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IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

SCS Implant

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

Pain Management Physician

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

X Overturned (Disagree)

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 patient is a male who on XX/XX/XX, was pushing a 450-pound block of wood under manifold, when he felt pain and pop in his back and injured it.

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On XX/XX/XX, an MRI of the lumbar spine was completed. The study revealed degenerative disc disease quite prominent with moderate facet arthropathy and ligamentum flavum hypertrophy contributing to mild central canal stenosis, mild-to-moderate neural foraminal stenosis with abutment of the exiting L4 nerve root at the neural foraminal level bilaterally. In addition, a focal disc protrusion with annular tear was noted. Disc protrusion with osteophyte was noted at the L5-S1 level centrally and slightly to the right with a broad-based bulging disc with slight touching of the L5 nerve root bilaterally at the neural foraminal level. There was disc desiccation with bilateral foraminal narrowing due to hypertrophy of the facet joint. There was minimal degree of levoscoliosis.

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On XX/XX/XX, the patient was seen for complaints of low back pain radiating down his legs, primarily the right leg with occasional paresthesias. He rated it at about a 10/10. He reported some difficulty emptying his bladder. His symptoms were worse at night and the pain awakened him. He had had previous treatment including physical therapy (PT) and injections which worsened the symptoms. Medical history was significant for anxiety, depression, sexual difficulty, stomach ulcer, appendectomy and right arm surgery. He was on hydrocodone, Lyrica, tramadol and cyclobenzaprine. Examination revealed 4/5 strength in dorsiflexion in the right lower extremity, decreased sensation in the L4 dermatome in the right lower extremity, positive straight leg raise with reproduction of back and some leg pain, more right sided than left sided. There was some pain and tenderness diffusely through the lumbar spine ranging about L3-L4, L4-L5 and L5-S1. There was pain with both flexion and extension. MRI findings were reviewed. XX assessed low back pain secondary to lumbar disc disease at L4-L5 and L5-S1 with mild stenosis at L4-L5 and L5-S1. The patient had had almost six months of conservative treatment including PT, medication management and pain management. He had had six injections performed and continued with ongoing pain. He had currently presented for a second opinion. He had had another opinion which recommended surgical intervention. XX disagreed with this. He recommended a discogram from L2 to S1 and gave the patient a neuromuscular stimulator. Arthrotec was prescribed.

On XX/XX/XX, XX performed a functional capacity evaluation (FCE) and noted the patient was currently not working secondary to the injury. His job required physical demand level (PDL) was Medium. As per the Oswestry Functional Questionnaire, the patient scored 70%, which placed them in the crippled category.

Weekly Progress Reports were documented from XX/XX/XX-XX/XX/XX. The patient underwent a work hardening program (WHP). The patient's pain rating decreased significantly as well as his pain perception. His depressive symptomatology was in the mild range. He reported significant improvement in his overall functioning. He reported being dedicated to developing a healthy lifestyle and using the program as a starting point. Plan was to continue with plan of care with emphasis on improving overall strength and function.

On XX/XX/XX, XX saw the patient in follow-up. He had completed the pain management program at XX. He reported benefiting from it. However, he had ongoing pain and was very frustrated. A discogram had been denied, but XX felt a discogram was warranted.

On XX/XX/XX, XX noted he had ordered a CT discogram and the patient was on IRO. XX briefed him about the process for the denial.

On XX/XX/XX, XX evaluated the patient who was having quite a bit of back pain radiating down his right leg. He had paresthesias involving the L5 and possibly the L4 dermatomes. He had a positive straight leg raise (SLR). An updated MRI was recommended to find out why the changes had occurred.

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On XX/XX/XX, an MRI of the lumbar spine was completed. The study revealed lateral disc protrusion at L5-S1 on the right at the neural foraminal level with compression of the L5 nerve root. There was also disc desiccation with anterior spondylosis. Paracentral disc protrusion/early herniation at the L4-L5 level with possible early annular tear with broad-based diffuse bulging annulus centrally and to the right with compression of the L4 nerve root on the right. Early spinal stenosis and foraminal stenosis were noted due to significant hypertrophy of the facet joint.

