



CLAIMS EVAL

*Utilization Review and
Peer Review Services*

Notice of Independent Review Decision-WC

DATE OF REVIEW: 10-26-10

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Pump refill/reprogramming with refill kit under fluoro (62368, 95991, A4220, 77003)

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

American Boards of Physical Medicine and Rehabilitation and Pain Management

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.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- Interrogation and programming of SynchroMed pump for Dilaudid and Fentanyl on 7-10-03, 9-2-03, 10-13-03, 11-24-03, 12-29-03, 2-10-04, 3-22-04, 5-3-04, 6-7-04, 6-16-04, 7-15-04, 8-23-04, 10-7-04, 11-23-04, 1-13-05, 3-3-05, 4-21-05, 6-20-05, 8-22-05, 10-24-05, 12-5-05, 1-4-06, 3-7-06, 5-3-06, 7-5-06, 9-6-06, 11-16-06, 1-18-07, 3-29-07, 6-6-07, 8-9-07, 10-22-07, 11-13-07, 1-7-08, 3-18-08, 6-3-08, 8-13-08, 1-22-09, 4-13-09, 7-1-09, 10-13-09, 11-30-09, 12-21-09, 1-11-10, 2-1-10, 2-16-10, 3-9-10, 4-14-09, 5-4-10, 6-16-10, 7-8-10, 7-29-10, 8-19-10, and 9-15-10.
- 7-21-03 Dr. performed a caudal epidural steroid injection and left sacroiliac joint block. .
- 5-18-09 MD., performed an Independent medical evaluation.
- X-rays of the right ribs dated 1-13-04.
- 6-10-04 X-rays of the chest.
- 6-10-04 Surgery performed by MD.
- 7-23-05 Emergency Department visit.
- 7-23-05 X-ras of the lumbar spine.
- 7-23-05 X-rays of the right hip.
- 8-28-05 MD., performed a Peer Review.
- Physical therapy visits on 9-22-05, 9-27-05, 9-29-05, 10-4-05, 10-11-05, and 10-13-05.
- 10-10-05 MD., office visit.
- On 6-6-06 Surgery performed by DO.

- 6-12-06 MD., performed a Peer Review.
- 2-21-07 Emergency Department visit.
- 2-21-07 Acute abdominal series with chest x-rays.
- 2-22-07 DO., office visit.
- UDS dated 8-9-07.
- 8-13-07 DO., performed a Peer Review.
- 8-29-07 DO., performed a Designated Doctor Evaluation.
- 9-29-07 Dr. provided an addendum.
- 5-25-08 MD., performed a Peer Review.
- 2-29-09 MD., performed an addendum report.
- 5-18-09 MD., performed an independent medical evaluation.
- 7-15-09 MD., office visit.
- 7-21-09, MD., performed an addendum report.
- 7-21-09 MD., performed an independent medical evaluation addendum.
- 7-27-09 Surgery performed by Dr..
- 7-29-09 Emergency Department visit.
- 7-29-09 X-rays interpreted by Dr..
- 7-29-09 Surgery performed by Dr..
- 10-9-09 Emergency Room visit.
- 2-16-10 UDS.
- 4-1-10 MD., performed an independent medical evaluation.
- 10-1-10 DO., performed a Utilization Review.

- 10-11-10, DO., performed a Utilization Review.
- 10-14-10 DO., performed an emergency refill of Synchromed pump and interrogation programming of SynchroMed pump.

PATIENT CLINICAL HISTORY [SUMMARY]:

On 7-10-03, the claimant underwent interrogation and programming of SynchroMed pump for Dilaudid and Fentanyl.

On 7-21-03, Dr. performed a caudal epidural steroid injection and left sacroiliac joint block. His current medications include Neurontin, MsContin.

On 7-21-03, the claimant was provided with a refill of SynchroMed pump.

5-18-09 MD., performed an Independent medical evaluation. Diagnosis: Axis I: Nicotine dependence, Conversion reaction, Opiate dependence. Axis II: rule out Anti-social personality disorder. Axis III: Status post gunshot wound to the abdomen in 1987 with multiple abdominal adhesions. Probably producing recurrent abdominal pain although claimant reports legally he never had a gunshot wound.

