

AccuReview

An Independent Review Organization

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Notice of Independent Review Decision

[Date notice sent to all parties]: August 23, 2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Pump Refill and Reprogramming

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

This physician is a Board Certified in Anesthesiology with over 6 years of experience.

REVIEW OUTCOME:

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

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.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

06-11-04: History and Physical

12-07-04: MRI Lumbar Spine w/o and w/contrast at Imaging

07-19-11: Peer Review/Medical Records Review

08-08-12: Pain Clinic Worksheet

08-08-12: Pain Pump Readings

09-11-12: Pain Clinic Worksheet

04-11-13: CT Lumbar Spine w/o contrast

04-11-13: Myelogram Complete Spine

05-30-13: Request for Treatment

06-03-13: Pain Clinic Worksheet

06-03-13: Pain Pump Readings

06-10-13: UR performed

06-17-13: Pain Clinic Worksheet

06-17-13: Addendum/Request for Reconsideration

06-20-13: Request for Reconsideration
06-26-13: UR performed
07-15-13: Pain Clinic Worksheet
08-12-13: Pain Clinic Worksheet

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a male who was injured in a work related incident xx/xxxx with a two level disc herniation. He underwent lumbar laminectomy in February 2003 and had Intrathecal Pain Pump placed in 2004.

06-11-04: History and Physical. Claimant complained of severe lower back pain and bilateral leg pain which is more pronounced on the left side. Previous imaging studies show evidence of left side L3-4 disc herniation with indentation to the nerve root and with spinal canal stenosis. Medications: Norco 10/325 3-4 times daily totaling no more than 12 tablets per day for pain, Vioxx 50mg PO daily, discontinued Duragesic patches due to severe headaches. Pain evaluation: Note 3-inch midline surgical scar, well healed. There is severe pain and tenderness along the lumbar spine extending from L3 to S1 severe restriction of lumbar ROM. The claimant is unable to stand and balance on one foot. He is unable to squat. Upright position causes severe pain on the left side radiating to posterior side of the leg and ankle. Back to leg pain ration 60/40. Left side SLR is positive at 45 degrees. Deep tendon reflexes are slightly reduced on the left side. Examination of the bilateral and SI joint structure shows evidence of severe pain on the left SI joint area with positive Gaenslen's test. Pain is worse in the morning with radiating pain to the left groin. Pain rated: lower back 8-9/10, left leg 6-8/10, and left SI joint is also 6-8/10. Impression: 1. Failed back syndrome, 2. Axial lower back pain, 3. Left side lumbar radiculopathy, 4. Left side SI joint dysfunction. Treatment Plan: Claimant is very symptomatic with left side lower back and left leg pain, recommend diagnostic/therapeutic block to control pain. Will proceed with left side L4-5 and L5-A1 nerve root injections with left side SI joint blocks. Adjusted pain medications.

12-07-04: MRI Lumbar Spine w/o and w/contrast. Impression: 1. Degenerative changes with narrowing at L3-4 with edema at the adjacent end plates; mild discitis cannot be excluded. However, the findings could be related to post-operative changes with recurrent, approximately 6-7 mm left posterolateral HNP impinging the left neural foramen with mild to moderate spinal stenosis and mild right foraminal encroachment. 2. Slight narrowing of the neural foramina at L4-5. Otherwise, unremarkable MRI of the lumbar spine without and with contrast.

08-08-12: Pain Clinic Worksheet. Problem focus: LBP, chronic pain syndrome. PE: Pain is currently at 6/10. Claimant returns for narcotic pump maintenance. Current treatment helped controlling pain. Less pain in low back; less radiating leg pain. SLR causes little discomfort in low back without radiating leg pain. Pump is functional. Assessment: Failed back syndrome, Intractable LBP, Radiating RT leg pain, Lumbosacral osteoarthritis, chronic pain syndrome. Plan: Rationale for selection of intrathecal drug dosage and concentration is based upon the recommendation for Polyanalgesic Consensus Conference in 2003.

Currently, third line treatment is applied. Pump refill was done under aseptic technique. Residual volume was removed and wasted before the pump refill. Goal of Therapy: To continue/improve pain relief. To maintain/reduce current medications. To maintain/improve or restore daily activities. Prescriptions & medication changes: Lorcet 10/650mg PO TID, Provigil/Nuvigil for the treatment of narcolepsy. Follow-up: return for pump refill on 9/24.

08-08-12: Pain Pump Readings. Infusion Drug Concentration: 1. Morphine 25.0mg/ml, 2. Fentanyl 1000.0 ug/ml, 3. Marcaine 1.5 mg/ml, 4. Baclofen 250.0 ug/ml, 5. Clonidine 100.0 ug/ml. Infusion Mode Simple Continuous Drug Dose Per Day: 1. Morphine 9.458 mg/day, 2. Fentanyl 378.3 ug/day, 3. Marcaine 0.5675 mg/day, 4. Baclofen 94.58 ug/day, 5. Clonidine 37.83 ug/day.

