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Notice of Independent Review Decision

December 23, 2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Replacement of implantable pulse generator (IPG) for spinal stimulator

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
The Reviewer is Board Certified in the area of Neurological Surgery with over 16 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.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

02/03/2007: Peer Review
02/07/2008: Consultation
02/08/2008: Follow up visit
02/13/2008: Follow up visit
03/26/2008: Follow up visit
03/26/2008: Radiology Report
05/12/2008: Follow up visit
05/12/2008: Radiology Report
07/31/2008: Follow up visit
10/23/2008: Follow up visit
12/12/2008: Rebuttal
02/11/2009: Follow up visit

02/11/2009: Radiology Report
04/10/2009: Follow up visit
05/26/2009: Follow up visit
11/05/2009: Follow up visit
11/05/2009: Radiology Report
06/24/2010: Follow up visit
10/12/2010: Follow up visit
11/01/2010: Operative Report
11/11/2010: Follow up visit
12/29/2010: Follow up visit
02/07/2011: Operative Report
02/22/2011: Follow up visit
05/03/2011: Follow up visit
05/03/2011: Radiology Report
08/02/2011: Follow up visit
08/02/2011: Radiology Review
09/17/2013: Evaluation
10/04/2013: DX Myelography LS Spine
10/16/2013: Follow up
10/28/2013: UR performed
11/14/2013 UR performed
12/09/2013: Prospective Review (M2) Response letter

PATIENT CLINICAL HISTORY [SUMMARY]:
The claimant is a female who was injured on xx/xx/xx after falling to the ground when the chair she was sitting in broke. The claimant was diagnosed with low back pain and bilateral leg pain that has been responsive to spinal cord stimulation in the past. The patient has had multiple lumbar spine operations in the past from L3-4 through L5-S1. She has had an Implantable Pulse Generator (IPG) battery replaced 11/10. This is reportedly a Medtronic system.

02/07/2008: Consultation. Impression: Low back pain with intervertebral derangements noted at the L3-L4 and L4-L5 level with radiculopathy and positive straight leg raises. Plan: Taking into consideration extensive workup at this point and due to lack of some imaging at this time, we would need to proceed with the CT myelogram in order to visualize the spinal canal and the nerve roots as well as the thecal sac of the lumbar spine. We would also like to obtain the report of the diskogram that was performed and evaluate the CT that was performed with that, evaluate the architecture of the disk if it was two needle technique pressure mamometry as well as pain analog scale as well as if there was controlled disk involved in the study. Will attempt to obtain a CT myelogram today as well as the report and have claimant follow up once those have been obtained.

02/08/2008: Follow up visit. Claimant was seen after a CT myelogram. CT myelogram shows that she has a slight disk protrusion present at the L3-4 level. The rest of the levels show no significant stenosis or neuroformainal stenosis seen. There are no fractures identified. Discussed with claimant that given this

the L3-4 segment may be contributing to her pain. Recommended a diskogram from L2 to S1.

02/13/2008: Follow up visit. Claimant had a diskogram performed which showed that she had 10/10 concordant diskogenic pain at the L3-4 level. At L2-3, she had 2/10 pain. At L4-5 and L5-S1, she had 0/10 pain. Claimant also had annular fissuring seen at the L3-4 segment which was her concordant level. Based off of this, the L3, I feel the L3-4 is amendable to treatment. Discussed with claimant options are artificial disk replacement versus fusion. I feel at the L3-4 segment a fusion done minimally invasive is going to be her best option. Discussed with the claimant the X-LIF procedure which is done minimally invasive as well as minimally invasive pedicle screws. Discussed the goal of the surgery is to reduce the pain. Advised claimant that the surgery will alleviate her pain completely and she understood and accepted this. Claimant understood that she will need to undergo a postoperative rehab and will need to wear a brace.

03/26/2008: Follow up visit. Claimant was seen 2 weeks postop. Claimant is status post XLIF 360. Claimant is doing remarkably well. Claimant reported substantial reduction in her pain and denies any fever or chills. Claimant stated that her leg pain has completely resolved both legs and beginning to regain sensation in her lower extremities. **Objective**: Exam showed 5/5 strength testing. Sensation is intact. Negative straight leg raise. Normal deep tendon reflexes. No long tact signs were seen. Incision is clean, dry and intact. No evidence of crythema or drainage. **Impression**: Status post XLIP 360. **Plan**: Claimant stated physical therapy. Claimant began decreasing her medication, weaning her off the hydrocodone down to the Darvocet. Claimant was given a prescription for Ambien CR to help sleep. Recheck in 6-8 weeks.