On XX/XX/XX, the patient was seen for a follow-up after the MRI scan. He reported being the same. MRI findings were reviewed. The patient's main problem was the L4-L5 and L5-S1. Above the L4-L5 level, the spine looked normal. The patient had been off work for a year with pain level at low back and leg rated at 10/10. He had failed conservative management. XX recommended surgical intervention and provided him with a prescription for Chantix.

On XX/XX/XX, the patient was evaluated for back pain. The patient was status quo. He had a psych evaluation scheduled and needed medication refills. He reported good pain relief and was better able to perform activities of daily living (ADLs) on the current regimen. Examination revealed an antalgic gait and difficulty with ambulation. XX assessed thoracic or lumbar radiculitis and opined that continuing conservative care only was indicated with no additional diagnostic studies, interventions or referrals anticipated at the current time. The patient was advised to continue with the home exercise program (HEP). MS Contin extended release was prescribed.

On XX/XX/XX, the patient was evaluated for a presurgical psychological consultation. Surgery was not contraindicated by the psychological evaluation. The MBMD suggested the patient had the following moderate-to-marked psychological risk factors for surgery: pain sensitivity, medication abuse, fear of illness complications, self-indulgence, unstable/erratic routines and poor adjustment to pain treatment. Diagnoses were pain disorder associated with both psychological factors and a general medical condition, adjustment disorder with anxiety and depressed mood, chronic pain syndrome secondary to back pain, chronic pain, and GAF of 50. Postsurgical counseling was recommended.

On XX/XX/XX, and XX/XX/XX, XX evaluated the patient. X-rays were completed showing some disc space narrowing seen at L5-S1. XX assessed the patient was not at maximum medical improvement (MMI). He was pending surgery. XX did not agree with the impairment rating on XX/XX/XX. The patient continued to have pain in his back and down his legs. XX opined that the recommended laminectomy was not the right procedure for the patient's problems of discogenic pain. Plan was to obtain flexion/extension x-rays.

On XX/XX/XX, XX reviewed the patient's flexion/extension x-rays which showed he had some disc space narrowing at L4-L5 and L5-S1. There was no significant instability. He had normal-appearing hip joints and SI joints. XX opined the patient mostly likely had internal disc derangement contributing to his pain and recommended a CT discogram from L3 through S1.

On XX/XX/XX, the patient underwent an MMI/IR evaluation by XX, who opined that the patient was not at MMI and estimated an MMI date of XX/XX/XX, his statutory date.

On XX/XX/XX, the patient was seen by XX. He reported being worse. Surgery had been denied due to no instability. Workers' Compensation under ODG guidelines did not cover a discogram. XX noted he could not offer the patient a surgery without the discogram. He was referred to chronic pain management.

On XX/XX/XX, XX evaluated the patient and assessed chronic pain syndrome, lumbar radicular syndrome right greater than left lower extremity, lumbar degenerative disc disease with disc protrusions at L4-L5 and L5-S1 and hypertension. XX recommended lumbar discograms.

On XX/XX/XX, the patient underwent provocative lumbar discography of L3-L4, L4-L5 and L5-S1, with regional lumbar anesthesia, fluoroscopic guidance and radiographic interpretation. Postoperative diagnoses were (1) Normal nonpainful L3-L4 disc. (2) Severely painful moderate degenerative disc disease with posterior disc protrusion, L4-L5 disc concordantly painful. (3) Severely painful posterior disc protrusion with degenerative disc changes, L5-S1 with concordant painful changes.

