

June 3, 2005

DEE TORRES
TEXAS WORKERS COMP. COMMISSION
AUSTIN, TX 78744-1609

CLAIMANT: ___
EMPLOYEE: ___
POLICY: M2-05-1594-01/5278
CLIENT TRACKING NUMBER: M2-05-1594-01/5278

Medical Review Institute of America (MRIOA) has been certified by the Texas Department of Insurance as an Independent Review Organization (IRO). The Texas Workers Compensation Commission has assigned the above mentioned case to MRIOA for independent review in accordance with TWCC 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 TWCC approved doctor list (ADL). The reviewer has signed a statement indicating they have no known conflicts of interest existing between themselves and the treating doctors/providers for the patient in question or any of the doctors/providers who reviewed the case prior to the referral to MRIOA for independent review.

Records Received:

Records from the State:

Notification of IRO Assignment, 5/23/05
Notice of request for Medical Dispute Resolution, 5/23/05
Medical Dispute Resolution Request/Response form, 4/22/05
Table of Disputed Services
Letters from Jack Zigler, MD 12/29/04, 2/9/05, 3/2/05
Letters from Utilization Review Nurse, 1/25/05, 2/23/05
Letter from Toni Evans, RN, 4/29/05
Peer Review Analysis Case Reports, 1/25/05, 2/23/05

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Records from the Respondent:

Notice of request for Medical Dispute Resolution, 5/23/05

Letter from Toni Evans, RN, 4/29/05

Peer Review Analysis Case Reports, 1/25/05, 2/23/05

Fax Coversheet/Preauthorization requests, Texas Back Institute, 1/17/05, 2/17/05

Surgery Scheduling Slip/Checklist, 12/29/04

Letters from Dr. Zigler, 10/13/04, 11/3/04, 11/23/04, 12/29/04, 2/9/05

Progress note, 9/24/04

Note by Mark Fredrickson, MD with report of electrodiagnostic study of the right lower extremity, 3/16/04

Operative report, 12/17/04

MRI of the lumbar spine, 10/29/04

Letter from Donna-Bea Tillman, PhD, Department of Health & Human Services

Related articles

Injured worker information sheet, 5/21/04

Summary of Treatment/Case History:

The claimant is being treated for a work-related injury to his low back which occurred while he was lifting with a twisting motion on _____. He saw referred to Dr. Fredrickson for electrodiagnostic study because of "radiating lumbar discomfort on his right leg.... He had an MRI scan which was apparently positive for some type of disc disruption." Physical exam only indicated "pain with palpation at the right sacroiliac joint." There was "no evidence of membrane instability found on needle examination of the right lower extremity." The right SI joint was injected.

A note by Dr. Cable dated 09/24/04 states the patient "had his transforaminal epidural steroid injection. Unfortunately, this was not at all helpful [and] it feels like it may have made him worse.... He did see Dr. Ratliff [who] felt that he may be a candidate for surgery at this point." PE revealed tenderness at L4-5 and L5-S1. Flexion [was] not as painful as extension. Positive SLR on the right at 60 degrees. Dr. Cable's impression: Lumbar radicular syndrome with herniated nucleus pulposus at L4-L5 and L5-S1. He was referred to Dr. Zigler, having exhausted conservative measures per Dr. Cable.

The patient was evaluated by Dr. Zigler on 10/13/04 who stated again that the patient was thought to have failed conservative care. His "persistent complaints are predominantly and significantly low back pain...just about every day... He has some pain that radiates down his right leg, but this is a secondary complaint for him. An MRI scan had been done on 03/08/04 and was read by Dr. V. T. Reddy: DDD at L4-5 and L5-S1 with broad-based, central, right-sided disc herniation at L4-5 and extending behind the L5 body with obliteration of the epidural fat and impingement on the sac, and at L5-S1, a combination of disc herniation and posterior osteophyte on the left side and centrally with obliteration of the epidural fat and impingement on the thecal sac. PE: revealed tenderness of the LS spine, significant paraspinal spasm. There were no focal deficits and mild to moderately positive sitting SLR. X-rays indicated mild right truncal list, five mobile lumbar vertebrae, otherwise normal. There was

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significant degeneration at L5-S1 with decreased height leaving only 10 to 15% of the anticipated height. At L4-5, there was a 3- to 4- millimeter relatively fixed retrolisthesis of L4 on L5. A repeat MRI scan was recommended.

MRI of the lumbar spine was done on 10/29/04: 1) minimal L4-5 annular bulge, 2) advanced L5-S1 DDD, 3) broad protrusion of the posterolateral L5-S1 disc with minimal asymmetric osteoarthritic ridge formation combine to produce extradural S1 nerve root displacement and degenerative stenosis of the left neural foramen. Dr. Zigler recommended a discogram to compare levels L4-5 and L5-S1 to L2-3 as the control.

