CareReview™

PO Box 120457
Arlington, TX 76012
P 817.860.7800
F 817.860.7810
www.care-review.com

Notice of Independent Review Decision

DATE OF REVIEW: NOVEMBER 19, 2010

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Inpatient cervical surgery to include anterior decompression and discectomy, arthrodesis with cages, anterior instrumentation at C4-5-6-7 with 2 day expected length of stay.

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

This physician is a Board Certified Neurosurgeon with 43 years of experience.

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

On December 14, 2007, the claimant was evaluated by M.D., an orthopedic surgeon for an independent medical examination. Dr. addressed questions in regards to his lumbar spine, left shoulder, and left knee.

On August 18, 2008, the claimant underwent a pre-surgical evaluation as performed by M.A., LPC Intern. It was recommended that the claimant participate in individual counseling 1 x 6 weeks to address anxiety and stress.

On September 23, 2008, M.D., an orthopedic surgeon evaluated the claimant. He had complaints of back pain and bilateral leg pain although little bit worse on the right than on the left. The claimant is to undergo internal fixation with a bone growth stimulator, which will require removal 6 months postoperatively.

On May 18, 2009, an MRI of the Cervical Spine was performed. Impression: C3-4 and C4-5 contained disk herniation rated as stage II with annual herniation, nuclear protrusion, and stenosis. C5-6 and C6-7, non-contained disk herniation rate as stage III with annular herniation, nuclear extrusion, and spinal stenosis.

On May 19, 2009, M.D., an orthopedic surgeon evaluated the claimant. Physical examination of the neck reveals mild paravertebral muscle spasm, trigger point levator scapular origin bilaterally, and mid portion of the trapezius on the right, decreased brachioradialis jerk bilaterally, weakness in elbow flexion, paresthesias in the C6 and C7 nerve root distribution on the right and left. Impression: Multiple level cervical HNP with instability at C5-6 and C6-7. Dr. recommended provocation discography and subsequent anterior cervical decompression discectomy.

On August 11, 2009, the claimant was re-evaluated by M.D. He presented with emergency room documentation from August 24, 2007, documenting his clinical symptoms of his cervical spine, lumbar spine, knee and radiculopathy.

On January 14, 2010, M.D., a pain management specialist evaluated the claimant. He presented with ongoing complaints of severe spine pain and severe low back pain. He has had numerous spasms in his left shoulder. The insurance carrier has denied compensability of the cervical spine herniations and lumbar spine. Dr. prescribed Hydrocodone 7.5 mg.

On March 2, 2010, the claimant was re-evaluated by M.D. He continues to complain of neck pain, arm pain worse on the left than the right. His Benefit Review Conference is this month, to get issue resolved to he can proceed with surgical intervention.

On August 16, 2010, the claimant was re-evaluated by M.D. The TDI ruled in the claimant's favor and has ordered the insurance carrier to pay and accept the claimant's extent of injury to include both cervical and lumbar herniations. He is referred by to M.D.

On September 7, 2010, the claimant was re-evaluated by M.D. He wants to proceed with surgical intervention of the cervical spine. Dr. recommended a repeat MRI scan of the cervical and lumbar spine.

On September 22, 2010, an EMG/NVC was performed. Impression: Mild acute C5 radiculopathy on the right and left. There is also electrodiagnostic evidence of mild right C7 nerve root irritation as interpreted by M.D.

On October 4, 2010, an MRI of the cervical spine revealed C4-5, C5-6, and C6-disc herniation rage as stage II with annular herniation, nuclear protrusion, disc desiccation consistent with T2 weighted image changed and spinal stenosis as interpreted by M.D.

On October 5, 2010, the claimant was re-evaluated by M.D. Physical examination of the cervical spine remains unchanged. He is going to proceed with surgical intervention of the cervical spine to include anterior cervical decompression and discectomy and arthrodesis with internal fixation at C4-5, C5-6 and C6-7.

On October 19, 2010, M.D., an orthopedic surgeon, performed a utilization review on the claimant. Rational for Denial: The pain complaints appear to be vague and bilateral in nature. The examination findings seem to suggest a more diffuse picture with multi-level pathology that may or may not correlate with imaging study findings. Without the knowledge of the recent MRI and a better sense of whether or not it documents neural compression would be consistent with the claimants clinical complaints as well as it would be of sufficient magnitude to warrant a three level surgery. Therefore, it is not certified.

On November 2, 2010, M.D., a hand surgeon, performed a utilization review on the claimant Rational for Denial: ODG Guidelines would not recommend a three level procedure based on discogenic pain. Pain generators are not identified. There was no documentation of a psychosocial assessment. Therefore, it is not certified.

PATIENT CLINICAL HISTORY:

On, the claimant was involved in a motor vehicle accident in which the claimant's truck jack-knifed and he sustained injuries to his low back, neck, left shoulder and left knee.

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

Based on the claimant's physical findings, diagnostics of studies of the cervical spine (i.e. EMG/NCV on September 22, 2010 and two cervical MRIs), and the claimant has exhausted conservative treatment the previous decisions are overturned per the ODG Guidelines.

Per ODG Guidelines:

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)
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)**