ReviewTex

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Notice of Independent Review Decision

Date notice sent to all parties: April 17, 2013

IRO CASE #: 45374

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Appeal of redo anterior cervical fusion at C4-5, removal of anterior cervical plate at C4-5 with anterior cervical discectomy, and fusion at C5-6 and reinstrumentation via anterior cervical C4-5 and C5-6/co-surgeon/one day inpatient stay

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

Board Certified Orthopedic Spine Surgeon, Practicing Neurosurgeon

REVIEW OUTCOME:

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

☒ Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

clinical notes 04/05/12-02/21/13
Laboratory reports 03/27/12-01/02/13
CT thoracic spine 03/08/12
Impairment evaluation 12/05/12
Independent medical evaluation 10/04/12
Chronic pain management reports 02/22/13-03/15/13
Medical necessity requests 03/20/13 and 01/21/13
Operative report 08/19/11

Radiographs spine 08/19/11
Swallow study 09/06/11
Radiographs cervical spine 11/16/11
CT cervical spine 03/08/12
Clinical note 03/09/12
Procedure note 03/22/12
Radiographs cervical spine 05/30/12
Clinical note 10/03/12-01/10/13
CT myelogram cervical spine 10/22/12
Electrodiagnostic studies 10/24/12
Clinical record 11/27/12
Procedure note 01/03/13
Psychological evaluation 01/15/13
Prior reviews 02/05/13 and 02/18/13

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male who initially sustained an injury on xx/xx/xx. Prior to the date of injury, the patient underwent anterior cervical discectomy and fusion at C4-5 on 08/19/11. Following the date of injury, the patient reported pain in the cervical spine with restricted range of motion and weakness in the left upper extremity. The patient was followed for concerns regarding pseudoarthrosis at C4-5. CT myelogram of the cervical spine on 10/22/12 identified fusion at C4-5. There was no evidence of hardware failure or loosening and the radiologist could not confirm the presence of solid fusion at C4-5. At C5-6, there was a right paracentral disc protrusion with no contact deformity of the cervical cord. There was no evidence of central canal or neural foraminal stenosis at this level. Electrodiagnostic studies on 10/24/12 were normal with no evidence of cervical radiculopathy. The patient was recommended for selective nerve root blocks at C5-6 which were performed on 01/03/13. Follow-up on 01/10/13 indicated that the patient had no significant response to the selective nerve root block. The patient was referred for a psychological evaluation in regards to further surgery. The psychological evaluation was performed on 01/15/13. The patient reported a significant amount of anxiety due to his experience with pervious cervical spine surgery. The patient was cleared as an appropriate candidate for spinal surgery. However, the patient was recommended for individual psychotherapy for 4 sessions to develop tools and skills for management of pain and disturbances in mood and sleep. Following this psychological evaluation, it is noted that the patient began attending a chronic pain management program through 03/13.

The request for revision of the anterior cervical fusion at C4-5 with removal of the previous plating and fusion at C5-6 with re-instrumentation at C4-5 and C5-6 was

denied by utilization review on 02/05/13 as there was no evidence of significant disc pathology at C5-6. Electrodiagnostic studies were negative for radiculopathy and there was no objective evidence regarding myelopathy.

The request was again denied by utilization review on 02/18/13 as there was no correlating pathology noted at C5-6.

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

The clinical documentation provided for review establishes that the patient has ongoing complaints of pain in the neck and upper extremities. There is conflicting evidence regarding cervical radiculopathy. The patient's objective findings reveal weakness in the upper extremities; however, electrodiagnostic studies were negative for radiculopathy and CT myelogram studies of the cervical spine found no evidence of disc pathology at C5-6. The patient was reported not to have responded to selective nerve root blocks at C5-6 establishing that this does not appear to be a pain generator for the patient. The radiologist was not able to confirm fusion at C4-5; however, no clear evidence of pseudoarthrosis was present. Additionally, it is now noted that the patient was undergoing a chronic pain management program in 03/13 and given this program of tertiary level pain management, it is now unclear whether the patient continues to be considered a surgical candidate at all. Given the absence of any clear clinical indications for cervical fusion at C5-6 that would require removal of instrumentation and re-instrumentation, it is this reviewer's opinion that medical necessity for the request is not established.

IRO REVIEWER REPORT TEMPLATE -WC

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

☒ **MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**

☒ **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**

Official Disability Guidelines, Online Version, Neck & Upper Back Chapter

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) Cervical fusion may demonstrate good results in appropriately chosen patients with cervical spondylosis and axial neck pain. (Wieser, 2007) 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-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. (Troyanovich, 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) See also Laryngoscopy (screening for recurrent laryngeal nerve injury prior to revision ACDF).
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, gainful employment, higher preoperative NDI and normal ratings on biopsychosoical 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. (Anderson, 2009) (Peolsson, 2006) (Peolsson, 2003) Patients who smoke have compromised fusion outcomes. (Peolsson, 2008)
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. (FDA MedWatch, 2008) 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). (Cahill-*JAMA*, 2009)