Vanguard MedReview, Inc.

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Notice of Independent Review Decision

August 25, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
62311 Injection, diagnostic/therapeutic substance, 72275 Epidurogram

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
This physician 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 female who was injured while working on xx/xx/xx. She had a lumbar fusion after failure of conservative measures on July 31, 2001; a left L5/S1 laminectomy and discectomy was performed. Back and leg pain persisted, and caudal epidural steroid injections were performed April 2, 2002, and an EMG evaluation was performed November 2002, revealing left L5/S1 radiculopathy. She received a spinal cord stimulator implant.

03/05/2013: Operative Report. **Preoperative Diagnosis:** Depleted Synergy battery. This has been out of use for 6 years during which a patient trying desperately to deal with the insurance company to get approval for reimplantation of a bilateral lower extremity LRS (lumbosacral radicular syndrome) chronic pain syndrome. This was originally implanted in 2003. **Procedure:** 1. Removal and replacement of depleted synergy with a restore rechargeable battery. Note on the battery, we used 8 through 15 portals. 3. Please also note that we had to place an adaptor to allow this to function with 2 quadripole leads.

03/18/2013: Office Visit. **HPI:** The patient is pleased with the outcome of the spinal cord stimulator battery replacement. She has no new complaints besides her symptoms of infection. **Assessment:** Patient is doing well. No signs or symptoms of infection at the incision site. Motor sensations are intact in her bilateral lower extremities. Gait and station are normal. Patient is obese. **Plan:** Patient will meet with the Medtronics representative to review the progress of functioning and any instructions associated with the new battery. Patient to return to clinic as needed.

05/28/2013: Office Visit. **HPI:** s/p SCS battery revision, healed well. Complains of residual side effect on the thighs again and would like to switch. She takes her Lortab name brand 4 times a day. She's had no status changes and her other health. **Problems:** Chronic pain syndrome, Lumbar intervertebral disc without Myelopathy-LRS, Lumbosacral neuritis or Radiculitis-unspecified, Degen Lumbar/lumbosacral intervertebral disc, low back pain, post laminectomy syndrome lumbar. **Medications:** Lortab 10-500 MG tabs, one tablet by mouth 3-4 times daily as needed max 4 tablets, Lisinopril 10 MG tabs, take one by mouth daily, Atorvastatin calcium 40 MG tabs, 1 at bedtime. Plavix 75 MG tabs, take one by mouth daily. Metoprolol tartrate 25 MG tabs, ½ tablet 2 times a day. Aspirin 325 MG tabs, take one by mouth daily. Nitro stat subl, as needed. Magnesium 500 MG tabs, 1-1/2 daily. Cinnamon tabs, take one by mouth daily. Baclofen 10 MG tabs, take one by mouth 3 times daily, morning, afternoon and evening. **Physical Examination:** Surgical incision is healing well. Paravertebral muscles are tender bilateral. Lumbar ROM is painful and restricted to the following: flexion is painful, extrension is painful, rotation on the right is painful, rotation on the left is painful, lateral bending to the right is painful, lateral bending to the left is painful. Spinous processes are non-tender. Lower strength is symmetrically present in all lower extremity muscle groups. Lower reflexes are symmetrically present and normal. Light touch is normal. **Plan:** Continue Lortab 4 times daily. Discontinue tizanidine, initiate baclofen 3 times daily as needed, urine drug screen obtained today.

01/14/2014: Office Visit. **HPI:** s/p SCS battery revision, healed well. She has reduced her Lortab name brand to BID. She's had no status changes and her other health. Had questions about the change in Lortab formulation. No new issues. Meds are beneficial. Symptoms today are 6/10. Last month 4/10. Ranges in the moderate on meds, severe when off meds. Pain and SCS improves function. **Assessment:** Chronic pain syndrome with history of spine surgery, status post spinal cord stimulator battery revision. **Plan:** Continue Lortab, but change to 5/250 1-2 twice daily, Baclofen 3 times daily as needed. UDT at last visit was consistent. Recheck in one year. New medication: Norco 10-325 mg tabs, Take one by mouth 3 times daily; morning; afternoon and evening.

