AccuReview An Independent Review Organization 569 TM West Parkway West, TX 76691 Phone (254) 640-1738 Fax (888) 492-8305

January 2, 2018

IRO CASE #: XXXXX

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Left L5/S1 transforaminal lumbar interbody fusion, stability spine: alphatec arsenal (rods & screws) cage is (Novel) precision assist, monitoring concepts, 22633, 22840, 22851, 22612, 20936, 20930

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

This physician is Board certified in Orthopaedic Surgery with over 15 years of experience.

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 <u>each</u> of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a XXXX sustained a work-related lumbar injury on XXXX, with subsequent lumbar and left lower extremity symptoms. XXXX has been treated in the past with activity modification, medications, ESIs with little or no relief.

XXXX: MRI of the Lumbar Spine without Contrast dictated by XXXX. Impression: 1. Bulging disc at L4-L5 with some compromise of the neural foramine bilaterally. 2. Protruding disc paramedian to the left at the L5-S1 level with compromise of the left neural foramen.

XXXX: Encounter dictated by XXXX. CC: claimant stated XXXX was XXXX injury XXXX lower back happen XXXX. C/O back pain and left leg pain. Current medications: Lyrica 150mg, methocarbamol 500mg, tramadol 50mg, tramadol ER 200mg. PE: +SLR on left side. We are going to repeat the MRI of XXXX lumbar spine due to biggest problem being low back pain. Assessment: M54.5 low back pain, S39.012S strain of muscle, fascia and tendon of lower back, initial encounter.

XXXX: MRI Lumbar Spine without contrast dictated by XXXX. Impression: 1. There is a focal bridging osteophyte formation along the left lateral region at the L5/S1. This produces moderate narrowing of the left neuroforamen and the anatomic images suggest impingement of the exiting portion

of the left L5 nerve root. The osteophyte formation also closely approaches, and may displace the descending portion of the left S1 nerve root. Recommend correlation with claimant's clinical presentation to help determine the presence or absence of radicular symptoms within the distribution of the left L5 and S1 nerve roots as described above. 2. Mild degenerative disc disease and bilateral facet arthropathy at L4/L5. 3. Other findings are normal.

XXXX: Encounter dictated by XXXX. CC: low back pain, not improving and with leg pain. Assessment/Plan: The claimant has left-sided foraminal disk herniation at L5-S1 and has had symptoms for quite some time now with imaging findings that match the symptoms. This is causing compression of the left side S1 nerve roots. Suggest that surgery might be indicated due to failed ESIs and oral pain medication. XXXX asked for MMI. 1. Displacement of lumbar intervertebral disc without myelopathy.

XXXX: MMI dictated by XXXXX. MMI Discussion: The claimant has reached a point of statutory MMI effective XXXX. However, XXXX is not at Clinical MMI and is pending lumbar surgery therefore further material recovery and last improvement to XXXX current symptoms can be reasonably anticipated.

XXXX: UR performed by XXXX. Reason for denial: The claimant has never had surgery at the L5-S1 level. There is no documentation of a preop psychiatric evaluation. There is no evidence of fracture/instability/spondylolisthesis at the L5-S1 level. The documented physical exam does little to indicate an L5 or S1 left radiculopathy. XXXX documentation does not fulfill the ODG criteria for lumbar fusion, and the request is therefore non-certified.

XXXX: UR performed by XXXX. Reason for denial: The claimant has persistent low back pain going down XXXX left leg. Exam revealed TTP, spasms and guarding the lumbar spine with decreased painful ROM. XXXX had radicular pain and sensory changes following the left L5 and S1 nerve distribution. Imaging corroborated the clinical pathology with moderate narrowing of the left neuroforamen, suggestion impingement of the exiting portion of the left L5 nerve root. The osteophyte formation also closely approaches and may displace, the descending portion of the left S1 nerve root. Reasonable non-operative treatment in the form of physical therapy, medications, injections and activity modifications has been tried and failed. However, dynamic flexion/extension x-rays demonstrating instability, reference to impending intra-operative instability and/or a psychosocial screen are not instability, reference to impending intra-operative instability and/or a psychosocial screen are not documented. Therefore, this request is not medically reasonable and necessary, at this time.

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

The request for left L5/S1 transforaminal lumbar interbody fusion with posterior spinal fusion is denied. This claimant is a XXXX who was injured in XXXXX. XXXX has back and left lower extremity symptoms. XXXX has failed epidural steroid injections and oral pain medication. XXXX most recent MRI (XXXXX) documents mild degenerative disc bulges at L4-5 and L5-S1. XXXX has moderate narrowing of the left neuroforamen at L5-S1. The treating physician has recommended a transforaminal interbody fusion with posterior spinal fusion. The Official Disability Guidelines (ODG) supports spinal fusion in patients with spinal instability or fracture. Spine fusion is not recommended in workers' compensation patients with degenerative disc disease or disc herniation. Psychological screening is required prior to spinal fusion. This claimant has no documentation of spondylolisthesis or instability at L5-S1. XXXX has had no psychological screening. Therefore, after reviewing the medical records and documentation provided, the request for Left L5/S1 transforaminal lumbar interbody fusion, stability spine: alphatec arsenal (rods & screws) cage is (Novel) precision assist, monitoring concepts, 22633, 22840, 22851, 22612, 20936, 20930 is not medically necessary and denied.

Per ODG:

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 <u>Blue Patient Selection Criteria</u> 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 <u>Surgical decision making</u>, <u>Return to Work</u>, <u>Lumbar fusion in workers' comp</u>, and <u>Risk versus benefit</u>. See also <u>Adjacent segment</u> <u>disease/degeneration</u> (fusion) and <u>Iliac crest donor-site pain treatment</u>.

Patient Selection Criteria for Lumbar Spinal Fusion:

- (A) <u>Recommended</u> 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) <u>Instability criteria</u>: 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 include 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 SurgeryTM -- 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) <u>Pre-operative clinical surgical indications</u> 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) <u>Psychosocial screen</u> 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 <u>Hospital length of stay</u> (LOS).

	TO MAKE THE DECISION:	
ACOEM- AMERICAN CO UM KNOWLEDGEBASE	DLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICIN	ΙE
☐ AHCPR- AGENCY FOR I	IEALTHCARE RESEARCH & QUALITY GUIDELINES	
☐ DWC- DIVISION OF WO	RKERS COMPENSATION POLICIES OR GUIDELINES	
☐ EUROPEAN GUIDELINE	S FOR MANAGEMENT OF CHRONIC LOW BACK PAIN	
☐ INTERQUAL CRITERIA		
MEDICAL JUDGEMENT WITH ACCEPTED MEDI	, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCI CAL STANDARDS	E
☐ MERCY CENTER CONS	ENSUS CONFERENCE GUIDELINES	
☐ MILLIMAN CARE GUID	ELINES	
⊠ ODG- OFFICIAL DISABI	LITY GUIDELINES & TREATMENT GUIDELINES	
☐ PRESSLEY REED, THE M	MEDICAL DISABILITY ADVISOR	
☐ TEXAS GUIDELINES FO PARAMETERS	R CHIROPRACTIC QUALITY ASSURANCE & PRACTICE	
☐ TEXAS TACADA GUIDE	LINES	
☐ TMF SCREENING CRITI	CRIA MANUAL	
☐ PEER REVIEWED NATION DESCRIPTION)	ONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A	
	ED, SCIENTIFICALLY VALID, OUTCOME (PROVIDE A DESCRIPTION)	