

AccuReview

An Independent Review Organization

569 TM West Parkway

West, TX 76691

Phone (254) 640-1738

Fax (888) 492-8305

Notice of Independent Review Decision

[Date notice sent to all parties]: September 16, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Purchase of bone growth stimulator; LSO off the shelf back brace; continuous cryotherapy unit rental x7 days; DVT venapro device

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

This physician is Board Certified Neurological Surgeon with over 23 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 each of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant experienced a low back injury on xx/xx/xx.

01-28-14: Lumbar Spine 7-Views. Impression: 1. 2-3 mm retrolisthesis of L4 vertebral body with reference to L5 in the standing lateral flexion view which gets reduced in the standing lateral extension view. 2. 2 mm anteriorlisthesis of L3 vertebral body in the standing lateral flexion view which gets reduced in the standing lateral extension view. 3. Early degenerative disc disease is seen involving the lumbar spine.

01-28-14: MRI of the Lumbar Spine w/wo Contrast. Conclusion: 1. Disc protrusion on the left side at L5-S1 level with downward displacement of the left S1 nerve root. 2. No evidence of central spinal canal stenosis. 3. No evidence of spondylosis or spondylolisthesis.

01-28-14: Lumbosacral Spine Series, Seven Views. Impression: 1. Grade 1 retrolisthesis at L5-S1 with 2 mm of posterior subluxation of the L5 vertebra. MRI of the Lumbar Spine w/o and with contrast: Impression: 1. Grade 1 retrolisthesis at L5-S1 with 2 mm of posterior subluxation of the L5 vertebra. 2. 4 mm recurrent left paracentral disc protrusion at L5-S1, which mildly impinges upon the thecal sac and the left S1 nerve root. There is also scar tissue which fills the remaining portion of the lateral recess. The area of enhancement measures 8 x 2 x 10 mm. 3. 2 mm posterior central disc protrusion at L4-L5, which mildly impinges upon the thecal sac. 4. Mild disc desiccation at L5-S1 with a full-thickness annular tear seen in the posterior fibers of the disc.

02-03-14: Follow-up Visit. Claimant is status post a lumbar microdiscectomy, laminectomy, Foraminotomy and partial facetectomy at L5-S1 on the left performed July 30, 2013. Claimant complained of low back pain with radiation into the left lower extremity along the lateral thigh and calf, and intermittently into the lateral aspect of the left foot with associated numbness and tingling in a similar distribution. The claimant also describes no improvement in the weakness and numbness in the right lower extremity along the lateral thigh and calf, and intermittently into the dorsum of the right ankle. Current pain rated 7/10 with worsening symptomatology following prolonged sitting, standing, coughing, sneezing and Valsalva maneuver. Neurological Examination: Lumbar ROM was decreased in forward flexion secondary to pain. Motor exam revealed 4/5 strength of the tibialis anterior and extensor hallucis longus muscles on the right, and there is 4/5 strength of the gastrocnemius muscles on the left, otherwise 5/5 throughout. Deep tendon reflexes were +1 of the ankle jerk on the left, otherwise +2 throughout and symmetrical. Claimant had marked difficulty with heel and toe walk secondary to pain; tandem walk was also difficult secondary to pain. SLR positive bilaterally, right side greater than left, at 45 degrees. Sensory exam revealed a hypoesthetic region over the L5 distribution on the right and S1 distribution on the left to pin prick and light touch, otherwise intact. Impression: 1. Recurrent lumbar radiculopathy. 2. Lumbar spondylolisthesis at L4-5 and L5-S1, grade I. 3. Lumbar mechanical/discogenic pain syndrome. 4. Recurrent herniated nucleus pulposus at L4-5 and L5-S1. 5. Lumbago, status post lumbar microdiscectomy, laminectomy, Foraminotomy and partial facetectomy at L5-S1 on the left for a previous history of lumbar radiculopathy. Recommendations: Evaluation for epidural steroid therapy.

