

Case Number:	CM15-0186034		
Date Assigned:	09/28/2015	Date of Injury:	01/08/2007
Decision Date:	11/30/2015	UR Denial Date:	08/21/2015
Priority:	Standard	Application Received:	09/21/2015

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:

This is a 51 year old female whose date of injury was January 8, 2007. Medical documentation on 8-12-15 indicated the injured worker was treated for post-laminectomy syndrome of the lumbar spine. She reported low back pain. Previous treatment included lumbar fusion in 2005, lumbar surgery in 2008, and intrathecal pump implantation on 10-3-13. Her intrathecal opiate trial provided 75% relief for four to five hours. She has responded favorably to intrathecal therapy. Her medications included Baclofen, cyclobenzaprine 10 mg, Duragesic 50 mcg patch, Hydrocodone-APAP 10-325 mg, Levoxyl, Lidoderm patch 5%, Lyrica, Zanaflex, Zolofit and Zolpidem. Objective findings included well-healed right subcostal and lumbosacral incisions and resolved lower extremity swelling. Her lumbosacral range of motion was not tested due to ruptured left Achilles tendon surgery on 6-8-15. Her intrathecal pump was refilled and reprogrammed. A request for authorization for pump refill and reprogramming with ultrasound guidance #3 future pump refill visits, office visit #3 for future pump refill visits, and Fentanyl 10 mg-ml #6,000 units for 3 future pump refill visits was received on 8-12-15. On August 21, 2015, the Utilization Review physician determined pump refill and reprogramming with ultrasound guidance #3 future pump refill visits, office visit #3 for future pump refill visits, and Fentanyl 10 mg-ml #6,000 units for 3 future pump refill visits was not medically necessary based on Official Disability Guidelines.

IMR ISSUES, DECISIONS AND RATIONALES

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

Office visit #3 future pump refill visits: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain chapter. Office visits.

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. (Hassenbusch, 2004) Per the ODG According to the FDA, the manufacturer's manuals should be consulted for specific instructions and precautions for initial filling, refilling and programming. (FDA, 2010) 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 she has been using a pump with intrathecal opiates with success with documentation of up to 75% pain relief, the continued use appears appropriate, therefore the request for Office visit #3 future pump refill visits is medically necessary.

Pump refill: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain.

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. (Hassenbusch, 2004) Per the ODG According to the FDA, the manufacturer's manuals should be consulted for specific instructions and precautions for initial filling, refilling and programming. (FDA, 2010) For most pumps, the maximum dose that can be delivered between refills is 1000mg. If refills are usually administered after 16 to 17mL 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 she has been using a pump with intrathecal opiates with success with documentation of up to 75% pain relief, the continued use appears appropriate, therefore the request for Office visit #3 future pump refill visits is medically necessary.

Fentanyl 10/mg/ml #6,000 unites for 3 future pump refill 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): Implantable drug-delivery systems (IDDSs), 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. (Hassenbusch, 2004) Per the ODG According to the FDA, the manufacturer's manuals should be consulted for specific instructions and precautions for initial filling, refilling and programming. (FDA, 2010) For most pumps, the maximum dose that can be delivered between refills is 1000mg. If refills are usually administered after 16 to 17mL 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 she has been using a pump with intrathecal opiates with documentation of up to 75% pain relief, the continued use appears appropriate, therefore the request for Fentanyl 10 mg/ml #6,000 unites for 3 future pump refill visits is medically necessary.

Reprogramming with ultrasound guidance #3 future pump refill visits: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain.

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. (Hassenbusch, 2004) Per the ODG According to the FDA, the manufacturer's manuals should be consulted for specific instructions and precautions for initial filling, refilling and programming. (FDA, 2010) For most pumps, the maximum dose that can be delivered between refills is 1000mg. If refills are usually administered after 16 to 17mL 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 she has been using a pump with intrathecal opiates with success, with documentation of up to 75% pain relief, the continued use appears appropriate, it is noted that ultrasonic pump refill is indicated due to deep implantation, high BMI and hypermobility of the pump, this appears appropriate, therefore the request for Reprogramming with ultrasound guidance #3 future pump refill visits is medically necessary.