Parker Healthcare Management Organization, Inc.

3719 N. Beltline Rd Irving, TX 75038
972.906.0603 972.906.0615 (fax)

Notice of Independent Review Decision

DATE OF REVIEW: NOVEMBER 11, 2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Medical necessity of proposed Artificial Disc Replacement C6-C7 (22551, 22851, 95941, 20931, 22856, 22845)

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

This case was reviewed by a Medical Doctor licensed by the Texas State Board of Medical Examiners. The reviewer specializes in orthopedic surgery and is engaged in the full time practice of medicine.

REVIEW OUTCOME

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

XX Upheld (Agree)

☐ Overturned (Disagree)

☐ Partially Overturned (Agree in part/Disagree in part)

Primary Diagnosis	Service being Denied	Billing Modifier	Type of Review	Units	Date(s) of Service	Amount Billed	Date of Injury	DWC Claim#	IRO Decision
723.4	22551		Prosp	1			Xx/xx/xx	xxxxx	Upheld
723.4	22851		Prosp	1			Xx/xx/xx	xxxxx	Upheld
723.4	95941		Prosp	1			Xx/xx/xx	xxxxx	Upheld
723.4	20931		Prosp	1			Xx/xx/xx	xxxxx	Upheld
723.4	22856		Prosp	1			Xx/xx/xx	xxxxx	Upheld
723.4	22845		Prosp	1			Xx/xx/xx	xxxxx	Upheld

INFORMATION PROVIDED TO THE IRO FOR REVIEW

TDI-HWCN-Request for an IRO-21 pages

Respondent records- a total of 85 pages of records received to include but not limited to:

letter 10.21.13; Pain and Rehabilitation Record 4.11.13; Back Institute records 4.29.13-7.25.13; Solutions letter 8.20.13, 9.30.13; letters 8.20.13, 10.2.13; IRO request forms; MRI C spine 11.19.12, MRI T-Spine 11.19.12, NCV/EMG study 2.12.13; DWC forms 69; RME 3.14.13

Requestor records- a total of 32 pages of records received to include but not limited to: records 4.29.13-7.25.13; MRI C spine 11.19.12, MRI T-Spine 11.19.12, NCV/EMG study 2.12.13; DWC forms 69; RME 3.14.13; Pain and Rehabilitation 4.11.13

PATIENT CLINICAL HISTORY [SUMMARY]:

The injured employee is a gentleman who reported sustaining an injury while at work.

An MRI of the cervical spine was performed on November 19, 2012, documenting reversal of the normal cervical lordosis, uncovertebral hypertrophy, and traction disc bulge at C5-C6 resulting in mild right and moderate left neuroforminal stenosis. Mild posterior disc bulging was noted at C3-C4 and C4-C5 with AP spinal canal diameter of 9 mm. A thoracic MRI documented no significant thoracic disc herniation, central spinal stenosis, or neural foraminal stenosis.

Electrodiagnostic studies were performed on February 12, 2013, suggesting a left cervical radiculopathy affecting the C6-C7 nerve root. An epidural steroid injection was recommended.

On March 14, 2013, performed a Report of Medical Evaluation certifying that the injured employee had not reached Maximum Medical Improvement to date. A surgical consultation was recommended.

performed an evaluation on April 11, 2013, for neck pain. It was noted at that time that the injured employee had two prior cervical epidural steroid injections over the past few months which helped. Medications included Ibuprofen and Zanaflex, in addition, the use of a TENS unit was also noted. The physical examination documented normal sensation, reflexes, and strength. Ultracet and a surgical evaluation were recommended.

subsequently evaluated the injured employee in July of 2013 and recommended surgical intervention consisting of an anterior cervical discectomy and fusion at C5-C6 with artificial disc replacement at C6-C7.

A Peer Review was performed on August 20, 2013, suggesting that the aforementioned surgery did not meet the Official Disability Guidelines treatment recommendations. This decision was appealed on September 30, 2013, and again deemed not medically necessary.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION. IF THERE WAS ANY DIVERGENCE FROM DWC'S POLICIES/GUIDLEINES OR THE NETWORK'S TREATMENT GUIDELINES, THEN INDICATE BELOW WITH EXPLANATION.

