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Notice of Independent Review Decision

DATE OF REVIEW: NOVEMBER 22, 2010

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Dye study for pain pump for lumbar spine

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

This reviewer is licensed by Texas Board of Anesthesiology and Pain Medicine with 40 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

On July 10, 2002, the claimant was evaluated by M.D., a pain management physician. He underwent a lumbar fusion at L4-5 May 3, 2000. He has been

complaining of low back pain and was placed on different drug regimens that included Fentanyl patches, later on MS-Contin and Norco and a variety of medications for pain and depression. He reports that he is still in pain even with the amount of drugs he is taking. Dr. prescribed Paxil for 1 weeks of 10 mg in the morning and increase it to 20 mg. Zanaflex 6mg, in the evening, Hydrocodone 5 mg #30, Klonopin ½ mg 4 times a day. The claimant expressed interest in a medicine pump as a better way to deal with his pain. His pain is deep in nature, normal gait, normal strength 5/5 bilaterally,. Deep tendon reflexes are decreased and sensory in both legs. An MRI dated June 4, 2002 revealed partial Interbody fusion of the bone graft within the left paracentral disc cage at L4-5, no definite evidence of D.O.

On October 18, 2010, the claimant was evaluated by D.O. The claimant has a 70% improvement of his ongoing back, buttock, arm, and hand pain complaints following intrathecal therapy. His calculated residual volume was 4.78 cc. His pump was refilled with Dilaudid 20mg/ml containing Baclofen. He is on this infusion at 7 mg/day.

On October 25, 2010, the claimant was re-evaluated by D.O. He is complaining of increasing pain and feels that his pump may not be functioning in a consistent manner. Due to his concern with withdrawal effects, he does want to undergo dye study to rule out any irregularity within the pump catheter and/or infusion system.

On October 28, 2010, M.D., an orthopedic surgeon, performed a utilization review was performed on the claimant. Rational for Denial: This is a complex pain case. The patient is concerned that pump coverage works only sometimes. He questions the patency of catheter versus function of pump. I will review pump data and render a decision after doing so. The pump is three years old. It was last filled on 10/18/10. Calculated and residual volumes are equal at 4.78 cc, so the pump is likely infusing. Therefore, it is not certified.

On November 2, 2010, D.O., a pain management physician, performed a utilization review was performed on the claimant. Rational for Denial: There is no definitive sign of catheter dysfunction or disconnect which needs the requested dye study. Intermittent pain increases are not a sign of malfunctioning catheter. Therefore, it is not certified.

PATIENT CLINICAL HISTORY:

The claimant is a male who has complaints of lumbar spine pain.

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

The claimant had a 70% improvement of his ongoing back, buttock, arm and hand pain complaints following intrathecal therapy on October 18, 2010. The pump was refilled with Dilaudid 20 mg/ml containing Baclofen. His calculated residual volume was 4.78 ml.

On October 25, 2010, on follow-up examination, he is complaining of intermittent and inconsistent pain relief. Calculated and residual volumes are equal at 4.78 ml, so the pump is probably infusing. There are no objective signs that the catheter is not functioning, or that the catheter is disconnected. The cyclical increasing pain levels in a chronic pain management patient is not objective evidence that the catheter is malfunctioning. Therefore, the previous decisions are upheld.

Per ODG:

Implantable drug-delivery systems (IDDSs)

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)