02/28/2014: Office Visit. **Assessment:** Chronic pain syndrome with history of spine surgery. Status post spinal cord stimulator battery revision, episode of bowel loss times 2 but currently functions fine. Cannot rule out a stenotic cause of these incidents. **Plan:** She does have moderate stenosis at L4-5. Would have for follow-up with one of her spinal surgeons for further evaluation. She may need a

urology evaluation as well. Continue the Norco and increased to every 4-6 hours given her increase in pain.

03/10/2014: Office Visit. **HPI:** lumbar decompression x2, spinal cord stimulator 2013, back pain with left leg pain and weakness, cane for ambulation, getting worse, undergoing a cardiac workup, also takes care of her husband who is a teacher fibrillation. **Assessment:** 5 out of 5 strength on the right leg, 4/5 left anterior tibialis, EHL and gastrocsoleus and quadriceps, cane for ambulation, tension signs positive on the left leg. **Plan:** post laminectomy syndrome, lumbar radicular syndrome. Patient is not interested in surgical intervention at this time. I would prefer non operative treatment. Refer at this time. Lumbar CT scan showed degenerative changes, especially at L4-5 and L5-S1, urology consultation for urodynamics is indicated.

03/27/2014: Office Visit. **HPI:** She is here for follow up. She said she saw. She is going to try weight loss surgery. She has an appointment pending for urology. Her cardiologist recommended weight loss surgery as well. **Assessment:** post laminectomy syndrome, lumbar radicular syndrome. **Plan:** She is going to follow through with her urology consultation and her weight loss surgery consultation. Continue medications prescribed. Activities as tolerated. Continue the spine cord stimulator.

04/28/2014: Office Visit. **Chief Complaint:** Second opinion for lumbar fusion after seeing. **Assessment:** SCS, Chronic LBP, lumbar facet Arthropathy, bowel and bladder incontinence, tremor, obesity. **Plan:** CT myelogram of cervical, thoracic and lumbar spine to assess for pathology regarding bowel and bladder dysfunction. Follow up proceed after neuro eval and urodynamics and completion of cc myelogram for further discussion.

06/27/2014: Office Visit. **HPI:** History of SCS implant most recently 1 year ago, LBP left> right with radiation to bilateral lower extremities, bilateral lower extremities well covered by SCS, LBP severely increased x1 year, bowel incontinence x6 over last year, daily urinary incontinence x1 year, wearing padded underwear, saddle region of numbness at times during incontinence and when wiping afterward, low back pain worse with standing and ambulating, low back pain relieved by sitting, now using her cane at home x1 month, prior was outside the home x2 years, LLE feels weaker when stepping, LLE feels cold and is sometimes darker in color than the right, LLE chronically numb above the knee, Tremor x6 months, not yet followed up with a urodynamics per, gastric sleeve performed on 5/20/14. She has lost 24 pounds today. She is off her heart pills as well as her diuretic. Lumbar CDT February 2014: Degenerative change with near complete collapse of disc height at T12-L1 through L5-S1. Arthritic change throughout lumbar spine. No central or foraminal stenosis noted. SCS noted. Interestingly, some of her symptoms have improved since weight loss surgery, the bowel bladder dysfunction. **Assessment:** 5 out of 5 strength on the right leg, 4/5 left anterior tibialis, EHL and gastrocsoleus and quadriceps, cane for ambulation, tension signs positive on the left leg. Paravertebral muscles are tender bilateral. Lumbar ROM is painful and restricted to the following: flexion is painful, extension

