

October 11, 2006

TX DEPT OF INS DIV OF WC
AUSTIN, TX 78744-1609

CLAIMANT: ___

EMPLOYEE: ___

POLICY: M2-06-1982-01

CLIENT TRACKING NUMBER: M2-06-1982-01-5278

Medical Review Institute of America (MRIOA) has been certified by the Texas Department of Insurance as an Independent Review Organization (IRO). The Texas Department of Insurance Division of Workers Compensation has assigned the above mentioned case to MRIOA for independent review in accordance with DWC Rule 133 which provides for medical dispute resolution by an IRO.

MRIOA has performed an independent review of the proposed care to determine if the adverse determination was appropriate. In performing this review all relevant medical records and documentation utilized to make the adverse determination, along with any documentation and written information submitted, was reviewed. Itemization of this information will follow.

The independent review was performed by a peer of the treating provider for this patient. The reviewer in this case is on the DWC approved doctor list (ADL). The reviewing provider has no known conflicts of interest existing between that provider and the injured employee, the injured employee's employer, the injured employee's insurance carrier, the utilization review agent, or any of the treating doctors or insurance carrier health care providers who reviewed the case for decision before referral to the IRO.

Records Received:

Records from state:

Notification of IRO Assignment 09/08/2006

Letter to MRIOA from DWC 08/22/2006

Medical Dispute Resolution Request/Response form

Table of Disputed Services

List of treating providers

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UR Report 07/03/2006

UR Report 07/25/2006

Records from requestor:

Preauthorization Request form

MRI Lumbar Spine 08/16/2004

Medical Records Dr. Scott Blumenthal

Radiology Report 01/10/2005

EMG/NCV Study 02/16/2006

Lumbar Discography Report 05/26/2006

Background Charite Artificial Disc

UR Report 07/03/2006

Response to Denial 07/17/2006

UR Report 07/25/2006

Records from respondent:

Letter to MRIOA from ESIS 10/03/2006

Medical Records (324 pages)

Summary of Treatment/Case History:

The patient is a 37 year old male who has a history of multiple lower back injuries over the past 20 years. The patient's original injury occurred after a motor vehicle accident in 1985 after which he underwent an L5-S1 laminectomy/discectomy on the right. The patient had 2 subsequent injuries which resulted in laminectomy/discectomies in 1991 and again in 1997.

The patient sustained an on-the-job injury on _____. On this date the patient is reported to have lifted a 20 inch television monitor and fell backwards with it. The patient reports the development of left-sided low back pain as a result of this event. The patient was evaluated by Dr. Scott Blumenthal on 01/10/2005. At this time he reports the history noted above. He further indicates that the patient is under the care of Dr. Ahmed and being treated with pain medications and muscle relaxants. He reports that other conservative treatments have included physical therapy and transforaminal lumbar epidural steroid injections. On physical examination the patient is ambulating without significant difficulty. He is able to heel toe walk easily. The patient has no tenderness to palpation over the lumbar spine. There is no tenderness noted at the sacroiliac joint. Forward flexion is limited to approximately 30 degrees which increases left-sided back pain. Manual motor strength testing reveals 4/5 strength bilaterally for the EHL, and the tibialis anterior is rated as 5/5 bilaterally. Deep tendon reflexes are 2+ and symmetric for the knees and 1+ and symmetric for the ankles. Imaging studies were discussed. As a result, Dr. Blumenthal opines that the patient has severe disc degeneration at the L4-5 level with a recurrent left-sided herniation as

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well as degenerative disc disease at the L5–S1 level. Dr. Blumenthal recommends the patient undergo lumbar discography and discusses the potential of a two–level artificial disc replacement. The patient was referred for electrodiagnostic studies on 02/16/2006. This study reports physiologic evidence of a lumbosacral radiculopathy at L4 through S1 on the left, worse at L4–5. This was compared with a prior EMG performed on 12/23/2003, and there is a worsening noted in the interval period. The patient eventually underwent lumbar discography on 05/26/2006. At this point the patient is noted to have a degenerated disc at L4–5 with extravasation of contrast into the epidural space. This disc was reported to be nonconcordant with a VAS score of 0. At L5–S1 the patient is noted to have a degenerative disc producing a concordant pain without radiation into the left lower extremity. As a result of the patient’s long–standing low back pain that has failed to respond to conservative care, Dr. Blumenthal requested a two–level artificial disc replacement.

The record indicates that the patient has undergone extensive conservative treatment, including physical therapy, transforaminal epidural steroid injections, and epidural steroid injections. The record further indicates that the patient clearly has multi–level degenerative disease at L4–5 with compromise of the annulus at this level and L5–S1 which is reported to have provided concordant pain on lumbar discography.