03/26/2008: Radiology Report. AP and lateral views show excellent position of the interbody cage as well as the screws. There was no evidence of subsidence or loosening seen.

05/12/2008: Radiology Report. AP and lateral views show excellent position of the interbody cages as well as pedicle screws without any evidence of loosening or subsidence. No significant bone formation is seen yet.

07/31/2008: Follow up visit. Claimant reported pain in her low back. Claimant reported to have area of pain, which on exam has significant tenderness right over the heads of the inferior most screws. Advised she is having hardware pain from the inferior most pedicle screws bilaterally. **Radiology Review**: A CT myelogram was performed that shows no significant canal stenosis, neuroforaminal stenosis. Pedicle screws appear to be in good position. **Plan:** Recommend consideration for hardware injection. Advised not to remove hardware until claimant has a solid fusion. Could diagnostically attempt to identify the hardware as the source of pain with a hardware injection.

10/23/2008: Follow up visit. Claimant reported quite a bit of pain in her low back radiating down her leg. Pain has been persistent and has not let up any. On

exam, has a 5/5 strength testing. Sensation is intact. Positive straight leg raise, which repeated some of the leg pain. Tenderness over the hardware. I do believe that the component of the pain could be coming from the hardware. Discussed with claimant about improving with a hardware injection by anesthetically blocking the soft-tissue adjacent to the hardware, this may alleviate some of her pain on a temporary basis. Prescribed her Lyrica 75. Discontinue the Neurotin.

02/11/2009: Follow up visit. Claimant reported quite a bit of pain in her low back. The pain is across the low back and almost exclusively on the left side. Claimant has pain radiating down her legs, which she has had for quite some time now, which has been treated with her spinal cord stimulator implant. Followed up after a hardware injection. Claimant reported that during the hardware injection she had maybe 10% to 15% relief of pain. Based off of this, I do not feel that this is where her hardware is from and I do not feel she needs the hardware removal based on this. On exam, again, she has exquisite tenderness in the left paraspinal muscles not the region of her incision. Noted on X-rays in the left paraspinal muscle, there is noted to be some ectopic bone formation seen just lateral to the pedicle screws. I believe this maybe where her pain is coming from, based off of the fact that this is where her pain is located and the fact that she has ectopic bone formation here. I feel that this may be her pain generator. Discussed with claimant exploring and removing the ectopic bone formation to see if this will help relieve her pain. Discussed the risks with her. Claimant would like to ahead and get this set up at her convenience. Claimant also had a previous CT byelogram, which did not show any conclusive evidences as to where she would have so much of the back pain. The only thing I can figure her pain is coming from based after the extensive workup is from the ectopic bone formation. Will plan to remove this to see if this will improve her pain.

02/11/2009: Radiology Report. Review of claimant X-rays, AP lateral flexion/extension views show good position of pedicle screw instrumentation as well as interbody cage. There was some bone formation seen within the cage. No signs of hardware failure, loosening, subsidence, or nonunion. The rest of the disk spaces appear normal, sacroillac joint appears normal, hip joints appear normal. Claimant does have also apparent spinal cord stimulator placed.

04/10/2009: Follow up visit. Claimant reported doing very well from the resection of the heterotopic ossification she had. Pathology report is negative for any cancer. Claimant reported she had complete reduction of pain in the area where this was and she is very happy with this. Still has issues, however, with pain in the lower extremities more with RSD complete regional pain syndrome. Claimant has spinal cord stimulator which does help reduce and control this but is still having difficulty with this and managing. Discussed with claimant that because of the complete and chronic pain syndrome she has in the lower extremities, will send claimant over to Advantage chronic pain management.

11/05/2009: Follow up visit. Claimant reported doing well. She is using her stimulator and it helps with pain in her legs. Still have complaints of strange

sensations in her lower extremities. States that her feet will drop, occasionally her legs give out on her. She is not concerned. **Objective:** Exam showed 5/5 strength testing. Sensation is intact. Negative straight leg and normal deep tendon reflexes. No long tract signs were seen. **Impressions:** 1. Status post 360 fusion done minimally invasive which significantly has helped the claimant's pain. 2. Neurologically symptoms involving primarily the lower extremities. 3. Previous spinal cord stimulator which appears to be working properly. **Plan:** Recommend claimant to be evaluated by a neurologist. In addition, claimant is taking methadone to help with pain. Will refer her over to pain management for possible intrathecal pump trial.