On the same date, a CT of the lumbar spine with discogram at L3-L4, L4-L5 and L5-S1 was completed. The study identified mild lumbar dextroscoliosis. At L3-L4, modified XX grade 1 annular tears, 2 mm disc bulge. The AP dimension of the central canal measured 15 mm. At L4-L5, 4.5 mm disc osteophyte complex with posterocentral protrusion. Modified XX grade IV annular tears. The AP dimension of the central canal measured 10.3 mm. There was mild bilateral neural foraminal stenosis. At L5-S1, modified XX grade IV annular tear, 5.5 mm posterocentral and right paracentral disc protrusion abutting the descending S1 nerve root in the lateral recess. The AP dimension of the central canal measured 13 mm. There was mild right neural foraminal stenosis.

On XX/XX/XX, the patient was evaluated by XX. He reported ongoing complaints of pain in his low back. His pain had worsened. His discogram revealed conclusive evidence that his pain generator was at L4-L5 and L5-S1. Based on this, XX recommended minimally invasive fusion at L4-L5 and L5-S1.

On XX/XX/XX, the patient underwent corpectomy at L4-L5 and L5-S1, anterior lumbar fusion at L4-L5 and L5-S1 using allograft bone with bone marrow aspiration, bone marrow aspiration x3, implantation of PEEK interbody cage at L4-L5 and L5-S1, anterior lumbar plate fixation using Life Spine plate at L4-L5 and L5-S1, SSEP and EMG monitoring of nerve roots L2 through S2 bilaterally. Postoperative diagnoses were internal disc derangement L4-L5 and L5-S1 with instability.

On XX/XX/XX, XX evaluated the patient postoperatively. He had some low back pain which was to be expected. The incision was clean, dry and intact without evidence of erythema or drainage. XX recommended starting physical therapy (PT) and advised him to continue wearing his brace.

On XX/XX/XX, the patient was evaluated. The patient had had normal healing and continued to use an external bone stimulator but continued to complain of significant pain at a level of 8-9/10 despite multiple opiate and non-opiate pain medications. He had not returned to work. He complained of low back pain and also that the right foot felt cold and numb. Examination revealed palpable tenderness in the axial and periaxial lumbar spine. SLR reproduced back pain only. XX recommended interdisciplinary rehabilitation program and recommended medication reduction associated with the program.

On the same date, the patient underwent psychological evaluation and was assessed to be an appropriate candidate for an interdisciplinary rehabilitation program that focused on functional restoration.

On the same date, the patient underwent an FCE. The patient's required PDL was Medium and his current PDL was closest to the Light work level.

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On XX/XX/XX, XX documented a Case Summary of the interdisciplinary rehabilitation program and recommended a more intensive, multi-disciplinary chronic pain program.

On XX/XX/XX, the patient was seen by XX. He was status post a 360-degree fusion at L4-L5 and L5-S1 and was doing well. He felt the surgery had helped him. He had had a fall and was concerned about whether he disrupted the hardware. X-rays revealed good position of the implant and no subsidence, loosening or hardware failure. XX recommended WHP. Mobic and a transdermal pain cream as well as meloxicam were prescribed.

On XX/XX/XX, the patient was evaluated by XX. The patient had been referred for an impairment rating by XX who had determined him to be at MMI. XX placed the patient at clinical MMI effective XX/XX/XX, and assigned him whole person impairment (WPI) rating of 10%.

On XX/XX/XX, a PT reassessment note was documented by XX. Ongoing treatment was recommended 2-3 times per week for 4-6 weeks. The patient underwent PT including manual therapy and therapeutic exercises.

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On XX/XX/XX XX evaluated the patient for low back strain and lumbar radiculopathy follow-up. The patient reported severe bilateral chronic low back pain with weakness in both legs, more on the right and tingling in the right foot. XX advised him to contact XX to let him know what was going on. Tramadol was prescribed.

