

Case Number:	CM15-0169161		
Date Assigned:	09/09/2015	Date of Injury:	10/03/2003
Decision Date:	10/27/2015	UR Denial Date:	07/29/2015
Priority:	Standard	Application Received:	08/27/2015

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: Arizona, Michigan

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

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 55 year old male who sustained an injury on 10-3-03. The medical records indicate he had lumbar laminectomy and decompression on 2-10-06; intrathecal opioid delivery system was implanted on 4-9-10 and surgery was performed on 8-5-13 on his failed fusion. The progress report from 6-11-15 indicates complete intrathecal opioid delivery system management since the implantation and is being evaluated monthly. 7-10-15 progress report the IW presents for pump analysis, pump refill and pump reprogramming. He has had to go without taking the Tizanidine as it was denied. He complains of having spasms all the time and the pain is exacerbated if he stands or sits over 10 minutes. His complaints of pain are right posterior lower extremity including the right buttock to the heel and Achilles regions; it is aching, burning, shooting and radiating. His activities of daily living (ADL) escalate the symptoms. Physical examination of the lumbar spine revealed well healed lumbar incision; tender bilaterally in the paravertebral muscles of the lumbar spine. Diagnosis was post laminectomy syndrome, lumbar. The ultrasound pump refills include Morphine 25 mg; Clonidine 100 mg. The Morphine and Hydromorphone 2% was advanced to decrease his pain and increase his functional capacity and is complaining that without the Tizanidine he has more spasms. He is rated moderately severe impairment category and can perform ADL only with substantial modifications and unable to perform many routine activities such as driving a car. The physical examination demonstrates severe pain related limitations that made the examination difficult to perform and results difficult to interpret. Tizanidine capsules 6 mg every 6 hrs. #120 was prescribed. Current requested treatments 3 pump fill visits and reprogramming; 3 ultrasound guidance for pump refill;

morphine 25 mg 150 units for 3 pump fill visits; Clonidine 100 mg, ml 6 units for 3 pump fill visits. Utilization review 7-29-15 modified the 3 pump fill visits and reprogramming to 1 pump fill visit and reprogramming; 3 ultrasound guidance for pump refill modified to 1 pump fill visit with Ultrasound guidance; 1 prescription for Morphine 25 mg, ml 150 units for 3 pump fill visits modified to 1 prescription of Morphine 25 mg, ml 150 units for 1 pump fill; 1 prescription for Clonidine 100 mg, ml 6 units for 3 pump fill visits modified to 1 prescription of Clonidine 100 mg, ml 6 units for 1 pump fill.

IMR ISSUES, DECISIONS AND RATIONALES

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

3 pump fill visits and reprogramming: 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): Intrathecal drug delivery systems, medications. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) / Implantable drug-delivery systems (IDDSs).

Decision rationale: Per the MTUS, "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." "Per the ODG 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." A review of the injured workers medical records reveal that the injured worker is seen monthly for pump refills, this is in line with guideline recommendations, therefore the request for 3 pump fill visits and reprogramming is medically necessary.

3 ultrasound guidance for pump refill: Overturned

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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) Pain (Chronic) / Implantable drug-delivery systems (IDDSs).

Decision rationale: Per the MTUS, "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." "Per the ODG 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." A review of the injured workers medical records reveal that the injured worker is seen monthly for pump refills, this is in line with guideline recommendations, therefore the request for 3 ultrasound guidance for pump refill is medically necessary.

Morphine 25mg/ml 150 units for 3 pump fill visits: 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): Intrathecal drug delivery systems, medications. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) / Implantable drug-delivery systems (IDDSs).

Decision rationale: Per the MTUS, "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." "Per the ODG 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." A review of the injured workers medical records reveal that the injured worker is seen monthly for pump refills, this is in line with guideline recommendations, It is noted that he experiences pain relief and improved function with the use of morphine with clonidine therefore the request for Morphine 25mg/ml 150 units for 3 pump fill visits is medically necessary.

Clonidine 100mg/ml 6 units for 3 pump fill visits: Overturned

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009,

Section(s): Clonidine, Intrathecal.

Decision rationale: Per the MTUS, intrathecal clonidine is recommended only after a short-term trial indicates pain relief in patients refractory to opioid monotherapy or opioids with local anesthetic. There is little evidence that this medication provides long-term pain relief (when used in combination with opioids approximately 80% of patients had < 24 months of pain relief) and no studies have investigated the neuromuscular, vascular or cardiovascular physiologic changes that can occur over long period of administration. Side effects include hypotension, and the medication should not be stopped abruptly due to the risk of rebound hypertension. The medication is FDA approved with an orphan drug intrathecal indication for cancer pain only. Clonidine is thought to act synergistically with opioids. Most studies on the use of this drug intrathecally for chronic non-malignant pain are limited to case reports. (Ackerman, 2003) Clonidine (Catapres) is a direct-acting historically as an antihypertensive agent, but it has found new uses, including treatment of some types of neuropathic pain. Additional studies: One intermediate quality randomized controlled trial found that intrathecal clonidine alone worked no better than placebo. It also found that clonidine with morphine worked better than placebo or morphine or clonidine alone agonist prescribed historically as an antihypertensive agent, but it has found new uses, including treatment of some types of neuropathic pain. A review of the injured workers medical records reveal that the injured worker is seen monthly for pump refills, this is in line with guideline recommendations, It is noted that he experiences pain relief and improved function with the use of morphine with clonidine therefore the request for Clonidine 100mg/ml 6 units for 3 pump fill visit is medically necessary.