

Vanguard MedReview, Inc.

4604 Timken Trail
Fort Worth, TX 76137
P 817-751-1632
F 817-632-2619

Notice of Independent Review Decision

February 16, 2015, Amended February 19, 2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

NU Bone Growth Stimulator E0748 x1, NU Continuous Cryo Unit Rental x 7 days E0217 x1, TENS Unit x1 month trial use E0730 x1, Conductive Garment Purchase E0731 x1

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

This reviewer is a Board Certified Orthopedic Surgeon with over 13 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 is a male who underwent posterior fusion and decompression at L5-S1 with pedicle screw fixation on January 13, 2015.

03/21/2014: MRI of the Lumbar Spine without and with contrast. **Impression:** 1. Status post partial discectomy and partial-left sided laminectomy at L5-S1. There is grade 1 retrolisthesis at this segment and a 4mm recurrent left foraminal disc protrusion. The disc protrusion contacts the thecal sac, the left L5 and S1 nerve roots and the foramina and lateral recess. 2. 2 mm posterior central disc protrusion at L4-5 3. 3mm left paracentral disc protrusion at L3-4, which mildly impinges upon the thecal sac and moderately narrows the left lateral recess. 4. 3 mm posterocentral disc protrusion at L2-3. 5. Grade 1 retrolisthesis at L3-4 and L5-S1. 5. Mild disc desiccation and minimal degenerative spondylosis from L3-4

through L5-S1. 7. Acute enhancing annular tears in the posterior fibers of the discs from L2-3 through L5-S1.

03/21/2014: Lumbosacral Spine Series, five views. **Impression:** 1. Grade 1 retrolisthesis at L3-4. 2. Minimal degenerative spondylosis at L2-3 and L3-4.

08/14/2014: Office Visit. **HPI:** is seen in follow up post status a lumbar microdiscectomy, laminectomy, foraminotomy and partial facetectomy at L5-S1 on the left performed August 21, 2013. The patient was last evaluated on May 15, 2014, at which time it was recommended he be evaluated for epidural steroid therapy. The patient has completed therapy with no significant improvement in his previous symptomatology described as aggravated preoperative symptomatology secondary to performing exercises in physical therapy with severe low back pain radiating mainly into the left lower extremity along the lateral thigh and calf and intermittently into the lateral aspect of the left foot with associated numbness in a similar distribution. Pain is described as 5/10 on a visual analog scale with worsening symptomatology following prolonged sitting, standing, cough, sneezing or Valsalva maneuver. **Examination:** Lumbar ROM was decreased in forward flexion secondary to pain. Motor exam reveals 4/5 strength of the gastrocnemius and biceps femoris 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. Plantar responses were flexor bilaterally. Gait: The patient had difficulty with toe walk and less difficulty with heel walk. Tandem walk was within normal limits. Straight leg raise was positive at 40 degrees on the left and negative on the right. Sensory exam reveals a hypoesthetic region over the S1 distribution on the left to pin prick and light touch, otherwise intact. **Impression:** 1. Recurrent Lumbar radiculopathy. 2. Recurrent herniated nucleus pulposus L5-S1. 3. Lumbar mechanical/discogenic pain syndrome. 4. Lumbago, status post lumbar microdiscectomy, laminectomy, foraminotomy and partial facetectomy at L5-S1 on the left. **Recommendations:** Due to failure of conservative medical therapy including physical therapy and epidural steroid therapy, pain duration greater than six months, current neurologic status with evidence of the retrolisthesis of L5 on S1 approximately 3-4 mm with recurrent disc herniation paracentrally and toward the left approximately 4-5mm with associated foraminal component and severe left sided foraminal, lateral, recess stenosis and contact with the L5 and S1 nerve root sheaths on the left, at this time I recommend: 1. Anterior lumbar interbody fusion at L5-S1 with posterior lumbar decompression, posterolateral fusion and pedicle screw instrumentation at L5-S1.

