

Notice of Independent Review Decision

DATE OF REVIEW: APRIL 28, 2010

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

A dispute has arisen in regards to a pump replacement with dye study under fluoro with IV sedation for the lumbar spine.

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

The physician is a Board Certified by ABPM&R with 17 years of experience.

REVIEW OUTCOME

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

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Per the Workers Compensation First Report dated xx/xx/xx, the examinee incurred lower back pain due to excessive driving. The examinee was employed as a xxxx at the time of his complaint.

On January 20, 2000, M.D., an orthopedic surgeon, evaluated the examinee. Impression: Low back pain.

On May 15, 2000, M.D., a neurologist, evaluate the examinee. Impression: Back pain possibly old and due to musculoskeletal in nature because of intactness of the neurological examination. Leg pain on rest. Maybe leg cramps. Neuropathy pain unlikely, but cannot be ruled out.

On June 8, 2000, MRI of the lumbar spine was taken. Impression: 6mm left paracentral subligamentous disc protrusion at the L5-S1 level impinging on the exiting nerve root as above. Remaining MRI of the lumbar spine is within normal limits.

On June 28, 2000, D.C. placed the examinee at MMI as of May 1, 2000 and assigned the examinee a 7% whole person impairment per the 3rd Edition *AMA Guidelines*. Diagnoses: Chronic HNP. Chronic degenerative disc disease. Resolved lumbar spine sprain.

On August 21, 2000, M.D. evaluated the examinee. Assessment: 1. Chronic low back pain, which will not be helped by any surgical procedure. 2. Degenerative disk disease at L5-S1 with moderate central disk bulge versus herniation. There is no evidence of nerve root compression by MRI study. 3. There is no evidence of the Left S1 radiculopathy by examination. 4. The examinee's complaints of chest pain and left arm pain, which are not related to low back problems. 5. The examinee gives no history of injury to suggest that this is a job-related injury. In my opinion, simple driving will not result in disk herniation.

On September 29, 2000, M.D. performed an EMG on the examinee. Impression: Evidence of acute and chronic polyradiculopathy on the left side including L4 and L5/S1 radiculopathy with evidence of ongoing denervation in the respective myotome. No evidence of radiculopathy has been found in the right leg. Sensory neuropathy has been appreciated with diminished amplitude in the sural nerve testing bilaterally. No evidence of myopathy has been found. Needle examination was to some extent compromised because he was very sensitive to needles.

On October 19, 2000, D.C. placed the examinee not at MMI pending a ortho and neuro consult.

On December 27, 2000, M.D. evaluated the examinee. Impression: Since he has not had ESI we will try those. If that does not help, we can consider microdiscectomy or discography and possible fusion.

On January 8, 2001, M.D. performed a lumbar ESI on the examinee.

On March 30, 2001, per the operative report M.D. performed a provocative lumbar discography at L3-L4, L4-L5, and L5-S1.

On March 30, 2001, CT of the lumbar spine was performed. Impression: L3-4 and L4-5 discs appear normal. At L5-S1 there is severe disc degeneration with contrast extending into a small central disc protrusion. There does not appear to be significant canal or foraminal stenosis.

On August 21, 2001, M.D. evaluated the examinee. Assessment: Lumbar disk disruption with spinal stenosis at the level of L5-S1. Tobacco Addiction. GI and DVT prophylaxis.

On August 21, 2001, per the operative report M.D. performed the following: 1. A laminectomy and complete facetectomy left L5-S1 with micro-discectomy at this level. 2. Harvest of autologous bone graft, right iliac crest. 3. Placement of blackstone pedicle screws, left L5-S1. 4. Posterolateral fusion L5-S1 bilaterally. 5. Interbody fusion using autologous bone L5-S1. 6. Placement of cage L5-S1.

On October 25, 2001, X-rays were taken of the lumbar spine. Impression: Anterior and posterior fusions L5-S1 with left posterolateral instrumentation. Satisfactory alignment overall.

On January 25, 2002, M.D. placed the examinee at MMI as of January 15, 2002 with a 10% whole person impairment.

On March 28, 2002, M.D. performed a re-exam on the examinee. Impression: Postop TLIF at L5-S1 with persistent low back pain and muscle spasm.

On May 31, 2002, M.D. performed a peer review on the examinee and decided that the muscle stimulator was not recommended.

On July 17, 2002, M.D. performed a ESI at L4-5.

On October 30, 2002, per the operative report M.D. performed a Trans Epidural LUM on the examinee.

On January 27, 2003, per the operative report ,M.D. performed a lumbar medial branch block L3-L4 bilaterally.

On January 31, 2003, M.D. re-examined the examinee. Impression: Confirm the facet-mediated pain with medial branch blocks providing 80% pain relief. Status post PLIF at L5-S1 with persistent low back pain and muscle spasms. Continue use of RS medical stimulator. Insomnia due to chronic pain.

On April 30, 2003, per the operative report ,M.D. performed a sacroiliac joint injection.

On September 26, 2003, per the operative report M.D. surgically placed spinal cord stimulator.

On December 15, 2003, per the operative report ,M.D. surgically placed an intrathecal drug infusion catheter.

On February 2, 2004, per the operative report ,M.D. surgically placed an intrathecal drug infusion catheter.

