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Notice of Independent Review Decision

DATE OF REVIEW:
03/05/2009 – amended 03/06/2009

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE
Anterior cervical diskectomy with interbody fusion C3-4, C4-5 and C5-6 with three day inpatient hospital stay.

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

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

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.
The request for anterior cervical diskectomy with interbody fusion C3-4, C4-5 and C5-6 with three day inpatient hospital stay is not medically necessary.

INFORMATION PROVIDED TO THE IRO FOR REVIEW
- TDI/DIVISION OF WORKERS' COMPENSATION referral form
- 02/20/09 Invoice, Photo-Stat
- 02/19/09 MCMC Referral
- 02/17/09 Notice of Assignment of Independent Review Organization, DWC
- 02/17/09 Notice to Utilization Review Agent of Assignment, DWC
- 02/17/09 Notice to MCMC, LLC Of Case Assignment, DWC
- 02/13/09 Utilization Review Agent's Request, DWC
- 02/11/09 Request For A Review By An Independent Review Organization
- 02/10/09 Notice of Utilization Review Findings,
- 02/10/09 letter from
- 02/02/09 Fax cover sheet with note from Orthopedics
- 01/29/09 Follow Up Consultation, D.O., Orthopedics
- 01/29/09 Work Status Report, DWC
- 01/21/09 Notice of Utilization Review Findings,
- 01/21/09 letter from
- 01/15/09 Fax cover sheet with note from Orthopedics

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- 01/15/09 Insurance Verification (02/02/09 with Appeal added to date)
- 01/13/09 Follow Up Consultation, , D.O., Orthopedics
- 12/18/08 report from, M.D.,
- 12/04/08 Facsimile Cover Sheet with note from, D.C.
- 12/02/08 letter from, M.D.
- 11/11/08 Follow Up Consultation, D.O., Orthopedics
- 11/03/08 Physician Review Report, M.D.
- 10/23/08 Follow Up Consultation,, D.O., Orthopedics
- 10/16/08 MRI cervical spine, MRI
- 09/09/08 Follow Up Consultation, D.O., Orthopedics
- 08/29/08 Physician Review Report
- 08/22/08 Physician Review Report, , M.D.
- 06/25/08 report from, M.D.,
- 06/25/08 Electrodiagnostic Results,
- 06/25/08 handwritten chart note (poor quality)
- Undated IRO decision instructions, DWC
- Note: Carrier did not supply ODG Guidelines

PATIENT CLINICAL HISTORY [SUMMARY]:

The injured individual is a xx year who was reported to have sustained a work-related injury on xx/xx/xx. The initial treatment records are not available for review. It is reported that the injury occurred in a slip and fall near the steam table in the kitchen. The injury was a soft tissue strain that reportedly resolved with conservative treatment. She then developed symptoms again in 08/2008. It is unclear how these symptoms were causally related to the original occupational injury. Electrodiagnostic studies performed on 06/25/08 by M.D. were normal. MRI performed on 10/16/08 revealed evidence of multi-level degenerative disc disease. The official report documented C2-C3 a 1mm broad-based disc protrusion, C3-C4 mild left neuroforaminal narrowing and mild central canal stenosis with a broad-based protrusion 2mm to the right and 3mm to the left of midline, C4-C5 broad 1mm disc protrusion, and C5-C6 broad 1-2 mm disc protrusion with mild cental canal stenosis and mild bilateral neuroforaminal narrowing. D.O. recommended surgical intervention at C3-C4 which was then denied. He referred the injured individual to M.D. on 12/18/08. Dr. documented a normal neurological examination and noted the normal electromyogram/nerve conduction velocity (EMG/NCV) studies. He opined that the injured individual would benefit from a C3-C6 anterior cervical discectomy and fusion (ACDF) despite his documented objective physical findings. The injured individual returned to Dr. who then placed a request for the disputed surgical procedure. Both Drs. and Myles physical examination showed no evidence of significant neurological compromise.

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

The injured individual is a xx year old who appears to have sustained a soft tissue injury as a result of a work-related slip and fall on xx/xx/xx. This was treated conservatively and the symptoms resolved. Ten months (08/2008) after the original incident she developed symptoms again. The specific details are absent from the reviewed material and it is unclear how they are causally related. MRI revealed evidence of multi-level degenerative disc disease which is clearly pre-existing and a “disease of life”.

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It would be expected that these degenerative changes may result in periodic symptoms as the injured individual ages. Her physical examination has always documented a normal neurological examination and EMG/NCV does not document any evidence of radiculopathy. Drs. and reported a negative Spurling test.