On XX/XX/XX, the patient was evaluated by XX for back pain. The patient had been doing well with his surgery. He felt it had helped him but he had gone back to work as a X and began to have more pain in his back. He reported only back pain, no leg pain. On examination, he was very thin right over the incisions and right over the hardware, in fact the screws were palpable. He had intense

pain, more so on the right than the left but all screws appeared to be initiating pain for him. XX opined he was having a strong component of hardware pain and recommended a hardware injection. Tylenol with codeine #4 was prescribed and lumbar spine x-rays were ordered.

On XX/XX/XX, the patient underwent a bilateral L4 to S1 hardware injection by XX.

On XX/XX/XX, a urine drug screen was completed and noted to be positive for ethyl-glucuronide, butalbital, amitriptyline, cyclobenzaprine, pregabalin and cotinine.

On XX/XX/XX, XX saw the patient after his hardware block. The patient reported 80-90% relief of pain for about 3-4 hours and then the pain began to return. It was currently at baseline. He had had a significant amount of pain reduction with the anesthetic phase of the injection indicating that the hardware was causing his pain. XX recommended removal of the pedicle screw instrumentation and exploration of the fusion with revision if necessary.

From XX/XX/XX- XX/XX/XX, the patient underwent hospitalization. Preoperative investigations were completed. On XX/XX/XX, he underwent removal of pedicle screw instrumentation from L4 to S1, exploration of the fusion of L4 to S1, revision of posterior spinal fusion using allograft bone with bone marrow aspiration and bone marrow aspiration times three. Postoperative diagnosis was low back pain with hardware pain.

On XX/XX/XX, XX evaluated the patient postoperatively. He was doing well and felt surgery had definitely helped him. He reported a reduction in his pain. His incisions were clean, dry and intact without evidence of erythema or drainage. Plan was to send him to PT. XX recommended he go back to work light duty next week and prescribed Norco.

On XX/XX/XX, the patient was evaluated for a flare-up. He reported that while working, he was on a flatbed truck and doing some loading and he twisted, felt a pain and a snapping sensation in his back, became concerned about this, had pain. He had some pain, tenderness, and spasticity in the lumbar spine around the L4-L5 and L5-S1 segments. XX prescribed Zanaflex, Medrol Dosepak and Mobic.

On the same date, a urine drug screen (UDS) was completed and was consistent with prescriptions.

On XX/XX/XX, the patient underwent a PT evaluation and was recommended PT sessions 2 times a week for 6-7 weeks. Modalities recommended were therapeutic exercises, manual therapy, joint/soft tissue mobilization, aquatic therapy, neuromuscular re-education, functional activity, gait training, ultrasound and electrical stimulation.

On XX/XX/XX, XX evaluated the patient for worsening pain in his low back. The patient was working. He was trying to cope with the pain but it had been difficult for him. He had been set up for PT but due to miscommunication on his visits, he had been discharged from therapy and had only one appointment. XX switched him to Tylenol No. 4, added Zanaflex and started him on

Vimovo. He reordered PT and gave him a neuromuscular stimulator. An MRI was ordered.

On XX/XX/XX, the patient underwent a PT evaluation and was recommended ongoing treatment 2 times a week for 4-6 weeks.

On XX/XX/XX, an MRI of the lumbar spine was completed at Preferred Imaging and interpreted by XX. The study revealed there were postoperative changes status post anterior and posterior interbody fusion at the lower two lumbar levels. Posterior hardware had been removed. There was no significant central or foraminal stenosis at these levels. There was anterior spurring at the L1-L2 level with minor mixed Modic type I and II endplate changes adjacent to this disc space.

On XX/XX/XX, XX evaluated the patient. MRI was reviewed. No abnormality was seen to warrant his pain. XX assessed the patient was having chronic pain in the L4-L5 and L5-S1 region and recommended consideration for a spinal cord stimulator trial. Norco was refilled.

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On XX/XX/XX, the patient underwent a presurgical psychological evaluation. Based on the evaluation, XX assessed the patient was clear for the stimulator with a good prognosis for pain reduction and functional improvement.