Status post small bowel obstruction. Status post ventral hernia repair secondary in February 2000 exploratory laparotomy not related to the work injury but to small bowel adhesions from a gunshot wound. Status post right knee surgery, thumb surgery, toe surgery and appendectomy. Ventral umbilical hernia repair what appears to be 2006 that was successful. No further evidence of hernia. Axis IV: Severity of psychosocial stressors- catastrophic. Axis V: Global assessment of functioning 50/50. Current medical treatment is not reasonable and medically necessary and related to the work injury. I could find no ventral hernia on my examination. Please note that he may have intermittent herniation however this is not typically a painful condition unless the hernia is incarcerated which is not documented in any of the medical records. Please note that a gunshot wound to the abdomen with multiple adhesions with small bowel incarceration and documented by Dr. can produce abdominal pain. The claimant reports that at a Benefit Review Conference they stated he didn't have a gunshot wound to the abdomen legally but that's not consistent with medical record. There's no documented functional improvement with intrathecal Dilaudid and fentanyl pump and it is not reasonable or medically necessary. There does not appear to be any illicit substance abuse. Urine drug screen was consistent with medications that he's been given through his pump. Narcotic medications are not helping the claimant return to work. If narcotics were working to relieve pain claimant would be working full duty with no restrictions. They're clearly not working to relieve the alleged pain. Therefore, narcotics are not reasonable or necessary. Furthermore, narcotics are not a treatment for a conversion reaction which appears to be highly medically probable. He concurred with Dr. regarding the current Hydromorphone dose. However, there's no documented functional improvement with current dose. Continuing to escalate dosage and prescribe narcotics

is not consistent with current disability management philosophy. Other than getting more narcotics, he could not discern a reasonable plan and the claimant cannot explain one. The claimant is apparently gradually titrated. Based on the claimant's history I diagnosed him with opiate dependency. He needs to be tapered and detoxified off of current medications, the pump needs to be removed, he may need to be on Suboxone (for detox or chronically), go to Narcotics or alcoholics Anonymous, get a sponsor, and participate in a twelve-step program and reintegrate back into society (work). Weaning of medication is not being considered as far as he could tell. Urine drug screens have been consistent with the drugs being provided. Summary opinion: Narcotics need to be discontinued and the pump needs to be removed. Withdrawal symptoms can be handled with Suboxone. Any residual pain complaints can be handled with Suboxone. Having the claimant obtunded, not working, and having no functional objective improvement or even subjective improvement in pain complaints is not consistent with quality medicine or quality disability management. It is also not supportive of somebody who meets criteria for diagnosis of a conversion reaction and opiate dependency. As mentioned, he needs to be tapered and detoxified off of current medications, the pump needs to be removed, he may need to be on Suboxone (for detox or chronically), go to Narcotics or alcoholics Anonymous, get a sponsor, and participate in a twelve-step program and reintegrate back into society (work).

X-rays of the right ribs dated 1-13-04 showed a negative rib series. Old right clavicular fracture.

6-10-04 X-rays of the chest showed no evidence of active cardiopulmonary disease.

6-10-04 Surgery performed by MD., notes the claimant was seen for possible malfunctioning pump. An aspiration of the pump and redosing was performed. Postop diagnosis: Pump functioning normally.

Medical records reflect the claimant continued with pump refills and interrogations.

On xx/xx/xx, the claimant was seen at a local ED due to right leg pain. Diagnosis provided was right leg sciatica and chronic pain. It was noted the claimant had multiple abdominal surgeries/hernia repairs/chronic adhesions. Th claimant reported gradually worsening of right gluteal pain with sharp and lancing pains into the right thigh for 12 days. There was no evidence of exam of vascular compromise of his right lower extremity or neuro compromise. The claimant reported that his pain pump medications of Dilaudid and Fentanyl were not helping the pain.

X-ras of the lumbar spine showed moderate lumbar spondylosis. No acute abnormalities.

X-rays of the right hip showed no acute abnormality.