Questions for Review:

1. Is disc arthroplasty at L4–5 and L5–S1 medically necessary?

Explanation of Findings:

1. Is disc arthroplasty at L4–5 and L5–S1 medically necessary? No. The FDA has approved the Charite Artificial Disc for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at one level from L4–S1. The indications for the implantation of the Charite Artificial Disc define DDD as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. According to the FDA–approved labeling, these DDD patients should have no more than 3 mm of spondylolisthesis at the involved level. The FDA approved labeling states that patients receiving the Charite Artificial Disc should have failed at least six months of conservative treatment prior to implantation of the Charite Artificial Disc. According to the FDA–approved labeling, the Charite Artificial Disc should not be implanted in patients with the following conditions: osteoporosis; osteopenia; pars defect; bony lumbar stenosis; active systemic infection or infection localized to the site of implantation; allergy or sensitivity to implant materials; and isolated radicular compression syndromes, especially due to disc herniation. The FDA–approved labeling of the Charite Artificial Disc states that the safety and effectiveness of the device has not been established in patients with the following conditions: pregnancy; morbid obesity; two or more degenerative discs; spondylolisthesis greater than 3 mm; or two or more unstable segments.

The Charite Artificial Disc is currently not approved by the FDA for multilevel arthroplasty. Studies

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regarding multilevel arthroplasty have recently concluded and this data is currently in peer review. A two level disc arthroplasty would be considered experimental in the United States under the current criteria. Because the long-term safety and effectiveness of the Charite Artificial Disc is unknown, the FDA has required the manufacturer to conduct a post-approval study using a maximum of 366 subjects (201 randomized investigational subjects; 67 training investigational subjects; and 98 control subjects). The manufacturer will be required to evaluate subjects Overall Success and secondary endpoints, and submit annual reports for a total of 5 years post-implantation. Data on the long-term outcomes of the Charite Artificial Disc comes from France, where the artificial disc has been in use for more than a decade. David (2000) reported in abstract form on a retrospective review of the outcome of 92 patients with chronic low back pain who were implanted with the artificial disc. The investigators reported “excellent or good” results in 75 percent of patients after a minimum of 5 years follow up, with no disc space height loss and no loosening or expulsion of the core. Lemaire, et al., described their 5-year and 10-year results with the Charite Artificial Disc. In the paper reporting on 10-year results, Lemaire, et al. (2002) reported an excellent or good outcome in 90 percent of 100 patients with a return to work rate of 91.6 percent. In addition, the investigators reported no sublaxations or core expulsions, a reoperation rate of 5 percent and a 2 percent rate of adjacent-level disc disease. The mean flexion/extension range of motion was 10.3 degrees, with a mean lateral bending motion of 5.4 degrees.

Conclusion/Decision to Not Certify:

Disc arthroplasty at L4-5 and L5-S1 is not medically necessary.

References Used in Support of Decision:

1. McAfee PC, Cunningham B, Holsapple G, et al. A prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of lumbar total disc replacement with the CHARITE artificial disc versus lumbar fusion: Part II: Evaluation of radiographic outcomes and correlation of surgical technique accuracy with clinical outcomes. *Spine*. 2005; 30(14): 1576-1583; discussion E388-390.
2. Letter from Donna-Bea Tillman, Ph.D., Director, Office of Device Evaluation, Center for Devices and Radiological Health, U.S. Food and Drug Administration, Rockville, MD, to William Christenson, Vice President, Clinical and Regulatory Affairs, DePuy Spine, Inc., Raynham, MA, regarding FDA approval of Charite Artificial Disc, P040006, October 26, 2004.
3. Lemaire JP. [SB Charite III intervertebral disc prosthesis: Biomechanical, clinical, and radiological correlations with a series of 100 cases over a follow-up of more than 10 years.] *Rachis [Fr]*. 2002; 14: 271-285, cited in DePuy Spine, Inc. Charité Artificial Disc. Technical Monograph. SA01-030-000. JC/AG. Raynham, MA: DePuy; November 2004.
4. Tropiano P, Huang RC, Girardi FP, et al. Lumbar total disc replacement. Seven to eleven-year follow-up. *Bone Joint Surg Am*. 2005; 87(3): 490-496.