11/05/2009: Radiology Report. X-ray examination indicated good position of the hardware. There was no subsidence, loosening failure seen. Claimant does not have a significant amount of bone formation seen within the cage. There was some but do not know if she has a solid fusion as of yet.

06/24/2010: Follow up visit. Claimant was seen to get a follow up from her referral for a CT and EMG. The claimant reported she is in a lot of pain and she is now having to walk with a cane. The radicutor symptoms down her left leg are increasing. **Objective:** Strength test is a 4=/5 on the right side versus the left. Sensation is grossly intact. Pulse is equal bilaterally. Negative seated straight leg raise. Negative long tract signs. **Radiology Review:** The report from the CT does show at the L4-5 and the L5-S1 that there is some mild bilateral foraminal stenosis. There is also slight disk protrusion paracentrally in the left foramen at the L5-S1 level. The EMG does show that there is an SI radiculopathy. **Impression:** Lower back pain due to radicular symptoms from the L1 nerve root, bilateral foraminal stenosis at the L4-5 and the L5-S1 level with mild paracentral and left foraminal protrusion at the L5-S1 level. **Plan:** Plan for the claimant is to continue again with some conservative treatment doing physical therapy with aquatherapy, core strengthening, and stability training, epidural steroid injection of the lumbar spine. Claimant stated that she has not had one for quite some time and the Medrol Dosepak . The claimant was advised to continue to take her anti-inflammatories and muscle spasm medication as prescribed by her pain management doctor. Will see her back in 6-8 weeks. The claimant was also told that if her symptoms were to significantly increase during this time, that she is to make her appointment sooner than later.

10/12/2010: Follow up visit. Claimant reported increased pain in her back and down her legs. Claimant stated that her pain over time has been worsening. She had Medtronic rep evaluate her and interrogate her stimulator. She has a depleted battery at this point. She needs to have this revised and changed. Will go and get her set up for this. Discussed the risks of the procedure with her, and will set up as soon as possible.

11/01/2010: Operative Report Preoperative/Posterative Diagnosis: Failed implantable pulse generator battery. Operative Procedure**:** Revision replacement of Medtronic implantable pulse generator battery**.**

11/11/2010: Follow up visit. Claimant was seen post replacement of IPG. Claimant has complete stimulation down her lower extremities. Claimant reported she has persistent pain, however, in her low back. The IPG stimulator is stimulating in the area of her low back. Claimant reported that she feels coverage in this area; however, it is not helping her low back pain in any way. Claimant has complete control of her pain in the legs, but not in her lumbar spine. On reevaluating back when she had the hardware injection performed, claimant stated that during a short period of time, the anesthetic phase of the injection, she had significant relief of her pain and did have secondary pain component with the ectopic bone formation which has since been removed. Recommended claimant removing the pedicle screw instrumentation, also exploring the fusion, possible revising the fusion. Claimant does not have much bone formation seen within the interbody cage. I believe she may have a pseudoarthrosis there as well contributing to her pain. Recommend exploring at the time of removing the hardware and possibly revising the fusion at that point if necessary.

12/29/2010: Follow up visit. Claimant reported frustrated and tearful. She was still having quite a bit of pain in her low back. The spinal cord stimulator is helping her leg pain, but not her back pain. She had, I believe, a pseudoarthrosis. Claimant had a previous fusion and hardware pain. Claimant had a hardware injection which relieved her pain. Claimant received a denial stating that the removal of hardware is not indicated because there is no hardware failure. That was not the reason for removal of the hardware. The reason for the hardware removal is for painful hardware. Painful hardware is a condition in which it can aggravate the surrounding tissues, in this case, the lumbar spinal muscles. The erector spinae muscle are inflamed, irritated, and painful as a result of the hardware and the excessive load and motion that is placed across this. With that said, this was an indication for surgery. Pseudoarthrosis with repair is also an indication for surgery according to ODG guidelines. Claimant is having psychosocial evaluation. I do believe that claimant has a degree of depression associated with this, but I believe it is due to the frustration of the Work Comp System. Will see claimant back prior to surgery once approved.

