

Vanguard MedReview, Inc.

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IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Pump Refill (Morphine Sulfate 13.5mg/ ml/ Hydromorphone HCL45mg/ ml. Bupivacaine Hcl 27mg)

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

This case was reviewed by a Board Certified Physical Medicine and Pain Rehabilitation doctor with over 20 years of experience.

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adversedeterminations 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.

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a male who was injured on XX/XX/XX when he was doing x. He developed persistent low back pain and subsequently underwent a lumbar laminectomy, with little relief. He has been using a pain pump and is currently requesting a refill.

XX/XX/XX: Follow-up Visit. **Subjective:** XX is complaining of chronic pain which he rates 5/10 today. He is not as lethargic as the previous appointment. At that time we had decreased his pump from 11.9-11.02 mg/day. Patient's here today to receive his refill of his intrathecal narcotic pump. We did a complete pump analysis with reprogramming and removed 3.5 cc of old medications and installed new medications at the same concentrations. PTM has been disabled for a few weeks. At that time we will lower his daily dosage and add a bolus several times a day to help with his pain. Hopefully using the bolus and set of the daily dosage will decrease his drowsiness. Patient also takes Ambien to help him sleep at night as well as Skelaxin. We will refill these with 2 additional refills. **Current Medications:** Flomax 0.4mg 1 tab daily, Lisinopril 2.5 mg 1 tab daily, Pravastatin. **Exam:** Abdomen: ITP tip 7-8:00 position. ITO left lower ergometer quadrant with corresponding vertical surgical scar. Soft, NT/ND. Extremities: There is mild edema still on the left lower extremity but not on the right. Vertical surgical scars anterior knee bilaterally from multiple surgical procedures. Neurologic: A/O x 3. Gait slightly staggered without assistive devices. Psychiatric: Intact memory, judgement and insight, normal mood and effect. Speech normal rate and tone. **Diagnosis/Assessment:** Chronic Pain syndrome **Plan:** e-prescribing some Rx G8446 Follow up 2 weeks.

XX/XX/XX: Procedure Note. **Procedure:** Electronic Analysis of Pump with Reprogramming

XX/XX/XX: Encounter Summary. **Subjective:** Patient has been a lot more active than he has previously. The decrease in medication has allowed him to have more mental acuity. He does not have any frank decline in his functional status. Just continuously reports increased pain levels. His wife complains that he is slightly sleepy. And unfortunately even with the decrease in dosing the Dilaudid still seems to be causing over sedation intermittently. Opioid-based sedation continues major issue. He has been active and ambulatory. Patient reports that eh pain is a debilitating factor in performing ADL's. **Objective:** Decreased ROM and spasms in the lumbar spine and cervical spine. No evidence of any changes in gait. He does have a kyphotic posture. The pump is located in the left lower quadrant. Scar has evidence of neuroma formation without any evidence of exhortation. **Assessment:** Lumbago, post laminectomy syndrome of lumbar region **Plan:** Physical therapy evaluation was completed. Currently awaiting approval. Believe patient will benefit tremendously from pt. Skelaxin 400mg twice a day. Given this patient is evidence that he has had long-term exposure of opioids, he has less likely up sensitized his new receptors. Given this long history of opiate-based pain control program and his high doses that he was on previously is going to be very difficult for him to wean down. It is clear to me that he is very active. I can observe his hands and he has callus formation he has excellent reflexes in upper and lower extremities and excellent strength in upper and lower extremities. There is no evidence of any acute decline. I would like for him to wean completely of the opioid medications even though it may be extremely difficult however an opioid holiday and detoxification program will be ideal in his particular case. Patient will benefit from continual weaning from opioids. Also, I will like to start him on Prialt as he has over sedation from the opioids. Medtronics SynchroMed 2 pump interrogation was completed. The pump was analyzed and reprogrammed. The results revealed a decrease 12% of drug dose. There were no complications from the reprogramming. Patient tolerated the procedure well. Patient has rescue medications available in the event of a pump failure.