09-11-12: Pain Clinic Worksheet. Problem focus: LBP, chronic pain syndrome. PE: Pain is currently at 6/10. Claimant showed interval improvement of pain with current treatment. Examination shows less pain in low back; less radiating leg pain. SLR causes mild lumbar discomfort without radiating effects. Current treatment helped partially controlling pain. He is here for oral pain meds refill. Assessment: Failed back syndrome, Intractable LBP, Radiating RT leg pain, Lumbosacral osteoarthritis, chronic pain syndrome. Plan: Continue current medications, follow-up and adjustment of pain management. Goal of Therapy: To continue/improve pain relief. To maintain/reduce current medications. To maintain/improve or restore daily activities. Prescriptions & medication changes: Lorcet 10/650mg PO TID, Provigil/Nuvigil 200mg PO QAM. Rationale for prescribed drugs: narcotic analgesic for primary pain control, Provigil/Nuvigil for the treatment of narcolepsy. Follow-up: return in 4 weeks for routine follow-up or sooner if pain worsens.

04-11-13: CT Lumbar Spine w/o contrast. Impression: Intrathecal placement of the stimulator wire, degenerative disc disease at L2-L3 and L3-L4 as described with mild central canal stenosis at L3-L4, there is a metallic foreign body in the posterior thecal sac at L1-L2 eccentric to the left, non-specific calcification in the liver, comparison with prior would be helpful.

05-30-13: Request for Treatment. Procedures requested: 95991 x 1 pump refilling, 62368 x 1 pump reprogramming, J2275 x 1 Morphine, J3010 x 1 Fentanyl, J0475 x 1 Baclofen, J0735 x 1 Clonidine, S0020 x 1 Marcaine. Medical Necessity: Work related injury on 04/12/01; he is s/p narcotic infusion pump implant in 2004. Pump refilling varies about every 4 to 8 weeks. Diagnosis: 722.83 Failed back syndrome, 724.2 Intractable low back pain, 724.3 Radiating right leg pain, Lumbosacral osteoarthritis, 338.4 Chronic pain syndrome.

06-03-13: Pain Clinic Worksheet. Problem focus: LBP, chronic pain syndrome. PE: The claimant was not able to continue with IT narcotic pain management and he was adjusted with oral medication including Oxycontin 40mg TID, Percocet 5mg TID, Ambien and Klonopin 2mg x2 QHS. He reported his low back pain was not stable and he has been in "horrible" pain. Musculoskeletal revealed moderate tenderness in the right iliolumbar area with positive Patrick's sign. There is

increased pain on flexion, extension and lateral bending. Neuro exam revealed decreased pinprick levels along right L4/S1 dermatomes with decreased dorsiflexion. Assessment: Failed back syndrome, Intractable LBP, Radiating RT leg pain, Lumbosacral osteoarthritis, chronic pain syndrome. Plan: Continue current treatment plan and request restart of IT narcotic infusion. Goal of Therapy: Short Term: To continue/improve pain relief. Long Term: To maintain/reduce current medications. To maintain/improve or restore daily activities. Prescriptions & medication changes: OxyContin 40mg PO TID, Dilaudid 4mg PO TID PRN, Provigil 200mg PO QAM, Gabitril 4mg PO OD. Follow-up: 4 weeks.

06-03-13: Pain Pump Readings. Infusion Drug Concentration: 1. Morphine 25.0mg/ml, 2. Fentanyl 1000.0 ug/ml, 3. Marcaine 1.5 mg/ml, 4. Baclofen 250.0 ug/ml, 5. Clonidine 100.0 ug/ml. Infusion Mode Simple Continuous Drug Dose Per Day: 1. Morphine 9.458 mg/day, 2. Fentanyl 378.3 ug/day, 3. Marcaine 0.5675 mg/day, 4. Baclofen 94.58 ug/day, 5. Clonidine 37.83 ug/day.

06-10-13: UR performed. Reason for denial: IW went under the dash when he was struck by another vehicle. Diagnosis: failed back syndrome, intractable LBP, radiation RT leg pain, lumbosacral OA, chronic pain syndrome. IW went on to get infusion pump 2004 with increase in meds by 10% in 2011 and last pump refill 8/2012, meds morphine, Fentanyl, baclofen, clonidine, marcaine. However, note from 9/11/12 shows "interval improvement" with use of pump without objective discussion and IW was still taking oral Lorcet TID and provigil. Doctor notes states s/p narcotic infusion pump implant 2004, pump refilling varies about 4-8 wks. However, no discussion of efficacy from use of this pump and no discussion as to why pump need to be reprogrammed. Request is for Pump Refill/Reprogramming. Based on the diagnosis and the lack of any current or recent objective discussion of functional benefit from ongoing use of this pump and lack of current exam and lack of clear indications for need to re-program device at this time, according to ODG (low back and chronic pain) Treatment Guidelines, the request is not medically necessary.

