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Description of the service or services in dispute:
Morphine 10 mg/mL pump refill

Description of the qualifications for each physician or other health care provider who reviewed the decision:
Board Certified Anesthesiology

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)

Patient Clinical History (Summary)
XXXX is a XX-year-old XX who was injured on XXXX. XX XXXX causing XX to XXXX. The diagnosis was complex regional pain syndrome I of the left lower limb. XX had a history of anxiety, depression and arthritis.

XXXX underwent refill procedures of the left side pump and right side pump (Morphine 10mg/mL) on XXXX and XXXX respectively by XXXX, MD.

XXXX was evaluated by Dr. XXXX on XXXX for complaints of left foot pain, depression and anxiety. XX was not working at the time. XX was ambulatory with no assistance. XX reported pain in the left piriformis. XX medication list was updated on XXXX. There was no pill count on Gabapentin as the patient had not brought in the pills that day. XX needed a refill for the Gabapentin. The examination revealed adequate range of motion of the shoulders, elbows, wrists, hips, knees and ankles bilaterally. Examination of the back revealed triggers felt with taut bands in the left piriformis, and upon palpation, produced twitch response with characteristic pain pattern of the muscle group. There was limited range of motion. The assessment inlcuded complex regional pain syndrome I of the left lower limb. Per the note, the Morphine pump was helping with the complex regional pain syndrome. The plan inlcuded steroid injection to the left piriformis with ultrasound, urine toxicology screening and starting the patient on chronic opioid therapy to control the pain.

A Urine drug screen testing dated XXXX was positive for Alpha-Hydroxyalprazolam, Morphine and cZolpidem (Zolpidem metabolite) and was consistent with the prescribed medications, which included Alprazolam, Morphine and Zolpidem. Paroxetine, Olanzapine and Gabapentin were detected but could not be matched to any of the prescribed medications.

Treatment to date consisted of medications (Neurontin, Ambien, Alprazolam, Clonzapem), injections, surgeries to include back nerve stimlator therapy in XXXX, Morphine pump implant in XXXX, stimulator implant XXXX and chronic opioid therapy.

Per an Adverse Determination Notice dated XXXX by XXXX, MD, it was determined that the request for Morphine pump refill 20 mL (10mg/mL) was not medically necessary, medically appropriate or indicated based on the review of medical records provided.

Per an Adverse Determination After Reconsideration Notice dated XXXX by XXXX, MD, it was documented that the proposed treatment consisting of Morphine pump refill was not appropriate or medically necessary for the diagnosis and clinical findings. The documentation did not support the effectiveness of the intrathecal Morphine. There was no quantitative assessment on how it helped (percentage of relief, how long this relief lasted), no mention of a urine drug screen that showed compliance and no increase in function or activity. Therefore, the request was not medically necessary.

Analysis and Explanation of the Decision include Clinical Basis, Findings and Conclusions used to support the decision.

This reviewer disagrees with the prior two adverse determinations provided on XXXX and XXXX. I do not find the evidentiary basis for their finding that the efficacy of the intrathecal medication is in question. There is no evidence that the patient VAS scores are out of control, or that function or ADLs are negatively impaired.

The patient is highly dependent on a polypharmaceutical approach in which several classes of drugs with concomitant effects are being used. The reviewers are correct in their criticism that the use of intrathecal opiates is not designed to be combined with additional oral pharmaceutical agents. But, this is a pathophysiologic state that has taken years to evolve and can only be corrected with objective pharmaceutical principles that require many months. The patient's provider, is the individual who knows the patient clinically and is the best possible professional to make these pharmaceutic adjustments. There is no evidence that there are issues of non-compliance in this patient – the UDS appears consistent.

On a safety issue, not filling a morphine intrathecal pump has a high probability of acute withdrawal with concomitant problems related to cardiac morbidity, possible renal complications and psychological "suffering." Once a pump is implanted, the decision to abandon this therapy should not be made lightly.

Notably, this issue was adjudicated in November 4, 2004 in Weslaco, Texas. In a medical contested case hearing no 13050, Julio Gomez, Jr. ruled that the patient was entitled to a morphine pump refill.

This reviewer recommends that the intrathecal opiate therapy should be continued in this patient, with continued adjustments of oral pharmaceutical agents by the patient's provider.

