

<b>Case Number:</b>	CM15-0201152		
<b>Date Assigned:</b>	10/16/2015	<b>Date of Injury:</b>	10/30/2007
<b>Decision Date:</b>	12/22/2015	<b>UR Denial Date:</b>	09/25/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/13/2015

### 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 49 year old female, who sustained an industrial injury on 10-30-2007. A review of the medical records indicates that the injured worker (IW) is undergoing treatment for cervical disc disease and radiculopathy with neck pain, right shoulder pain, lumbar disc disease, radiculopathy and facet syndrome with low back pain, and bilateral knee osteoarthritis. Medical records (03-27-2015 to 08-28-2015) indicate ongoing neck, low back, right shoulder, and bilateral knee pain. Pain levels were rated 6-8 out of 10 in severity on a visual analog scale (VAS). Records also indicate no changes in activity levels or level of functioning. Per the treating physician's progress report (PR), the IW has not returned to work. The physical exam, dated 08-28-2015, revealed an antalgic gait, right shoulder pain and immobility due to surgery, mild left shoulder pain over the acromioclavicular joint, decreased range of motion (ROM) in the left shoulder, diffuse lumbar tenderness, moderate to severe facet tenderness at L4-S1, positive sacroiliac testing bilaterally, positive Kemp's test, positive straight leg raises bilaterally, limited ROM in the lumbar spine, decreased sensation in the L4 and L5 dermatomes, some slightly decreased motor strength in the lower extremities, and bilateral knee tenderness upon palpation. Relevant treatments have included: right shoulder surgery, lumbar surgery, physical therapy (PT), cortisone injections to the knee, work restrictions, and medications. Current medications include oxycodone, Soma, Lidoderm patches, ranitidine, Percocet and Lyrica which have been prescribed to the IW since at least 03-2015. The treating physician indicates that the IW's morphine equivalent has been higher than 80mg per day for the past 6 months and that the IW is at high-risk for narcotic abuse or misuse. The request for authorization (09-21-2015)

shows that the following equipment and medications were requested: H-Wave unit (30 day trial for home use), oxycodone 30mg #120, Soma 350mg #60, Lidoderm patches 5% #30, ranitidine 150mg #60, Percocet 10-325mg #90, and Lyrica 100mg #90. The original utilization review (09-25-2015) non-certified the request for H-Wave unit (30 day trial for home use), oxycodone 30mg #120, Soma 350mg #60, Lidoderm patches 5% #30, ranitidine 150mg #60, Percocet 10-325mg #90, and Lyrica 100mg #90.

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

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

#### **H-Wave unit, 30 day trial for home use: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Transcutaneous electrotherapy.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Transcutaneous electrotherapy.

**Decision rationale:** Per the MTUS, H-wave stimulation is not recommended as an isolated intervention, but a one-month home-based trial of H-Wave stimulation may be considered as a noninvasive conservative option for diabetic neuropathic pain (Julka, 1998) (Kumar, 1997) (Kumar, 1998), or chronic soft tissue inflammation if used as an adjunct to a program of evidence-based functional restoration, and only following failure of initially recommended conservative care, including recommended physical therapy (i.e., exercise) and medications, plus transcutaneous electrical nerve stimulation (TENS). There is no evidence that H-Wave is more effective as an initial treatment when compared to TENS for analgesic effects. A randomized controlled trial comparing analgesic effects of H-wave therapy and TENS on pain threshold found that there were no differences between the different modalities or HWT frequencies. A review of the injured workers medical records do not reveal that she has tried and failed all recommended first line therapy including TENS, however given the chronicity of her clinical presentation and the high MED of opioids she is on a trial of H wave stimulation is appropriate, therefore the request for H-Wave unit, 30 day trial for home use is medically necessary.

#### **Oxycodone 30mg #120: 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): Opioids, criteria for use.

**Decision rationale:** Per the MTUS, opioids should be discontinued if there is no overall improvement in function, unless there are extenuating circumstances, Opioids should be continued if the patient has returned to work or has improved functioning and pain. Ongoing management actions should include prescriptions from a single practitioner, taken as directed and all prescriptions from a single pharmacy. The lowest possible dose should be prescribed to

improve pain and function. Documentation should follow the 4 A's of analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors. Long term users of opioids should be regularly reassessed. In the maintenance phase the dose should not be lowered if it is working. Also, patients who receive opioid therapy may sometimes develop unexpected changes in their response to opioids, which includes development of abnormal pain, change in pain pattern, persistence of pain at higher levels than expected when this happens opioids can actually increase rather than decrease sensitivity to noxious stimuli. It is important to note that a decrease in opioid efficacy should not always be treated by increasing the dose or adding other opioids, but may actually require weaning. A review of the injured workers medical records that are available reveal an appeal to utilization review denial that notes improvement in pain and function with the use of opioids, it is reported that the injured worker has a level of stability with her current regimen, therefore the continued use of oxycodone is appropriate and the request for Oxycodone 30mg #120 is medically necessary.