On 8-28-05 MD., performed a Peer Review. It was his opinion that it is not medically probable that the complaints of low back pain are related to the hernia repairs that were

a result apparently of the injury. There were no medical records available to me from Dr. regarding an exam of the low back. The claimant is xx years old and it is more medically probable that he has some disease of life findings related to the complaints of the low back. There would be no correlation between those diseases of life findings and a hernia repair.

On 10-10-05, MD., evaluated the claimant. He noted that this injury falls outside my area of expertise and training as an orthopedic surgeon so he was unable to comment on the medications and treatment needs. He would recommend this be addressed by a general surgeon or an internal medicine specialist. A functional capacity evaluation was not performed because of the examinee's claims of severe pain and restricted activity. In his opinion the examinee did give full effort today on examination with the motions and maneuvers that he requested of him. In my opinion, the surveillance video does indicate he has reasonable ability to move. He is shown bending from the waist to remove items from the trunk of his car, straightening up and carrying them. In his opinion, he can return to work for up to 4 hours per day with lifting of up to 5 pounds and no kneeling/squatting, bending/stooping, pushing/pulling, twisting or climbing and limited standing and sitting. Please see attached TWCC-73. I asked the examinee very carefully regarding his history of the gunshot wound. He reports he only had a gunshot wound of the right knee, a superficial wound over the right patella. I note that the medical records appear to indicate the gunshot was to the abdomen and that he underwent a total knee replacement in 1992 secondary to a motor vehicle accident. But he noted the scar on his knee is smaller than he would expect for a total knee replacement and as the records begin in 2000 there is little information on the gunshot. This issue falls outside my training and expertise as an orthopedic surgeon. In his opinion this is better addressed by a general surgeon or an internal medicine specialist. The examinee reported he was taking only Provigil and the pain pump medications. Please see my comments above regarding these. The adjuster also furnished copies of prescription billings, which document the Provigil use. The only other medications included are a single charge for Hydrocodone and another single charge for Cipro. These would not be considered significant due to their single appearance in the record.

On 6-6-06 Surgery performed DO., notes the claimant his bowel obstructions secondary to adhesions. He was taken to surgery. The adhesions were lysed.

On 6-12-06, MD., performed a Peer Review. The evaluator reported that the records reflect that the pump refill notes indicate that the majority of the refills are being performed under fluoroscopy. This is completely unnecessary. The evaluator would ask Dr. to justify the added expend and radiation exposure of fluoroscopy in the routine refill of subcutaneous SynchroMed pump.

Emergency Department visit. The claimant presents from incarceration with a history that his "hernia is out." He was seen yesterday for the same problem. He had been vomiting and unable to keep anything down. On exam, the claimant has a healed incision int eh lower midline. There is no evidence of hernia. Abdomen is quite distended and is tympanitic throughout to percussion. Lab testing performed. The

claimant was given pain medications with some relief. Impression: partial small bowel obstruction. The case was discussed with Dr. Turrentine who has operative on him before. The claimant was provided with a nasogastric tube and IV fluids to be observed and hopefully will open up without requiring further operative intervention.

Acute abdominal series with chest showed bowel ass pattern consistent with constipation.

On, the claimant was seen by DO. He noted that the claimant's blood count is within normal range. He will try to treating him conservatively and hope he can relieve his bowel obstruction.

UDS dated 8-9-07 was inconsistent for opiates, Hydromorphone.

On 8-13-07, DO., performed a Peer Review. It was his opinion that the intrathecal pump was not reasonable or medically necessary. The trial was never appropriate as the initial mode of therapy. The psychological evaluation clearly provided evidence of multiple contraindications against consideration fo an intrathecal narcotic delivery system. The continued intrathecal administration of Dilaudid and Fentanyl, two highly potent opiates is not medically reasonable or necessary to treat his current medical condition. There was no justification or medical indication to be using an outpatient surgery center o fluoroscopy to refill the intrathecal narcotic pump. Nothing to indicate the inability to refill the pump in an office setting, which is the usual and customary site for such refills. Given the documentation provided by Dr., the claimant obtains no more than 45% pain reduction during the trial in October 2000, it is not all surprising that the claimant has not obtained significant, sustained clinical benefit. There was absolutely no medical reason or necessity for the pump to be replaced. There was no medical reason or necessity for any consideration or revising this pump or the pump catheter if either of them develops a problem.