05-05-14: Follow-up Visit. Claimant has completed therapy with no improvement at all in his previous symptomatology which he described as low back pain with radiation into the left lower extremity along lateral thigh and calf, and intermittently in the lateral aspect of the left foot with associated numbness and tingling in a similar distribution. He described no improvement in the weakness and numbness in the right lower extremity along the lateral thigh and calf, and intermittently into the dorsum of the right ankle. Claimant stated current pain level 8/10 with worsening symptomatology following prolonged sitting, standing, coughing, sneezing and Valsalva maneuver. PE unchanged. Impression: 1. Recurrent lumbar radiculopathy. 2. Lumbar spondylolisthesis at L4-5 and L5-S1,

grade I. 3. Lumbar mechanical/discogenic pain syndrome. 4. Recurrent herniated nucleus pulposus at L4-5 and L5-S1. 5. Lumbago, status post lumbar microdiscectomy, laminectomy, Foraminotomy and partial facetectomy at L5-S1 on the left for a previous history of lumbar radiculopathy. Recommendations: Due to failure of conservative medical therapy including PT and epidural steroid therapy, current neurologic status with evidence of the large recurrent disc herniation at L4-5 paracentral and to the right with moderate facet and ligamentum flavum hypertrophy contributing to right sided foraminal and lateral recess stenosis, the anteriorlisthesis of L4 on L5 approximately 63-4 mm which reduces upon extension as well as the recurrent disc herniation at L5-S1 paracentrally and to the left approximately 3-4 mm with contact of the S1 nerve root on the left and foraminal and lateral recess stenosis on the left, in addition to a slight retrolisthesis of L5 on S1, recommend: anterior lumbar interbody fusion at L4-5 and L5-S1 with posterior lumbar decompression, posteriolateral fusion and pedicle screw instrumentation at L4-5 and L5-S1.

05-28-14: Pre-Surgical Consultation and Behavioral Assessment (Update Report). Impressions: There is a strong indication that the claimant is experiencing pain that is creating interference in his life. It appears as though he is having long-term adjustment problems of depression and anxiety which are secondary to his work-related injury. DSM-IV: Axis I: 307.89 Chronic pain disorder associated with both psychological factors and a general medical condition; Axis II: V71.09 deferred; Axis III: 722.10, 738.4, 724.4, 724.2; Axis IV: chronic pain, financial struggles, multiple social losses, and problem with family; Axis V: GAF=60. Conclusions and Recommendations: Recommended that the treating physician continue with medical lines of treatment and assist the claimant with his recovery. The claimant's BDI-II: 36 and BAI: 32 are in the severe range, reflecting symptoms of depression and anxiety. Any physical complaints and emotional stressors that the claimant reported experiencing are most likely due to the chronic nature of his pain and his want to recover and return to an active and fulfilling lifestyle. Recommend anterior lumbar interbody fusion at L4-5 and L5-S1 with posterior lumbar decompression, posteriolateral fusion and pedicle screw instrumentation at L4-5 and L5-S1.

07-11-14: Peer Review. Approved anterior lumbar interbody fusion at L4-5 and L5-S1, posterior lumbar decompression with posteriolateral fusion and pedicle screw instrumentation at L4-5 and L5-S1 (22558, 22585, 22851, 20902, 38220, 77002, 95937, 22612, 22614, 63047, 63048, and 22842) with a 2 day stay.

08-06-14: Certificate of Medical Necessity. Lumbar equipment: bone growth stimulator, LSO brace; Electric Therapy: TENS unit w/supplies, conductive garment, hot/cold therapy system. Other equipment ordered: DVT for home use.

08-13-14: Letter of Medical Necessity. On 8/21/14 the claimant is scheduled to undergo a 360 fusion of L4-5 and L5-A1. In this procedure the patient is operated on from both the front and the back. The surgery is medically necessary to stabilize the area fusion. Due to the nature of this procedure there is associated significant muscular weakness. In addition the claimant's post-operative condition

puts him at a significant risk predisposing him to a potential injury and or exacerbation. Therefore, by placing him in a L0637 chair-back brace post surgically that they have a greater sense of muscular comfort and stability which leads to a faster or greater mobilization, a reduced hospital stay, faster recovery, reduced adhesion, a faster transition to post surgical PT and a greater recovery rate by patients. Upon review of this claimant's medical and approved surgical procedure, this brace is medically necessary for the above noted reasons.