02/07/2011: Operative Report. Postoperative Diagnosis: Hardware pain, possible pseudoarthrosis. Procedures: 1. Removal of pediole screw instrumentation at L4-L5. 2. Exploration of fusion. 3. Revision posterior spinal fusion using allograft bone with bone marrow aspira…4. Bone marrow ….x3. 5. Cellular grafting using platet..-rich plasma (Report unreadable)

05/03/2011: Follow up visit. Claimant reported doing remarkable well since the hardware removal back on February 7, 2011. Claimant is very happy with her surgical results and is not taking much in the way of medication. Objective: On exam shows 5/5 strength testing. Sensation is intact. Negative straight leg raise with normal deep tendon reflex. No long tract sign seen. Plan: Follow up in 3 months. Will re-x-ray at that time.

05/03/2011: Radiology Report. Claimant had AP and lateral X-rays done which showed bone formation seen within the cage but also in the lateral recess, appears to be bridging across the facet joint. No loosening or subsidence noted.

08/02/2011: Radiology Review. Claimant had X-ray, AP and lateral views shows she has a solid fusion. There is some disk space narrowing seen at L4- and L5-S1 but overall claimant is stable.

09/17/2013: Evaluation. Claimant requested follow up due to her SCS battery running out and LBP. Claimant presents with back pain and leg pain located on the both right and left side. Claimant reported painful hardware or Graft, Hx of Hypertension. **Assessment**: Upon examination, claimant showed that she has exquisite tenderness and pain over the region of the L4-L5 and L5-S1 bilaterally. She stated in a slightly forward hunched-over position. As claimant extends, pain worsens. Also had some pain with flexion, but worse with extension. Claimant had 5/5 strength testing. Sensation is intact. Normal deep tendon reflexes. Slightly positive straight leg raise on both sides. She had a spinal cord stimulator that appeared to be, according to her, stimulating all the areas where her pain is, but her pain is just continuing to progress. **Plan for today's visit:** Based off visit, discussed getting a CT myelogram of the lumbar spine to evaluate this. Going to give her a Medtol Dosepak with Celebrex. Will see claimant back after the CT myelogram.

10/04/2013: DX Myelography LS Spine interpreted. 1. Postoperative changes are identified at L3/4. Disc spacers at this level appear well-positioned. There are chronic appearing schmorl's nodes identified involving the inferior endplate of L3 and upper endoplate of L4. 2. The posterior spinal stabilization hardware at L3/L4 had been removed. 4. Mild degenerative lumbar spine spondylosis at L4/5 and L5/S1 as described. There is no significant canal or foraminal narrowing.

10/16/2013: Follow up. Claimant was seen for follow-up after a CT myelogram. According to the report, no significant stenosis is identified. Claimant had previous fusion with previous pedicle screw removal as well as the spinal cord stimulator. Spinal cord stimulator was interrogated, had normal impedances. Claimant has problem with the battery, IPG has expired. Claimant is going to need surgery for a new IPG. Claimant is very happy with the stimulator and stated that it does help her pain and reduce her medication usage. Going to refill medications until she can get ready for the next pain management doctor.

10/28/2013: UR performed. Rational for Denial: The request for replacement of the implantable pulse generator for the spinal cord stimulator would not be supported at this time. Objective documentation of battery failure has not been noted. The records report that the claimant has had prior implantable pulse generator battery replacement on November 1, 2010. The guidelines state that the typical battery life is eight to nine years, but can depend on the unit. Without objective documentation determining the estimated battery life of the devise or interrogation and objective documentation determining that the battery life has

reached its end, the request cannot be supported. The request for replacement of the implantable pulse generator for a spinal cord stimulator is not certified.

11/14/2013: UR performed. Rational for Denial: They stated their last call date related to this patient was 05/06. The last battery change noted by them was 04/05. They had no documentation of the 11/10 revision. Prior to any approval off the requested services, the model number as well as settings need to be verified/clarified. The national answering service number to obtain the local representative. Until this information is obtained, the requested services are denied.

