



Specialty Independent Review Organization

Notice of Independent Review Decision

DATE OF REVIEW: 4/12/2011

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

The item in dispute is the prospective medical necessity of an autograft for spine surgery, electrical stimulation to aid bone healing-noninvasive, arthrodesis-anterior interbody-cervical below C2, application of prosthetic device, cervical vertebral corpectomy with decompression, microsurgical tech-requiring use of operating microscope, inpatient non-surgical room, and implant spinal canal catheter (20936, 20974, 22554, 22851, 63081, 69990, RC110, 62351).

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

The reviewer is a Medical Doctor who is board certified in Orthopedic Surgery. The reviewer has been practicing for greater than 10 years.

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)

The reviewer disagrees with the previous adverse determination regarding prospective medical necessity of an autograft for spine surgery, electrical stimulation to aid bone healing-noninvasive, arthrodesis-anterior interbody-cervical below C2, application of prosthetic device, cervical vertebral corpectomy with decompression, microsurgical tech-requiring use of operating microscope, inpatient non-surgical room, and implant spinal canal catheter (20936, 20974, 22554, 22851, 63081, 69990, RC110, 62351).

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Records were received and reviewed from the following parties, MD and Management Organization

These records consist of the following (duplicate records are only listed from one source):
Records reviewed from, MD: Orthopedic Reports – 3/26/08-3/7/11, Orthopedic Consult – 2/27/08, Telephone Conference notes – 9/25/08-3/22/11, Letter of Medical Necessity – 12/4/08, Cervical X-ray requests – 2/27/08-12/22/10, MMT/ROM report – 12/22/10, CMT/ROM reports – 2/27/08-9/28/10, EMG/NCV request – undated, Surgery Reservation Sheets – 12/17/08-3/14/11, Reconsideration requests – 12/17/08 & 3/17/11, Procedure Orders – 4/25/08-9/18/08, History/Physical – 4/21/08, AAOS Instructional Course Lectures Spine by, MD, AAOS Orthopaedic Knowledge update – Spine – Acute Neck Pain and Cervical Disk Herniation, ODG

– Neck Fusion Chapter; various DWC69 – 5/2/08, 11/20/08, 7/15/09, & 2/25/10; MD notes – 11/20/08 & 2/25/10; DWC 73; Designated Doctor assignments – 4/16/08 & 2/11/10; MD report – 2/3/10; fax – 1/12/10; MD DDE report – 5/2/08; Inbody, MD Electro-Diagnostic Interpretation report – 2/23/11; MD Cervical Spine MRI – 3/1/11, Cervical CT Myelogram – 10/22/09, Cervical MRI – 4/7/08, Left Shoulder MRI – 4/8/08; Injury Management Org Pre-auth letter – 12/17/08-2/15/11, Denial Letters – 10/30/08-3/17/11; MD Surgical Pathology report – 3/24/10; LPT FCE report – 6/26/09; MD Neurophysiological Monitoring Report – 2/3/09 Clinical Lab report – 1/30/09, Operative Reports – 8/1/08 & 2/3/09; LHL009's – 12/6/08 & 3/24/11; Physician Information Request – 1/28/11, Operative Report – 3/24/10, Posting Sheet – 3/17/10; letter – 12/17/08; Pre-auth letters – 5/1/08 & 7/2/08; Independent Review IRO report – 5/13/08; and Surgery Center Operative Report – 5/16/08.

Records reviewed from Injury Management Organization: Denial Letter – 3/24/11 and, MD RME report – 2/25/11.

A copy of the ODG was provided by the URA for this review.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is noted to be status post an ACDF and repair of eventual pseudarthrosis at C3-4, the latter being one year ago. There have been diagnostic imaging studies that include a CT-myelogram from 10/09, which evidenced spinal narrowing, centrally, and bilateral foraminal narrowing at C5-6 and C6-7. A 3/1/11 dated cervical MRI revealed similar findings. Electrical studies revealed a left C7 radiculopathy.