The discogram was done by Dr. David Hagstrom on 12/17/04 with the following impression: 1) L5-S1 broad protrusion, posterolateral disc with extradural S1 nerve root displacement with advanced DDD, 2) L4-5 minimal annular disc bulging, 3) normal-appearing discs at L2-3 and L3-4, 4) minimally painful L3-4 disc with anterior central annular tear, 5) moderately painful L4-5 disc with mild DDD and posterior disc extrusion. A post-discogram CT scan was recommended but there is no report to review. The body of the report also states: 1) L3-4 disc had an anterior annular tear but did not appear to be a major pain generator, 2) The L4-5 disc had a disc height that was 80% of what was expected with moderate degenerative appearance and posterior extension of the contrast and a possible annular tear. He had pain on injection at this level, 3) The L5-S1 disc had a height that was 50 to 60% of what was expected with severe degenerative appearance and posterior extension of contrast. This caused right low back pain, but no leg pain.

He saw Dr. Zigler again who felt that the abnormality at level L3-4 precluded a two-level arthrodesis because this procedure would result in too much stress being placed on level L3-4. Instead, he recommended a two-level arthroplasty at levels L4-5 and L5-S1. This request was denied because "medical necessity [was] not established and this decision was appealed by Dr. Zigler. This appeal was again denied due to "two-level Charite disc replacement is considered experimental and investigational and not medically necessary." This decision was again appealed.

Questions for Review:

1. Please address the medical necessity of the item(s) in dispute: Preauthorization denied for Arthroplasty L4-5, L5-S1 Replacement with Mobil Spacer.

Explanation of Findings:

Recommendations from the FDA state that "patient selection is extremely important" and patients must meet the following criteria: 1) Be skeletally mature (yes), 2) Have DDD at one level from L4-S1 (no), 3) No more than 3-mm of spondylolisthesis at the involved level (in this case L5-S1 is most involved but there is no spondylolisthesis at this level noted in the documents), 4) Failed at least 6 months of conservative care (yes.) In addition, the patient's occupational activities (lifting), history of mental illness (not mentioned), alcohol or drug abuse (not mentioned), and history of other degenerative disease that may reduce the life of the implant (the patient does have degenerative disease at multiple levels.) He has no know specific contraindications.

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Of note, two-level disc arthroplasty is considered investigational and has not been studied fully. According to the FDA: "The safety and effectiveness of the Charite artificial disc [has] not been established in patients ... with: two or more degenerated discs. The Charite disc is currently approved only for single-level insertions and there have been no long-term outcome studies for these disc arthroplasties.

There are no clear indications in this case for a two-level disc arthroplasty especially in light of the fact that this multiple level procedure has not been studied or established as effective in these cases. This procedure remains investigational and even the single-level arthroplasty has not been shown to be more effective than lumbar fusion surgery. Additional randomized prospective studies are needed.

Conclusion/Decision to Not Certify:

1. Please address the medical necessity of the item(s) in dispute: Preauthorization denied for Arthroplasty L4-5, L5-S1 Replacement with Mobil Spacer.

The proposed two-level disc arthroplasty replacement with Mobil Spacer, is not medically necessary.

References Used in Support of Decision:

Scott, SD, et al. An AOA critical issue: Disc replacements: This time will we really cure low-back and neck pain? Journal of Bone and Joint Surgery 2004 Feb; 86-A (2): 411-422.

Tropiano, P, et al. Lumbar total disc replacement. Journal of Bone and Joint Surgery 2005 Mar; 87-A (3): 490-496.

FDA device information.

The physician providing this review is board certified in Emergency Medicine. The reviewer is also board certified by the American Board of Independent Medical Examiners. The reviewer is board eligible in Preventive Medicine - Occupational Medicine. The reviewer is also a certified Aviation Examiner. The reviewer is a member of the American College of Occupational and Environmental Medicine. The reviewer is in the process of obtaining their Masters degree in Public Health. The reviewer has been in active practice since 1984.

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, patient and the TWCC.

YOUR RIGHT TO REQUEST A HEARING

Either party to the medical dispute may disagree with all or part of this decision and has a right to request a hearing.

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If disputing a spinal surgery prospective decision, a request for a hearing must be in writing and it must be receiving the TWCC chief Clerk of Proceedings within ten (10) days of your receipt of this decision as per 28 Texas Admin. Code 142.5.

If disputing other prospective medical necessity (preauthorization) decisions, a request for a hearing must be in writing and it must be received by the TWCC Chief Clerk of Proceedings within twenty (20) days of your receipt of this decision as per Texas Admin. Code 102.4 (h) or 102.5 (d). A request for hearing should be sent to:

Chief Clerk of Proceedings
Texas Workers' Compensation Commission
POB 40669
Austin, TX 78704-0012

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

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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vso

cc: Requestor
Respondent