A description and the source of the screening criteria or other clinical basis used to make the decision:

- ☐ ACOEM-America College of Occupational and Environmental Medicine um knowledgebase
- ☐ AHRQ-Agency for Healthcare Research and Quality Guidelines DWC-Division of Workers
- ☐ Compensation Policies and Guidelines European Guidelines for Management of Chronic Low Back
- ☐ Pain Interqual Criteria
- ☑ Medical Judgment, Clinical Experience, and expertise in accordance with accepted medical standards
- ☐ Mercy Center Consensus Conference Guidelines
- ☐ Milliman Care Guidelines
- ☑ ODG-Official Disability Guidelines and Treatment Guidelines

Pain Chapter

<u>Implantable drug-delivery systems (IDDSs)</u>

Recommended only as an end-stage treatment alternative for selected patients for specific conditions indicated in the blue criteria below, after failure of at least 6 months of less invasive methods, and following a successful temporary trial.

<u>Indications for Implantable drug-delivery systems:</u>

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)

<u>Permanently implanted intrathecal (intraspinal) infusion pumps</u> 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, psychologic 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 psychologic 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.

(9) For average hospital LOS if criteria are met, see Hospital length of stay (LOS).

If treatment is determined to be medically necessary, as with all other treatment modalities, the efficacy and continued need for this intervention and refills should be periodically reassessed and documented.

There is insufficient evidence to recommend the use of implantable drug-delivery systems (IDDS) for the treatment of chronic pain. There are no high-quality studies on this topic that document that this therapy is safe and effective. Further, significant complications and adverse events have been documented and the data identifies a substantial risk to patients. (Washington State Health Care Authority, 2008) Results of studies of opioids for musculoskeletal conditions (as opposed to cancer pain) generally recommend short use of opioids for severe cases, not to exceed 2 weeks, and do not support chronic use (for which a pump would be used). This treatment may be considered relatively late in the treatment continuum, when there is little hope for effective management of chronic intractable pain from other therapies. (Angel, 1998) (Kumar, 2002) (Hassenbusch, 2004) (Boswell, 2005) (Deer, 2009) (Patel, 2009)

For most patients, it should be used as part of a program to facilitate restoration of function and return to activity, and not just for pain reduction. The specific criteria in these cases include the failure of at least 6 months of other conservative treatment modalities, intractable pain secondary to a disease state with objective documentation of pathology, further surgical or other intervention is not indicated, there are no contraindications to a trial, psychological evaluation unequivocally states that the individual has realistic expectations and the pain is not psychological in origin, and a temporary trial has been successful prior to permanent implantation as defined by a 50% reduction in pain. (Tutak, 1996) (Yoshida, 1996) (BlueCross, 2005) (United Health Care, 2005) See also Opioids and the Low Back Chapter. In a study of IDDS in 136 patients with low back pain, after one year 87% of the patients described their quality of life as fair to excellent, and 87% said they would repeat the implant procedure. However, complication rates (i.e., infection, dislodging, and cerebrospinal fluid leak) are likely to

rise with time in these procedures and more longitudinal outcome studies need to be conducted. (Deer, 2004) In one survey involving 429 patients with nonmalignant pain treated with intrathecal therapy, physician reports of global pain relief scores were excellent in 52.4% of patients, good in 42.9%, and poor in 4.8%. In another study of 120 patients, the mean pain intensity score had fallen from 93.6 to 30.5 six months after initiation of therapy. In both studies, patients reported significant improvement in activities of daily living, quality of life measures, and satisfaction with the therapy. (Winkelmuller, 1996) (Paice, 1997) One study in patients suffering from chronic low back pain caused by failed back syndrome found a 27% improvement after 5 years for patients in the intrathecal drug therapy group, compared with a 12% improvement in the control group. (Kumar, 2002) Supporting empirical evidence is significantly supplemented and enhanced when combined with the individually based observational evidence gained through an individual trial prior to implant. This individually based observational evidence should be used to demonstrate effectiveness and to determine appropriate subsequent treatment. Generally, use of implantable pumps is FDA approved and indicated for chronic intractable pain. Treatment conditions may include FBSS, CRPS, Arachnoiditis, Diffuse Cancer Pain, Osteoporosis, and Axial Somatic Pain. As we have gained more experience with this therapy, it has become apparent that even intrathecal opioids, when administered in the long term, can be associated with problems such as tolerance and other side effects. Consequently, long-term efficacy has not been convincingly proven. However, it is important to note that there is a distinction between "tolerance" and "addiction", and the levels of drugs administered intrathecally should be significantly below what might be needed orally in their absence. (Osenbach, 2001) (BlueCross BlueShield, 2005) See also Intrathecal drug delivery systems, medications.