Denial letters indicated that an anterior C5-6 fusion would not be reasonable and medically necessary at this time, based on an indication for further diagnostic evaluation. In addition, the rationale including the possibility of increased adjacent level stress and strain.

On 2/3/10, Dr. had identified C6 radiculopathy. The 2/25/11 post-designated doctor's follow-up RME note discussed an absent biceps reflex and an atrophied deltoid muscle left. Decreased sensation, possibly along the C7 dermatome, was noted. Additional diagnostic clarification was felt applicable. Attending Physician notes were reviewed, including from 3/7/11. A positive Spurling and decreased sensation in a C6 distribution along with weak shoulder abduction, was noted. A 2/25/11 dated electrical study was positive for C5 and C6 radiculopathy. There was felt to be a diagnosis of HNP at C5-6, with increased radiculopathy. An ACDF at C5-6 was felt applicable by the Attending Physician, Dr. On 1/28/11, the Attending Physician identified that the patient had developed a rapid neurological progression, along with severe neck and left arm pain since about 11/10. A prior 12/22/10 dated Attending Physician record discussed a partial left shoulder cuff tear, + impingement and an injection into the subacromial space.

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

Despite the prior surgical intervention at the C2-3 level, the claimant has clinical and radiographic support for a C6 radiculopathy. This has been documented as having significantly worsened over time, despite medication and Physical Therapy. The claimant has an indication for the proposed procedure, due to the corroborated diagnosis and progressive neurological symptoms and signs, and failure of reasonable non-operative treatment. Applicable ODG criteria have been met.

According to the ODG - Cervical spine - 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. 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. Conservative anterior cervical fusion techniques appear to be equally effective compared to techniques using allografts, plates or cages. Cervical fusion may demonstrate good results in appropriately chosen patients with cervical spondylosis and axial neck pain. 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. One disadvantage of fusion appears to be abnormal kinematic strain on adjacent spinal levels. The advantage of fusion appears to be a decreased rate of kyphosis in the operated segments.

(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). A problem with autograft is morbidity as related to the donor site including infection, prolonged drainage, hematomas, persistent pain and sensory loss. Autograft is thought to increase fusion rates with less graft collapse.. 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.

(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.

(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. 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-preserved disc height. This only appears to affect outcome in a positive way in cage patients that achieve

fusion (versus cage patients with pseudoarthrosis). 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. 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.) The significance on outcome of kyphosis or loss of cervical lordosis in terms of prediction of clinical outcome remains under investigation.

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.

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.

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, gainful employment, higher preoperative NDI 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, litigation and workers' compensation. Patients who smoke have compromised fusion outcomes.

See Plate fixation, cervical spine surgery. See also Adjacent segment disease/degeneration (fusion) & Iliac crest donor-site pain treatment.

Use of Bone-morphogenetic protein (BMP): FDA informed healthcare professionals of reports of life-threatening complications associated with recombinant human Bone Morphogenetic Protein (rhBMP) when used in the cervical spine for spinal fusion. The safety and effectiveness of rhBMP in the cervical spine have not been demonstrated, and these products are not approved for this use. These complications were associated with swelling of neck and throat tissue, which resulted in compression of the airway and/or neurological structures in the neck. Bone-morphogenetic protein was used in approximately 25% of all spinal fusions nationally in 2006, with use associated with more frequent complications for anterior cervical fusions. No differences were seen for lumbar, thoracic, or posterior cervical procedures, but the use of BMP in anterior cervical fusion procedures was associated with a higher rate of complication occurrence (7.09% with BMP vs 4.68% without BMP) with the primary increases seen in wound-related complications (1.22% with vs 0.65% without) and dysphagia or hoarseness (4.35% with vs 2.45% without).

For hospital LOS after admission criteria are met, see Hospital length of stay (LOS).

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

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN
- INTERQUAL CRITERIA
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
- MILLIMAN CARE GUIDELINES
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS
- TEXAS TACADA GUIDELINES
- TMF SCREENING CRITERIA MANUAL
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)