

Case Number:	CM15-0184430		
Date Assigned:	09/24/2015	Date of Injury:	09/21/1998
Decision Date:	11/06/2015	UR Denial Date:	09/08/2015
Priority:	Standard	Application Received:	09/18/2015

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 58 year old, male who sustained a work related injury on 9-21-98. The diagnoses have included post lumbar laminectomy syndrome, lumbar radiculopathy, spinal-lumbar degenerative disc disease and status post intrathecal pump placement. He is being treated for low back pain. Treatments have included 3 low back surgeries and medications. Current medications include Rozerem for sleep, Hydromorphone (Dilaudid) 50mg-ml for pump, MS Contin, Neurontin and Embeda. Past medications include Lyrica (discontinued for possible skin issue), Lidoderm patch (discontinued 4-2013 for unknown reason) and Topiramate (made no significant difference). In the progress notes dated 1-27-15 through 8-4-15, the injured worker reports low back pain radiating from low back down both legs. He rates his pain level a 5-8 out of 10 with medications and an 8-10 out of 10 without medications. He reports "no new problems or side-effects." He reports "poor" sleep quality. He wakes up frequently due to pain and restlessness. He does simple chores around the house and does minimal activities outside the home at least two days a week. On physical exam, he has restricted range of motion due to pain. He has tenderness to palpation of lumbar paravertebral muscles, hypertonicity, spasm, tenderness and tight muscle band noted on both sides. He is not working. The treatment plan includes a slow progression of activity and exercise and to decrease intrathecal (IT) pump slowly. IT pump medication was decreased by 5% this visit. Most recent urine drug toxicology test dated 5-13-15 was positive for opiates. In the Utilization Review, dated 9-8-15, noted that "based on the currently available information, the medical necessity for the continued use of this narcotic at the current dose has not been established." The requested treatment of Hydromorphone (Dilaudid) 50mg/ml (20ml total for IT pump refill) #20 was modified to Hydromorphone (Dilaudid) 50mg/ml (20ml total for IT pump refill) #15.

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

Hydromorphone (Dilaudid) 50mg/ml (20ml total for IT pump refill) #20: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Implantable drug-delivery systems (IDDSs). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back - Lumbar & Thoracic (Acute & Chronic) Chapter under Implantable drug-delivery systems.

Decision rationale: The patient presents on 08/04/15 with lower back pain rated 5/10 with medications (8/10 without) which radiates into the bilateral lower extremities. The patient's date of injury is 09/21/98. Patient is status post multiple lumbar spine surgeries, last in the year 2000, and has had an IT pump placed in 2000, and revised in 2008. The request is for Hydromorphone (Dilaudid) 50mg/ml (20ml total for IT pump refill) #20. The RFA is dated 08/04/15. Physical examination dated 08/04/15 reveals tenderness to palpation, hypertonicity, and spasm in the lumbar paravertebral musculature, and decreased sensation to pinprick over the lateral foot, medial, foot, and medial calf bilaterally. The patient is currently prescribed Prozac, Viagra, Rozerem, IT Dilaudid, Klonopin, MS Contin, Neurontin, and Embeda. Patient is currently classified as permanent and stationary, is not working. MTUS Guidelines, Implantable drug-delivery systems (IDDSs) section, pages 52-53 has the following criteria for the use of IDDS: "1. Documentation, in the medical record, of the failure of 6 months of other conservative treatment modalities (pharmacologic, 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; 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 and that benefit would occur with implantation despite any psychiatric comorbidity; and 5. No contraindications to implantation exist such as sepsis 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." Official Disability Guidelines, Low Back - Lumbar & Thoracic (Acute & Chronic) Chapter under Implantable drug-delivery systems (IDDSs) states: 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. According to the FDA, the manufacturer's manuals should be consulted for specific instructions and precautions for initial filling, refilling and programming. 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. In regard to a refill of medications for this patient's intrathecal pump, the request is appropriate. This patient has a significant surgical history of three previous spinal fusion surgeries, and has had an IT pump in place for nearly 15 years. Progress note dated 08/04/15 notes the performance of an IT pump refill consistent with the request under review. The provider includes adequate documentation of pain reduction from 8/10 to 5/10 attributed to medications and IT pump, provides several activity-specific functional improvements, and notes a lack of aberrant behavior and consistent urine drug screening to date. Furthermore, it appears that this patient is currently in the process of tapering his IT pump dosage, as the provider states the intent to perform additional titrations in 5% increments to lower this patient's dosage as much as possible. UR dated 09/08/15 non-certified this request on grounds that the current dosage is unnecessary (12.9mg/day). However, the patient is currently being weaned to a lower dosage for both his oral narcotics, as well as his intrathecal pump. Therefore, the request IS medically necessary.