

P&S Network, Inc.

8484 Wilshire Blvd, Suite 620, Beverly Hills, CA 90211

Ph: (323)556-0555 Fx: (323)556-0556

Notice of Independent Review Decision

DATE OF REVIEW: 11/09/2009

IRO CASE #:

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

This case was reviewed by a Pain Management (Board Certified), Licensed in Texas and Board Certified. The reviewer has signed a certification statement stating that no known conflicts of interest exist between the reviewer and the injured employee, the injured employee's employer, the injured employee's insurance carrier, the utilization review agent (URA), any of the treating doctors or other health care providers who provided care to the injured employee, or the URA or insurance carrier health care providers who reviewed the case for a decision regarding medical necessity before referral to the IRO. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Implantation of intrathecal programmable pump; 62362; dx: 355.71

REVIEW OUTCOME

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

Overturned (Disagree)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- o Submitted medical records were reviewed in their entirety.
- o Treatment guidelines were provided to the IRO.
- o 05-16-06 Consult-History and Physical from Dr.
- o 06-06-06 Psychodiagnostic Assessment from LPC
- o 06-29-09 Progress Note from Dr.
- o 07-10-09 Operative Report, Morphine intrathecal trial, from Dr.
- o 07-28-09 Progress Note from Dr.
- o 08-21-09 New Patient Office Note from Dr.
- o 08-25-09 Progress Note and exam notes from Dr.
- o no date Surgery Planner from Dr.
- o 09-01-09 Patient Information Report, unsigned
- o 09-02-09 Pre-authorization from Dr.
- o 09-08-09 Initial non-determination letter
- o 09-30-09 Pre-authorization request form Dr.
- o 10-01-09 Pre-authorization from Dr.
- o 10-08-09 Letter of non-determination for reconsideration
- o 10-12-09 Request for IRO from the provider
- o 10-17-09 Summary sheet
- o 10-21-09 Confirmation Receipt of IRO from TDI
- o 10-21-09 Notification of Case Assignment - IRO from TDI
- o 10-26-09 Prospective Review (M2) Response

PATIENT CLINICAL HISTORY [SUMMARY]:

According to the medical records and prior reviews the patient is a male while tying down a xx. He underwent a lumbar surgery with fusion at L4-5. In May 2006, his provider felt he had cauda equina syndrome and sent him for a pain management consultation.

In pain management on May 15, 2006 the patient reported severe pain in the left low back radiating into the left leg and right thigh. He was noted to have had two epidural injections with partial relief. The patient's medical history is positive for hypertension, kidney stones, difficulty urinating and diabetes. Motor strength and sensation were noted as normal. An MRI of January 2006 was noted to reveal prior bilateral laminotomies at L4-5 with persistent evidence of thecal sac compression and a right paracentral disc protrusion impinging on the right L5 nerve root.

Epidural injection was administered on June 8, 2006 with no significant benefit reported.

Neurostimulator trial of May 3, 2007 provided no improvement. Neurostimulator trial subcutaneous leads done on September 7, 2007 provided no improvement.

Per a Psychodiagnostic assessment of June 6, 2008 the patient has a 40% MMI rating. He was assessed in regard to his candidacy for an implantation procedure. He has not worked since October 2005. He reports frequent sweats and chills and muscle spasms and cramps. He appeared to be an appropriate candidate for an opioid trial pump.

The patient returned to pain management on June 29, 2009. He has numbness to the left leg and both thighs without muscle weakness. He is using OxyContin, Norco, Lyrica, Ambien CR, Cymbalta and Tofranil PM. Cymbalta is reduced slightly with concern for elevated liver enzymes. He has been in PT for over a month with no significant benefit. He is seeing a urologist. He is 6' and 280 pounds (BMI = 38.0). Assessment is chronic low back pain status post fusion syndrome October 2007, lumbar radiculopathy bilaterally worse on the left, use of high-risk medication and history of cauda equina with continued loss of bowel and bladder control. Approval for an IDDS is pending.

On July 10, 2009 the patient underwent trial of intrathecal Morphine with injection of 1 mg of Morphine into the spinal canal.

Pain management notes of July 28, 2009 note the patient has pain level of 9/10 without meds and 6/10 with meds. Pain is made worse "with everything." A recent pump trial gave him 80% relief until about 6 PM that day and he reports the next day was even better in terms of activity tolerance. He hopes to have a permanent pump soon.

The patient was provided a consultation to assess his suitability for implantation of a pain pump on August 21, 2009. He has had several surgeries at L4-5 and ultimately an anterior posterior fusion. He complains of low back pain and left leg pain in the L5 distribution. He has tried a variety of treatments but his provider believes his condition is chronic. His fusion appears to be solid. He does have a history of diabetes and hypertension. He is a non-smoker. He does not notice any weakness in his legs that is severe. All activities seem to make his pain worse. Per a myelogram there is some persisting constriction of the foramen on the left at L5. He has not gotten any significant relief with nerve decompression in the past which suggest that further decompression is unlikely to help that nerve and certainly not his most severe symptom which is his low back pain. According to the case worker, he is apparently approved for the device. Other than the mentioned L5 condition which he will discuss further with his pain management provider, he should be good to go with implantation.