Safety Precautions & Warnings: Oral opioid prescribing, use and how to best keep patients as safe as possible have all have been the subject of increasing discussion, in part, due to related accidental deaths. (Phillips, 2008) Use of intrathecal opioids, as for all routes of administration, is not without risk. Constipation, urinary retention, nausea, vomiting, and pruritus are typical early adverse effects of intrathecal morphine and are readily managed symptomatically. Other potential adverse effects include granuloma formation, amenorrhea, loss of libido, edema, respiratory depression, death, and pump and catheter malfunctions. (Winkelmuller, 1996) (Paice, 1997) (Washington State Health Care Authority#2, 2008) Common causes of mortality in implanted pump patients appear to be preventable through adherence to dosing and monitoring information for drugs approved for chronic intrathecal administration. Follow product instructions and dosing recommendations. Failure to comply with all implanted infusion pump product instructions can lead to technical errors or improper use and result in additional surgical procedures, a return of underlying symptoms, or a clinically significant drug underdose or fatal drug overdose. (Medtronic, 2009) The mortality rate in the implanted pump population is higher than some operative benchmarks and similar at approximately 30 days and 1-year post discharge to open spine surgery in the Medicare population. (Coffey, 2009) Patients who receive the implanted device should be monitored in an adequately equipped facility for a sufficient time to monitor drug effects. When using concomitant medications with respiratory or CNS depressant effects, appropriate supervision and monitoring should be provided. (Medtronic, 2009)

Patient selection (in addition to criteria below): Cole 2003 recommends that, after other criteria are met, patients with neuropathic pain are better candidates for spinal cord stimulation (SCS), and patients with nociceptive pain are better candidates for intrathecal drug delivery (IDD). It also recommends psychological evaluation and clearance before any implantation, plus positive response to a trial. (Cole, 2003)

Medications for IDDS if determined to be medically necessary:

First stage: Morphine is generally the initial IDDS medication. The maximum recommended dose for this drug is 15 mg/day with a concentration of 20 mg/mL. An alternative non-FDA approved medication is hydromorphone. The maximum recommended dose for this medication is 4 mg/day with a concentration of 10 mg/mL. Other opioids (including Fentanyl and Sufentanil) have been used for intrathecal chronic non-malignant pain but are non-FDA approved and have little research associated with their use. (Waara-Wolleat, 2006) (Deer, 2007) The previous 2003 Polyanalgesic conference recommended a maximum dose of intrathecal morphine at 15 mg/day with a maximum concentration of 30 mg/mL. They also recommended a maximum dose of hydromorphone of 10 mg/day with a concentration of 30 mg/mL. (Hassenbusch, 2004) The newer maximum concentrations were recommended, in part, to prevent granulomas.

Second stage: If side effects occur, an upper limit of dosing is reached, or neuropathic pain is present, clonidine is next recommended as an addition to an opioid (maximum recommended dose of 1 mg/day and a concentration of 2 mg/mL). Bupivacaine has also been recommended as an alternative to clonidine (maximum dose of 30 mg/day and a concentration of 40 mg/mL). Clonidine, which is FDA approved for intrathecal delivery, is thought to provide analgesic effect via a non-opioid mechanism. It has been found to offer only short-term relief when used as a single agent. (Deer, 2007)

Third stage: The recommendation has been made to add both clonidine and bupivacaine. Baclofen has been used to treat intractable spasticity from brain injury, cerebral palsy, and spinal cord injury and has resulted in improvement in muscle tone and pain relief. (Guillaume, 2005) See also Ziconotide (Prialt®), which is recommended after documentation of a failure of a trial of intrathecal morphine or hydromorphone (Dilaudid).

Refills*: IDDSs dispense drugs according to instructions programmed by the clinician to deliver a specific amount of drug per day or to deliver varying regimens based on flexible programming options, and the pump may need to be refilled at regular intervals. The time between refills will vary based on pump reservoir size, drug concentration, dose, and flow rate. A programming session, which may occur along with or independent of a refill session, allows the clinician to adjust the patient's prescription as well as record or recall important information about the prescription. (Hassenbusch, 2004) According to the FDA, the manufacturer's manuals should be consulted for specific instructions and precautions for initial filling, refilling and programming. (FDA, 2010) For most pumps, the maximum dose that can be delivered between refills is 1000mg. If refills are usually administered after 16 to 17 mL have been infused, and most pumps are 18-20mL, the minimum time between each visit is 42 days if the daily dose rate is 20 mg/day. Given that a refill visit presents a good opportunity for monitoring, this panel suggested that the concentration be adjusted to allow refill visits a minimum of every 4 to 6 weeks, and maximum of every 2–3 months. (Bennett, 2000)*

- ☐ Pressley Reed, the Medical Disability Advisor
- ☐ Texas Guidelines for Chiropractic Quality Assurance and 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)