention as is recommended. I would finally restate the issue of listhesis was raised by Dr himself and this, if it is real, is an absolute contraindication to TDR. In conclusion, the surgical indication is not warranted. The request as submitted is not medically necessary.

ODG as of January 2007 states that TDDR is 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' compensation health plans (BlueCross BlueShield, 2004), or by some workers' compensation 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 and 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) 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. Note: On August 14, 2006, the FDA approved the ProDisc Total Disc Replacement by Synthes Spine, Inc.

The ACOEM Guidelines, Page 306, Second Edition, Chapter 12 notes that given the extremely low level of evidence available for artificial disc replacement, it is recommended that these procedures be regarded as experimental at this time, even though the replacement disc has just been authorized by the FDA. Please note also the following: Presently there are multiple contraindications to total disc replacement surgery in the spine including lumbar stenosis, facet arthrosis, herniated nucleus pulposus with radiculopathy, post-surgical deficiency of the posterior elements, pseudoarthrosis, osteoporosis, scoliosis, spondylosis, and spondylolisthesis, which was 95% of the patients in the author's series (Huang, in Spine Vol. 29, #22, 2004 pages 2538-41). As published in the Spine Journal (3) 2003:67S-171S, authored by Dr Huang he references the variable contraindications for TDR and concludes that of the patients preliminarily selected only 5% passed scrutiny after close review. JBJS 87A, 2005: Pages 490-496 notes there is no clear evidence that disc replacement results in pain relief that is superior to fusion. There is no study that has clearly demonstrated that normal segmental motion has been consistently restored. Comparative long term data demonstrating a reduced incidence of adjacent segment disease compared to fusion are not yet available.

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

ODG:ODG 2007(Cinotti-Spine, 1996) (Klara-Spine, 2002) (Zeegers, 1999) (Blumenthal, 2003) (Zigler, 2003) (McAfee, 2003) (Anderson-Spine, 2004) (Gamradt-Spine, 2005) (Gibson-Cochrane, 2005)

ACOEM: Second Edition, Chapter 12, p.306

TEXAS DEPARTMENT OF INSURANCE COMPLAINT PROCESS: the Texas Department of Insurance requires Independent Review Organizations to be licensed to perform Independent Review in Texas. To contact the Texas Department of Insurance regarding any complaint, you may call or write the Texas Department of Insurance. The telephone number is 1-800-578-4677 or in writing at: Texas Department of Insurance, PO Box 149104 Austin TX, 78714. In accordance with Rule 102.4(h), a copy of this Independent Review Organization (IRO) Decision was sent to the carrier, the requestor and claimant via facsimile or U.S. Postal Service from the office of the IRO on 05/01/2007.