Official Disability Guideline (ODG) Indications for Surgery -- Discectomy/laminectomy (excluding fractures):
Washington State has published guidelines for cervical surgery for the entrapment of a single nerve root and/or multiple nerve roots. (Washington, 2004) Their recommendations require the presence of all of the following criteria prior to surgery for each nerve root that has been planned for intervention (but ODG does not agree with the EMG requirement):
A. There must be evidence of radicular pain and sensory symptoms in a cervical distribution that correlate with the involved cervical level or presence of a positive Spurling test.
B. There should be evidence of motor deficit or reflex changes or positive EMG findings that correlate with the cervical level. Note: Despite what the Washington State guidelines say, ODG recommends that EMG is optional if there is other evidence of motor deficit or reflex changes. EMG is useful in cases where clinical findings are unclear; there is a discrepancy in imaging, or to identify other etiologies of symptoms such as metabolic (diabetes/thyroid) or peripheral pathology (such as carpal tunnel). For more information, see EMG.
C. An abnormal imaging (CT/myelogram and/or MRI) study must show positive findings that correlate with nerve root involvement that is found with the previous objective physical and/or diagnostic findings. If there is no evidence of sensory, motor, reflex or EMG changes, confirmatory selective nerve root blocks may be substituted if these blocks correlate with the imaging study. The block should produce pain in the abnormal nerve root and provide at least 75% pain relief for the duration of the local anesthetic.
D. Etiologies of pain such as metabolic sources (diabetes/thyroid disease) non-structural radiculopathies (inflammatory, malignant or motor neuron disease), and/or peripheral sources (carpal tunnel syndrome) should be addressed prior to cervical surgical procedures.
E. There must be evidence that the patient has received and failed at least a 6-8 week trial of conservative care.

The injured individual does not meet the criteria as outlined above.

Recommended as an option if there is a radiographically demonstrated abnormality to support clinical findings consistent with one of the following:
(1) Progression of myelopathy or focal motor deficit;
(2) Intractable radicular pain in the presence of documented clinical and radiographic findings; or
(3) Presence of spinal instability when performed in conjunction with stabilization. (See Fusion, anterior cervical.)
Surgery is not recommended for disc herniation in a patient with non-specific symptoms and no physical signs. The American Academy of Orthopaedic Surgeons has recommended that an anterior approach is appropriate when there is evidence of radiculopathy, and/or when there is evidence of central location and there is any degree of segmental kyphosis. A posterior approach has been suggested by the same group when there is evidence of lateral soft disc herniations with predominate arm pain and for caudal lesions in large, short-necked individuals. (Albert, 1999) The overall goals of

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cervical surgery should be decompression, restoration of alignment, and stability. (Jacobs-Cochrane, 2004) (Dowd, 1999) (Colorado, 2001) In terms of posterior procedures, there does not appear to be sufficient evidence to support the use of laminoplasty versus laminectomy based on outcomes or post-operative morbidity. Research has indicated that as many as 60% of patients who received laminoplasty had posterior neck and shoulder girdle pain post-operatively (versus 25% in the laminectomy group). (Hosono, 1996) (Heller, 2001) Some authors continue to prefer laminoplasty to anterior spinal decompression and fusion (for myelopathy due to disc herniation) as they feel the risk of chronic neck pain is less troublesome than the risk of bone graft complications and/or adjacent spondylosis that can be found with the fusion procedure. (Sakaura, 2005) It is not clear from the evidence that long-term outcomes are improved with the surgical treatment of cervical radiculopathy compared with nonoperative measures. However, relatively rapid and substantial relief of pain and impairment in the short term (6-12 weeks after surgery) after surgical treatment appears to have been reliably achieved. (Haldeman, 2008)
Late deterioration: Has been found with both anterior and posterior approaches. (Rao, 2006) With the anterior approach, recurrent symptoms have been found secondary to deterioration of the adjacent segment, inadequate decompression at the time of the initial surgery, pseudoarthrosis, graft or implant failure, and/or continued growth of osteophytes. With the posterior approach, recurrent symptoms have been found secondary to development of kyphosis, instability, spread of ossification of the posterior longitudinal ligament, and development of stenosis at new levels. 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)
Pre-operative evaluation:
MRI: This is a very sensitive test for radicular disorders but has a lower negative predictive value. Disc bulges have been found in one study in 52% of subjects and protrusions in 27% without back pain. At age 60 years, 93% of subjects in one study had disc degeneration/bulges on MRI. (Boden, 1990)
EMG: Optional for cervical surgery. See Electromyography

There is no evidence of spinal instability, radiculopathy or dermatomal sensory changes or focal motor deficit documented in the medical record.

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

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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).

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(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)

The injured individual does not fit the criteria for a cervical fusion based on the criteria as outlined above. The requested procedure is not supported based upon the medical documentation and review of ODG criteria. The pain generator has not been clearly identified. The injured individual has evidence of multi-level degenerative cervical spine disease.

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

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES