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Date notice sent to all parties:

February 5, 2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

L3/L4 Extreme Lateral Interbody Fusion, (XLIF) Post Fusion and Decompression with 3 days in Patient Stay.

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

Board Certified Orthopedic Surgeon (Joint)

REVIEW OUTCOME:

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

☒ Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male who reported an injury to his low back on XX/XX/XX. The therapy note dated XX/XX/XX indicates the patient having completed 12 physical therapy sessions addressing the low back complaints. The MRI of the lumbar spine dated XX/XX/XX revealed a spondylolisthesis and circumferential slightly diffuse disc protrusion at L3-4. The disc protrusion measured 8.5mm resulting compression of thecal sac to addressing the nerve roots. Slight neural foraminal narrowing was identified. Mild hypertrophic changes were identified at the facet joints. The clinical note dated XX/XX/XX indicates the patient stated initial injury occur when he was shifting a pool heater resulting in low back complaints. Prolonged standing, walking and laying down all exacerbated the patient's pain. Upon exam, the patient demonstrated no significant reflex changes in the lower extremities. The patient was able demonstrate 5/5 strength. The note indicates the patient able to demonstrate good range of motion throughout all extremities. Upon lessee the

patient was able to demonstrate a normal gait pattern. No wild yet Waddell sign was identified. Normal sensation was identified in the upper extremities and lower extremities. The note indicates the patient utilizing Zanaflex and Celebrex for pain relief. The clinical note dated XX/XX/XX indicates the patient undergoing an assessment to determine the patient's medical improvements to date. The patient rated the ongoing pain as 5/10. The patient was able demonstrate 50 degrees of lumbar flexion, 20 degrees of extension and 20 degrees of bilateral lateral flexion. There is an indication the patient has 4/5 strength on it at the right knee with flexion/extension. Pain, tenderness and muscle guarding were identified throughout the lumbar spine, primarily on the right. There is indication the patient has a slight positive straight leg raise on the right at 60 degrees. Reflex deficits are identified at the right knee. The psychological evaluation completed on XX/XX/XX indicates the patient recommended for a surgical intervention. No contraindications are identified from the psychological perspective. The utilization reviews dated XX/XX/XX and XX/XX/XX resulted in denials as insufficient information was submitted confirming the patient's instability, specifically the L3-4 level.

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

The documentation indicates the patient complaining of low back pain. The more

recent clinical notes indicate the patient demonstrating strength deficits at the right knee, specifically flexion/extension. There is also indication his patient is diminished reflexes at the right lower extremity as well. A few lumbar fusion is indicated for patients with confirmation the patient's instability at the appropriate levels. No x-rays were submitted for review. Additionally, the MRI revealed minimal spndylolisthesis at the L3-4 level. Given the lack of confirmation the patient's significant findings regarding significant instability the L3-4 level, the request is not supported. Therefore, the recommendation is for a non-certification for the L3-4 extreme lateral interbody fusion with a post fusion and decompression with three day inpatient stay.

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

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

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

Fusion (spinal)
Recommended as an option for spondylolisthesis, unstable fracture, dislocation, acute spinal cord injury with post-traumatic instability, spinal infections with resultant instability, scoliosis, Scheuermann's kyphosis, or tumors, as indicated in the Blue Patient Selection Criteria below. Not recommended in workers' compensation patients for degenerative disc disease (DDD), disc herniation, spinal stenosis

without degenerative spondylolisthesis or instability, or nonspecific low back pain, due to lack of evidence or risk exceeding benefit. See rationale below including Surgical decision making, Return to Work, Lumbar fusion in workers' comp, and Risk versus benefit.

Lumbar spinal fusion surgeries use bone grafts, interbody spacers, and are often combined with metal implants designed to facilitate a process similar to the healing of a fracture between two or more adjacent vertebrae. The therapeutic objective of spinal fusion surgery is to unite two or more vertebrae to prevent any movement of the motion segment thereby reducing instability and stabilizing any neurological deficit caused by excess motion. For complete references, see separate document with all studies focusing on Fusion (spinal).

There is limited scientific evidence about the long-term effectiveness of fusion for degenerative disc disease compared with natural history, placebo, or conservative treatment. (Gibson-Cochrane, 2000) (Savolainen, 1998) (Wetzel, 2001) (Molinari, 2001) (Bigos, 1999) (Washington, 1995) (DeBarard-Spine, 2001) (Fritzell-Spine, 2001) (Fritzell-Spine, 2002) (Deyo-NEJM, 2004) (Gibson-Cochrane/Spine, 2005) (Soegaard, 2005) (Glassman, 2006) (Atlas, 2006) (Resnick, 2005) (Fritzell, 2004) (Airaksinen, 2006)For chronic LBP in the absence of instability, prospective randomized controlled trials have concluded that therapeutic exercise combined with cognitive behavioral intervention appears to result in pain and functional outcomes at 1-2 years equivalent to lumbar fusion without the potentially high surgical complication rates including revision surgery. (Brox-Spine, 2003) (Keller-Spine, 2004) (Fairbank-BMJ, 2005) (Brox, 2006) (Brox, 2010) (Mannion, 2013) (Mannion, 2014) One prospective randomized controlled trial concluded a small benefit for lumbar fusion at 2 years over usual care regarding pain and function; however, the control group in this trial involved unstructured care, including physical therapy (content and visits depending upon clinicians), and thus was not comparable. (Fritzell-Spine, 2001) In addition, benefits decreased at year 2 and functional improvement in the fusion group may not have met Minimum Clinically Important Difference. (Fritzell-Spine, 2001) (Fritzell-Spine, 2002) (Fritzell, 2004) The four-year follow-up evaluating the results of two combined RCTs of fusion versus cognitive intervention and exercises for disc degeneration with chronic low back pain concluded that this invasive and high-cost surgical procedure does not afford better outcomes compared with conservative care. (Brox, 2010) Long term follow-up (8-15 years, average 11 years) of three multicenter randomized controlled trials of fusion vs. cognitive behavioral and exercise rehabilitation found no significant clinical difference in patient self-reported outcomes. Outcomes considered included a primary outcome of function, and secondary outcomes of pain, medication use, work status, health-related quality of life, satisfaction with care and global treatment outcome. (Mannion, 2013) (Mannion, 2014)

There have been several systematic reviews regarding fusion for chronic low back pain. There are differences in focus of these reviews (e.g. diagnoses, surgery vs. non-operative care, comparison of alternative surgical techniques) and the types of studies included (e.g. controlled or uncontrolled, prospective or retrospective, levels of bias). A systematic review of randomized controlled trials of surgical vs. non-

surgical treatments of chronic low back pain (CLBP) noted that lumbar fusion is not more efficacious than structured cognitive-behavioral interventions combined with exercise therapy, though surgery may be more efficacious than unstructured nonsurgical care. (Mirza, 2007) Three additional systematic reviews of surgery for degenerative lumbar spondylosis, chronic non-specific low back pain and low back disorders had similar conclusions regarding equivalent clinical outcomes for fusion vs. cognitive behavioral interventions combined with therapeutic exercise. (Gibson, 2005) (Andrade, 2013) (Jacobs, 2013) One systematic review suggested improvements in pain and function associated with fusion to treat CLBP; however, the analysis included multiple types of studies (fusion vs. non-operative treatment, comparisons of surgical treatments) and variable study designs (prospective and retrospective, randomized and non-randomized, and some studies with substantial risk of bias). (Phillips, 2013) An evidence review by the American Pain Society recommended that fusion is no better than intensive rehabilitation with a cognitive-behavioral emphasis for improvement in pain or function. This review found that less than half of patients experience optimal outcomes following fusion. (Chou, 2009)

A prospective observational cohort study observed that lumbar fusion is the least successful common elective orthopedic surgery (including procedures involving hip and knee replacement, decompression for lumbar spinal stenosis and disc herniation, surgery for knee meniscal tears and fusion for ankle and subtalar osteoarthritis). The data show that patients with back pain are rendered worse off by surgery with respect to self-reported outcomes including pain and participation in usual activities. (Hansson, 2008)

In contrast to these results, recent studies document a 220% increase in lumbar spinal fusion surgery rates, and without demonstrated improvements in patient outcomes or disability rates. (Deyo, 2009) Among Medicare recipients, the frequency of complex spinal fusion procedures increased 15-fold in just six years. Several factors may contribute to these observations including geographic trends, the lack of evidence and variability of surgical decision making and financial incentives. (Weinstein, 2006) (Willems, 2011) (Willems, 2013) (Deyo, 2015) A recent 13 state analysis found that workers were more likely to undergo low back surgery in locations with higher concentrations of orthopedic surgeons and neurosurgeons and in areas where doctors receive higher surgical reimbursements. (Yee, 2015) The introduction and marketing of new surgical devices and financial incentives may stimulate more invasive surgery. (Deyo-JAMA, 2010)

See also Adjacent segment disease/degeneration (fusion) & Iliac crest donor-site pain treatment.

SPECIFIC RECOMMENDED CONDITIONS:

Spondylolisthesis: Recommended as an option for symptomatic isthmic or degenerative spondylolisthesis with instability; and/or symptomatic radiculopathy, and/or symptomatic spinal stenosis, with corroborating physical findings and imaging, and after failure of non-operative treatment subject to criteria below.

(Washington, 2009) (Weinstein-SPORT, 2007) (Deyo-NEJM, 2007) (Jacobs, 2013) (Resnick, 2014)

Posterolateral fusion in adult lumbar isthmic spondylolisthesis results in a modestly improved long-term outcome compared with a 1-year exercise program. At long-term follow-up, pain and functional disability were significantly better than before treatment in instrumented and non-instrumented patients and no significant differences were observed between instrumented and non-instrumented patients. (Ekman, 2005) One study found 27% of patients met the “highly effective” success criteria after spinal fusion for low back pain and “discogenic pain” based on a positive discogram, versus a 72% success rate in patients who underwent fusion for unstable spondylolisthesis. (Carragee, 2006) A systematic review of observational studies failed to find a clear association of isthmic spondylolisthesis with low back pain, raising questions regarding use of lumbar fusion to treat low back pain with isthmic spondylolisthesis in the absence of documented instability or radiculopathy. (Andrade, 2015)

Patients with degenerative spondylolisthesis who undergo laminectomy and fusion showed substantially greater improvement in pain and function during a period of 2 years than patients treated non-surgically. (Weinstein-SPORT, 2007) (Deyo-NEJM, 2007) For degenerative lumbar spondylolisthesis, spinal fusion may lead to a better clinical outcome than decompression alone. (Martin, 2007) Unilateral instrumentation for the treatment of degenerative lumbar spondylolisthesis is as effective as bilateral instrumentation. (Fernandez-Fairen, 2007) Fusion is most appropriate for spondylolisthesis, and decompressive laminectomy alone most appropriate for spinal stenosis. (Pearson, 2010) The latest SPORT study concluded that leg pain is associated with better surgical fusion outcomes in degenerative spondylolisthesis than low back pain. (Pearson, 2011) Comparative effectiveness evidence from SPORT shows good value for laminectomy and/or bilateral single-level fusion for degenerative spondylolisthesis, compared with non-operative care over 4 years. (Tosteson, 2011) There is a lack of evidence to support lumbar fusion

to treat symptomatic spinal stenosis in the absence of spondylolisthesis or instability. (Resnick, 2014)

Spinal cord injury (SCI): In acute spinal cord injury (SCI), if the spine is unstable following injury, surgical fusion and bracing may be necessary. (Bagnall-Cochrane, 2004) (Siebenga, 2006)

Scheuermann's kyphosis: Recommended as an option for adult patients with severe deformities (e.g. more than 70 degrees for thoracic kyphosis), neurological symptoms, and pain not adequately resolved non-operatively (e.g. physical therapy, back exercises). Good outcomes have been found in a relatively large series of patients undergoing either combined anterior-posterior or posterior only fusion for Scheuermann's kyphosis. (Lonner, 2007) See also Fusion for adult idiopathic scoliosis.

OTHER GUIDELINES: A study on improving quality through identifying inappropriate care found that use of guideline-based Utilization Review (UR) protocols resulted in a denial rate for lumbar fusion 59 times the denial rates using non-guideline based UR. (Wickizer, 2004) Data on geographic variations in medical procedure rates suggest that there is significant variability in spine fusion rates, which may be interpreted to suggest a poor professional consensus on the appropriate indications for performing spinal fusion. (Deyo-Spine, 2005) (Weinstein, 2006). According to the Medicare Coverage Advisory Committee Technology Assessment, the evidence for lumbar spinal fusion does not conclusively demonstrate short-term or long-term benefits compared with nonsurgical treatment. (CMS, 2006) According to the AANS/NASS Guidelines, lumbar fusion is recommended as a treatment for carefully selected patients with disabling low back pain due to one- or two-level degenerative disc disease after failure of an appropriate period of conservative care. This recommendation was, in part, based on one study that contained numerous flaws, including a lack of standardization of conservative care in the control group. At the time of the 2-year follow up in that study, it appeared that pain had significantly increased in the surgical group from year 1 to 2. In addition, there remains no direction regarding how to define the "carefully selected patient." (Resnick, 2005) (Fritzell, 2004)

The European Guidelines concluded that fusion surgery for nonspecific chronic LBP cannot be recommended unless 2 years of all other recommended conservative treatments, including multidisciplinary approaches with combined programs of cognitive intervention and exercises, have failed, or such combined programs are not available. (Airaksinen, 2006) The ECRI health technology assessment concluded that the evidence is insufficient to support lumbar fusion being more effective (to a clinically meaningful degree) than nonsurgical treatments (intensive exercise and rehabilitation plus cognitive behavioral therapy) in patients with and without prior surgery. (ECRI, 2007) In response to a denial of coverage by BlueCross, the presidents of AAOS, NASS, AANS, CNS, and SAS issued a joint statement to BlueCross recommending patient selection criteria for lumbar fusion in degenerative disc disease. The criteria included at least one year of physical and cognitive therapy, inflammatory endplate changes (i.e., Modic changes), moderate to severe disc space collapse, absence of significant psychological comorbidities (e.g. depression, somatization disorder), and absence of litigation or compensation issues. The criteria of denying fusion if there are compensation issues might apply to workers' compensation patients. (Rutka, 2011) The Washington State Department of Labor & Industries 2009 guidelines recommend lumbar fusion in workers' compensation only for radiographically documented instability and for grade 2 or greater spondylolisthesis. (Washington, 2009) The draft AHRQ Comparative Effectiveness Research concluded that limited data suggests that fusion leads to greater improvement in back pain relief and function than physical therapy at 2-year follow-up, but whether the difference is clinically significant is unclear, and serious adverse events occurred in the fusion group but not the noninvasive-intervention group. (Clancy, 2012)

OTHER CONSIDERATIONS:

Surgical decision making: There is a lack of consensus regarding the utility of tests to assist decision making for lumbar fusion in chronic back pain patients. There is variability in clinician recommendations regarding the need for surgery, as well as the type of surgical procedure advised. A survey of surgeons in the Dutch Spine Society found a lack of consensus regarding the utility of lumbar MRI, discography and immobilization to assist in decision making for fusion. (Willems, 2011) Another study involving surgeons involved in clinical outcomes research found variability in recommendations for surgery vs. non-operative treatment, and the type of fusion surgery when presented with two clinical vignettes of patients with back pain due to lumbar spondylosis and lumbar spondylolysis. (Lee, 2011)

Surgeons were also asked about their recommendations in specific settings compared to related research. Over 30% would consider fusion of three or more levels, 53% would fuse obese and 24% morbidly obese chronic back patients, and 41% would fuse heavy smokers despite evidence of poor outcomes in these surgical groups. A systematic review of the accuracy of tests for patient selection concluded that “no subset of patients with chronic low back pain could be identified for whom spinal fusion is a predictable and effective treatment.” (Willems, 2013) Psychological distress and poor coping skills are factors associated with less optimal outcomes from low back pain care including surgery. However, spine surgeons may have limited ability to detect these conditions. A prospective study of patients presenting for spine evaluation looked at physician clinical impressions of patient psychological distress compared with the results based upon the use of a standardized questionnaire (Distress and Risk Assessment Method [DRAM]). Overall, 64% of patients had some level of psychological distress and 22% were identified as having high levels of distress using the DRAM. However, only 28.7% of patients with high levels of distress were identified by clinical evaluation, with non-operative spine specialists having higher rates of clinical detection (41.7%) of high distress patients than surgeons (19.6%) (Daubs, 2010)

Techniques/implants: Outcomes from complicated surgical fusion techniques (with internal fixation) may be no better than the traditional posterolateral fusion. (van Tulder, 2006) (Maghout-Juratli, 2006) Despite the new technologies, reoperation rates after lumbar fusion have become higher. (Martin, 2007) No obvious additional benefit was noted by combining decompression with an instrumented fusion in patients with single-level degenerative disc disease and foraminal stenosis. (Hallett, 2007) Postmenopausal female patients who underwent lumbar spinal instrumentation fusion were susceptible to subsequent vertebral fractures within 2 years after surgery (in 24% of patients). (Toyone, 2010) See also Bone-morphogenetic protein (BMP). Posterolateral bone-grafting fusion is not necessary when a Denis type-B thoracolumbar burst fracture associated with a load-sharing score of <or=6 is treated with short-segment pedicle screw fixation. (Dai, 2009)

Return to Sports and Work: Literature regarding return to work or return to athletics primarily consists of narrative reviews, observational studies and expert opinion

surveys. According to one publication based upon published research and the author's clinical practice decision making, when lumbar fusion surgery is performed, either with lateral fusion alone or with interbody fusion, unlike cervical fusion, there is no absolute contraindication to patients returning even to contact sports after complete recovery from surgery. Like patients with a thoracic injury, those with a lumbar injury should have no disabling neurological deficit, and exhibit evidence of bone fusion on x-ray films before returning. (Burnett, 2006) A systematic review of literature regarding return to play post lumbar fusion noted the absence of prospective randomized controlled trials. Conclusions based upon low level evidence concluded that a positive return to play decision can be made 6 months after surgery when there is complete anatomical and functional healing, safety issues are addressed during training and competition, sport-specific skills are regained, and the athlete is psychosocially ready. (Niederer, 2014) The authors noted that some patients never manage to return to full contact sports or sports with collisions. An uncontrolled observational study of post-lumbar fusion patients who participated in a 4-week sports conditioning program focusing on strength and endurance noted significant gains in physical demand levels, with 13% in medium, 35.2% medium/heavy, 9.3% heavy and 37% very heavy PDLs. (Cole, 2009)

Return to work in Workers' Comp (WC) patients: See detailed discussion below
Studies assessing return to work after lumbar fusion in workers' compensation have demonstrated limited benefits. A Washington State cohort of workers who underwent lumbar fusion between 1986 and 1987 for a variety of diagnoses observed that 68% were disabled at 2 year follow-up (Franklin, 1994) A subsequent Washington State study of workers who underwent lumbar fusion between 1994 and 2001 reported 63.9% work disability at 2 year follow-up. (Maghout-Juratli, 2006) A retrospective cohort study of workers with lumbar fusion between 1999 and 2006 reported early and later assessments. At the time of the initial report, only 6% of lumbar fusion subjects were able to go back to work a year later (Nguyen, 2007) At two year follow-up, only 26% of workers treated with fusion were able to return to work compared with 67% of subjects evaluated as non-surgical controls. (Nguyen, 2011)

Lumbar fusion in workers' comp (WC) patients: In cases of workers' compensation, patient outcomes related to fusion may have other confounding variables that may affect overall success of the procedure, and which should be considered. It appears that workers' compensation populations require particular scrutiny when being considered for fusion for chronic low back pain, as there is evidence of poorer outcomes in subgroups of patients who were receiving compensation or involved in litigation. (Fritzell-Spine, 2001) (Harris-JAMA, 2005) (Maghout-Juratli, 2006) (Atlas, 2006) (Gum,2013) (Anderson, 2015) Despite poorer outcomes in workers' compensation patients, utilization is much higher in this population than in group health. (Texas, 2001) (NCCI, 2006) In the Washington state system, the most frequent cause of death in those who had had a lumbar fusion was reported as opioid analgesic overdose, suggesting the fusion was not successful. (Juratli , 2009)

Pre-surgical biopsychosocial variables predict patient outcomes from lumbar fusion,

which may help improve patient selection. Workers' compensation status, smoking, depression, and litigation were the most consistent pre-surgical predictors of poorer patient outcomes. (DeBerard-Spine, 2001) (DeBerard, 2003) (Deyo, 2005) (LaCaille, 2005) (Maghout-Juratli, 2006) (Trief-Spine, 2006) Clinical depression is a strong predictor of poor lumbar fusion outcomes among workers' compensation subjects. (Anderson, 2015b) Obesity and litigation in workers' compensation cases predict high costs associated with interbody cage lumbar fusion. (LaCaille, 2007) A systematic review found some evidence that catastrophizing is associated with worse outcomes including pain and disability in patients with acute, subacute, and chronic low back pain, and thus could impact post-fusion outcomes as well. (Wertli, 2014)

