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DATE OF REVIEW: 11/02/2009

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

IRO -

1. Assistant Surgeon
2. 1 Day inpatient stay
3. Anterior Cervical Discectomy with Fusion C3-C4

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

This case was reviewed by a Texas licensed MD, specializing in Orthopedic Trauma, Orthopedic Surgery. The physician advisor has the following additional qualifications, if applicable:

ABMS Orthopaedic Surgery

REVIEW OUTCOME:

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

Upheld

Health Care Service(s) in Dispute	CPT Codes	Date of Service(s)	Outcome of Independent Review
IRO - 1. Assistant Surgeon 2. 1 Day inpatient stay 3. Anterior Cervical Discectomy with Fusion C3-C4	63081, 22554	-	Upheld

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INFORMATION PROVIDED TO THE IRO FOR REVIEW:

No	Document Type	Provider or Sender	Page Count	Service Start Date	Service End Date
1	Referral	UniMed Direct	1	10/28/2009	10/28/2009
2	Designated Doctor Report	MD	4	11/18/2008	11/18/2008
3	Designated Doctor Report	MD	9	08/21/2008	08/21/2008
4	Diagnostic Test	Imaging Center	6	07/18/2007	02/29/2008
5	FCE Report	Diagnostics	6	12/11/2008	08/18/2009
6	Op Report	MRI & Diagnostic	2	06/24/2009	06/26/2009
7	Office Visit Report	Injury Clinic , DC)	2	07/23/2007	07/23/2007
8	Office Visit Report	Orthopedics , MD)	23	04/16/2008	08/18/2009
9	Office Visit Report	MD	2	10/15/2008	11/25/2008
10	Peer Review Report	MD	5	01/30/2009	01/30/2009
11	Psych Evaluation		8	12/23/2008	02/06/2009
12	Initial Denial Letter		9	09/30/2009	10/08/2009
13	Initial Denial Letter		7	06/11/2008	06/23/2008
14	Initial Approval Letter		6	12/24/2008	05/27/2009
15	IRO Record Receipt		16	07/10/2008	10/13/2009
16	Diagnostic Test	MD	16	10/20/2008	12/16/2008
17	Archive		55		
18	IRO Decision		8	07/22/2008	07/22/2008
19	IRO Request	MD	8	07/08/2008	10/12/2009
20	Order/Settlement/Agreement	TDI-DWC	30	10/20/2008	07/24/2009
21	Initial Request	Orthopedics MD	4	06/06/2008	09/25/2009
22	Initial Request		7	12/23/2008	12/23/2008
23	Appeal Denial Letter		3	10/02/2009	10/02/2009

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male who was injured on xx/xx/xx while at work. . He complained of cervical and lumbar pain. He was evaluated extensively. His initial evaluation and treatment appears to have been focused on lumbar symptoms. He underwent imaging studies on 7/18/07. Plain x-rays of the cervical and lumbar spines were negative, failing to reveal any significant bone or joint abnormality. An MRI of the cervical and lumbar spines revealed degenerative disc disease at level C3-C4, L4-L5 and L5-S1. The patient has been treated with physical therapy, pain medication and activity modification. He has also undergone psychological evaluation and 4 sessions of psychotherapy. An effort was made to obtain a discogram in anticipation of a recommendation for lumbar fusion surgery. This request was considered; denied; reconsidered; and denied. A contested case hearing was held and a final denial was provided 07/20/09.

The patient underwent a designated doctor evaluation on 08/18/09 performed by , MD. He was found to be at MMI and a WPI rating of 0% was awarded. He was authorized to return to work and reportedly did so. Recently, the patient has been evaluated for cervical pain and pain radiating into both shoulders. There are no physical findings suggestive of radiculopathy. A cervical ESI has been performed with little benefit in resolving complaints of pain. Recently, the provider has recommended an anterior cervical discectomy and fusion at the level C3-C4. A request was submitted to pre authorize this surgery with a surgical assistant and a 1 LOS as an inpatient.

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

I find no justification for the performance of a C3-C4 anterior cervical discectomy and fusion. Medical necessity has not been established. The prior denials of the request to pre authorize this surgical procedure were appropriate and should be upheld. The pathology defined on an MRI 7/18/07 did not demonstrate compression of neural elements adjacent to the bulging disc at C3-C4. There are no physical findings to suggest radiculopathy.

Therefore, since the primary request to perform anterior cervical discectomy and fusion should be denied. This request is dependent on the approval of the primary request. As such, the request for a surgical assistant and 1 day inpt. length of stay should be denied also.

Decision Upheld.

Fusion, anterior cervical	<p>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:</p> <p><i>(1) Anterior cervical discectomy compared to anterior cervical discectomy with interbody fusion with a bone graft or substitute:</i> 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)</p> <p><i>(2) Fusion with autograft versus allograft:</i> 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.</p> <p><i>(3) Fusion with autograft with plate fixation versus allograft with plate fixation, Single level:</i> 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</p>
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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. ([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](#))

	<p><i>Predictors of outcome of ACDF:</i> 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) Patients who smoke have compromised fusion outcomes. (Peolsson, 2008)</p> <p>See Plate fixation, cervical spine surgery. See also Adjacent segment disease/degeneration (fusion) & Iliac crest donor-site pain treatment.</p> <p><i>Use of Bone-morphogenetic protein (BMP):</i> 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)</p>
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A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

ODG: Low Back Chapter