On 8-29-07, DO., performed a Designated Doctor Evaluation. He felt the claimant was unable to work in any capacity. He should be able to do very little sedentary type stuff mot would not be able to sustain it for any significant length of time.

On 9-29-07, Dr. provided an addendum. The evaluator reported that his most recent UDS demonstrated the presence of Hydromorphone and Fentanyl. Given the fact that Dr. is prescribing intrathecal Dilaudid as well as oral Fentanyl, the urine drug screen was appropriate. The evaluator found no objective evidence in Dr. report to substantiate the allegation that the claimant is unable to work in any capacity. There was nothing in his history or physical exam that the claimant was unable to work in any capacity.

On 5-25-08 MD., performed a Peer Review. He reported that as noted by the previous reviewers an implantable pump is a treatment of last resort, which would not be the case for the claimant. It appears that the claimant was never adequately evaluated for his GI symptoms by a non-surgical GI specialist. This would include ruling out

conditions such as functional GI disorders. The use of an implantable pump at this point was not reasonable and necessary as an appropriate diagnosis had not been established. There was minimal evidence of conservative medication treatment before the trial, therefore indicating that this was not a treatment of last resort. As pointed out in the review, the claimant never received an appropriate psych screen prior to implantation (assuming this would be a medically reasonable and necessary treatment). A psych screen of this nature would include all scores on the validity scales of the MMPI-2, particularly as the Hs scale (Hypochondriasis) was elevated. There also appears to be little indication that anyone had any concern about possible risks of current dependence on opioids at the time of the trial or for screening for risks of potential dependence with long-term use of opioids. There are several screening tools that are listed in the ODG in the Pain Chapter, and it can be seen that at the point of the implantation, the claimant had several risk factors for potential addiction including heavy smoking, family history and legal problems. There were instances of possible withdrawal from opioids. Another serious indicator of potential problems was the rapid escalation of Duragesic while in the pain management program. This was identified by both Mr. and Dr., but no action was taken. Prior to implantation, these issues surrounding dependence potential should have been addressed. This trial was inadequate to approve this pump implant. The first problem was the fact that a Morphine trial was not attempted. The Dilaudid trial itself used a minimal dose, which may have been necessary for the trial as there was little to no indication of what dose of opioid would be required (based on the limited utilization of oral and/or transdermal opioids at that point). It should be reiterated that according to the 8/16/00 note by Dr., the claimant had not used opioids for treatment of pain since 6/00. This again indicates that conservative management was not utilized prior to implantation, and that this implant was not medically reasonable and necessary. It is entirely possible that this claimant's GI symptoms are primarily due to his opioid use (nausea, bloating, ileus and pain). At least two examples of admissions secondary to opioid complications were noted. He was readmitted on 1/17/00 for post-operative ileus due to opioids. - On 9/6/04 he was noted to have fecal stasis in his right colon on KUB. In addition, the claimant appears to be suffering from a condition referred to as Narcotic Bowel Syndrome. This is characterized as a condition when pain is the primary symptom, and this pain increases despite progressive increase in opioid medication. Ultimately increased dosages of opioids enhance the adverse effects on pain sensation and delayed motility. Abdominal x-rays may show signs of a partial obstruction, but this is more likely to be due to adynamic ileus or pseudo-obstruction. Large amounts of fecal retention may be seen. Mr. exhibits other signs of the effect of opioids. These include decreased energy and impaired wound healing. His anemia may also be secondary, in part, to opioids. Peripheral edema has been a serious complication in the past, but is no longer mentioned. recalled it SynchroMed EL pumps, SynchroMed II pumps and IsoMed pumps on 3/21/08. One of the major problems was the concern of catheter malfunction and of intrathecal granulomas at the catheter tip. The former condition appears to have been that which was evaluated in 6/04. It is still not clear what was occurring at this time and why the claimant appeared to be in withdrawal on 6/7/04. His pump was working properly. There was no drug screen at any point of this evaluation. On the other hand, intrathecal granulomas appear to occur based on concentration of

