

<b>Case Number:</b>	CM15-0023903		
<b>Date Assigned:</b>	02/18/2015	<b>Date of Injury:</b>	04/09/1996
<b>Decision Date:</b>	04/07/2015	<b>UR Denial Date:</b>	02/02/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/09/2015

### 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 47 year old female, who sustained an industrial injury on 4/09/1996. The diagnoses have included reflex sympathetic dystrophy, fibromyalgia, and chronic pain. Treatment to date has included an intrathecal pain pump, physical therapy, medications, home exercise, stretches, and activity modification. She has undergone replacement of narcotic pump with lumbar catheter (10/27/2009) and replacement of lumbar catheter and pump (5/09/2012). Currently, the IW complains of ongoing pain to the lower back and left leg rated as 5/10 on a good day and 9/10 on a bad day. Objective findings included tenderness to palpation at L5-S1, diffuse tenderness, reduced range of motion, tenderness at the bilateral sciatic notch and positive straight leg raise bilaterally. She has an antalgic gait. On 2/02/2015, Utilization Review modified a request for pump refill and maintenance: office visit, pump refill and maintenance: pump analysis, pump refill and maintenance: ultrasound guidance for needle replacement and pump refill and maintenance: refill kit and non-certified a request for pump refill and maintenance: analysis with reprogramming, pump refill and maintenance: office visit and pump refill and maintenance, noting that the clinical information submitted for review fails to meet the evidence based guidelines for the requested service. The MTUS an ODG were cited. On 2/09/2015, the injured worker submitted an application for IMR for review of pump refill and maintenance: office visit, pump refill and maintenance: pump analysis, pump refill and maintenance: ultrasound guidance for needle replacement and pump refill maintenance: refill kit, pump refill and maintenance: analysis with reprogramming, pump refill and maintenance: office visit and pump refill and maintenance.

## IMR ISSUES, DECISIONS AND RATIONALES

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

### **Pump Refill and Maintenance: Office Visit QTY: 6: Overturned**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Implantable drug delivery systems (IDDSs) Page(s): 52-54. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (chronic).Implantable drug delivery systems (IDDSs).

**Decision rationale:** Per the MTUS, 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. (Hassenbusch, 2004). In addition the ODG states that 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. (Bennett, 2000). A request for Pump Refill and Maintenance: Office Visit QTY: 6 between 01/01/2015 and 6/30/2015 appears to be within the guidelines of every 4-6 weeks and is medically necessary and appropriate in this injured worker.

### **Pump Refill and Maintenance: Pump Analysis QTY: 6: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 53-54.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Implantable drug delivery systems (IDDSs) Page(s): 52-54. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic)Implantable drug delivery systems (IDDSs).

**Decision rationale:** Per the MTUS, 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. (Hassenbusch, 2004). In addition the ODG states that 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. (Bennett, 2000). A request for Pump Refill and Maintenance: pump analysis QTY: 6 between 01/01/2015 and 6/30/2015 appears to be a duplicate request and a pump analysis with reprogramming is being addressed in a separate request therefore this request exceeds the recommended frequency of visits and is not medically necessary and appropriate in this injured worker.

**Pump Refill and Maintenance: Ultrasound Guidance for Needle Placement QTY:6:**  
Overturned

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Implantable drug delivery systems (IDDSs) Page(s): 52-54. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic).Implantable drug delivery systems (IDDSs).

**Decision rationale:** Per the MTUS, 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. (Hassenbusch, 2004). In addition the ODG states that 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. (Bennett, 2000). A request for Pump Refill and Maintenance: ultrasound guidance for needle placement QTY: 6 between 01/01/2015 and 6/30/2015 appears to be within the guidelines of every 4-6 weeks and is medically necessary and appropriate in this injured worker.

**Pump Refill and Maintenance: Refill Kit QTY: 6:** 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).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Implantable drug delivery systems (IDDSs) Page(s): 52-54. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic).Implantable drug delivery systems (IDDSs).

**Decision rationale:** Per the MTUS, 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. (Hassenbusch, 2004). In addition the ODG states that 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. (Bennett, 2000). A request for Pump Refill and Maintenance: refill kit QTY: 6 between 01/01/2015 and 6/30/2015 appears to be within the guidelines of every 4-6 weeks and is medically necessary and appropriate in this injured worker.

**Pump Refill and Maintenance: Pump Analysis with Re-programming QTY: 6:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 53-54.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Implantable drug delivery systems (IDDSs) Page(s): 52-54. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic).

**Decision rationale:** Per the MTUS, 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. (Hassenbusch, 2004). In addition the ODG states that 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. (Bennett, 2000). A request for Pump Refill and Maintenance: pump analysis with re-programming QTY: 6 between 01/01/2015 and 6/30/2015 appears to be within the guidelines of every 4-6 weeks and is medically necessary and appropriate in this injured worker.

**Pump Refill and Maintenance: Office Visit QTY: 6: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Implantable drug delivery systems (IDDSs) Page(s): 52-54. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic).Implantable drug delivery systems (IDDSs).

**Decision rationale:** Per the MTUS, 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. (Hassenbusch, 2004). In addition the ODG states that 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. (Bennett, 2000). A request for Pump Refill and Maintenance: Office Visit QTY: 6 between 01/01/2015 and 6/30/2015 has already been addressed in a separate request and this appears to be either a duplicate request or an additional request and exceeds the guidelines of every 4-6 weeks and therefore is not medically necessary and appropriate.

**Pump Refill and Maintenance: QTY 6: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Implantable drug delivery systems (IDDSs) Page(s): 52-54. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic).Implantable drug delivery systems (IDDSs).

**Decision rationale:** Per the MTUS, 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. (Hassenbusch, 2004). In addition the ODG states that 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. (Bennett, 2000). A request for Pump Refill and Maintenance: QTY: 6 between 01/01/2015 and 6/30/2015 has already been addressed in multiple separate requests and this appears to be either a duplicate request or an additional request and exceeds the guideline recommendation of every 4-6 weeks and therefore is not medically necessary and appropriate.