On XX/XX/XX, x-rays of the chest revealed no acute cardiopulmonary process.

On XX/XX/XX, the patient underwent spinal cord stimulator trial times two leads using Medtronic leads and epidurography with interpretation without a radiologist present by XX. Postoperative diagnosis was chronic pain syndrome.

On XX/XX/XX, XX evaluated the patient postoperatively. The patient reported about 70-80% relief of his pain with the stimulator trial. He was very happy with it and requested to have it implanted. The plan was to set him up for this at his convenience. Zanaflex and Norco were refilled.

Per correspondence dated XX/XX/XX, XX documented the implants used for the hardware removal of the lumbar spine were medically necessary due to the fact the patient had pseudarthrosis. In order to enhance the fusion the use of bone graft and a bone growth stimulator was needed.

On XX/XX/XX, XX evaluated the patient for a follow-up visit. The patient reported ongoing pain. Norco was refilled. Plan was to await approval from insurance for the spinal cord stimulator implant since he had a successful trial.

Per Utilization Review dated XX/XX/XX, XX denied the requested services (Spinal Cord Stimulator Implant) with the following rationale: *“Based on the clinical information submitted for this review and using the evidence-based, peer-reviewed guidelines referenced above, this request is non-certified, as the records failed to document medication reduction or functional improvement after the temporary trial.”*

On XX/XX/XX, the patient was evaluated for a follow-up visit. He presented to discuss the denial of the SCS implant. He had reported 70-80% relief of his pain following the SCS trial. He stated he was able to reduce his medication usage. Once the trial was eliminated, he then had to go back on heavy dose of the Norco. He also reported improvement in his function, stating he was able to stand and walk for a longer duration and longer distances. XX opined it was appropriate to consider him for an SCS implant.

Per utilization review dated XX/XX/XX, XX documented the reconsideration of the denied services was received on XX/XX/XX. XX upheld the denial with the following rationale: *“Based on the clinical information submitted for this review and using the evidence-based, peer-reviewed guidelines referenced above: this request is non-certified. There was still no documented evidence of medication reduction and significant functional improvement following the temporary trial prior to this request for implantation.”*

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

Official Disability Guidelines Treatment in Worker’s Comp 2009 Updates, (i.e. Pain – Spinal Cord Stimulator and Psychological Screens)

According to the ODG Pain Chapter –

- Failed back syndrome (persistent pain in patients who have undergone at least one previous back operation and are not candidates for repeat surgery), when all of the following are present: (1) symptoms are primarily lower extremity radicular pain; there has been limited response to non-interventional care (e.g. neuroleptic agents, analgesics, injections, physical therapy, etc.); (2) psychological clearance indicates realistic expectations and clearance for the procedure; (3) there is no current evidence of substance abuse issues; (4) there are no contraindications to a trial; (5) Permanent placement requires evidence of 50% pain relief and medication reduction or functional improvement after temporary trial. Estimates are in the range of 40-60% success rate 5 years after surgery. Neurostimulation is generally considered to be ineffective in treating nociceptive pain. The procedure should be employed with more caution in the cervical region than in the thoracic or lumbar due to potential complications and limited literature evidence

The patient meets the Failed back syndrome criteria with persistent back and right lower extremity pain with limited response to extensive conservative care as documented per the chart. There is no current evidence of substance abuse issues. The SCS trial was successful

with a reported 70-80% relief of his pain following the SCS trial. As per the office note dated, 5/5/2016, he stated he was able to reduce his medication usage from Norco 10mg QID to Ultram 2 per day. Once the trial was eliminated, he then had to go back on heavy dose of the Norco. He also reported improvement in his function, stating he was able to stand and walk for a longer duration and longer distances.

Psychological Evaluations - Recommended pre spinal cord stimulator (SCS) trial.

The patient meets the ODG criteria for Spinal Cord Stimulator permanent placement, thus the previous adverse determinations are overturned.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

X ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES