

midline disc protrusion at L5-S1 with some changes of chronic nature in the

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Notice of Independent Review Decision

DATE OF REVIEW: May 14, 2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Artificial disc replacement, lumbar spine at L5-S1

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

The physician providing this review is a spinal neurosurgeon. The reviewer is national board certified in neurological surgery. The reviewer is a member of the American Association of Neurological Surgeons, The Congress of Neurological Surgeons, The Texas Medical Association, and The American Medical Association. The reviewer has been in active practice for 38 years.

REVIEW OUTCOME

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

Overturned (Disagree)

Medical documentation **supports** the medical necessity of artificial disc replacement, lumbar spine at L5-S1

ODG criteria have been utilized for the denials.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a xx-year-old female who was involved in a motor vehicle accident on xx/xx/xx. She was driving a van and as she stopped for some construction on a road, she was struck from behind by a concrete truck going at about 50 miles an hour. She sustained significant injury to her neck and lower back. There was no loss of consciousness.

Following the injury, the patient was seen at the emergency room (ER) of Medical Center for neck and low back pain and abrasions over the forehead. X-rays of the cervical spine and lumbar spine and computerized tomography (CT) of the brain were unremarkable. Magnetic resonance imaging (MRI) of the neck and thoracic spine showed evidence of disc herniation at C2-C3 and disc protrusion at C3-C4. MRI of the lumbar spine revealed degenerative disc disease (DDD) with diffuse L5-S1 disc bulge and large broad-based central and

midline disc protrusion at L5-S1 with some changes of chronic nature in the left/right paracentral disc protrusion associated with mild spinal stenosis and bilateral foraminal narrowing; facet arthritis at L3-L4, L4-L5, and L5-S1; and mild disc bulges at T11-T12, T12-L1, and L1-L2. , M.D., prescribed medications and ordered physical therapy (PT). The patient was advised to return to restricted work duty and was issued a back brace. However, PT was of no help and therefore she was treated with thoracic and lumbar epidural steroid injections (ESIs) followed by lumbar facet blocks. She was also referred to a chiropractor, D.C., who performed a traction-based decompression therapy but to no avail. Due to failed conservative measures including PT, manipulation, decompression therapy, facet injection, and ESI, she was felt to be a surgical candidate and was referred to, M.D., who ordered lumbar discography.

In January 2008, Dr. reported that the patient had an intervening motor vehicle accident (MVA) on xx/xx/xx, at which time she sustained injuries to her neck and back. She did not have any new pain or symptoms. She was continued on medications. MRI of the lumbar spine revealed mild bilateral facet arthritis at L2-L3, L3-L4, and L4-L5, a 4-mm synovial cyst adjacent to the right facet joint at L3-4, and a diffuse disc desiccation and diffuse 4-5 mm disc bulge and a broad-based central disc protrusion at L5-S1 mildly contacting the ventral aspect of the thecal sac associated with mild bilateral foraminal narrowing and facet arthritis. MRI of the cervical spine revealed mild DDD at C2-C3, C3-C4, C4-C5, and C5-C6.

In February 2008, lumbar discogram demonstrated severe 10/10 concordant middle and slight right buttock pain with posterior fissuring at L5-S1. Post-discogram CT scan revealed a broad-based posterior central fissure with morphologic disc protrusion and associated osteophyte with posterior disc narrowing at L5-S1. The patient underwent a psychological evaluation and was cleared for the surgical intervention. Dr. felt that due to failed conservative measure, a lumbar fusion would be effective in reducing pain and improving function, but at the cost of decreased range of motion (ROM) of the lumbar spine, increase pressure on the adjacent levels, and accelerated breakdown of other segments. Therefore, Dr. recommended artificial disc replacement at L5-S1.

M.D., concurred with the proposed surgical intervention at L5-S1. Dr. opined that the degenerative condition of the L5-S1 disc likely pre-dated her initial MVA but she was not significantly symptomatic or disabled until the MVA of xx/xx/xx. He further stated that based on reasonable medical probability, causation for the persistent disabling pain attributed to the L5-S1 disc which was from the MVA of xx/xx/xx. He also stated that the accident of xx/xx did not significantly change her condition which existed following the xx/xx/xx, accident.