08-15-14: UR. Reason for denial: The request was modified. Request: purchase of bone growth stimulator; LSO off the shelf back brace; continuous cryotherapy unit rental x7 days; DVT venapro device. Peer review rationale correlated with applied guideline: The ODG guidelines criteria for use for invasive or non-invasive electrical bone growth stimulators includes (3) Fusion to be performed at more than one level. The claimant specifically meets criteria #3. As such, medical necessity of the request for purchase of the bone growth stimulator is supported. The ODG guidelines indicate: Postoperative back braces are: Under study. The ODG guidelines do not address the need for continuous cryotherapy, notes appropriate use of cold packs only. The ODG guidelines do not address use of DVT Venapro device. AS such, the medical necessity of the requested: The request for the purchase of bone growth stimulator is medically necessary with the application of the ODG guidelines. The remaining DME: LSO off the shelf back brace, continuous cryotherapy unit rental x7 days, DTV Venapro device is not medically necessary with the application of the ODG guidelines. This modification was agreed upon per the discussion.

08-21-14: UR. The ODG guidelines Low Back Chapter states regarding lumbar supports. Not recommended for prevention. There is strong and consistent evidence that lumbar supports were not effective in preventing neck and back pain. Treatment: Recommend as an option for compression fractures and specific treatment of spondylolisthesis, documented instability, and for treatment of nonspecific LBP (very low-quality evidence, however, may be a conservative option). Under study for post-operative use. This is an off the shelf model and it would meet this portion of the guideline under study for post-operative use. The doctor's letter of necessity from 08/13/14 describes 360-degree fusion at L4-L5 and L5-S1 and he describes a potential for muscle weakness following these types of surgeries as a matter of course of having watched other patients following this type of surgery. The request would be supported and would essentially meet the guidelines in this particular incident with a two-level fusion. However, without provider or designee contact, it was not possible to modify this request. Therefore, medical necessity of this request has not been established. The ODG guidelines Low Back Chapter does not discuss cryotherapy units following fusion surgery; however the ODG Shoulder and Knee Chapters state regarding cryotherapy, recommend as an option after surgery, however, not for nonsurgical treatment. Postoperative use generally may be up to 7 days, including home use. In the postoperative setting, continuous-flow cryotherapy units have been proven to decrease pain, inflammation, swelling, and narcotic usage; however, the effect on more frequently treated acute injuries (e.g., muscle strains and contusions) has not been fully evaluated. Continuous-flow

cryotherapy units provide regulated temperatures through use of power to circulate ice water in the cooling packs. Complications related to cryotherapy (i.e., frostbite) are extremely rare however, can be devastating. For their continuous cold cryotherapy unit, seven-day rental, ODG guidelines would recommend that continuous cold therapy is recommended for a post-operative use as a seven-day rental following the surgery however, not for non-operative use. Therefore, a seven-day rental would be supported within guidelines. However, without provider or designee contact to modify this request, medical necessity of this request has not been established. The ODG Low Back chapter does not discuss this type of DME following fusion surgery; however, the ODG Knee and Leg Chapter was referenced and states regarding venous thrombosis, recommend identifying subjects who are at a high risk of developing venous thrombosis and providing prophylactic measures such as consideration for anticoagulation therapy. Minor injuries in the leg are associated with greater risk of venous thrombosis. This guideline further states a venous thrombosis is a blood clot that forms within a vein. Deep vein thrombosis (DVTs) form in the deep veins of the legs, and if a piece of blood clot formed in a vein breaks off it can be transported to the right side of the heart, and from there into the lungs, and is called an embolism, and this process called a venothromboembolism (VTE). In regards to the VenaPro device, the ODG guidelines would recommend identifying patients at risk of developing DVT. In this case, there is no info on DVT risk to support the part of request. Therefore, medical necessity of this request has not been established.

