

The DYLL REVIEW

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25 Highland Park Village #100-177 Dallas TX 75205

Phone: 888-950-4333 Fax: 888-9504-443

Notice of Independent Review Decision

DATE OF REVIEW: 04/29/2011

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

A prospective review of medical services has been requested for *CPT* codes 62350, 62362, 62368, 95991, 77002, 00630. These *CPT* codes are for replacement of an implanted medication pump, which reportedly has failed to function and has been present for a period of approximately five years

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

The physician performing this review is Board Certified, American Board of Physical Medicine & Rehabilitation. He is certified in pain management. He is a member of the Texas Medical Board. He has a private practice of Physical Medicine & Rehabilitation, Electrodiagnostic Medicine & Pain Management in Texas. He has published in medical journals. He is a member of his state and national medical societies.

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)

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.

Uphold current denial for pump replacement.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Records Received: 15 page fax 4/13/11 Texas Department of Insurance IRO request, 118 page fax 4/15/11 URA response to disputed services including administrative and medical records. 20 page fax 4/14/11 Provider response to disputed services including administrative and medical records

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PATIENT CLINICAL HISTORY [SUMMARY]:

This claimant was employed. She was injured in the course of her work on xx/xx/xx when she was assaulted. The patient has most recently been followed by Dr. for chronic pain management and ultimate placement of an intrathecal pain pump that is monitored and refilled on a regular basis. The patient, in addition to this, has regularly been receiving medications with no indication that there was any lowering of medication amounts including narcotics with utilization of the implanted medication pump. Medications have included Imitrex, Lidoderm patches, Tigan, Zolof, Armour thyroid, Nexium, tizanidine, phenergan, Norco, and morphine sulfate.

In addition, the patient has continued to have considerable amounts of ongoing pain symptoms. The follow-up notes indicate that in the report of 06/21/10 it was noted that the patient had significantly increased pain, and there was a question as to whether or not the pump catheter was functioning correctly. It was noted at that point in time that fluoroscopic evaluation should be undertaken to determine the status. The records since then do not indicate that such monitoring has taken place, and the patient has continued to receive regular refills of medication into the pump. Also, the follow-up records indicate right hip pain in the 11/12/10 report with an injection provided. In the follow-up note of 12/20/10, the records reflect that the patient had fallen two to three weeks previously and had significant increase of hip and thigh pain along with low back pain, and in the 03/16/11 follow-up note, it was indicated that the patient had a new pelvic fracture(?), possibly related to the fall.

A part of the rationale for the replacement of the intrathecal pump is noted as indicating the intrathecal pump is sticking out at a 45-degree angle, and pants are rubbing on the pump and it is causing skin irritation and breakdown. Revision was needed so that it does not cause this any longer. The records also appear to indicate that prior there had been problems with pump location, and the pump had been moved to its current location. There does not appear to be any objective documentation of catheter malfunction.

The preauthorization and reconsideration rationales utilizing the *ODG* criteria indicate that there is no current, ongoing objective documentation of intrathecal administration of medication as being effective for pain relief and increase in function. It is noted in the preauthorization request reviews that the patient has been continued on significant amounts of oral medication, which have gradually increased over time, and no objective documentation of reduction in the use of oral medications. Based on this lack of objective information, the patient does not meet the criteria for *ODG* use of an intrathecal pump, and the consensus from the preauthorization information is that pump removal would be supported and no support from the *ODG* for replacement.

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

As per noted in the prior preauthorization commentary and from my review of the above medical information, the records do not document any effectiveness of the intrathecal pump, reduction in the use of oral medication, or increase in objective functional activities. There is also the recent notation of a new pelvic fracture unrelated to the original work injury.

ODG Implantable drug-delivery systems (IDDSs)	<p>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. (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</p>
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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](#)

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

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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 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:

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- 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.

- **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

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	<p>indicated or likely to be effective; and</p> <p>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</p> <p>5. No contraindications to implantation exist such as sepsis, spinal infection, anticoagulation or coagulopathy; and</p> <p>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.</p> <p>For average hospital LOS if criteria are met, see Hospital length of stay (LOS).</p>
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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)