12/29/2014: UR. **Rationale for Denial:** The clinical information submitted for review fails to meet the evidence based guidelines for the requested service. The patient is a 43 year old male who reported an injury on 03/09/2013. The mechanism of injury occurred while he was working as a truck driver, he was pulling a plastic support pad from the left to the right while moving a crate into another place when he felt a pain to the lower back. Diagnoses included lumbar sprain/strain. Past surgical history included a microdiscectomy, laminectomy, foraminotomy, and a facetectomy performed on 08/21/2013. Diagnostic studies included an official MRI of the lumbar spine performed on 03/11/2014 that

revealed a grade 1 retrolisthesis at the L3-4 and the L5-S1, other lumbar vertebrae were in anatomic alignment and position. There is no marrow signal abnormalities and mild degree of disc desiccation and minimal degenerative spondylosis was seen at the L3-4 and L5-S1. The clinical notes dated 08/14/2014 revealed a motor evaluation of 4/5 strength, revealed deep tendon reflexes were 1+ of the ankle jerked on the left, otherwise 2+ throughout and symmetrical. Plantar responses were flexor bilaterally. Gait, the patient had difficulty with toe walk and less difficulty with heel walk. Tandem walk was within normal limits. Straight leg raise was 40 degrees on the left and negative to the right. The sensory examination revealed a hypoesthetic over the S1 distribution on the left to pinprick and light touch otherwise intact. Coordination was intact in finger to toe exam, and rapid alternating movements. The lumbar incision was well healed. Documentation also indicated that the patient had failed conservative medical therapy including physical therapy, epidural steroid injection, and pain duration over 6 months. The recommendation is for an anterior lumbar interbody fusion at the L5-S1 with posterior lumbar decompression, posterolateral fusion and pedicle screw instrumentation at the L5-S1. Review of the guidelines indicate that there is no consistent medical evidence to support the use of a bone growth stimulator. Lumbar back braces are under study, but given the lack of evidence of supporting the use of these devices, a standard brace would be preferred over a custom postop brace depending on the experience and expertise of the treating physician. There is conflicting evidence, so case to case recommendations. The documentation lacked supporting documentation for the use of the back brace. The guidelines indicate that cryotherapy is recommended as an option for acute pain. However, the patient was noted to have chronic lower back pain that is consistent. Additionally, the guidelines state that the TENS unit is for a 1 month home based, and there should be a trial use for a TENS unit. The documentation was not evident that the patient had a trial use of the TENS unit and the documentation did not address the length of time the unit was to be utilized. The conductive garment purchase is a non-ancillary item.

01/13/2015: Operative Report. **Postoperative Diagnosis:** Recurrent lumbar radiculopathy with recurrent disk herniation at L5-S1 **Procedures:** 1. Arthrodesis, posterolateral technique at L5-S1 2. Posterior lumbar laminectomy of L5, partial laminectomy of S1, and bilateral foraminotomies at L5 3. Posterior lumbar laminectomy of L5, partial laminectomy of S1, and bilateral foraminotomies at S1 4. Posterior nonsegmental pedicle screw fixation at L5-S1 bilaterally and 6.5 x 40 mm on the right at S1 and 6.5 x 35 mm on the left at S1 5. Bone marrow aspiration of the left posterior iliac crest 6. Autograft for spine surgery 7. Neuromonitoring of SSEPs, motor evoked potentials, nerve roots, and pedicle screws 8. Use of intraoperative fluoroscopy.

01/20/2015: UR performed. **Rationale for Denial:** Based on clinical information provided, the appeal request for NU Bone Growth Stimulator E0748 x 1; APPEAL NU lumbar back brace off the shelf L0637 x 1; APPEAL NU continuous Cryo Unit Rental x 7 days E0217 x 1; APPEAL VenaPro Compression Device x 2 E0676 x 2; APPEAL TENS unit x 1 month Trial Use E0730 x1; APPEAL Conductive Garment Purchase E0731 x 1 is not recommended as medically necessary. Initial

request was non-certified noting that review of the guidelines indicate that there is no consistent medical evidence to support the use of a bone growth stimulator. Lumbar back braces are under study, but given the lack of evidence of supporting the use of these devices, a standard brace would be preferred over a custom postop brace depending on the experience and expertise of the treating physician. There is conflicting evidence, so case to case recommendations. The documentation lacked supporting documentation for the use of the back brace. The guidelines indicate that cryotherapy is recommended as an option for acute pain. However, the patient was noted to have chronic low back pain that is consistent. Additionally, the guidelines state that the TENS unit is for a 1 month home based, and there should be a trial use for a TENS unit. The documentation was not evident that the patient had a trial use of the TENS unit and the documentation did not address the length of time the unit was to be utilized. The conductive garment purchase is a non-ancillary item. I spoke on 1/16/15 at 10:00AM CDT and the case was discussed. Per our discussion, the patient's BMI currently is 31 and they want to reduce stress on the fusion graft with the lumbar brace. Furthermore, the patient's obesity places him at higher risk for clots. Given this additional information there was a mutual agreement for purchase of the off-the-shelf lumbar brace and use of the venapro compression device only. There were no other noted indications for the remainder of the requested durable medical equipment.