The series of retrospective cohort studies in Washington State and Ohio noted in the return to work section have shed additional light on lumbar fusion outcomes in worker's compensation patients. (Franklin, 1994) (Maghout-Juratli, 2006) (Nguyen, 2007) (Nguyen, 2011) The outcomes of lumbar fusion in worker's compensation in Washington State included 67.7% reporting increased pain and 55.8% no improvement in quality of life. Further surgery was performed in 23%. (Franklin, 1994) Repeat surgery was performed in 22.1% of workers' compensation fusion patients in the second Washington State study. (Maghout-Juratli, 2006) The authors also assessed post-operative and three year mortality, observing that 21% of all deaths were associated with analgesic use, with increased risks associated with instrumented fusions and patients diagnosed with degenerative disc disease. (Juratli, 2009) The Ohio study of workers' compensation patients who had lumbar fusion found that a year later, 27% needed another operation, and over 90% were in enough pain that they were still taking narcotics at follow-up. (Nguyen, 2007) At two years follow-up, 76% continued opioid use with an estimated 41% increase in mean daily opioid dose (MED). This large historical cohort study suggests that lumbar fusion may not be an effective operation in workers' compensation patients with disc degeneration, disc herniation, and/or radiculopathy, and it is associated with significant increase in disability, opioid use, prolonged work loss, and poor RTW

status. (Nguyen, 2011)

A comparative study evaluated pain, function and general health status outcomes after lumbar fusion in worker's compensation patients vs. a matched group. The authors concluded that only 9% of patients receiving worker's compensation achieved substantial clinical benefit in function compared to 33% of those not receiving worker's compensation. (Carreon, 2009) After controlling for covariates known to affect lumbar fusion outcomes, patients receiving workers' comp have significantly less improvement, including only 19% with minimum clinically significant improvement in disability and 16% in physical health status. (Carreon, 2010) Another study demonstrated a significant difference in outcomes after lumbar spinal fusion between workers' comp populations and those on long-term disability or government supported insurance. Both populations only achieved marginal improvement after lumbar fusion, but workers' compensation had a clear, negative influence on outcome even when compared to other disability compensation patients. (Gum, 2012) Another cohort study comparing single level lumbar fusion

outcomes for workers' compensation (WC) subjects with degenerative disc disease (DDD) vs. spondylolisthesis concluded that DDD is a questionable indication for spinal fusion. (Anderson, 2015) Based on thirty-one studies (12 involved only decompression, 19 were fusion), workers' compensation patients have a two-fold increased risk of an unsatisfactory outcome from spine surgery compared with non-compensated patients after surgery. (Cheriyan, 2015)

Risk versus benefit: For non-recommended conditions, there are equivalent outcomes of pain, function, and quality of life in RCTs comparing conservative care with cognitive behavioral and rehabilitation exercise vs. lumbar fusion. However, fusion is associated with significant risks in these RCTs. Early complications were identified in 18% with a fusion rate of 84% according to one RCT (Brox-Spine, 2003), with 9% early complications in their subsequent RCT. (Brox, 2006) Another large RCT observed surgical complications in 14% with repeat surgery performed in 8% within 2 years. (Fairbank-BMJ, 2005) Lumbar fusion outcomes studies have also noted significant surgical risks including complications and repeat surgery. Surgical complications were reported from 11.8% (Maghout-Juratli, 2006) up to 36%. (Nguyen, 2011) Observations regarding the rate of repeat surgery were reported as 23% (Franklin, 1994), 24% (DeBerard-Spine, 2001), 22.1% (Maghout-Juratli, 2006), and 27% (Nguyen, 2011). Risks are even greater in obese patients undergoing lumbar spine fusion surgery. The incidence of postoperative complications was significant in 45% of morbidly obese and 44% of obese patients. The authors proposed that morbidly obese patients should undergo bariatric surgery before spine fusion surgery. (Vaidya, 2009) There is a high rate of complications (56.4%) in spinal fusion procedures, especially related to instrumentation. (Campbell, 2011) The type of fusion procedure may also affect perioperative morbidity and mortality, with procedure related complications in 15.7% for Posterior Spinal Fusion, 18.7% for Anterior Spinal Fusion and 23.8% for Anterior/Posterior Spinal Fusion patients. (Memtsoudis, 2011) Another long term complication to consider is described in Adjacent segment disease/degeneration.

