



DATE OF REVIEW: October 31, 2007

IRO Case #:

Description of the services in dispute:

Preauthorization – Cervical Surgery

A description of the qualifications for each physician or other health care provider who reviewed the decision

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

Review Outcome

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

Upheld

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.

Medical necessity does not exist for the requested cervical surgery.

Information provided to the IRO for review

Records from Texas Department of Insurance:

Fax from to, 10/15/07, 1 page

Notice to Medical Review Institute of America, INC. of case assignment, 10/15/07, 1 page

Letter from, 10/11/07, 2 pages

Online application for requesting a review by an independent review organization, 03/12/07, 6 pages

Request for a review by an independent review organization, 10/1/07, 4 pages

Utilization review determination, 09/6/07, 1 page

Reconsideration/appeal of adverse determination, 09/18/07, 2 pages

Records from:

Office note, xx/xx/xx, 1 page
Radiology report, xx/xx/xx, 1 page
Texas Workers' Compensation Work Status Report, xx/xx/xx, 1 page
Office note, 07/12/07, 1 page
Texas Workers' Compensation Work Status Report, 07/19/07, 1 page
Office note, 07/24/07, 1 page
Texas Workers' Compensation Work Status Report, 07/24/07, 1 page
MRI report, 07/30/07, 1 page
Office note, 08/1/07, 1 page
Texas Workers' Compensation Work Status Report, 08/1/07, 1 page
Texas Workers' Compensation Work Status Report, missed appointment, 08/15/07, 1 page
Patient notes, 07/12/07-08/24/07, 1 page
Texas Workers' Compensation Work Status Report, 08/27/07, 1 page
Physicians order for physical therapy, 08/7/07, 1 page
Initial evaluation, 08/21/07, 2 pages
Office note, 08/27/07, 1 page
Texas Workers' Compensation Work Status Report, 08/27/07, 1 page
Authorization for use of disclosure of health information, 09/20/07, 2 pages
Physical requirements list, 09/20/07, 1 page
Professional consent, 09/20/07, 1 page
Acknowledgement of receipt of notice of privacy practices, 09/20/07, 1 page
Texas Workers' Compensation Work Status Report, 09/20/07, 1 page
Initial evaluation report, 09/27/07, 3 pages
Letter from, MD to Dr. 09/28/07, 2 pages

Records from:

Letter from to Ms., 10/18/07, 2 pages
ODG Treatment, integrated treatment/ disability duration guidelines, undated, 2 pages
Check from Claims, 10/17/07, 1 page

Patient clinical history [summary]

The patient is a male who is reported to have sustained an injury to his cervical spine on xx/xx/xx. On this date the patient was climbing a ladder when he hit his head on an I-beam injuring his neck. The patient subsequently sought care from Dr. on xx/xx/xx. At this time the patient complains of cervical pain. On physical examination the patient has limited range of motion in lateral rotation and extension with full forward flexion. He is tender to palpation across the cervical spine and

tender to palpation across the trapezius. The patient is noted to have full range of motion of the extremity. Motor and sensory appear intact. The patient was diagnosed with a cervical strain. Plain radiographs performed on xx/xx/xx indicate minimal disc space narrowing at C3–4 with small anterior osteophytes at C5–6. There is no evidence of fracture or subluxation. This study indicates that there is no change in the appearance of the cervical spine when compared to a study dated 04/22/05. The patient was seen in follow up on 07/12/07. The patient reports soreness. On physical examination the patient is tender in the cervical paraspinal muscles and there is mildly reduced range of motion. The patient continues to have full active range of motion of the extremities.

The patient was seen in follow up on 07/24/07. At this time he continues to complain of soreness. There is no change since his last visit. He further complains of bilateral numbness and tingling. The patient's physical examination is unchanged. The patient was referred for MRI (magnetic resonance imaging) of the cervical spine on 07/30/07. This study reports the cervical vertebral bodies are of essentially normal height and signal intensity with scattered mild osteophytosis most marked at C5–6. There is a broad based central disc extrusion with bilateral foraminal involvement slightly greater on the left at C3–4. This is larger than on a previous study dated 12/05/00. The subarachnoid space, cervical spinal cord and cervical nerve rootlets are otherwise unremarkable. The overall impression is a broad based central disc extrusion with bilateral foraminal involvement slightly greater on the left at C3–4 increasing in size since 12/05/00. The patient was subsequently referred to physical therapy and received cervical traction. The record indicates that the patient was subsequently referred to Dr. A physical therapy evaluation dated 08/21/07 indicates that the patient had an MRI performed and there were no significant findings, and that the patient is currently working light duty. The available records indicate that Dr. has requested ACDF (anterior cervical discectomy and fusion) x 2, which was not approved on physician review. The patient was subsequently referred to Dr. on 09/08/07. This note indicates that the patient has cervical pain with radiation into the shoulders and intermittent numbness in the hands. A nerve conduction test performed recently revealed likely carpal tunnel syndrome and the patient has previously undergone carpal tunnel releases. The patient is reported to have completed one round of physical therapy without any significant improvement. The patient is recommended to undergo cervical epidural steroid injections.