drug delivered, maximum drug delivery and duration of treatment. The claimant is at extremely high risk for development of an intrathecal granuloma as his concentration of Hydromorphone is 80 mg/cc (maximum dose recommended is 10 mg/cc), his daily dose is 16 mg/day (maximum dose recommended is 4 mg/day) and his treatment duration is 7 years. Hydromorphone is a first-line intrathecal treatment and Fentanyl is a second-line treatment. The problem in terms of medication appears to be the delivery of dose at concentrations higher than indicated and above the maximum recommended. It should be brought up that a predicted residual volume has never once been reported for this claimant. This is one mechanism to determine if a pump has been tampered with. Based on the above concerns of possible risks for drug dependence, it would appear that this would be a necessary precaution for treatment. The claimant may still be taking Provigil at this point. This drug is of concern based on some evidence of escalation of dose over that which was prescribed (specifically in 4/03 and from 11/04 to 12/04). Provigil can produce psychological dependence. This medication is known to produce nausea and vomiting in 10% of individuals with use, as well as diarrhea in 3 to 4%. The necessity of use in this case (to apparently counteract opioid depression/fatigue) would not be indicated as (1) the opioid dose utilized does not appear to be working, and (2) the opioid in question may be the reason for the claimant's pain. Weaning was to have commenced as of 11/15/07. The ODG suggests weaning at a slow taper of 10% every 2 to 4 weeks until 2/3 of the dose is weaned. Then weaning should occur at a 5% rate. Weaning to 16 mg should have occurred within 2-4 weeks (by 12/9/08). As of 3/18/08 (18 weeks later) the claimant had only had this one 10% decrease in dose. This claimant should be weaned as an in-patient under the direction of a specialist in this type of protocol. The duration of weaning would be determined by this specialist. Weaning does not mean that the claimant will not require opioids in the future, but this should be under the treatment supervision of a physician that is trained in addiction as well as approved by a GI specialist (preferably non-surgical) as appropriate treatment.

On 2-29-09 MD., performed an addendum report. She reported that her opinion remained unchanged. The claimant was receiving Dilaudid well over that recommended in terms of dose and concentration. The maximum concentration of Hydromorphone recommended was 10 mcg/cc and the maximum daily dose was 4 mg. there was no evidence that the weaning plan she proposed was occurring. No further pump refills should be authorized until a treatment plan has been submitted.

On 5-18-09, MD., performed an independent medical evaluation. It was his opinion that current medical treatment was not reasonable or medically necessary. He could not find a ventral hernia on his exam. There does not appear to be any illicit substance abuse. UDS was consistent with the medications he is being given through his pump. Narcotic medications are not helping him return to work. There are or relieving his alleged pain. Therefore, narcotics are not reasonable or necessary. Furthermore, narcotics are not a treatment for a conversion reaction which appears to be highly medically probable. He concurred with Dr.. There is no documented functional improvement with current dose. Continuing to escalate dosage and prescribed narcotics is not consistent with current disability management philosophy. The evaluator provided a diagnosis of opiate dependency. He needs to be tapered off and

detoxified off the current medications, the pump needs to be removed, he may need to be on Suboxone, go to narcotics or alcoholics anonymous, get a sponsor and participate in a 12-step program and reintegrate back to society (work).

On 7-15-09, the claimant was evaluated by MD. The claimant's morphine pump is in an alarming state. The claimant reported that the pump has worked very well for him, but it has been noted to be in an alarm state at his last battery refill. He has not heard the alarm personally. The evaluator did interrogate the pump in the office and did find that the pumps alarms are enabled and after a second interrogation, the battery is in alarming state. He turned off the audible alarm because it was known that he had to replace the pump. The evaluator recommended exchange of the morphine pump.

On 7-21-09, MD., performed an addendum report. Additional questions remain the following. There are several case studies in the literature of individuals diverting drugs from implantable pump. Has this been considered in this case. Urine drug screens have been suggested. Have any been performed recently, or are they planned. This has been requested in the previous reviews. Is there any current plan to obtain a substance dependence screen for this claimant?