A systematic review by the International Society for the Study of the Lumbar Spine estimated the odds of common complications associated with spinal surgery with a goal of helping surgeons provide evidence based information to patients. (Ng, 2011)

Additional risk considerations include potential continued and increased opioid use post-fusion. At two years follow-up, 76% of post-fusion Ohio cohorts were still taking opioids. Estimated increase in mean opioid MED was 41% post fusion in the Ohio study. (Nguyen, 2011) (Anderson, 2015c) The 3-year cumulative mortality rate in the Washington State study post-fusion was 1.93% and analgesic-related deaths were responsible for 21% of all deaths and 31.4% of all potential life lost. (Juratli, 2009)

NNH/NNT: Without taking into account specific risk factors, like smoking, obesity, or workers’ comp, the NNH (number needed to harm) is about 2, and the NNT (number needed to treat) about 10, compared to conservative treatment.

Patient Selection Criteria for Lumbar Spinal Fusion:

(A) Recommended as an option for the following conditions with ongoing symptoms, corroborating physical findings and imaging, and after failure of non-operative treatment (unless contraindicated e.g. acute traumatic unstable fracture, dislocation, spinal cord injury) subject to criteria below:

(1) Spondylolisthesis (isthmic or degenerative) with at least one of these:

(a) instability, and/or

(b) symptomatic radiculopathy, and/or

(c) symptomatic spinal stenosis;

(2) Disc herniation with symptomatic radiculopathy undergoing a third decompression at the same level;

(3) Revision of pseudoarthrosis (single revision attempt);

(4) Unstable fracture;

(5) Dislocation;

(6) Acute spinal cord injury (SCI) with post-traumatic instability;

(7) Spinal infections with resultant instability;

(8) Scoliosis with progressive pain, cardiopulmonary or neurologic symptoms, and structural deformity;

(9) Scheuermann's kyphosis;

(10) Tumors.

(B) Not recommended in workers' compensation patients for the following conditions:

(1) Degenerative disc disease (DDD);

(2) Disc herniation;

(3) Spinal stenosis without degenerative spondylolisthesis or instability;

(4) Nonspecific low back pain.

(C) Instability criteria: Segmental Instability (objectively demonstrable) - Excessive motion, as in isthmic or degenerative spondylolisthesis, surgically induced segmental instability and mechanical intervertebral collapse of the motion segment and advanced degenerative changes after surgical discectomy, with relative angular motion greater than 15 degrees L1-2 through L3-4, 20 degrees L4-5, 25 degrees L5-S1. Spinal instability criteria includes lumbar inter-segmental translational movement of more than 4.5 mm. (Andersson, 2000) (Luers, 2007) (Rondinelli, 2008)

(D) After failure of two discectomies on the same disc [(A)(2) above], fusion may be an option at the time of the third discectomy, which should also meet the ODG criteria. (See ODG Indications for Surgery -- Discectomy.)

(E) Revision Surgery for failed previous fusion at the same disc level [(A)(3) above] if there are ongoing symptoms and functional limitations that have not responded to non-operative care; there is imaging confirmation of pseudoarthrosis and/or hardware breakage/malposition; and significant functional gains are reasonably expected. Revision surgery for purposes of pain relief must be approached with

extreme caution due to the less than 50% success rate reported in medical literature. Workers compensation and opioid use may be associated with failure to achieve minimum clinically important difference after revision for pseudoarthrosis (Djurasovic, 2011) There is low probability of significant clinical improvement from a second revision at the same fusion level(s), and therefore multiple revision surgeries at the same level(s) are not supported.

(F) Pre-operative clinical surgical indications for spinal fusion should include all of the following:

(1) All physical medicine and manual therapy interventions are completed with documentation of reasonable patient participation with rehabilitation efforts including skilled therapy visits, and performance of home exercise program during and after formal therapy. Physical medicine and manual therapy interventions should include cognitive behavioral advice (e.g. ordinary activities are not harmful to the back, patients should remain active, etc.);

(2) X-rays demonstrating spinal instability and/or myelogram, CT-myelogram, or MRI demonstrating nerve root impingement correlated with symptoms and exam findings;

(3) Spine fusion to be performed at one or two levels;

(4) Psychosocial screen with confounding issues addressed; the evaluating mental health professional should document the presence and/or absence of identified psychological barriers that are known to preclude post-operative recovery;

(5) For any potential fusion surgery, it is recommended that the injured worker refrain from smoking for at least six weeks prior to surgery and during the period of fusion healing; (Colorado, 2001) (BlueCross BlueShield, 2002)

(6) There should be documentation that the surgeon has discussed potential alternatives, benefits and risks of fusion with the patient;

(7) For average hospital LOS after criteria are met, see Hospital length of stay (LOS)