On October 21, 2004, M.D. performed a RME on the examinee. Dr. opined that no further diagnostics testing is necessary. Dr. did indicate refills for indwelling morphine pump as medical necessary.

On March 5, 2009, per the operative report M.D. performed an aspiration of intrathecal catheter, removal of medication from reservoir and pump refill.

On April 2, 2009, MRI of the lumbar spine was taken. Impression: No evidence of granule associated with morphine pump catheter. Minimal broad based disc protrusion at L4-5 with no canal or foraminal stenosis. Thin lipoma of the filum terminate.

On April 2, 2009, X-rays were taken of the lumbar spine. Impression: Prior 360 fusion L5-S1 with no complication identified. Lumbar epidural catheter appears to be in satisfactory position.

On April 2, 2009, X-rays were taken of the thoracic spine. Impression: Thoracic spine series demonstrates on acute abnormality. An epidural catheter is noted to be in satisfactory position.

On June 16, 2009, M.D. performed a peer review on the examinee. Diagnosis: Chronic pain syndrome.

On October 8, 2009, D.O. evaluated the examinee. Impression: Displacement of thoracic or lumbar intervertebral disc without myelopathy. Lumbar nerve root compression.

On January 15, 2010, D.O. evaluated the examinee. Impression: Postlaminectomy syndrome. Pseudoarthrosis at L5-S1. Failed back surgery. Nicotine addiction.

On January 21, 2010, D.O. evaluated the examinee. Impression: Chronic post lumbar laminectomy pain syndrome having failed both surgical fusion and

currently on intrathecal morphine sulfate. Persistent lumbar radiculopathy. Cannot rule out RSD of the lower extremities. Generalized deconditioning with longstanding Valium utilization at a moderate dose. Chronic nicotine consumption and reactive depression in a chronic pain state.

On February 4, 2010, Dr. re-examined the examinee. Recommendations: Holistic interdisciplinary approach. Wellbutrin therapy. Plus decreasing his Valium consumption.

On February 22, 2010, Dr. recommended a replacement interval for the Medtronic implanted 8672L18.

On March 8, 2010, Dr. performed a utilization review and denied the examinee's pump replacement. Reasons for denial: 1. Documentation in the medical record of the failure of 6 months of other conservative treatment modalities, if appropriate and not contraindicated. 2. Intractable pain secondary to a disease state with objective documentation of pathology in the medical records. 3. Further surgical intervention or other treatment is not indicated or likely to be effective. 4. Psychological evaluation has been obtained and evaluation states that the pain is not primarily psychogenic in origin, the examinee has realistic expectations and that benefit would occur with implantation despite any psychiatric comorbidity. 5. No contraindications to implantation exist such as sepsis, spinal infection, anticoagulation or coagulopathy. 6. A temporary trial of spinal opiates has been successful prior to permanent implantation as defined by at least 50% to 70% reduction in pain and documentation in the medical records of functional improvement and associated reduction in oral pain medication use.

On March 12, 2010, M.D. performed a peer review on the examinee. Dr. opined that the examinee would need continued care with a pain specialist and denied chiropractic care.

On March 26, 2010, M.D. performed a utilization review and agreed with Dr. stating the pump replacement is not medically necessary.

PATIENT CLINICAL HISTORY:

The examinee's mechanism of injury was excessive driving, the examinee drove approximately 1000 to 1500 miles per week.

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

Upon reviewing the medical records and documents submitted to me, I uphold and concur with the decision to deny the replacement intrathecal pump. There is

no documentation of a 50-70% pain reduction with functional improvement and reduction in oral pain medication use with use of the spinal opiates. Additionally, records do not indicate objective documentation of a disease state causing intractable pain. As per the ODG, all the criteria for a spinal pump implantation replacement has not been met.

Per the ODG Guidelines:

Indications for Implantable drug-delivery systems:

Implantable infusion pumps are considered medically necessary when used to deliver drugs for the treatment of:

Primary liver cancer (intrahepatic artery injection of chemotherapeutic agents);

Metastatic colorectal cancer where metastases are limited to the liver (intrahepatic artery injection of chemotherapeutic agents);

Head/neck cancers (intra-arterial injection of chemotherapeutic agents);

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)

Permanently implanted intrathecal (intraspinal) infusion pumps for the administration of opiates or non-opiate analgesics, in the treatment of chronic intractable pain, are considered medically necessary when:

- Used for the treatment of malignant (cancerous) pain and all of the following criteria are met:
 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. 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. Tumor encroachment on the thecal sac has been ruled out by appropriate testing; and
 4. No contraindications to implantation exist such as sepsis or coagulopathy; and
 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 *temporary* trial of intrathecal (intraspinal) infusion pumps is considered medically necessary only when criteria 1-4 above are met.
- Used for the treatment of non-malignant (non-cancerous) pain with a duration of greater than 6 months and all of the following criteria are met:
 1. Documentation, in the medical record, of the failure of 6 months of other conservative treatment modalities (pharmacologic, injection, surgical, psychologic or physical), if appropriate and not contraindicated; and
 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. Further surgical intervention or other treatment is not indicated or likely to be effective; and
 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. No contraindications to implantation exist such as sepsis, spinal infection, anticoagulation or coagulopathy; and
 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 functional improvement 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

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)