is painful, rotation on the right is painful, rotation on the left is painful, lateral bending to the right is painful, lateral bending to the left is painful. Spinous processes are non-tender. SCS chronic LBP, lumbar facet Arthropathy, bowel and bladder incontinence, tremor, obesity. **Plan:** She is going to follow through with her urology consultation, continue the medications as prescribed. Activities as tolerated. Continue the spine cord stimulator. For the symptomatic relief if everything was negative we could get an epidural but we can't since we still have diagnostics pending.
07/15/2014: UR. **Rational for Denial:** Based on the medical records submitted for review on the above reverenced claimant, caudal ESI is NON-AUTHORIZED. Claimant has had injections in the past, lumbar surgeries, SCS with no improvement of her symptoms. She does not meet the Official Disability Guidelines (ODG) criteria.
08/042014: UR. **Rational for Denial:** This is a non-certification of a request for reconsideration of an L5-S1 caudal injection. The previous non-certification on July 15, 2014, was due to lack of objective improvement with prior injections. The previous non-certification is supported. Additional records were not provided for review. The guidelines would not support repeat epidural steroid injections unless there is objective documentation of at least 50-70% pain relief for six to eight weeks. This was not noted objectively in the records. The request for reconsideration of an L5-S1 caudal injection is not certified.
ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:
The previous adverse determinations are upheld. The patient is not indicated for a lumbar injection (62311) and epidurogram (72275). The Official Disability Guidelines (ODG) support epidural steroid injection (ESI) for the treatment of radiculopathy associated with a lumbar herniated disc. The imaging studies should correlate with objective findings on physical examination. Repeat ESI can be considered following a positive response to the first injection, consisting of 50-70% pain relief for at least 6-8 weeks. This patient has failed previous lumbar decompression, epidural injections, and a spinal cord stimulator. She has several pain generators in her lower back, including multilevel degenerative disc disease (T12-L1 through L5-S1) and facet disease. The recent imaging study documented no central or foraminal stenosis. The records reviewed have not demonstrated lumbar radiculopathy associated with a specific herniated disc. The patient does not meet criteria for 62311 Injection, diagnostic/therapeutic substance, 72275 Epidurogram at this time.
Per ODG:
Criteria for the use of Epidural steroid injections:
Note: The purpose of ESI is to reduce pain and inflammation, thereby facilitating progress in more active treatment programs, reduction of medication use and avoiding surgery, but this treatment alone offers no significant long-term functional benefit.
(1) Radiculopathy (due to herniated nucleus pulposus, but not spinal stenosis) must be documented. Objective findings on examination need to be present. Radiculopathy must be corroborated by imaging studies and/or electrodiagnostic testing.
(2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants).
(3) Injections should be performed using fluoroscopy (live x-ray) and injection of contrast for guidance.
(4) *Diagnostic Phase:* At the time of initial use of an ESI (formally referred to as the "diagnostic phase" as initial injections indicate whether success will be obtained with this treatment intervention), a maximum of

one to two injections should be performed. A repeat block is not recommended if there is inadequate response to the first block (< 30% is a standard placebo response). A second block is also not indicated if the first block is accurately placed unless: (a) there is a question of the pain generator; (b) there was possibility of inaccurate placement; or (c) there is evidence of multilevel pathology. In these cases a different level or approach might be proposed. There should be an interval of at least one to two weeks between injections.
(5) No more than two nerve root levels should be injected using transforaminal blocks.
(6) No more than one interlaminar level should be injected at one session.
(7) *Therapeutic phase:* If after the initial block/blocks are given (see "Diagnostic Phase" above) and found to produce pain relief of at least 50-70% pain relief for at least 6-8 weeks, additional blocks may be supported. This is generally referred to as the "therapeutic phase." Indications for repeat blocks include acute exacerbation of pain, or new onset of radicular symptoms. The general consensus recommendation is for no more than 4 blocks per region per year. (CMS, 2004) (Boswell, 2007)
(8) Repeat injections should be based on continued objective documented pain relief, decreased need for pain medications, and functional response.
(9) Current research does not support a routine use of a "series-of-three" injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections for the initial phase and rarely more than 2 for therapeutic treatment.
(10) It is currently not recommended to perform epidural blocks on the same day of treatment as facet blocks or sacroiliac blocks or lumbar sympathetic blocks or trigger point injections as this may lead to improper diagnosis or unnecessary treatment.
(11) Cervical and lumbar epidural steroid injection should not be performed on the same day. (Doing both injections on the same day could result in an excessive dose of steroids, which can be dangerous, and not worth the risk for a treatment that has no long-term benefit.)

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)**