

<b>Case Number:</b>	CM15-0219266		
<b>Date Assigned:</b>	11/12/2015	<b>Date of Injury:</b>	03/09/2005
<b>Decision Date:</b>	12/29/2015	<b>UR Denial Date:</b>	10/28/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/06/2015

### 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 65-year-old male, who sustained an industrial injury on 3-9-2005. He reported abdominal and low back pain, bilateral hand, and arm and shoulder pain. According to physician documentation, the injured worker was diagnosed with lumbosacral strain with bilateral radiculitis, degenerative disc disease at L4-L5 (lumbar) and L5-S1 (sacral) and disc bulge at L4-L5 and L5-S1, umbilical hernia and depression secondary to orthopedic condition. Subjective findings dated 8-7-2015, were notable for low back pain that radiated to legs and rib pain secondary to pump and weight loss. Physician note states, the injured worker is post lumbar epidural (2-2-2015) with good improvement in low back and leg, which has allowed him to reduce the use of his Norco with easier walking and standing. He rates his pain as being 6 out of 10 with pain medication and 10 out of 10 without pain medication. Objective findings dated 9-9-2015, were notable for tenderness on palpation in the vertebral musculature, antalgic gait and ambulating with left lower extremity prosthesis. Right straight leg rise is approximately 50%, decreased sensation on the L5-S1 dermatomes and reduced deep tendon reflexes in the right Achilles. An MRI of the low back was performed on 7-15-2005, revealing mild hyperlordosis with minimal dextroscoliosis. Treatment to date have included Tylenol, Motrin, Norco 10/325, MS Contin 15mg, Ambien 10mg, Morphine pump (since 2-29-2008) (last pump refill 6-12-2015), Toradol injections 60mg, epidural injections, Flexeril 10mg, Relafen, Darvocet, bilateral wrist braces, hernia repair and physical therapy. The Utilization Review determination dated 10-28-2015 did not certify retrospective treatment/service requested for 1 pump refill for 10-2-2015.

## IMR ISSUES, DECISIONS AND RATIONALES

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

### **1 pump refill:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Intrathecal drug delivery systems, medications.

**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 09/09/15 with lower back pain, with an increasing radicular component in the posterolateral aspect of the bilateral lower extremities, and increasing burning sensations bilaterally. The patient's date of injury is 03/09/15. The request is for 1 PUMP REFILL. The RFA was not provided. Physical examination dated 09/09/15 reveals tenderness to palpation of the lumbar paravertebral musculature, an antalgic gait, positive straight leg raise test on the right, decreased sensation in the L5-S1 dermatomal distribution, and reduced deep tendon in the right Achilles. The patient's left lower extremity has been amputated below the knee. The patient is currently prescribed Norco, MS Contin, and Ambien. Patient's current work status is not provided. 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 (intraspinial) 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 betweenrefills 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. About a refill of medications for this patient's intrathecal pump, the request is appropriate. This patient has a significant surgical history of lumbar laminectomy and amputation of the left lower extremity with residual phantom limb pain in the left lower extremity. Progress note dated 10/02/15 notes the performance of an IT pump refill consistent with the request under review. The provider includes adequate documentation of pain reduction from 10/10 to 5/10 attributed to medications and IT pump, notes that the patient has been able to remain active and reduce his weight by approximately 70 pounds in the previous year. The provider also notes a lack of aberrant behavior and consistent urine drug screening to date. Utilization review non-certified this request citing limited functional improvements and a current oral MED dosing of 120 in spite of IDDS, stating, "Had IDDS been successful, one would reasonably expect the oral dosage to be considerably lower. For these reasons, as discussed above, continuation of pump refills is not medically necessary... As the refill on 10/02/15 has already been provided to the patient, no harm to the patient can arise from the appropriate denial of this service retrospectively." The reviewer goes on to imply that this patient's opiate medications and pump refills have been non-certified and later upheld by IMR in the past, though no such documentation was made available for the current review. It is not clear why the utilization reviewer would not attempt to taper this patient's oral narcotic medications to a more satisfactory level, rather than retrospectively deny a pump refill to this patient to initiate weaning of narcotics (all while leaving the current oral narcotic medication regimen unchanged). While the functional improvements noted are limited, this patient presents with morbid obesity, profound lumbar spine disability, and loss of a limb with apparent phantom limb syndrome. The current functional gains - namely an increased activity level leading to continued weight loss - likely represent the highest functional level possible for this patient, given his condition. Therefore, the request IS medically necessary.