**Soma 350mg #60: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Carisoprodol (Soma).

**Decision rationale:** Per the MTUS, recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Sedation is the most commonly reported adverse effect of muscle relaxant medications. Carisoprodol is not recommended for longer than a 2 to 3 week period. Carisoprodol is metabolized to meprobamate an anxiolytic that is a schedule IV controlled substance. Carisoprodol is classified as a schedule IV drug in several states but not on a federal level. It is suggested that its main effect is due to generalized sedation as well as treatment of anxiety. A review of the injured workers medical records reveal an appeal to utilization review denial that notes the use of soma as needed for spasticity, and is used as an adjunct to her other medications and a home exercise regimen, in this setting the continued use of soma is appropriate, therefore the request for Soma 350mg #60 is medically necessary.

**Lidoderm patches 5%, #30: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** Per the MTUS, topical analgesics are recommended as an option, they are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Many agents are compounded as monotherapy or in combination for pain control, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. Lidocaine is approved for use in the form of a dermal patch. A review of the injured workers medical records reveal documentation of pain and functional improvement with her current regimen and cites the benefit of adjunctive topical analgesics in limiting systemic and gastrointestinal adverse effects, In this injured worker who is already on high MED's of opioids avoiding additional oral pharmacology is prudent, therefore the request for Lidoderm patches 5%, #30 is medically necessary.

**Ranitidine 150mg #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Library of Medicine.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) / Proton Pump Inhibitors (PPIs).

**Decision rationale:** Per the MTUS, Clinicians should weigh the indications for NSAIDs against both GI and cardiovascular risk factors according to specific criteria listed in the MTUS and a selection should be made based on these criteria 1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Per the ODG, PPI's are "Recommended for patients at risk for gastrointestinal events. PPIs are highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. Studies suggest, however, that nearly half of all PPI prescriptions are used for unapproved indications or no indications at all. Many prescribers believe that this class of drugs is innocuous, but much information is available to demonstrate otherwise. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses, including esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Prilosec), pantoprazole (Protonix), dexlansoprazole (Dexilant), and rabeprazole (Aciphex). (Shi, 2008) A trial of omeprazole or lansoprazole had been recommended before prescription Nexium therapy (before it went OTC). The other PPIs, Protonix, Dexilant, and Aciphex, should be second-line. According to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective. (AHRQ, 2011)" However a review of the injured workers medical records do not reveal past or current gastrointestinal complaints that would indicate that the injured worker meets the guideline criteria for prophylactic gastrointestinal therapy, therefore the request for Ranitidine 150mg #60 is not medically necessary.

**Percocet 10/325mg #90:** 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): Opioids, criteria for use.

**Decision rationale:** Per the MTUS, opioids should be discontinued if there is no overall improvement in function, unless there are extenuating circumstances, Opioids should be continued if the patient has returned to work or has improved functioning and pain. Ongoing management actions should include prescriptions from a single practitioner, taken as directed and all prescriptions from a single pharmacy. The lowest possible dose should be prescribed to improve pain and function. Documentation should follow the 4 A's of analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors. Long term users of opioids should be regularly reassessed. In the maintenance phase the dose should not be lowered if it is working. Also, patients who receive opioid therapy may sometimes develop unexpected changes in their response to opioids, which includes development of abnormal pain, change in pain pattern, persistence of pain at higher levels than expected when this happens opioids can actually increase rather than decrease sensitivity to noxious stimuli. It is important to note that a decrease in opioid efficacy should not always be treated by increasing the dose or adding other opioids, but may actually require weaning. A review of the injured workers medical records that are available reveal an appeal to utilization review denial that notes improvement in pain and function with the use of opioids, it is reported that the injured worker has a level of stability with her current regimen, therefore the continued use of percocet is appropriate and the request for Percocet 10/325mg #90 is medically necessary.

**Lyrica 100mg #90:** 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): Antiepilepsy drugs (AEDs).

**Decision rationale:** Per the MTUS, antiepilepsy drugs are recommended for neuropathic pain. Gabapentin is considered first line treatment for neuropathic pain. The choice of specific agents reviewed below will depend on the balance between effectiveness and adverse reactions. A "good" response to the use of AEDs has been defined as a 50% reduction in pain and a "moderate" response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response of this magnitude may be the "trigger" for the following: (1) a switch to a different first-line agent (TCA, SNRI or AED are considered first-line treatment); or (2) combination therapy if treatment with a single drug agent fails. (Eisenberg, 2007) (Jensen, 2006) After initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. A review of the injured workers medical records reveal documentation neuropathic/radicular pain that is benefiting from the use of Lyrica, continued use is appropriate, therefore the request for Lyrica 100mg #90 is medically necessary.