06-17-13: Pain Clinic Worksheet. Problem focus: LBP, chronic pain syndrome. PE: Intractable LBP with radiating right leg pain continues all days with intermittent aggravation. Pain improves with lying in bed and is described as aching and shooting pain. Current oral medications only increase drowsiness but very little help to pain. Claimant endorsed 20% pain control with current medication treatment. He has been under IT narcotic management in the last 6 years with excellent tract of records. Assessment: Failed back syndrome, Intractable LBP, Radiating RT leg pain, Lumbosacral osteoarthritis, chronic pain syndrome. Plan: Continue current treatment plan; recent request to resume IT narcotic infusion was denied. Goal of Therapy: Short Term: To continue/improve pain relief. Long Term: To maintain/reduce current medications. To maintain/improve or restore daily activities. Prescriptions & medication changes: OxyContin 40mg PO TID, Dilaudid 4mg PO TID PRN, Neurontin 300mg PO Q8HRS, Gabitril 4mg PO OD. Follow-up: 4 weeks.

06-26-13: UR performed. Reason for denial: The claimant is a male whose DOI xx/xx/xx. Records indicate that the claimant had extensive treatment without significant improvement including a laser procedure for lateral disc herniation; nucleoplasty; ablation epidural steroid injections; laminectomy; and extensive rehab with pain management with pain pump placed in 2004. Records provided document last refill was in 8/2012 and he continued oral pain medications. Non-certification of pump refill and reprogramming. Based on the review of medical records provided, the proposed treatment consisting of pump refill and reprogramming is not appropriate or medically necessary for this diagnosis and clinical findings. The most recent progress note 5/30/13 does not include a current physical examination. There is no indication that oral medications are failing to control pain. As such, the request for pump refill and reprogramming is not recommended as medically necessary according to ODG pain chapter, Implantable drug-delivery system (IDDSs).

07-15-13: Pain Clinic Worksheet. Problem focus: LBP, chronic pain syndrome. PE: Severe LBP continues with claimant reported 40% pain control with current oral medication treatment; also c/o being drowsy with oral narcotics. The low back shows moderate spasm along the left L3/S1. SLR in 60 degrees on right and 45 degrees on the left. Forward bending at 30 degrees, backward at 15 degrees, left lateral bending at 15 degrees, right lateral bending at 15 degrees. Claimant cannot do heel and toe walking. DTR's are ¼ in patellar and Achilles. Previously, the claimant was treated with IT narcotic pump with satisfactory pain control. He was able to work fulltime as an automobile AC technician and enjoy a full active life; pain level was maintained from 0-2 VAS. For 8 years the claimant did not require a single lumbar injection; just a limited amount of oral medication for a breakthrough pain during the day. His treatment was interrupted since he moved out of town in 2012. The claimant has now returned with intractable LBP. He has no tolerance for standing and walking; he can't find a suitable job due to intractable pain. He c/o being very drowsy with oral narcotics. Claimant now request to return to previous regiment that had been working so well for his condition. Assessment: Failed back syndrome, Intractable LBP, Radiating RT leg pain, Lumbosacral osteoarthritis, chronic pain syndrome. Plan: Continue current treatment plan, request IME for IT narcotic pain management. Goal of Therapy: Short Term: To continue/improve pain relief. Long Term: To maintain/reduce current medications. To maintain/improve or restore daily activities. Prescriptions & medication changes: OxyContin 80mg PO TID, Dilaudid 4mg PO TID PRN, Neurontin 400mg PO Q8HRS, Gabitril 4mg PO OD. Follow-up: 4 weeks.

08-12-13: Pain Clinic Worksheet. Problem focus: LBP, chronic pain syndrome. PE: Severe LBP continues with claimant reported 30% pain control with current oral medication treatment described as tingling and numbness radiating to the right leg and ankle with reduced tolerance in standing and walking. There is a constant burning pain in the low back. Examination shows tenderness along the right lumbar paravertebral L4/S1 and reduction of lumbar ROM in flexion. There are patchy dysesthesia along the low back to posterior thigh, calf and lateral foot. SLR is restricted to 60 degrees with radiating pain to the right ankle. Assessment: Failed back syndrome, Intractable LBP, Radiating RT leg pain, Lumbosacral

osteoarthritis, chronic pain syndrome. Plan: Continue current treatment plan, request narcotic pump refill with Morphine Intrathecal. Goal of Therapy: Short Term: To continue/improve pain relief. Long Term: To maintain/reduce current medications. To maintain/improve or restore daily activities. Prescriptions & medication changes: OxyContin 80mg PO BID, Percocet 10/325mg PO Q6HRS, Ultram 50mg PO Q6HRS, Neurontin 400mg PO Q8HRS, Gabitril 4mg PO OD, Provigil 200mg PO QD. Follow-up: 4 weeks.