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

The previous adverse determinations are upheld and agreed upon. This surgery is not indicated based on the data presented so none of these devices (bone growth stimulator, LSO, cryotherapy and/or DVT venapro) are necessary. The patient’s lumbar x-rays and MRI from January 2014 don’t reveal a right sided disc bulge to explain any right leg symptoms. There is a disagreement between the levels of retrolithesis as reported. The amount of movement reported is minimal at 2-3 mm and there is no pars defect or spondylolisthesis to justify a fusion. The patient’s psychological profile reveals long term problems of depression and anxiety and yet does not indicate that these have been adequately addressed. The treatment of severe depression and anxiety is a requirement before any fusion surgery can be undertaken. There is no explanation for this patient’s leg weakness and numbness which raises a concern for neuropathy which needs to be assessed with EMG/NCVs of lower extremities. There is no MRI support for a “large recurrent disc bulge at L4/5” that notes. This surgery should be denied because of the issues above and this eliminates the need to consider a brace, cold packs, or DVT device. After review of the medical records and documentation provided, there is no medical necessity for the requested Purchase of bone growth stimulator; LSO off the shelf back brace; continuous cryotherapy unit rental x7 days; DVT venapro device and therefore denied.

Per ODG:

Cold/heat packs	Recommended as an option for acute pain. At-home local applications of cold packs in
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	<p>first few days of acute complaint; thereafter, applications of heat packs or cold packs. (Bigos, 1999) (Airaksinen, 2003) (Bleakley, 2004) (Hubbard, 2004) Continuous low-level heat wrap therapy is superior to both acetaminophen and ibuprofen for treating low back pain. (Nadler 2003) The evidence for the application of cold treatment to low-back pain is more limited than heat therapy, with only three poor quality studies located that support its use, but studies confirm that it may be a low risk low cost option. (French-Cochrane, 2006) There is minimal evidence supporting the use of cold therapy, but heat therapy has been found to be helpful for pain reduction and return to normal function. (Kinkade, 2007) See also Heat therapy; Biofreeze@ cryotherapy gel.</p>
<p>Bone growth stimulators (BGS)</p>	<p>Criteria for use for invasive or non-invasive electrical bone growth stimulators: Either invasive or noninvasive methods of electrical bone growth stimulation may be considered medically necessary as an adjunct to spinal fusion surgery for patients with any of the following risk factors for failed fusion: (1) One or more previous failed spinal fusion(s); (2) Grade III or worse spondylolisthesis; (3) Fusion to be performed at more than one level; (4) Current smoking habit (Note: Other tobacco use such as chewing tobacco is not considered a risk factor); (5) Diabetes, Renal disease, Alcoholism; or (6) Significant osteoporosis which has been demonstrated on radiographs. (Kucharzyk, 1999) (Rogozinski, 1996) (Hodges, 2003)</p>