The patient was seen in pain management on August 25, 2009. In consultation he discussed some pinching of L5 which could be surgical. He has been considering surgery versus implantation of a pump and is leaning toward a pump. Liver function tests have been ordered to determine if they have returned to normal with reduction of Cymbalta. He will decide if he wants a pump or a surgery.

The patient decided he would like to proceed with implantation of an intrathecal pain pump with formal pre-authorization submitted on September 2, 2009.

Request for implantation of an intrathecal pain pump was considered in review on September 1, 2009 and recommended for non-certification. The reviewer's notes indicate that the type of pump trial performed was not clarified and he would need to know more about the trial - one shot, continuous catheter etc and what type of drug was used for the trial. A return call from the provider's PA was anticipated but not realized. The provider was notified of the decision on September 8, 2009.

Request for implantation of intrathecal programmable pump was made again on September 30, 2009 for a diagnosis of causalgia of lower limb.

Request for reconsideration of implantation of intrathecal programmable pump was considered in review on October 1, 2009 and recommended for non-certification. Limited information submitted indicated he responded to a pain pump trial, but viewing the patient's own statement, the trial only helped for one day. The procedure note is now provided and indicates a single dose trial. Per ODG criteria number 6 has not been met: (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. Per the reviewer, the amount of relief and objective functional improvement over time has not been documented. The provider was notified of the decision on October 8, 2009.

Request was made for an IRO.

Per the carrier's response to the request dated October 26, 2009 the provider opines the patient to have a healed fusion, although

no recent imaging is cited. As noted by the reviewer, the provider failed to submit documentation of amount of relief and objective functional improvement over time with the pain pump trial.

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

The operative report of July 10, 2009 states a 23 gage Quincke needle was advanced to the L5-S1 intralaminar space from the posterior and midline approach. Unfortunately, CSF was unable to be obtained at this site. Next, attention was turned to the L3-4 interspace, where the 23-gauge Quincke was advanced using fluoroscopic guidance with return of clear spinal fluid confirmed ...Next, a total of 1 mg of preservative free morphine was injected into the spinal fluid. On July 28, 2009 the provider reported, a recent pump trial gave him 80% relief until about 6 PM that day and he reports the next day was even better in terms of activity tolerance. He hopes to have a permanent pump soon. Per specialty opinion, further decompression is unlikely to help the L5 nerve and certainly is not his most severe symptom which is his low back pain.

The patient has unrelenting pain associated with cauda equina syndrome and has attempted neurostimulation, physical therapy, pharmacological and interventional interventions for pain relief. He has a 40% MMI impairment rating, has not worked since 2005 and has been cleared psychologically for implantation of a pain pump. Assessment is chronic low back pain status post fusion syndrome October 2007, lumbar radiculopathy bilaterally worse on the left, use of high-risk medication and history of cauda equina with continued loss of bowel and bladder control. On July 10, 2009 the patient underwent trial of intrathecal Morphine with injection of 1 mg of Morphine into the spinal canal, with an initial response reported with 80% relief.

ODG criteria #6 states: 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.

The patient appears to be a candidate for implantation and no other treatment options are planned. The trial of morphine administered on July 10, 2009 indicates good response both subjectively and objectively with improved function and 80% relief. The patient meets guideline criteria to warrant this procedure.

Therefore, my recommendation is to disagree with the previous non-certification for implantation of intrathecal programmable pump; 62362; dx: 355.71

The IRO's decision is consistent with the following guidelines:

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

X 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

The Official Disability Guidelines, Pain Chapter (10-21-2009) Implantable Drug Delivery Systems:

Recommended only as an end-stage treatment alternative for selected patients for specific conditions indicated below, after failure of at least 6 months of less invasive methods, and following a successful temporary trial. 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), although IDDSs may be appropriate in selected cases of chronic, severe low back pain or failed back syndrome. This treatment should only be used relatively late in the treatment continuum, when there is little hope for effective management of chronic intractable pain from other therapies. 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.

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. 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. 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. 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 opiates, when administered in the long term, can be associated with problems such as tolerance, hyperalgesia, 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.

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 amenorrhea, loss of libido, edema, respiratory depression, accidental death and technical issues with the intrathecal system. 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. 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. Monitor patients in an adequately equipped facility for a sufficient time to monitor drug effects. When using concomitant medications with respiratory or CNS depressant effects, provide appropriate supervision and monitoring.

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.

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.