XX/XX/XX: UR. **Rationale for Denial:** This patient presents with chronic non-malignant pain. The request is for compound narcotics for a pump refill. However, ODG states that overall, the safety of long-term narcotic use has not been adequately studied, and some non randomized prospective studies suggest opioid treatment may actually retard functional recovery. This leads to a concern about confounding issues such as tolerance, opioid-induced hyperalgesia, long-range adverse effects such as hypogonadism and/or opioid abuse, and the influence of placebo as a variable for treatment effect. MTUS guidelines state that the long term efficacy of opioids for the treatment of chronic pain remains limited. Therefore, the requested compound narcotics for pump refill; morphine sulfate 13.5 mg/ ml/ hydromorphone HCl 45 mg/ml bupivacaine HCl 27 mg) would not be considered medically necessary.

XX/XX/XX: UR. **Rationale for Denial:** The proposed treatment is not appropriate and medically necessary for this diagnosis and clinical findings. The review of the available medical records indicates that the claimant has chronic non-malignant back pain. There is insufficient evidence to recommend the use of implantable drug delivery systems for the treatment of chronic pain. Besides this, review of supplied medical records do not document clinical efficacy of the implanted/intrathecal pump for this claimant. Specifically, submitted medical records do not document pain relief or improvement in function due to the implanted/intrathecal drug delivery system for this claimant.

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

Determination: denial of pump refill with Morphine Sulfate, Hydromorphone and Bupivacaine is OVERTURNED/DISAGREED WITH given submitted clinical information documenting effective management of chronic low back pain status post surgery so as to maintain function with appropriate office visits to monitor side effects resulting in reprogramming and changes commensurate with sedating side effects.

Indications for Implantable drug-delivery systems:

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

- o Primary liver cancer (intrahepatic artery injection of chemotherapeutic agents);
- o Metastatic colorectal cancer where metastases are limited to the liver (intrahepatic artery injection of chemotherapeutic agents);
- o Head/neck cancers (intra-arterial injection of chemotherapeutic agents);
- 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)

Permanently implanted intrathecal (intraspinal) infusion pumps for the administration of opioids or non-opioid 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) opioids 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 and documented by treating providers in the medical record:
 - (1) Non-opioid oral medication regimens have been tried and have failed to relieve pain and improve function (see [functional improvement](#)); and
 - (2) At least 6 months of other conservative treatment modalities (injection, surgical, psychological or physical), have been ineffective in relieving pain and improving function; and
 - (3) Intractable pain secondary to a disease state with objective documentation of pathology in the medical record (per symptoms, physical examination and diagnostic testing); and
 - (4) Further surgical intervention or other treatment is not indicated or likely to be effective; and
 - (5) Independent psychological evaluation has been obtained and evaluation states that the pain is not primarily psychogenic in origin, the patient has realistic expectations and that benefit would occur with implantation despite any psychiatric comorbidity; and
 - (6) No contraindications to implantation exist such as sepsis, spinal infection, anticoagulation or coagulopathy; and
 - (7) There has been documented improvement in pain and function in response to oral opioid medications but intolerable adverse effects preclude their continued use; and
 - (8) 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 1-7 above are met.

Morphine sulfate, *Morphine sulfate ER, CR (Avinza®; Kadian®; MS Contin®; Oramorph SR®; generic available, except extended release capsules)*: *Side Effects*: See opioid adverse effects. *Analgesic dose*: Immediate release tablets for acute pain (moderate to severe); Opiate naive patients should begin with 10mg PO every 4 hours as needed. Opioid tolerant patients may need higher starting doses to achieve pain relief (10-30mg every 4 hours as needed). See specific product for full prescribing information. Controlled, extended and sustained release preparations should be reserved for patients with chronic pain, who are in need of continuous treatment. Avinza® - morphine sulfate extended release for once daily dosing. The 60mg, 90mg and 120mg capsules are for opioid tolerant patients only.

Hydromorphone (*Dilaudid®; generic available*): 2mg, 4mg, 8mg. *Side Effects*: Respiratory depression and apnea are of major concern. Patients may experience some circulatory depression, respiratory arrest, shock and cardiac arrest. The more common side effects are dizziness, sedation, nausea, vomiting, sweating, dry mouth and itching. (Product Information, Abbott Labs 2006) *Analgesic dose*: Usual starting dose is 2mg to 4mg PO every 4 to 6 hours. A gradual

increase may be required, if tolerance develops. Exalgo (extended release hydromorphone) has been approved by the FDA, but there are no published studies demonstrating superiority. ([FDA, 2010](#))

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)