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

The previous adverse determinations are upheld. This patient has a long history of back and leg pain. She has been managed with a Spinal cord stimulator and a subsequent lumbar instrumented fusion in March 2008. Her lumbar hardware has been removed and her fusion supplemented with bone graft on February 2011. Her Spinal cord stimulator battery was reportedly replaced in November 2010 and now there is some concern for battery failure again in October 2013. The failure of the battery would be abnormal given the usual 7-9 year expectation for battery life. I agree that the overall function of the Spinal cord stimulator needs to be assessed better before any surgery can be approved, as the impedances are normal. If the stimulator battery is indeed not functioning, then it should be replaced to help with the leg pain. comments that the Registry doesn't know the details of the battery is concerning. Therefore, the request for Replacement of implantable pulse generator (IPG) for spinal stimulator is not found to be medically necessary at this time.

Per ODG:

Spinal cord stimulation (SCS)	Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated. See the Pain Chapter for *Indications for stimulator implantation*. There is some evidence supporting the use of Spinal Cord Stimulation (SCS) for Failed Back Surgery Syndrome (FBSS) and other selected chronic pain conditions. Spinal Cord Stimulation is a treatment that has been used for more than 30 years, but only in the past five years has it met with widespread acceptance and recognition by the medical community. In the first decade after its introduction, SCS was extensively practiced and applied to a wide spectrum of pain diagnoses, probably indiscriminately. The results at follow-up were poor and the method soon fell in disrepute. In the last decade there has been growing awareness that SCS is a reasonably effective therapy for many patients suffering from neuropathic pain for which there is no alternative therapy. There are several reasons for this development, the principal one being that the indications have been more

	clearly identified. The enhanced design of electrodes, leads, and receivers/stimulators has substantially decreased the incidence of re-operations for device failure. Further, the introduction of the percutaneous electrode implantation has enabled trial stimulation, which is now commonly recognized as an indispensable step in assessing whether the treatment is appropriate for individual patients. These implantable devices have a very high initial cost relative to conventional medical management (CMM); however, over the lifetime of the carefully selected patient, SCS may lead to cost-saving and more health gain relative to CMM for FBSS. See the Pain Chapter for complete list of references. Fair evidence supports the use of spinal cord stimulation in failed back surgery syndrome, those with persistent radiculopathy after surgery, according to the recently released joint American College of Physicians/ American Pain Society guideline recommendations on surgery and interventional treatments. (Chou, 2008) The National Institute for Health and Clinical Excellence (NICE) of the UK just completed their Final Appraisal Determination (FAD) of the medical evidence on spinal cord stimulation (SCS), concluding that SCS is recommended as a treatment option for adults with failed back surgery syndrome lasting at least 6 months despite appropriate conventional medical management. (NICE, 2008) *Recent research:* New 24-month data is available from a study randomizing 100 failed back surgery syndrome patients to receive spinal cord stimulation (SCS) plus conventional medical management (CMM) or CMM alone. At 24 months, the primary outcome was achieved by 37% randomized to SCS versus 2% to conventional medical management (CMM), and by 47% of patients who received SCS as final treatment versus 7% for CMM. All 100 patients in the study had undergone at least one previous anatomically successful spine surgery for a herniated disk but continued to experience moderate to severe pain in one or both legs, and to a lesser degree in the back, at least six months later. Conventional medical therapies included oral medications, nerve blocks, steroid injections, physical and psychological therapy and/or chiropractic care. (Kumar, 2008) There is fair evidence that spinal cord stimulation is moderately effective for failed back surgery syndrome with persistent radiculopathy, though device-related complications are common. (Chou3, 2009) A nonrandomized, prospective cohort study in workers comp patients with chronic back and leg pain after spine surgery, ie failed back surgery syndrome (FBSS), found no significant difference in pain, disability, or opioid use between patients that received (at least a trial of) SCS, care at a pain clinic, or neither (usual care) at 12 and 24 months. Only 25% of SCS patients in this study received psychological screening prior to the trial, whereas ODG recommends psychological screening prior to all SCS implantations. Because few patients in any group in this study achieved success at any follow-up, the authors suggested that no treatment has a substantial impact on average in this patient group. (Turner, 2010) In this sample of workers' compensation recipients, the high procedure cost of SCS was not counterbalanced by lower costs of subsequent care, and SCS was not cost-effective. The benefits and potential cost savings reported in RCTs may not be replicated in workers' comp patients. (Hollingworth, 2011) For average hospital LOS if criteria are met, see Hospital length of stay (LOS).

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)**