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

The previous adverse determinations have been overturned and disagreed with. The claimant is a male whose DOI xx/xx/xx. Claimant has had significant treatment post injury without significant improvement. Procedures including laser procedure for lateral disc herniation; nucleoplasty; ablation epidural steroid injections; laminectomy; and extensive rehab with pain management with pain pump placed in 2004 have all been without significant improvement. The claimant's last refill was in 8/2012 and has since continued oral pain medications. Based on the review of medical records provided, the proposed treatments consisting of pump refill and reprogramming are appropriate for this diagnosis and clinical findings. Recent progress notes include a current physical examination and demonstrate that oral medications are failing to control pain. As such, the request for pump refill and reprogramming is recommended as medically necessary per ODG. Therefore, after review of the medical records and documentation provided, the request for Pump Refill and Reprogramming is overturned and approved.

Per ODG:

<p>Implantable drug-delivery systems (IDDSs)</p>	<p>Indications for Implantable drug-delivery systems: <u>Implantable infusion pumps</u> are considered medically necessary when used to deliver drugs for the treatment of:</p> <ul style="list-style-type: none"> o o Primary liver cancer (intrahepatic artery injection of chemotherapeutic agents); o o Metastatic colorectal cancer where metastases are limited to the liver (intrahepatic artery injection of chemotherapeutic agents); o o Head/neck cancers (intra-arterial injection of chemotherapeutic agents); o o Severe, refractory spasticity of cerebral or spinal cord origin in patients who are unresponsive to or cannot tolerate oral baclofen (Lioresal®) therapy (intrathecal injection of baclofen) <p><u>Permanently implanted intrathecal (intraspinial) infusion pumps</u> for the administration of opiates or non-opiate analgesics, in the treatment of chronic intractable pain, are considered medically necessary when:</p> <ul style="list-style-type: none"> • • Used for the treatment of <u>malignant (cancerous) pain</u> and all of the following criteria are met: <ol style="list-style-type: none"> 1. 1. Strong opioids or other analgesics in adequate doses, with fixed schedule (not PRN) dosing, have failed to relieve pain or intolerable side effects to systemic opioids or other analgesics have developed; and 2. 2. Life expectancy is greater than 3 months (less invasive techniques such as external infusion pumps provide comparable pain relief in the short term and are consistent with standard of care); and 3. 3. Tumor encroachment on the thecal sac has been ruled out by appropriate testing; and 4. 4. No contraindications to implantation exist such as sepsis or
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	<p>coagulopathy; and</p> <p>5. 5. A temporary trial of spinal (epidural or intrathecal) opiates has been successful prior to permanent implantation as defined by a 50% reduction in pain. A <i>temporary</i> trial of intrathecal (intraspinal) infusion pumps is considered medically necessary only when criteria 1-4 above are met.</p> <ul style="list-style-type: none"> • • Used for the treatment of <u>non-malignant (non-cancerous) pain</u> with a duration of greater than 6 months and all of the following criteria are met: <ol style="list-style-type: none"> 1. 1. Documentation, in the medical record, of the failure of 6 months of other conservative treatment modalities (pharmacologic, injection, surgical, psychological or physical), if appropriate and not contraindicated; and 2. 2. Intractable pain secondary to a disease state with objective documentation of pathology in the medical record (per symptoms, exam and diagnostic testing); and 3. 3. Further surgical intervention or other treatment is not indicated or likely to be effective; and 4. 4. Psychological evaluation has been obtained and evaluation states that the pain is not primarily psychologic in origin, the patient has realistic expectations and that benefit would occur with implantation despite any psychiatric comorbidity; and 5. 5. No contraindications to implantation exist such as sepsis, spinal infection, anticoagulation or coagulopathy; and 6. 6. A temporary trial of spinal (epidural or intrathecal) opiates has been successful prior to permanent implantation as defined by at least a 50% to 70% reduction in pain and documentation in the medical record of <u>functional improvement</u> and associated reduction in oral pain medication use. A temporary trial of intrathecal (intraspinal) infusion pumps is considered medically necessary only when criteria 1-5 above are met. <p>For average hospital LOS if criteria are met, see Hospital length of stay (LOS).</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)