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Notice of Independent Review Decision

DATE OF REVIEW: March 13, 2009

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE
Redo arthrodesis with anterior interbody fusion at C3-C4, C4-C5, C5-C6, and C6-C7. Removal and redo anterior spinal instrumentation at C3-C7 with possible C5 corpectomy.

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

Board Certified Orthopedic Surgeon

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

☒ Upheld (Agree)

Medical documentation **does not support** the medical necessity of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Attorney
- Utilization reviews (01/29/09 - 02/10/09)
- Office visits (10/21/05 – 02/19/09)

- Utilization reviews (01/29/09 - 02/10/09)
- Office visits (10/31/07 - 12/16/08)

TDI
- Utilization reviews (01/29/09 - 02/10/09)

ODG criteria have been utilized for the denials.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male who tripped over a foot pedal and fell injuring his left knee, neck and lower back. The injury occurred on xx/xx/xx.

2005: The patient was initially evaluated by D.C., for low back pain, left knee pain, neck pain as well as numbness and tingling into the legs and arms. History was significant for lumbar laminectomy and fusion two years ago. Examination of the left knee revealed local tenderness and swelling. Examination of the cervical spine revealed decreased right and left rotation and cervical paraspinal muscle tenderness. Examination of the lumbar spine revealed left and right lumbar tenderness, a dermatological reaction, positive straight leg raise (SLR) bilaterally causing ipsilateral low back and leg pain, positive crossover sign, and decreased flexion and extension secondary to pain. Dr. assessed lumbar strain, left knee contusion, cervical strain, and lumbar radiculopathy and referred the patient to an orthopedic surgeon.

Computerized tomography (CT) scan of the lumbar spine revealed postsurgical changes including laminectomy and posterolateral fusion L3-L5 with solid appearing bony spinal fusion.

In December, the patient underwent foraminal blocks at L4, L5, and S1.

2006: In a medical evaluation M.D., noted the patient had undergone multiple back surgeries including lumbar laminectomies in 1974 and 1975, lumbar laminectomy and three-level fusion in 2002, and L4 through S1 fusion in March 2004. He recommended aggressive physical therapy (PT).

Magnetic resonance imaging (MRI) of the lumbar spine revealed postsurgical changes and fusion L3 through S1, mild lumbar spine curvature and spondylosis, and equivocal enhancement within L4-L5 interspace anteriorly for which differential consultations would include focal scar or inflammation.

Myelogram with post-myelogram CT scan of the cervical and lumbar spine revealed: (1) Minor disc findings at C3-C4 and C6-C7 consisting of tiny protrusions, central at C3-C4 and left paracentral at C6-C7 with broad-based disc and osteophyte formations at C4-C5 and C5-C6. (3) Tapering of the thecal sac at L2-L3. MRI of the cervical spine revealed diffuse disc protrusion of approximately 3 mm involving C4-C5, C5-C6, and C6-C7. A 2-mm central protrusion was present at C3-C4. The patient underwent psychological evaluation and was recommended individual psychotherapy sessions. A second opinion was obtained from M.D., who agreed with Dr. in considering L2-L3 laminectomy and decompression. Electromyography/nerve conduction velocity (EMG/NCV) study revealed chronic denervation in multiple myotomes, multiple radiculopathies at left L4, left S1, right L2, L3, and L4, or bilateral lumbosacral plexopathy. In July, postdiscogram CT scan revealed mild osteophyte formation posteriorly at C3-C4 and C4-C5 and foraminal narrowing on the left at C5-C6.

M.D., an orthopedic surgeon, recommended anterior cervical discectomy and fusion with clean out of lateral gutters.

On December 6, 2006, Dr. performed bilateral L2-L3 hemilaminectomy, medial facetectomy, foraminotomy; excision of scar tissue and evacuation of old pseudomeningocele.

2007: The patient attended extensive individual psychotherapy.

M.D., a designated doctor, opined that the patient was unable to return to work in any capacity. In a functional capacity evaluation (FCE) the patient qualified in the light strength category.

