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DATE NOTICE SENT TO ALL PARTIES: 3/9/16

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

The item in dispute is the prospective medical necessity of a routine refill of intrathecal pain pump with Sufentanil 50 mcg.

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

The reviewer is a Medical Doctor who is board certified in Anesthesia/Pain Management. The reviewer has been practicing for greater than 10 years.

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)

The reviewer agrees with the previous adverse determination regarding the prospective medical necessity of a routine refill of intrathecal pain pump with Sufentanil 50 mcg.

PATIENT CLINICAL HISTORY [SUMMARY]:

Claimant is a female who sustained an injury on XX/XX/XX. Her diagnoses include chronic cervicgia/cervical radiculitis and chronic low back pain/lumbar radiculitis. A request was made for intrathecal pain pump refill with Sufentanil 50 µg. She was status post placement of intrathecal drug delivery system.

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

The patient is a female who was injured on XX/XX/XX. She was diagnosed with chronic cervical and lumbar radiculitis. A request for routine refill of the

intrathecal pump with Sufentanil was made. She presented on XX/XX/XX for intrathecal pump refill. She was taking Vicodin and prednisone. She had an extensive list of allergies. She was currently on Sufentanil at 32.5 mcg per day. She did report benefit with a prednisone dose pack. She continues to take her oral hydrocodone for breakthrough pain. She did not report any adverse effects with combination of the intrathecal and oral medication. She continues to accomplish her ADLs with less difficulty due to pain relief. C5-T1 and L1-S2 were intact on physical examination. The patient's pain pump was refilled without change with scheduled follow up in one month. While the patient reported pain relief and functional improvement with Sufentanil, guidelines state that while this drug has been used for intrathecal chronic non-malignant pain, this usage is non-FDA approved and have little associated research to substantiate their use. Therefore, medical necessity is not established.

Official Disability 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)