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

The previous adverse determinations are upheld. The following postoperative DME has been requested: NU Bone Growth Stimulator E0748 x1, NU Continuous Cryo Unit Rental x 7 days E0217 x1, TENS Unit x1 month trial use E0730 x1, Conductive Garment Purchase E0731 x1. The patient underwent posterior fusion and decompression at L5-S1 with pedicle screw fixation on January 13, 2015. Bone marrow aspirate and autograft were used for the fusion.

1. Bone growth stimulator: The Official Disability Guidelines (ODG) recommends a bone growth stimulator following spinal fusion for the "high risk" patients who are at risk for pseudoarthrosis. These include failed spinal fusion, grade III or worse spondylolisthesis, multilevel spinal fusion, current smoker, diabetes, renal disease, alcoholism, or significant osteoporosis. This patient does not satisfy any of these criteria.
2. Continuous cryo unit rental x 7 days: This device is not medically necessary following a spinal fusion in this patient. The patient has chronic lower back pain, which does not meet requirements for this device.
3. TENS Unit x1 month trial with conductive garment: There is no evidence that the patient has responded to a TENS unit in the past.

For these reasons, the request for NU Bone Growth Stimulator E0748 x1, NU Continuous Cryo Unit Rental x 7 days E0217 x1, TENS Unit x1 month trial use E0730 x1, Conductive Garment Purchase E0731 x1 are not medically necessary and should be denied.

Per ODG:

Bone growth stimulators (BGS)

Under study. There is conflicting evidence, so case by case recommendations are necessary (some RCTs with efficacy for high risk cases). Some limited evidence exists for improving the fusion rate of spinal fusion surgery in high risk cases (e.g., revision pseudoarthrosis, instability, smoker). ([Mooney, 1990](#)) ([Marks, 2000](#)) ([Akai, 2002](#)) ([Simmons, 2004](#)) There is no consistent medical evidence to support or refute use of these devices for improving patient outcomes; there may be a beneficial effect on fusion rates in patients at "high risk", but this has not been convincingly demonstrated. ([Resnick, 2005](#)) Also see [Fusion](#) for limited number of indications for spinal fusion surgery. See [Knee & Leg Chapter](#) for more information on use of Bone-growth stimulators for long bone fractures, where they are recommended for certain conditions.

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](#))

Lumbar supports

Not recommended for prevention. Recommended as an option for treatment. See below for indications.

Prevention: Not recommended for prevention. There is strong and consistent evidence that lumbar supports were not effective in preventing neck and back pain. ([Jellema-Cochrane, 2001](#)) ([van Poppel, 1997](#)) ([Linton, 2001](#)) ([Assendelft-Cochrane, 2004](#)) ([van Poppel, 2004](#)) ([Resnick, 2005](#)) Lumbar supports do not prevent LBP. ([Kinkade, 2007](#)) A systematic review on preventing episodes of back problems found strong, consistent evidence that exercise interventions are effective, and other interventions not effective, including stress management, shoe inserts, back supports, ergonomic/back education, and reduced lifting programs. ([Bigos, 2009](#)) This systematic review concluded that there is moderate evidence that lumbar supports are no more effective than doing nothing in preventing low-back pain. ([van Duijvenbode, 2008](#))