Analysis and explanation of the decision include clinical basis, findings and conclusions used to support the decision.

The available medical record indicates that the patient sustained a cervical myofascial strain as a result of work place activity. The records indicate that initially the patient presented with cervical pain and tenderness. The patient's physical exam is relatively benign. There is no evidence of cervical myelopathy or cervical radiculopathy. The records further indicate that the patient has

undergone serial cervical spine x-rays which essentially indicate no change from pre-injury studies. The patient was later referred for MRI of the cervical spine, which indicates a progression of a degenerative disc already noted back in 2000. There is no evidence of acute injury on either of these two studies. The records further indicate that the patient has undergone physical therapy and been treated with oral medications; however, there is no indication that the patient has undergone or completed cervical epidural steroid injections. It is noted in the record that the patient complains of bilateral hand numbness and underwent electrodiagnostic studies, which found no evidence of cervical radiculopathy; however, did note a bilateral carpal tunnel syndrome. The available medical records do not substantiate the need for anterior cervical discectomy and fusion. The submitted records do not establish that the patient has failed conservative care. It should be further noted that cervical radiographs do not establish any evidence of instability. MR imagery has indicated a progression of a previously documented central disc herniation, which is chronic rather than acute, and expected nearly 5 years after the previous study. Provided this information, the request for ACDF is not considered medically necessary.

A description and the source of the screening criteria or other clinical basis used to make the decision:

The Official Disability Guidelines, 11th edition, The Work Loss Data Institute

Fusion, anterior cervical. Recommended as an option in combination with anterior cervical discectomy for approved indications, although current evidence is conflicting about the benefit of fusion in general. (See Discectomy/laminectomy/laminoplasty.) Evidence is also conflicting as to whether autograft or allograft is preferable and/or what specific benefits are provided with fixation devices. Many patients have been found to have excellent outcomes while undergoing simple discectomy alone (for one- to two-level procedures), and have also been found to go on to develop spontaneous fusion after an anterior discectomy. (Bertalanffy, 1988) (Savolainen, 1998) (Donaldson, 2002) (Rosenorn, 1983) Cervical fusion for degenerative disease resulting in axial neck pain and no radiculopathy remains controversial and conservative therapy remains the choice if there is no evidence of instability. (Bambakidis, 2005) Conservative anterior cervical fusion techniques appear to be equally effective compared to techniques using allografts, plates or cages. (Savolainen, 1998) (Dowd, 1999) (Colorado, 2001) (Fouyas-Cochrane, 2002) (Goffin, 2003) This evidence was substantiated in a recent Cochrane review that stated that hard evidence for the need for a fusion procedure after discectomy was lacking, as outlined below:

(1) Anterior cervical discectomy compared to anterior cervical discectomy with interbody fusion with a bone graft or substitute: Three of the six randomized controlled studies discussed in the 2004 Cochrane review found no difference between the two techniques and/or that fusion was not necessary. The Cochrane review felt there was conflicting evidence of the relative effectiveness of

either procedure. Overall it was noted that patients with discectomy only had shorter hospital stays, and shorter length of operation. There was moderate evidence that pain relief after five to six weeks was higher for the patients who had discectomy with fusion. Return to work was higher early on (five weeks) in the patients with discectomy with fusion, but there was no significant difference at ten weeks. (Jacobs–Cochrane, 2004) (Abd–Alrahman, 1999) (Dowd, 1999) (Martins, 1976) (Van den Bent, 1996) (Savolainen, 1998) One disadvantage of fusion appears to be abnormal kinematic strain on adjacent spinal levels. (Ragab, 2006) (Eck, 2002) (Matsunaga, 1999) (Katsuura, 2001) The advantage of fusion appears to be a decreased rate of kyphosis in the operated segments. (Yamamoto, 1991) (Abd–Alrahman, 1999)

(2) Fusion with autograft versus allograft: The Cochrane review found limited evidence that the use of autograft provided better pain reduction than animal allograft. It also found that there was no difference between biocompatible osteoconductive polymer or autograft (limited evidence). (Jacobs–Cochrane, 2004) (McConnell, 2003) A problem with autograft is morbidity as related to the donor site including infection, prolonged drainage, hematomas, persistent pain and sensory loss. (Younger, 1989) (Sawin, 1998) (Sasso, 2005) Autograft is thought to increase fusion rates with less graft collapse. (Deutsch, 2007). See Decompression, myelopathy.

