



Notice of Independent Review Decision

[Date notice sent to all parties]:

April 2, 2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Trial Intrathecal Morphine Pump Implant (CPT 62350, 62355, J2275, E0781.RR).

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

American Board of Physical Medicine and Rehabilitation Subcertification in Pain Medicine physician

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)

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Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

- Office visits on 10-13-11, 11-17-11, 11-18-11, 12-15-11, and 1-12-12.
- 1-17-13 Psychological Evaluation.
- 1-28-13, UR denial.
- 2-7-13, office visit.
- 2-7-13, UR denial.
- 2-26-13, office visit.

PATIENT CLINICAL HISTORY [SUMMARY]:

Office visits on 10-13-11, 11-17-11, 11-18-11, 12-15-11, and 1-12-12.
Recommendations made for referral to for trail IT pump.

1-17-13 Psychological Evaluation:

Diagnostic Impression:

Axis I: Pain Disorder with Psychological and Medical Factors. Axis II: V71.09.

Axis III: Low Back Pain.

Axis IV: Moderate.

Axis V: GAF= 95.

Summary/Recommendations: This patient's history and clinical interview data is most consistent with a diagnosis of a Pain Disorder with Psychological and Medical Factors. This patient is psychologically stable. He has some mild depressive and anxiety symptoms, but these symptoms were not severe enough to preclude her candidacy for an implantable device. The patient has a realistic understanding of the procedure and appears capable of providing informed consent. He has a realistic understanding of the procedure and the reasoning behind it. He appears to have compatible goals to reduce his reliance on pain medications and increase his functional status. The evaluator asked him to make an appointment to get his questions answered. He can provide psychological clearance for an implantable pump without reservations.

1-28-13, UR denial - The clinical documentation submitted for review lacks evidence of a recent thorough physical exam of the patient and documentation of exhausted conservative modalities to support the current request. The most recent clinical note submitted for review was dated from 02/07/2012. He called and discussed the case

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who noted that he is not the primary pain management physician and that he is only a surgical consultant in regards to the morphine pump. has not seen the patient since last year. indicates that he will have the patient come in for a repeat evaluation and document the current status of the patient's condition. The patient presents with psychological clearance for an intrathecal pump trial; however, due to lack of documentation of exhausted conservative modalities, imaging studies, and a recent thorough physical exam, the request for trial intrathecal, morphine pump, implant, trial pump is non-certified.

2-7-13, the claimant has chronic low back pain, failed back surgery syndrome and arachnoiditis. The evaluator recommended a psychological evaluation and intrathecal opiate trial.

2-7-13, UR denial - the claimant is a male who reported an injury on xxxxx. He is noted to have undergone a percutaneous discectomy in 1991 and an anterior lumbar fusion at L5-S1 in 1993. He is reported to have continued complaints of low back pain with radiation of pain to the left leg. A psychological assessment performed on 01/17/2013 reported the patient had realistic understanding of the procedure and appeared to have compatible goals to reduce his reliance on pain medications and increase his functional status, and he was given psychological clearance for an implantable pump without reservations. A clinical note signed on 02/07/2012 reported the patient underwent a lumbar spinal fusion in 1993 and felt some improvement at first but got worse shortly afterward. He is reported to have been treated with medications with some improvement and has undergone a trial spinal cord stimulator implant without improvement. He is noted to have been treated with epidural steroid injections without improvement and is reported to have received a morphine injection with significant short-lived improvement. His pain is reported to continue to escalate, and he is noted to be on Kadian 100 mg twice a day with morphine sulfate 3 times a day. The opiate doses cause some sedation, and the patient takes Nuvigil to decrease the side effects. The patient continues to experience pain with standing, sitting, and walking and can only ride in a car for 30 minutes. He reported his oral medications used to work but not any longer. He reported complaints of weakness and numbness in the left leg and is reported to use a cane. On physical exam, the patient is noted to have decreased range of motion of the lumbar spine in all planes with bilateral lumbar spasms, tenderness to palpation over the facet joints, with no provocative testing. The patient was noted to have an intact sensory exam to light touch, decreased knee and ankle jerk reflexes on the left, and decreased strength of plantarflexion and dorsiflexion on the left. The Official Disability Guidelines recommend an implantable drug delivery system with documentation of failure of 6 months of other conservative treatments with intractable pain secondary to an objective documentation of pathology. No further surgical interventions or other treatments are indicated or likely to be effective. A psychological evaluation has been obtained, and evaluation states that pain is not purely psychological in origin. The patient has realistic expectations that benefit would occur with implantation and no contraindications to implantation exist and a temporary trial of spinal (epidural or intrathecal) opioids have been successful prior

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to permanent implantation as defined by at least a 50% to 70% reduction in pain with documentation in the medical records of functional improvement and associated reduction in oral medications. As the patient is noted to have intractable pain since 1993 following his lumbar fusion; to have been treated conservatively with oral narcotics, epidural steroid injections, unsuccessful spinal cord stimulator, and a morphine injection; further surgical interventions or other treatments are not indicated; and a psychological clearance has been obtained; but the patient is not noted to have undergone a temporary trial of spinal opioids with at least 50% to 70% reduction in pain, documentation of functional improvements, and associated reduction in oral pain medication use; and as such, the request for a pain pump implantation for morphine does not meet guideline recommendations. Based on the above, the request for pain pump implantation for morphine is non-certified.

2-26-13, the claimant is seen for followup. His medications include Kadian, Morphine sulfate, Prozac, Nuvigil, Diovan, Advair, Albuterol prn, ASA, Zyrtec. On exam, the claimant has antalgic gait with a cane. Heel to toe walk is abnormal. The claimant is tender at facet joints. DTR are 2+ on the right and 1+ on the left. Motor testing is 4/5 at left plantar flexor and dorsiflexion. Impression: Chronic low back pain, failed back surgery syndrome, arachnoiditis. Opiate contract reviewed. Plan: Psychological evaluation. The claimant has continued with severe pain with inadequate response to oral medications and poor functional status. Will request intrathecal opiate trial.

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

Based on the records provided, the claimant is noted to have intractable pain since 1993 following his lumbar fusion. The claimant has not had updated diagnostic testing. There is no indication as to why this claimant has ongoing and intractable complaints of low back pain. Therefore, the trial Intrathecal Morphine Pump Implant (CPT 62350, 62355, J2275, E0781.RR) is not reasonable or medically necessary.

Per ODG 2013 Implantable Drug Delivery System: 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 DDSs 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. (Angel, 1998) (Kumar, 2002) (Hassenbusch, 2004) (Boswell, 2005) (Deer, 2009) (Patel, 2009) For

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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 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. (Osenbach, 2001) (BlueCross BlueShield, 2005) See also Intrathecal drug delivery systems, medications

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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. (Winkelmuller, 1996) (Paice, 1997) 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) 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. (Medtronic, 2009)

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)

Patient selection (in addition to criteria below): This textbook recommends that, after other criteria are met, patients with neuropathic pain are better candidates for spinal

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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)

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 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.

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· 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, psychological 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 (intraspinial) infusion pumps is considered medically necessary only when criteria 1-5 above are met.

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

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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)