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5. Ohio Bureau of Workers' Compensation (BWC). Position paper on artificial lumbar disc. Medical Position Papers. Columbus, OH: Ohio BWC; February 2005.
6. Blumenthal S, McAfee PC, Guyer RD, et al. A prospective, randomized, multicenter Food and Drug Administration investigational device exemptions study of lumbar total disc replacement with the CHARITE artificial disc versus lumbar fusion: Part I: Evaluation of clinical outcomes. Spine. 2005; 30(14): 1565–1575; discussion E387–391.
7. Huang RC, Sandhu HS. The current status of lumbar total disc replacement. Orthop Clin North Am. 2004; 35(1): 33–42.
8. Benini A. Indications for single–segment intervertebral prosthesis implantation. Revista Di Neuroradiologia. 1999; 12(Suppl): 171–173.
9. van Ooij A, Oner FC, Verbout AJ. Complications of artificial disc replacement: A report of 27 patients with the SB Charite disc. J Spinal Disord Tech. 2003; 16(4): 369–383.
10. Zeegers WS, Bohnen LM, Laaper M, et al. Artificial disc replacement with the modular type SB Charite III: 2–year results in 50 prospectively studied patients. Eur Spine J. 1999; 8(3): 210–217.
11. Diwan AD, Parvataneni HK, Khan SN, et al. Current concepts in intervertebral disc restoration. Orthop Clin North Am. 2000; 31(3): 453–464.
12. de Kleuver M, Oner FC, Jacobs WC. Total disc replacement for chronic low back pain: Background and a systematic review of the literature. Eur Spine J. 2003; 12(2): 108–116.
13. Zigler JE, Burd TA, Vialle EN, et al. Lumbar spine arthroplasty: Early results using the ProDisc II: A prospective randomized trial of arthroplasty versus fusion. J Spinal Disord Tech. 2003; 16(4): 352–361.
14. Guyer RD, Ohnmeiss DD. Intervertebral disc prostheses. Spine. 2003; 28(15 Suppl): S15–S23.
15. Caspi I, Levinkopf M, Nerubay J. Results of lumbar disk prosthesis after a follow–up period of 48 months. Isr Med Assoc J. 2003; 5(1): 9–11.
16. Geisler FH, Blumenthal SL, Guyer Rd, et al. Neurological complications of lumbar artificial disc replacement and comparison of clinical results with those related to lumbar arthrodesis in the literature: Results of a multicenter, prospective, randomized investigational device exemption study of Charite intervertebral disc. J Neurosurg (Spine 2). 2004; 1: 143–154.
17. Hochschuler SH, Ohnmeiss DD, Guyer RD, Blumenthal SL. Artificial disc: Preliminary results of a prospective study in the United States. Eur Spine J. 2002; 11(Suppl 2): S106–S110.
18. Zigler J, Burd T, Vialle E, Sachs B, Rashbaum R, Ohnmeiss D; Lumbar Spine Arthroplasty: Early Results Using the ProDisc II: A Prospective Randomized Trial of Arthroplasty versus Fusion; Journal of Spinal Disorders and Techniques; Vol. 16, 4: 362–361.
19. Regan J; Clinical Results of Charite Total Disc; Replacement Journal of Spinal Disorders and Techniques.

The physician who provided this review is a fellow of the American Board of Orthopaedic Surgery.

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This reviewer is a fellow of the North American Spine Society and the American Academy of Orthopaedic Surgeons. This reviewer has been in active practice since 1990.

Your Right To Appeal

If you are unhappy with all or part of this decision, you have the right to appeal the decision. The decision of the Independent Review Organization is binding during the appeal process.

If you are disputing the decision (other than a spinal surgery prospective decision), the appeal must be made directly to a district court in Travis County (see Texas Labor Code §413.031). An appeal to District Court must be filed not later than 30 days after the date on which the decision that is the subject of the appeal is final and appealable.

If you are disputing a spinal surgery prospective decision, a request for a hearing must be in writing and it must be received by the Division of Workers' Compensation, Chief Clerk of Proceedings, within ten (10) days of your receipt of this decision.

Chief Clerk of Proceedings /
Appeals Clerk
P. O. Box 17787
Austin, TX 78744

A copy of this decision should be attached to the request. The party appealing the decision shall deliver a copy of its written request for a hearing to all other parties involved in the dispute

In accordance with Division Rule 102.4(h), I hereby verify that 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 this 11 day of Oct/2006.

Lori Behrend

MRIOA is forwarding this decision by mail, and in the case of time sensitive matters by facsimile, a copy of this finding to the treating provider, payor and/or URA, and the DWC.

It is the policy of Medical Review Institute of America to keep the names of its reviewing physicians confidential. Accordingly, the identity of the reviewing physician will only be released as required by state or federal regulations. If release of the review to a third party, including an insured and/or provider, is necessary, all applicable state and federal regulations must be followed.

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The written opinions provided by MRIOA represent the opinions of the physician reviewers and clinical advisors who reviewed the case. These case review opinions are provided in good faith, based on the medical records and information submitted to MRIOA for review, the published scientific medical literature, and other relevant information such as that available through federal agencies, institutes and professional associations. Medical Review Institute of America assumes no liability for the opinions of its contracted physicians and/or clinician advisors. The health plan, organization or other party authorizing this case review agrees to hold MRIOA harmless for any and all claims which may arise as a result of this case review. The health plan, organization or other third party requesting or authorizing this review is responsible for policy interpretation and for the final determination made regarding coverage and/or eligibility for this case.

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cc: patient; provider

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