Treatment: Recommended as an option for compression fractures and specific treatment of spondylolisthesis, documented instability, and for treatment of nonspecific LBP (very low-quality evidence, but may be a conservative option). Under study for post-operative use; see [Back brace, post operative](#) (fusion). Among home care workers with previous low back pain, adding patient-directed use of lumbar supports to a short course on healthy working methods may reduce the number of days when low back pain occurs, but not overall work absenteeism. ([Roelofs, 2007](#)) Acute osteoporotic vertebral compression fracture management includes bracing,

analgesics, and functional restoration. ([Kim, 2006](#)) An RCT to evaluate the effects of an elastic lumbar belt on functional capacity and pain intensity in low back pain treatment, found an improvement in physical restoration compared to control and decreased pharmacologic consumption. ([Calmels, 2009](#)) This RCT concluded that lumbar supports to treat workers with recurrent low back pain seems to be cost-effective, with on average 54 fewer days per year with LBP and 5 fewer days per year sick leave. ([Roelofs, 2010](#)) This systematic review concluded that lumbar supports may or may not be more effective than other interventions for the treatment of low-back pain. ([van Duijvenbode, 2008](#)) For treatment of nonspecific LBP, compared with no lumbar support, an elastic lumbar belt may be more effective than no belt at improving pain (measured by visual analogue scale) and at improving functional capacity (measured by EIFEL score) at 30 and 90 days in people with subacute low back pain lasting 1 to 3 months. However, evidence was weak (very low-quality evidence). ([McIntosh, 2011](#)) Bracing is a low-risk, cost-effective method to treat certain thoracolumbar fractures, and it offers equivalent efficacy as surgical management in many cases. The evidence for bracing of osteoporotic-type fractures is less clear, and further investigation will be necessary to delineate its optimal role. ([Chang, 2014](#)) See also [Back brace, post operative](#) (fusion); [IntelliSkin posture garments](#); & [SpineCor brace](#).

TENS
(transcutaneous
electrical nerve
stimulation)

Not recommended as as an isolated intervention, but a one-month home-based TENS trial may be considered as a noninvasive conservative option for chronic back pain, if used as an adjunct to a program of evidence-based [conservative care](#) to achieve [functional restoration](#), including reductions in medication use.

Acute: Not recommended based on published literature and a consensus of current guidelines. No proven efficacy has been shown for the treatment of acute low back symptoms. ([Herman, 1994](#)) ([Bigos, 1999](#)) ([van Tulder, 2006](#))

Chronic: Not generally recommended as there is strong evidence that TENS is not more effective than placebo or sham. ([Airaksinen, 2006](#)) There is minimal data on how efficacy is affected by type of application, site of application, treatment duration, and optimal frequency/intensity.

([Brousseau, 2002](#)) There are sparse randomized controlled trials that have investigated TENS for low back pain. One study of 30 subjects showed a significant decrease in pain intensity over a 60-minute treatment period and for 60 minutes after. ([Cheing, 1999](#)) A larger trial of 145 subjects showed no difference between placebo and TENS treatment. ([Devo, 1990](#)) Single-dose studies may not be effective for evaluating long-term outcomes, or the standard type of use of this modality in a clinical setting.

([Milne-Cochrane, 2001](#)) ([Sherry, 2001](#)) ([Philadelphia Panel, 2001](#)) ([Glaser, 2001](#)) ([Maher, 2004](#)) ([Brousseau, 2002](#)) ([Khadikar, 2005](#)) ([Khadikar2, 2005](#))

Although electrotherapeutic modalities are frequently used in the management of CLBP, few studies were found to support their use. Most studies on TENS can be considered of relatively poor methodological quality. TENS does not appear to have an impact on perceived disability or long-term pain. Highfrequency TENS appears to be more effective on pain intensity when compared with low frequency, but this has to be confirmed in future comparative trials. It is also not known if adding TENS to an evidence-based intervention, such as exercise, improves even more outcomes, but studies assessing the interactions between exercise and TENS found no cumulative impact. ([Poitras, 2008](#)) For more information, see the [Pain Chapter](#).

Recent research: A recent meta-analysis concluded that the evidence from the small number of placebo-controlled trials does not support the use of TENS in the routine management of chronic LBP. There was conflicting evidence about whether TENS was beneficial in reducing back pain intensity and consistent evidence that it did not improve back-specific functional status. There was moderate evidence that work status and the use of medical services did not change with treatment. Patients treated with acupuncture-like TENS responded similarly to those treated with conventional TENS. ([Khadikar-Cochrane, 2008](#)) On June 8, 2012, the Centers for Medicare & Medicaid Services (CMS) issued an updated decision memo concluding that TENS is not reasonable and necessary for the treatment of chronic low back pain based on a lack of quality evidence for its effectiveness. Coverage is available only if the beneficiary is enrolled in an approved clinical study. ([Jacques, 2012](#))

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)**