URAC ACCREDITED

CLAIMS EVAL

Utilization Review and Peer Review Services

Notice of Independent Review Decision-WC

CLAIMS EVAL REVIEWER REPORT - WC

DATE OF REVIEW: 1-4-10 (AMENDED 1/12/10)

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE
Inpatient ACDF C5-C6, C6-C7 LOS 1 22554, 20936, 22585, 22845, 22851, 63075, 63076

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION
American Board of Orthopaedic Surgery-Board Certified

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)

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.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- 2-27-09 X-rays of the cervical spine.
- 2-27-09 X-rays of the thoracic spine.

- MD., office visits from 2-27-09 through 11-20-09 (9 visits).
- 4-10-09 X-rays of the cervical spine.
- 4-10-09 MRI of the cervical spine.
- MD., office visits from 5-5-09 through 11-16-09 (4 visits).
- MD., office visits on 6-17-09 and 8-19-09.
- 10-12-09 MRI of the thoracic spine.
- 12-1-09 DO., performed a Utilization Review.
- 12-16-09 MD., performed an Appeal Utilization Review.

PATIENT CLINICAL HISTORY [SUMMARY]:

2-27-09 X-rays of the cervical spine shows extensive spondylitic changes at the C5 through C7 levels. There is grade I anterolisthesis of C5 on C6.

2-27-09 X-rays of the thoracic spine was normal.

2-27-09 MD., the claimant is seen for evaluation of his back injury. The claimant reported he was injured when a backhoe struck him on the back. He has no x-rays or imaging performed. He has been steadily working since the injury. He is working light duty. On exam, the claimant has normal range of motion of the cervical spine. Thoracic spine range of motion is normal. There is normal range of motion of the lumbar spine. DTR are 2/4 bilaterally in the lower extremities. The evaluator felt the claimant had spasms of muscle, neck sprain, thoracic spine and question bony contusion or fracture. The claimant was provided with a prescription for Lodine, Skelaxin, and Darvocet. He was referred for x-rays to rule out fracture.

3-20-09 MD., the claimant is seen for evaluation of back injury. X-rays were reviewed. The claimant was continued on his medications.

3-23-09 MD., the claimant presents with complaints of posterior aspect of neck, left upper and right upper back pain. On exam, the claimant has decreased range of motion of the cervical spine and thoracic spine. Sensory, motor and DTR are within normal limits. The evaluator recommended manual therapy.

3-27-09 MD., the claimant is seen for posterior neck pain and left and right upper back pain. On exam, the claimant has decreased range of motion of the cervical and thoracic spine. Neurological exam is within normal limits. The claimant was referred to physical therapy.

4-1-09 MD., the claimant continued with posterior neck pain. The evaluator recommended the claimant continue with his medications. Skelaxin was changed for

Soma. The claimant will start physical therapy. The evaluator reported that an MRI was recommended by the radiologist.

4-10-09 X-rays of the cervical spine shows displacement of thoracic intervertebral disc without myelography, cervicalgia, and spasms of muscle.

4-10-09 MRI of the cervical spine shows cervical spondylotic changes throughout the cervical spine with at least grade I anterior spondylolisthesis of C5 on C6 with at least 60% narrowing of disc height along with irregularity involving the endplates. Small disc abnormality present at C3-C4, C4-C5 and C6-C7. Small disc abnormality present at T3-T4 level.

5-5-09 MD., the claimant complains of cervicalgia and right shoulder pain. The claimant reported that he was at work and a bucket from a backhoe struck him and threw him several feet. He landed and struck the back of his head. He has pain to the right shoulder and to the posterior cervical region also pain in the right shoulder with some crepitation. The pain shoots from the posterior midline cervical region into the right shoulder lateral and anterior. He has no pain on the left side. He had an MRI of the cervical spine. He is working light duty. He is taking Skelaxin, Lodine and Darvocet prn. On exam, the claimant has no paravertebral tenderness to the cervical spine. He has positive crepitation with range of motion of the shoulder. The claimant has positive impingement sign on the right. Neurological exam shows motor strength 5/5, sensation intact and reflexes symmetrical. X-rays from 4-10-09 showed significant anterolisthesis about 30% C5 on C6. At C6-C7, he has degenerative changes. The MRI showed anterolisthesis of about 40% of C5 on C6 but his canal and foramen are patent. At C6-C7, he has a broad protrusion and some mild to moderate degenerative change but no neural impingement. The evaluator recommended the claimant continue light duty. He recommended referral for consideration of epidural steroid injection.

6-17-09 MD., the claimant was referred due to his neck and arm pain. On exam, the claimant has decreased cervical range of motion, mild to moderate tenderness throughout the cervical facet joints bilaterally from C3-C4 through C6-C7. There is diffuse tenderness in the trapezius and rhomboid muscles bilaterally. Motor strength is 5/5. Sensation is slightly decreased in the left C7 dermatome when compared to the right. The evaluator recommended cervical epidural steroid injection. The claimant was continued with his medications.

8-19-09 MD., the claimant underwent a second epidural steroid injection three weeks ago. He noted additional improvement from between the first and second injection. Overall, he reported 75% improvement. Much of the left sided neck and shoulder pain is improved. Now he is having a bit more discomfort on the right side. On exam, the claimant had some mild to moderate improvement with range of motion from the first injection. There is some moderate tenderness along the trapezius and rhomboid muscles bilaterally with the right more tender than the left side. The evaluator recommended a third epidural steroid injection.