(3) Fusion with autograft with plate fixation versus allograft with plate fixation, Single level: A recent retrospective review of patients who received allograft with plate fixation versus autograft with plate fixation at a single level found fusion rates in 100% versus 90.3% respectively. This was not statistically significant. Satisfactory outcomes were noted in all non–union patients. (Samartzis, 2005)

(4) Fusion with different types of autograft: The Cochrane review did not find evidence that a vertebral body graft was superior to an iliac crest graft. (McGuire, 1994)

(5) Fusion with autograft versus fusion with autograft and additional instrumentation: Plate Fixation: In single–level surgery there is limited evidence that there is any difference between the use of plates and fusion with autograft in terms of union rates. For two–level surgery, there was moderate evidence that there was more improvement in arm pain for patients treated with a plate than for those without a plate. Fusion rate is improved with plating in multi–level surgery. (Wright, 2007) See Plate fixation, cervical spine surgery. Cage: Donor site pain may be decreased with the use of a cage rather than a plate, but donor site pain was not presented in a standardized manner. At two years pseudoarthrosis rate has been found to be lower in the fusion group (15%) versus the cage group (44%). A six–year follow–up of the same study group revealed no significant difference in outcome variables between the two treatment groups (both groups had pain relief). In the subgroup of patients with the cage who attained fusion, the overall outcome was better than with fusion alone. Patients treated with cage instrumentation have less segmental kyphosis and better–

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preserved disc height. This only appears to affect outcome in a positive way in cage patients that achieve fusion (versus cage patients with pseudoarthrosis). (Poelsson, 2007) (Varuch, 2002) (Hacker 2000) See also Adjacent segment disease/degeneration (fusion).

(6) Fusion with allograft alone versus with allograft and additional instrumentation: Plate Fixation: Retrospective studies indicate high levels of pseudoarthrosis rates (as high as 20% for one-level and 50% for two-level procedures) using allograft alone. In a recent comparative retrospective study examining fusion rate with plating, successful fusion was achieved in 96% of single-level cases and 91% of two-level procedures. This could be compared to a previous retrospective study by the same authors of non-plated cases that achieved successful fusion in 90% of single-level procedures and 72% of two-level procedures. (Kaiser, 2002) (Martin, 1999) See Plate fixation, cervical spine surgery.

Complications:

Collapse of the grafted bone and loss of cervical lordosis: collapse of grafted bone has been found to be less likely in plated groups for patients with multiple-level fusion. Plating has been found to maintain cervical lordosis in both multi-level and one-level procedures. (Trojanovich, 2002) (Herrmann, 2004) (Katsuura, 1996) The significance on outcome of kyphosis or loss of cervical lordosis in terms of prediction of clinical outcome remains under investigation. (Peolsson, 2004) (Haden, 2005) (Poelsson, 2007) (Hwang, 2007)

Pseudoarthrosis: This is recognized as an etiology of continued cervical pain and unsatisfactory outcome. Treatment options include a revision anterior approach vs. a posterior approach. Regardless of approach, there is a high rate of continued moderate to severe pain even after solid fusion is achieved. (Kuhns, 2005) (Mummaneni, 2004) (Coric, 1997)

Anterior versus posterior fusion: In a study based on 932,009 hospital discharges associated with cervical spine surgery, anterior fusions were shown to have a much lower rate of complications compared to posterior fusions, with the overall percent of cases with complications being 2.40% for anterior decompression, 3.44% for anterior fusion, and 10.49% for posterior fusion. (Wang, 2007) Predictors of outcome of ACDF: Predictors of good outcome include non-smoking, a pre-operative lower pain level, soft disc disease, disease in one level, greater segmental kyphosis pre-operatively, radicular pain without additional neck or lumbar pain, short duration of symptoms, younger age, no use of analgesics, and normal ratings on biopsychosocial tests such as the Distress and Risk Assessment Method (DRAM). Predictors of poor outcomes include non-specific neck pain, psychological distress, psychosomatic problems and poor general health. (Peolsson, 2006) (Peolsson, 2003) See Plate fixation, cervical spine surgery.

Fusion, posterior cervical. Under study. A posterior fusion and stabilization procedure is often used to treat cervical instability secondary to traumatic injury, rheumatoid arthritis, ankylosing spondylitis, neoplastic disease, infections, and previous laminectomy, and in cases where there has been insufficient anterior stabilization. (Callahan, 1977) (Liu, 2001) (Sagan, 2005) Although the addition of instrumentation is thought to add to fusion rate in posterior procedures, a study using strict criteria (including abnormal motion between segments, hardware failure, and radiolucency around the screws) reported a 38% rate of non-union in patients who received laminectomy with fusion compared to a 0% rate in a group receiving laminoplasty. (Heller, 2001) In a study based on 932,009 hospital discharges associated with cervical spine surgery for degenerative disease, complications and mortality were more common after posterior fusions or surgical procedures associated with a primary diagnosis of cervical spondylosis with myelopathy. The overall percent of cases with complications was 2.40% for anterior decompression, 3.44% for anterior fusion, and 10.49% for posterior fusion. (Wang, 2007) Patients undergoing occipitocervical fusion or C1-2 (high cervical region) fusion is an absolute contraindication for returning to any type of activity with a risk of re-injury (such as contact sports), because the C-1 arch is relatively fragile and stability depends on the status of the periodontoid ligaments. (Burnett, 2006)

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