Venous thrombosis

Recommend identifying subjects who are at a high risk of developing venous thrombosis and providing prophylactic measures such as consideration for anticoagulation therapy. Minor injuries in the leg are associated with greater risk of venous thrombosis. The relative risk for venous thrombosis is 3-fold greater following minor injury, especially if injury occurs in the 4 weeks prior to thrombosis, is located in the leg, and involves multiple injuries or rupture of muscle or ligament. Risk for venous thrombosis is higher in those with leg injury combined with family history of venous thrombosis (12-fold risk), Factor V Leiden mutation (50-fold risk), or Factor II 20210A mutation (9-fold risk). ([van Stralen, 2008](#)) A venous thrombosis is a blood clot that forms within a vein. Deep venous thromboses (DVTs) form in the deep veins of the legs, and if a piece of a blood clot formed in a vein breaks off it can be transported to the right side of the heart, and from there into the lungs, and is called an embolism, and this process called a venothromboembolism (VTE). Risk factors for venous thrombosis include immobility, surgery, and prothrombotic genetic variants. Studies have addressed the risk for thrombosis following major injury, and minor events, including travel, minor surgery, and minor trauma, are linked to a 3-fold increased risk for venous thrombosis. Venothromboembolism (VTE) is an important condition in hospitalized patients accounting for significant morbidity and mortality. Those at high risk should be considered for anticoagulation therapy during the post-hospitalization period. ([Yale, 2005](#)) Aspirin may be the most effective choice to prevent pulmonary embolism (PE) and venous thromboembolism (VTE) in patients undergoing orthopaedic surgery, according to a new study examining a potential role for aspirin in these patients. Patients who received aspirin had a lower VTE risk score than the patients who received warfarin. Patients who received aspirin had a much lower use of sequential compression devices than high-risk patients, but even aspirin patients should receive sequential compression as needed. ([Bozic, 2008](#)) Patients with suspected deep vein thrombosis (DVT) of the lower extremities are usually investigated with ultrasonography either by the proximal veins (2-point ultrasonography) or the entire deep vein system (whole-leg ultrasonography). The latter approach is thought to be better based on its ability to detect isolated calf vein thrombosis; however, it requires skilled operators and is mainly available only during working hours. These two ultrasound-based evaluations, both with their advantages and disadvantages, are about equally effective at guiding the management of patients with suspected lower-extremity deep-vein thrombosis (DVT), conclude the authors of a large RCT reported in JAMA. But the writer of an accompanying editorial gives the edge to one of the techniques (2-point ultrasonography), the one that's been around longer and is simpler and probably more widely available. However, the use of 2-point ultrasonography to diagnose DVT frequently requires repeated testing in 1 week to detect calf DVT, which can extend to the proximal veins. Whole-leg Doppler ultrasonography generally obviates this requirement, making 1-day testing possible. ([Bernardi, 2008](#)) A systematic review looked at 5 types of interventions used to prevent thromboembolism in pelvic and acetabular fracture patients: mechanical compression devices, inferior vena cava filters, low-molecular weight heparins, ultrasound screening, and magnetic resonance venography screening. They concluded that there was limited data to guide which method to choose. ([Slobogean, 2009](#)) Using data from the prospective Million Women Study in the UK, new research suggests that the risk of venous thromboembolism (VTE) after surgery is greater and lasts for longer than has previously been appreciated. They show that the risk is greatest in the first six weeks following surgery, peaking around three weeks afterward. But most patients receive prophylaxis only for the duration of their hospital stay, which averaged around six days. Risk also varied considerably by type of surgery, being highest after inpatient surgery for hip or knee replacement (relative risk 221). Overall, one in 140 women will be admitted to the hospital with VTE during the 12 weeks after any inpatient surgery, one in 45 after hip- or knee-replacement surgery, and one in 85 after surgery for cancer. This compares with one in 815 after a day case procedure and only one in 6200 women during a 12-week period without surgery. The use of recommended VTE prophylaxis is suboptimal, with only 59% of surgical patients receive recommended treatment. Current evidence suggests it is needed for inpatients undergoing many orthopedic-, general-, and cancer-surgery procedures and should be given for at least seven to 10 days. In addition, prolonged prophylaxis for four to five weeks also shows a net clinical benefit in high-risk patients and procedures. One reason for the poor uptake of VTE prophylaxis is the relative inconvenience of parenteral anticoagulants, such as low-molecular weight heparin (LMWH), the current recommended treatment, and previously the only oral option, warfarin, was not effective

Back brace, post operative (fusion)	<p>Under study, but given the lack of evidence supporting the use of these devices, a standard brace would be preferred over a custom post-op brace, if any, depending on the experience and expertise of the treating physician. There is conflicting evidence, so case by case recommendations are necessary (few studies though lack of harm and standard of care). There is no scientific information on the benefit of bracing for improving fusion rates or clinical outcomes following instrumented lumbar fusion for degenerative disease. Although there is a lack of data on outcomes, there may be a tradition in spine surgery of using a brace post-fusion, but this tradition may be based on logic that antedated internal fixation, which now makes the use of a brace questionable. For long bone fractures prolonged immobilization may result in debilitation and stiffness; if the same principles apply to uncomplicated spinal fusion with instrumentation, it may be that the immobilization is actually harmful. Mobilization after instrumented fusion is logically better for health of adjacent segments, and routine use of back braces is harmful to this principle. There may be special circumstances (multilevel cervical fusion, thoracolumbar unstable fusion, non-instrumented fusion, mid-lumbar fractures, etc.) in which some external immobilization might be desirable. (Resnick, 2005)</p>
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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)**