

<b>Case Number:</b>	CM15-0206760		
<b>Date Assigned:</b>	10/23/2015	<b>Date of Injury:</b>	01/23/1984
<b>Decision Date:</b>	12/09/2015	<b>UR Denial Date:</b>	09/17/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/20/2015

### 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 75-year-old female, with a reported date of injury of 01-23-1984. The diagnoses include chronic right leg pain, chronic knee pain, osteoarthritis, chronic pain syndrome, and status post intrathecal pump replacement. The progress report dated 07-29-2015 indicates that the injured worker stated that she was not doing very well on the day of the visit. She complained of right knee pain and stated that she had an issue with her right lower extremity. It was noted that there was swelling of the right lower extremity. She stated that the skin felt tight. The knee pain was constant, and was associated with constant throbbing and aching. The injured worker stated that until 07-28-2015, she felt well and the pump helped control the knee pain. It was noted that the injured worker was able to perform her activities of daily living as much as possible without assistance. The injured worker rated her pain 7.5 out of 10 compared to 7 out of 10 at the previous appointment (05-20-2015). She denied having any side effects with the Dilaudid in the intrathecal pump, and stated that the pump improved her pain level. The injured worker reported 50-60% pain relief with the intrathecal pump. The physical examination showed no apparent distress; use of an electric mobility device; increased swelling, redness, and warmth in the right lower extremity from mid-calf down to the foot; tenderness to palpation over the medial and lateral aspects of the right knee; restricted mobility of the right knee in all fields; inability to move the knee actively; minimal swelling around the right knee region; and tenderness over the right hip with minimal tenderness over the trochanteric bursa. The diagnostic studies to date have not been included in the medical records. Treatments and evaluation to date have included an intrathecal pump with Dilaudid (since at

least 03-2015), five right knee surgeries, and right total knee replacement. The request for authorization was dated 09-09-2015. The treating physician requested one pump refill of Dilaudid 60mg per milliliter at a rate of 13.9mg per 24 hours. On 09-17-2015, Utilization Review (UR) non-certified the request for one pump refill of Dilaudid 60mg per milliliter at a rate of 13.9mg per 24 hours.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

#### **1 pump refill of Dilaudid 60mg/ml at a rate of 13.9mg / 24h: Overturned**

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. 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 75 year old patient complains of constant right knee pain and swelling of the right lower extremity, as per progress report dated 07/29/15. The request is for 1 pump refill of Dilaudid 60mg/ml at a rate of 13.9mg / 24h. There is no RFA for this case, and the patient's date of injury is 01/23/84. The pain is rated at 7.5/10, as per progress report dated 07/29/15. Diagnoses included chronic right leg pain, chronic knee pain, osteoarthritis, chronic pain syndrome, back and hip pain (non-industrial), bilateral shoulder pain (non-industrial), and r/o right lower extremity cellulitis (non-industrial). The patient is status post five right knee surgeries and status post right total knee replacement associated with infection. The patient only relies on Dilaudid for relief. The patient's disability status is permanent and stationary, as per the same report. 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 this case, the Utilization Review denied the request for Dilaudid 60 mg/ml as this was concentration was greater than the recommended dose. Additionally, the patient is also receiving oral opioids from the primary care physician, and there is no documentation of objective outcomes. In an appeal letter dated 09/17/15 (same as the UR denial date), the physician states that the patient is getting opioids

through the intrathecal pump only for severe right knee pain, status post failed right knee replacement. The patient is receiving minimal amount of oral opioid medications from the primary care physician but these issues are not work-related. The letter further indicates that decrease in the dose of Dilaudid in the past led increased pain, and the patient had a "very difficult time getting around." The treater is concerned that denial will force them to prescribe oral opioids. The treater also states that they will begin to modify the concentration and dosage in an "appropriate way." In subsequent report dated 10/14/15 (after the UR denial date), the patient reports 50% reduction in pain and 50% improvement in function with the intrathecal pump. The patient states that she does not use any other narcotic pain reliever except the intrathecal Dilaudid and the medications helps her get out bed, dress herself, and perform other activities of daily living. Without the medication, she is completely disabled, and cannot even stand or walk. The patient was given a refill during the 10/14/15 visit, and the treater is requesting for authorization of refill before the next visit in January. Given the efficacy of the intrathecal pump and the patient's chronic pain, the request appears reasonable and IS medically necessary.