

Case Number:	CM14-0181422		
Date Assigned:	11/06/2014	Date of Injury:	10/05/2010
Decision Date:	12/19/2014	UR Denial Date:	09/29/2014
Priority:	Standard	Application Received:	10/31/2014

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. The expert reviewer is Board Certified in Family Medicine and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

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

Injured worker is a 57-years old female whom experienced an industrial injury 10/05/10. She experienced a slip and fall, striking a door and counter on the way to the ground. Her initial complaints consisted of low back pain, left hip pain, and right great toe pain. She was seen in the emergency room 10/06/10, had x-rays done, and was discharged home. She complained of lower back and right lower extremity pain. Diagnoses were lumbar sprain and right leg contusion. Report dated 03/08/12 noted x-rays were performed on 10/06/10 in the emergency room and results of the lumbar spine, showed degenerative disc disease. X-rays done the same day of the right foot and a Doppler venous ultrasound of the right lower extremity were non-diagnostic. Per this same report of 03/08/12, it stated a lumbar spine MRI was performed 10/29/10. The MRI results noted mild multilevel degenerative spondylosis and a shallow rightward disc bulge causing mild right neural foraminal stenosis. There was no evidence of disc herniation or stenosis. EMG/nerve conduction studies were done of the left lower extremity 11/24/10, which showed normal findings. There was also a MRI of the pelvis done 03/25/11. These results documented non-specific marrow edema within the left pubic symphysis that was felt to represent either degenerative changes or bone bruising. Surgery performed 05/12/11 consisted of left L5-S1 foraminotomy and cyst resection. Post-surgical complaints low back and lower extremity pain continued. She was treated with injection therapy, nerve blocks, and an intrathecal pump.

IMR ISSUES, DECISIONS AND RATIONALES

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

One (1) pump analysis: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Implantable Drug-Delivery Systems (IDDSs) Refills Page(s): 52-53.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Interventions and Treatments Page(s): 60-61. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low back with radiculopathy, Intrathecal pump and refill

Decision rationale: Implantable drug-delivery systems are recommended only as an end-stage treatment alternative in selected cases of chronic intractable pain. This treatment should only be used relatively late in the treatment continuum, when there is little hope for effective management of chronic intractable pain from other therapies. For most patients, it should be used as part of a program to facilitate decreased opioid dependence, restoration of function and return to activity, and not just for pain reduction. The specific criteria in these cases include the failure of at least 6 months of other conservative treatment modalities, intractable pain secondary to a disease state with objective documentation of pathology, further surgical intervention is not indicated, psychological evaluation unequivocally states that the pain is not psychological in origin, and a temporary trial has been successful prior to permanent implantation as defined by a 50-70% reduction in pain and medication use. The request for pump analysis is not reasonable as there is no clarification whether the pump is being used on a trial basis or whether there has been failure of at least 6 months of other conservative treatment modalities and that there has been successful prior to permanent implantation as defined by a 50-70% reduction in pain and medication use thus justifying continued use of the pump. It is also unclear when last pump analysis was performed.

One (1) refill kit: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Implantable Drug-Delivery Systems (IDDSs) Refills Page(s): 52-53.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 60-61. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG): Low back with radiculopathy, Intrathecal pump and refill

Decision rationale: Per ODG, 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) 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. The request for refill is not reasonable as there is no clarification as to whether the pump is being used on a trial basis or whether there has been failure of at least 6 months of other conservative treatment modalities and that there has been successful prior to permanent implantation as defined by a 50-70% reduction in pain and medication use thus justifying continued use of the pump. It is also unclear when last refill was performed.