RATIONALE:

The request for the medical necessity of the proposed artificial disc replacement at C6-C7 is not supported. The records would support that the injured employee has multilevel cervical stenosis and spondylosis with failure of prior epidural steroid injections, physical therapy, TENS unit, and oral medications. The request for an artificial disc replacement is considered investigational based on the lack of long-term prospective studies showing safety and efficacy. Additionally, surgical intervention would not be supported without clinical corroboration of the diagnostic imaging and physical examination findings. The most recent examination provided has noted normal strength, normal sensation, normal reflexes, and no muscle atrophy, not consistent with MRI or the electrodiagnostic testing provided for review. As such, the request is not

medically necessary per evidence-based guidelines. The artificial disc replacement at C6-C7 is not medically necessary.

As noted in the Division-mandated Official Disability Guidelines Neck and Upper Back Chapter, updated May 14, 2013, disc prosthesis is under study, with recent promising results in the cervical spine, but not recommended in the lumbar spine. While comparative studies with anterior cervical fusion yield similar results, the expectation of a decrease in adjacent segment disease development in long-term studies remains in question. And there is an additional problem with the long-term implications of development of heterotopic ossification. Additional studies are required to allow for a "recommended" status. These should include an evaluation of the subset of patient who will most benefit from this procedure as well as study of advantages/disadvantages of disc design and surgical procedure in terms of outcomes (particularly for development of heterotopic ossification and adjacent segment disease). This recommendation is based on balancing what we know so far about the benefits and the risks for the patient. Adjacent segment disease seems to be a natural aging process, and ADR has not proven any benefit in altering that progression. The risks of heterotopic calcification associated with ADR may make it a sure way to end up with a solid fusion, and major risks also include potential revisions and technical learning curve issues with widespread use.

Overall Comparison to Fusion: Overall studies have demonstrated statistically significant non-inferiority of ADR vs. fusion with superior trending on many outcomes but limited evidence of statistical superiority. This has persisted for longer-term follow-up (three to five years). Long-term studies have shown that necessity of adjacent-level surgery is similar in both the fusion and ADR groups along with similar rates of development of adjacent-segment disease. Complication rates are similar. Study quality is often severely limited with high dropout rates and there is no comparison to a non-surgical treatment. Neither treatment has been found to produce complete disappearance of symptoms. Return to work appears earlier in the ADR group but overall employment rate is not different at 2 years (including for a workers' compensation cohort) and 5 years. (Zechmeister, 2011) (Steinmetz, 2008) (Jawahar, 2010) (Kim, 2009) (Garrido, 2010) (Fekete, 2010) (Dettori, 2008) (Pointillart, 2001) (Cinotti, 1996) (Klara, 2002) (Zeegers, 1999) (Sekhon, 2003) (Sekhon, 2004) (Porchet, 2004) (Pimenta, 2004) (Sasso, 2007) (Heller, 2009) (Mummaneni, 2007) (Murrey, 2009) (Burkus, 2010) (ECRIb, 2009) (Tumialán, 2010) (Delamarter, 2010) (Kelly, 2011) See also the complete list, discussion, and rating of other Disc prosthesis references in the Fusion References Chapter.

Recommended Indications: The general indications for currently approved cervical-ADR devices (based on protocols of randomized-controlled trials) are for patients with intractable symptomatic single-level cervical DDD who have failed at least six weeks of non-operative treatment and present with arm pain and functional/ neurological deficit. At least one of the following conditions should be confirmed by imaging (CT, MRI, X-ray): (1) herniated nucleus pulposus; (2) spondylosis (defined by the presence of osteophytes); & (3) loss of disc height. (Dettori, 2008) At the current time radiculopathy is an exclusion criteria for the FDA studies on lumbar disc replacement, whereas cervical radiculopathy is an inclusion criteria for the FDA investigations of cervical arthroplasties. (McAfee, 2004) Decompression of nerve roots and/or the spinal canal is often the primary intervention that necessitates disc replacement with a goal of restoration of intervertebral disc and foraminal height to prevent recurrence of nerve root compression. Implant of a total disc requires intact ligaments, integrity of the facet joints, vertebral bodies with intact endplates and good bone quality. (Fekete, 2010) (Cepoiu-Martin, 2011)