9-9-09 MD., the claimant continues with complaints of posterior neck pain. The evaluator recommended the claimant use warm compresses, use capsaicin bid prn, and referral to ortho/neurosurgeon, Dr. Strausser.

9-21-09 MD., the claimant is status post two epidural steroid injection by Dr.. He reported that it helped initially, but then they wore off. He continues to have pain primarily in the upper thoracic region below C7. The evaluator reported that he would call the adjuster to see if the thoracic spine and right shoulder is compensable. The evaluator felt that he could also have rotator cuff pathology and some of his pain could be from the thoracic region.

9-30-09 MD., the claimant is seen for evaluation. The claimant reported that he had two epidural steroid injections, the last one given on 7-31-09 with good relief for three days. Now the pain has returned. Dr. is trying to get an injection for T3-T4 approved. The claimant is provided with a refill of medications. The claimant may need surgery.

10-1-09 MD., the claimant is seen for followup. The adjuster reported that the thoracic spine is compensable; nothing was mentioned about the shoulders. He continues to have pain at the upper thoracic region. It was noted in the cervical MRI that he had a T3-T4 protrusion on the right. Therefore, the evaluator recommended a thoracic MRI to assess for thoracic HNP since it may be contributing to his pain. The claimant had a cervical epidural steroid injection at the C6-C7 level, but did not improve his pain.

10-12-09 MRI of the thoracic spine shows no abnormality.

10-21-09 MD., the claimant presents for evaluation of his back. The claimant is still waiting approval for the T3-T4 injection and approval for a third epidural steroid injection. The claimant is continued with his medications, the use of capsaicin and warm compresses.

11-16-09 MD., the claimant continues to have significant cervical and thoracic pain with pain that radiates into the shoulder and arm. He has a diagnosis of right C6-C7 HNP and some degenerative changes at C5-C6. The evaluator reported the claimant has failed all conservative measures. This includes medications, time, activity modification, physical therapy and injections. He continues to have significant pain rated as 6-8/10. He does not want to continue living with this pain. He is working and wanted to continue to work, however, it is light duty. On exam, the claimant has some restricted range of motion in all planes. He has tenderness in the right posterior cervical, trapezius, and rhomboid region. He has 4/5 weakness, right triceps and wrist flexor. Reflexes are symmetric. There is no atrophy. Sensation is intact. The evaluator reported that at this point it is either going to live with his pain or consider surgery. He wants to proceed with surgery. The evaluator recommended C5-C6, C6-C7 ACDF with cage or allograft.

11-20-09 MD., the claimant is seen for evaluation of his back. Dr. is requesting approval for surgery. On exam, the claimant has decreased range of motion of the cervical spine. The claimant is tender to the posterior aspect of the neck and left upper back. Neurological exam shows reflexes are 2/4 with reinforcement. The evaluator recommended the claimant continue with the use of Capsaicin, warm compresses. The claimant is awaiting decision on surgery. If this is denied, the claimant will be sent for Functional Capacity Evaluation and an impairment rating. The claimant is provided with a refill of medications.

On 12-1-09 DO., performed a Utilization Review. It was his opinion that the claimant complains of significant cervical and thoracic pain radiating into the shoulder and arm. He has restricted range of motion in all planes, tenderness in the right posterior cervical, trapezius and rhomboid area, 4/5 weakness of the right triceps and wrist flexors and intact reflexes and sensation. Imaging studies demonstrated cervical spondylotic changes at C5-C6 with at least grade I anterior spondylolisthesis, 60% narrowing of the disc height and irregularity involving the endplates, and small paracentral disc bulge at C6-C7. Treatment to date includes physical therapy, epidural steroid injection, activities modifications, and injections without relief. However, no objective documentation of such treatment failure was noted on file in terms of progress notes and procedural reported. No evidence was presented that he had optimized oral medications. As such, the appropriateness, medical necessity and anticipated benefits of this requested procedure are not sufficiently substantiated.

On 12-16-09, MD., performed an Appeal Utilization Review. It was his opinion that the claimant presents with significant cervical and thoracic pain radiating into the shoulder and arm with 4/5 weakness of the right triceps and wrist flexors. An MRI of the cervical sine dated 10-12-09 revealed cervical spondylotic changes at C5-C6 with least grade I anterior spondylolisthesis, 60% narrowing of disc height, and irregularity involving the endplates and small paracentral disc bulge at C6-C7. There is no objective documentation of treatment failure noted on file. Physical therapy progress notes were still not submitted for review. Therefore, the evaluator reported that the request for ACDF and one-day length of stay is not medically necessary.

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

BASED ON THE MEDICAL DOCUMENTATION PROVIDED, THERE IS A STRONG INDICATION FOR A TWO LEVEL CERVICAL FUSION. THE CLAIMANT HAS NOT HAD LATERAL FLEXION/EXTENSION X-RAYS OF THE CERVICAL SPINE TO SEE IF THERE IS ANY INSTABILITY OR AN EMG/NCV OF THE NECK AND BOTH UPPER EXTREMITIES. THERE IS ABSENCE OF OBJECTIVE FINDING THAT CORRELATE WITH THE SUBJECTIVE COMPLAINTS AND SOFT EXAM FINDINGS. THEREFORE, THE REQUESTED ACDF AT C5-C6 AND C6-C7 WITH A ONE LOS IS NOT REASONABLE OR MEDICALLY NECESSARY AT THIS JUNCTURE.

ODG-TWC, last update 12-3-09 Occupational Disorders of the Neck and Upper Back – Cervical Fusion: 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 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. (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)

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)**