On April 11, 2008, the request of artificial disc replacement was denied with the following rationale: *There is no instability noted on any films, the claimant has no evidence of radiculopathy, only complaints of pain. ODG/disc prosthesis-not recommended at this time for either DDD or mechanical low back pain. According to this prospective, randomized, multi-center FDA IDE study, the ProDisc-L has been shown to be superior to circumferential fusion by multiple clinical criteria.*

midline disc protrusion at L5-S1 with some changes of chronic nature in the
On April 23, 2008, the appeal for ProDisc-L5-S1 surgery was non-certified with the following rationale: *The problem is described as that of low back pain in a female and date of event xx/xx/xx, described as an MVA. MRIs in July 2007 and January 2008 indicated the presence of bilateral facet disease at L3-L5 with a bulging disc and disc desiccation at L5-S1. Discography is reported to have produced severe concordant pain with L5-S1 injection. Psychological evaluation is stated to have cleared the claimant for surgery. The patient has no radiculopathy or instability. all avenues of conservative care should be exhausted prior to submitting some one of this age group to a surgical procedure without known long-term benefits. There is no indication that she has been involved in an intensive spinal rehabilitation program or an intensive home exercise program (HEP). The procedure, considering the information available for review, is not medically indicated, reasonable, or necessary. Hence, disc prosthesis was not recommended for either DDD or mechanical low back pain.*

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

Medical material reviewed and listed numerically:

1. Summary of clinical history for or by on 5/7/08
2. Medical Center ER records, 7/13/07
3. 7/20/07 neurological consult report by, M.D. and follow up reports by the same doctor from 7/27 through 11/19/07
4. Lumbar MRI report of 7/24/07 and 1/25/08
5. Lumbar discogram report of 2/25/08 by, M.D.
6. Incorporated reports of 4/8/08 and 4/25/08
7. utilization review report of 4/23/08 by, M.D., an orthopedic surgeon

This case involves a now xx year old female who had a motor vehicle accident on xx/xx/xx. She was rear ended by a concrete truck while driving a van and developed neck and lower back pain. She also had a head injury with probable loss of consciousness. Medications, rest, physical therapy and epidural steroid injections have failed in relieving her low back pain. Dr. her primary early care physician consulted Dr. regarding possible surgery on 11/19/07. This led to discographic evaluation which was strongly positive at the L5-S1 level only. A psychological evaluation by Dr. on 2/27/08 indicated "clear for surgery". Repeat lumbar MRI on 1/28/08 was similar to the initial study on 7/24/07 in that it showed facets at the two levels above. The patient was helped some by the early therapy but again increased symptoms occurred after another motor vehicle accident on 1/22/08. Dr. has recommended disc replacement at the L5-S1 in hopes of dealing with the patient's persistent pain.

I disagree with the denial for the lumbar disc replacement at the L5-S1 levels. Patient's symptoms and imaging studies including discographic evaluation strongly suggests that the source of her difficulty is the L5-S1 disc derangement. One may argue for fusion and discectomy at this level but with the changes at the levels above, this would throw additional stress on those levels and in all medical probability create problems in the future requiring more in the way of surgery including fusion. Conservative measures for the past 10 months have

midline disc protrusion at L5-S1 with some changes of chronic nature in the not been successful in dealing with trouble and that is a long enough period to consider these as being unsuccessful and no longer indicated. The lack of radiculopathy on clinical examination should not be a contraindication for lumbar disc replacement.

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

Guidelines developed by the reviewer over 38 years of evaluating spinal surgical problems.

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

Disc prosthesis	<p>Not recommended at this time for either degenerative disc disease or mechanical low back pain. 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 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 (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</p>
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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](#)) 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. Note: On August 14, 2006, the FDA approved the ProDisc® Total Disc Replacement by Synthes Spine, Inc.