Myelopathy: ADR is also recommended for myelopathy. The findings from two cohorts at two years postoperatively suggest that arthroplasty is equivalent to arthrodesis for the treatment of cervical myelopathy for a single-level abnormality localized to the disc space, but the study did not evaluate the treatment of retrovertebral compression as occurs in association with ossification of the posterior longitudinal ligament. (Riew, 2008)

Recommended exclusions: Suggested exclusions include evidence of facet arthritis, spinal instability or significant deformity. While patients with myelopathy are suggested as candidates this is precluded if there is evidence of multilevel pathology or significant degeneration. Other

suggested exclusions include the following: (1) axial neck pain as the solitary presenting symptom; (2) osteoporosis/ osteopenia; (3) spinal stenosis by hypertrophic spondyloarthrosis; (4) severe spondylosis (defined as bridging osteophytes, a loss of disc height greater than 50%, or absence of motion at less than 2%); (5) active infection; (6) material allergies; (7) presence of underlying comorbid disease such as HIV, hepatitis B or C, insulin-dependent diabetes, and/or autoimmune spondyloarthropathies such as rheumatoid arthritis; & (8) morbid obesity (BMI > 40). As of yet there are no recommendations for precautions in terms of underlying psychiatric pathology, smoking history, current drug use history, workers' compensation status, or litigation status. (Auerbach, 2008) (Zechmeister, 2011) (Sasso, 2007)

Rationale for development of this treatment: It is generally suggested that mobility in a degenerate joint is the cause of pain. In the spine a problem arises as the mechanism of pain is incompletely understood. Proponents of artificial disc replacement point out that while there is evidence of a high success rate for anterior cervical discectomy and fusion (ACDF) for treatment of radiculopathy and myelopathy, the procedure is thought to increase biomechanical stresses at adjacent segments that may hasten degeneration. This concept is controversial as there is debate over whether this is a stand-alone phenomenon accompanying fusion or a part of natural history of degeneration. By maintaining adjacent level kinematics the rate of adjacent level degeneration is thought to lessen, although there is limited evidence to support this. Other proposed benefits include quicker return to normal employment and lifestyle and elimination of risks and morbidity with bone graft procurement. Pseudoarthrosis is also not a problem with disc replacement. (Phillips, 2005) (Auerbach, 2008) (Cepoiu-Martin, 2011) (Zechmeister, 2011)

Concerns with use: There is an increasing interest in spinal arthroplasty as an alternative to fusion in conjunction with cervical discectomy, but at this time there are no comparative studies of ADR with other treatment modalities besides fusion. Longevity of this new procedure is unknown, which is important based on the targeted age of most patients who fit the current criteria for treatment (with a relatively young average age in workers' compensation patients). There is limited data in terms of mechanical failure and aseptic loosening. There is also limited evidence as to the long-term effect on index-level facet arthrosis and/or adjacent level degeneration/disease. It has been noted that the theoretical position that symptomatic adjacent segment disease leads to more surgery after fusion compared to less aggressive treatment is poorly founded, plus theses devices appear at best to yield results equal to or only incrementally better than fusion for the same indications. (Resnick, 2007) Finally, the consequences of failure of an implant in close proximity to the spinal cord, the esophagus, and the trachea are of concern. Current literature suggests that an analysis of these types of questions will take from five to ten years.

Complications: Implant malposition, loosening, subsidence, implant migration, fractures and infection have all been reported and may necessitate retrieval and proceeding with an interbody fusion. Other reported complications include delayed fusion around the prosthesis, asymmetric endplate preparation resulting in postoperative kyphosis, and reduction in vertebral body height. The most common complications of both ADR and fusion are wound infections, dysphagia/dysphonia and allergic reactions. (Zechmeister, 2011) (Anderson, 2008) (Yi, 2010)

Discectomy-laminectomy-laminoplasty: 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. In addition, although surgery for spondylosis and radiculopathy may offer some short term benefit, non-operative treatment with PT can provide similar improvement in pain and function at 12-16 months for patients without progressive neurologic deficits or instability. (Persson, 1997) 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 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.

ODG Indications for Surgeryä -- 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 six to eight week trial of conservative care.

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

XX DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES

☐ EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN

☐ INTERQUAL CRITERIA

XX MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

☐ MERCY CENTER CONSENSUS CONFERENCE GUIDELINES

☐ MILLIMAN CARE GUIDELINES

XX 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)