7-21-09 MD., performed an independent medical evaluation addendum. He reported that he reviewed a letter provided by Dr. which does not change his opinion. There was no demonstrated functional improvement. There are no longer ventral hernias that are present on physical exam. It is unclear what is being treated with intrathecal fentanyl and Dilaudid infusion.

On 7-27-09, the claimant underwent removal of morphine pump, removal of medication from the pump, fill of a new pump and placement of new pump and programming of a new pump. Surgery performed by Dr..

On 7-29-09, the claimant was seen at a local ER with complaints of pain in his abdomen and also his back. The severity is 10/10. He does not think that the pain pump is functioning. The claimant was given 2 mg of Dilaudid IV and Zofran and was advised to see Dr. tomorrow. The Dilaudid was repeated after x-rays were done.

7-29-09 X-rays interpreted by Dr. reported there was no evidence of the catheter becoming disconnected. There is a normal gap between the metal connectors but that is the design of the current system.

7-29-09 Surgery performed by Dr.: Revision of morphine pump catheter with replacement of catheter tip and reprogramming of morphine pump.

Emergency Room visit notes the claimant complains of chronic abdominal pain. He went to his pain management physician yesterday for a refill of the pump but due insurance problems he was unable to get it refilled. The claimant is on Dilaudid and Fentanyl intrathecally and the pump is out of medications. He has taken these

medications for 9 years. The claimant was given Dilaudid and Phenergan in the ED. He was asked to follow up with his pain management doctor on Monday.

2-16-10 UDS was consistent.

On 4-1-10 MD., performed an independent medical evaluation. He noted that his abdominal exam was normal. He had excellent bowel sounds. The use of drug pump for, in reasonable medical probability, opiate dependence and malingering is not reasonable or medically necessary. He noted that there was no weaning down. On 2-1-10, the Dilaudid rate was 13755 mg per day, fentanyl is 618.99 mcg per day and bupivacaine is 1.7194 mg per day. On 2-16-10, the Dilaudid was 14.2338 mg per day, fentanyl of 640.9 mcg per day and bupivacaine of 1.7792 mg per day. His concern was that there was no objective pathology to justify intrathecal narcotics pump, that there is no functional improvement and no explicit and rational extenuating circumstance plan for current treatment, and there is severe comorbid psychopathology.

On 9-15-10, the claimant was provided with a pump refill performed by, DO. His pump was refilled with Dil 25 mg/ml and Fent 900 mcg/ml.

On 10-1-10, , DO., performed a Utilization Review. It was his opinion that the request for pump refill and reprogramming under fluoroscopy is not certified. Clinical documentation indicates the patient has a prior medical history to include 6 abdominal surgeries. Documentation also indicates the patient has had an intrathecal pain pump in place since at least 11-21-00 with a decreasing amount of medication provided according to the refill sheet. The patient receives approximately monthly refills with the most recent refill being 9-15-10. The 9-15-10 refill note does not adequately document the patient's response to the last pump refill. Subsequent refills would not be indicated without objective documentation of the patient is functional and pain response to the most recent refill. As the request does not meet recommendations within current evidence based guidelines, certification is not supported at this time.

On 10-11-10, DO., performed a Utilization Review. He noted that there was no documentation to support the effectiveness of the intrathecal pump. Claimant is still on multiple po pain medications and multiple medications in the pump without documentation of decrease in pain, increase in function, increase in activity, increase in sleep, or decrease in po pain medications. The ODG Guidelines agree with pumps when they are effective.

On 10-14-10 DO., performed an emergency refill of SynchroMed pump and interrogation programming of SynchroMed pump.

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

Based on the records provided, I agree with the pump refill with his current medications with fluoro. Sudden discontinuation of his pump medications is not advisable and the

claimant could have secondary detrimental effects. The claimant has had this pump implanted and has been treated with intrathecal medications for at least 10 years. Therefore, based on the records provided, the pump refill/reprogramming under fluoro is medically necessary at this time.

ODG-TWC, last update 10-20-10 Occupational Disorders - Pain: – 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. (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 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 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)

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.

· 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.

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)