MRI of the lumbar spine revealed disc degeneration at L4-L5 and L5-S1, fluid collection in midline posterior to the spinal canal L4-S1.

Dr. assessed statutory maximum medical improvement (MMI) as of April 25, 2007, with 60% whole person impairment (WPI) rating.

2008: In January, the patient attended chronic pain management program (CPMP) and individual psychotherapy.

On February 11, 2008, Dr. performed a required medical evaluation (post DDRME) and opined the diagnosis was mild and early degenerative joint disease (DJD) at C4-C5 and C5-C6, minimally bulging of disc at C4-C5 and C6-C7, and a small C5-C6 HNP. It was possible that previous surgery and fusions at C5-C6 and C6-C7 could contribute to instability at the levels above this fusion.

Cervical myelogram CT scan showed increased sclerosis at the C3 through C7 levels with mild prevertebral soft tissue prominence in the area. Lumbar myelogram CT scan revealed mild diffuse annular bulging at L1-L2 with mild hypertrophic facet arthropathy.

M.D., evaluated the patient for urinary frequency with urge incontinence, complete impotence, and rectal incontinence. He recommended injection of vasoactive substance such as Caverject.

In June, the request for anterior cervical discectomy and fusion (ACDF) was non-authorized. A request for reconsideration was also non-authorized.

On October 9, 2008, M.D., a designated doctor, assessed MMI as of October 9, 2008, with 33% whole person impairment (WPI) rating.

In December, M.D., evaluated the patient and recommended anterior cervical revision surgery and also posterior fixation to increase chances of fusion.

2009: Dr. recommended anterior fusion revision first before embarking on posterior decompression and posterolateral fusion.

On January 26, 2009, the request for anterior arthrodesis and interbody fusion of cervical spine was denied by M.D., with the following rationale: *"The patient is now over xxx years post injury and has a very complex spine disorder largely due to surgery performed already. The patient is still a smoker. The reason for the new or repeat surgery is pseudoarthrosis at C4-C5 and C3-C4. There is also some anterior plate prominence. The post designated RME by the neurosurgeon did not find significant instability at C3-C4. At this time, the proposed surgery elected is not approved pending smoking cessation and an assessment by Dr. to address this proposed complex redo cervical spine surgery. Also the third opinion is from Dr. He did the prior surgery.*"

On February 10, 2009, M.D., denied the request for reconsideration redo arthrodesis with anterior interbody fusion C3-C7, removal of anterior spinal and redo spinal instrumentation C3-C7 and possible C5 corpectomy with the following rationale: *"This patient has had multiple prior surgeries and is noted to have pseudoarthrosis at C4-C5 and C3-C4. CT myelogram showed overlap of two plates at C5 with evidence of incomplete fusion at C3-C5 and partial fusion at C5-C7. There are also comminuted bony spurs posteriorly. The claimant continues to smoke. The bulk of the literature would argue against cervical fusion in a claimant that smokes. It is highly probable that the same outcome will result, particularly if this claimant smokes. Regardless, the literature specifically notes that there is a high rate of continued pain even after solid fusion is achieved. Predictors of poor outcome included nonspecific neck pain, psychological distress, psychosomatic problems, and poor general health. The patients who smoke have compromised fusion outcome. Treatment options include a revision anterior approach versus a posterior approach. Regardless of the approach, there is high rate of continued moderate to severe pain even after solid fusion is achieved."*

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

There is no clear documentation of pseudoarthrosis on the available imaging studies. The smoking history renders this person a worrisome operative candidate. Given all the factors involved, it certainly could not be stated with reasonable medical certainty that another surgery would render this person pain free. There is no clear documentation of instability.

Based on the available records alone, I am simply not able to recommend the proposed procedure as medically necessary.

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

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

Official Disability Guidelines Treatment in Workers' Comp 2009 Updates, neck and upper back

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)

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) 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.

Note: 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)