

<b>Case Number:</b>	CM15-0200142		
<b>Date Assigned:</b>	10/20/2015	<b>Date of Injury:</b>	10/08/2010
<b>Decision Date:</b>	12/23/2015	<b>UR Denial Date:</b>	10/09/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/12/2015

### 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 44-year-old female with a date of industrial injury 10-8-2010. The medical records indicated the injured worker (IW) was treated for sacroiliitis, right; lumbar sprain-strain; lumbar paraspinal muscle spasms; lumbar disc herniations; lumbar radiculitis-radiculopathy of the lower extremities; and chronic pain. In the progress notes (5-13-15, 7-8-15, 9-2-15), the IW reported worsening pain in the right buttock, radiating to the posterior and lateral aspect of the right thigh with numbness and tingling and lower back pain with severe muscle spasms with associated pain, numbness, tingling and weakness in the right leg. She also complained of pain in the right foot. The pain was exacerbated by sitting on hard surfaces, standing on uneven surfaces, climbing stairs or standing up from a seated position. Medications were Norco, Gabapentin, Flexeril, Omeprazole and Duragesic patches. Prescriptions were written for Flurbiprofen 25%, Dextromethorphan 10%, in Lipoderm base 180gm, Gabapentin 10%, Ketoprofen 10%, Tramadol 5%, Cyclobenzaprine 2% in Lipoderm base 180 gm, and Terocin patches, #30 on 9-2-15. There was no documentation of trials of antidepressants and antiepileptics prior to starting topical analgesics. On examination (9-2-15 notes), there was tenderness to the bilateral paravertebral muscles and the bilateral sacroiliac joints, stiffness in both hips and knees and low back pain throughout the arc of motion. Radiculopathy in the bilateral legs was noted as "consistent with L4, L5 and S1 dermatomes." Range of motion was (in degrees): flexion 70, extension 20, right and left lateral flexion 30 and right and left rotation 30. Straight leg raise, seated and supine, was positive. Motor strength was 3 to 4 out of 5, bilaterally, in all groups except the left ankle dorsiflexors, common toe extensors, gastrocnemius and peroneal. Reflexes at the knees and ankles were 2+. Patrick's Fabere's test was positive bilaterally and sacroiliac

joint thrust test was positive only on the right. Lower extremity sensation was intact. Treatments included right sacroiliac joint injection (5-27-15) and right L4-5 and L5-S1 epidural steroid injection (4-8-15 and 5-13-15) with 50% improvement of lower extremity radicular symptoms for six weeks; home exercise; and oral and topical medications. The IW reported decreased pain, improved range of motion and improved daily activity with topical medication. It was noted the IW signed a narcotic medication agreement. Urine drug tests on 3-30-15, 6-20-15 and 7-10-15 were inconsistent with prescribed medications. A Request for Authorization was received for injection with fluoroscopy to the right SI joint; right L4-5 and L5-S1 lumbar epidural steroid injections under fluoroscopy; P-STIM (#4); urine drug test; H-Wave unit with supplies; Omeprazole 20 mg #30; Flurbiprofen 25%, Dextromethorphan 10%, in Lipoderm base 180gm, #1; Gabapentin 10%, Ketoprofen 10%, Tramadol 5%, Cyclobenzaprine 2% in Lipoderm base 180 gm #1; Terocin patches #30; and Duragesic patches #10. The Utilization Review on 10-9-15 non-certified the request for injection with fluoroscopy to the right SI joint; right L4-5 and L5-S1 lumbar epidural steroid injections under fluoroscopy; P-STIM (#4); urine drug test; H-Wave unit with supplies; Omeprazole 20 mg #30; Flurbiprofen 25%, Dextromethorphan 10%, in Lipoderm base 180gm, #1; Gabapentin 10%, Ketoprofen 10%, Tramadol 5%, Cyclobenzaprine 2% in Lipoderm base 180 gm #1; Terocin patches #30; and Duragesic patches #10.

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

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

**Right SI joint injection with fluoroscopic guidance:** Overturned

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Hip & Pelvis (Acute & Chronic) / Sacroiliac injections, therapeutic.

**Decision rationale:** The MTUS did not specifically address the use of SI joint injections, therefore other guidelines were consulted. The ODG does "not recommend therapeutic sacroiliac intra-articular or periarticular injections for non-inflammatory sacroiliac pathology (based on insufficient evidence for support). Recommend on a case-by-case basis injections for inflammatory spondyloarthropathy (sacroiliitis). This is a condition that is generally considered rheumatologic in origin (classified as ankylosing spondylitis, psoriatic arthritis, reactive arthritis, arthritis associated with inflammatory bowel disease, and undifferentiated spondyloarthropathy). Instead of injections for non-inflammatory sacroiliac pathology, conservative treatment is recommended. Current research is minimal in terms of trials of any sort that support the use of therapeutic sacroiliac intra-articular or periarticular injections for non-inflammatory pathology. There is some evidence of success of treatment with injections for inflammatory spondyloarthropathy, although most rheumatologists now utilize biologic treatments (anti-TNF and/or disease modifying anti-rheumatic drugs) for treatment. A review of the injured worker medical records reveal a diagnosis of sacroiliitis, it is also reported that this injured worker had a 50% improvement in symptoms for six weeks with prior SI joint injection. Based on the injured workers favorable clinical response to prior SI joint injection the request for Right SI joint injection with fluoroscopic guidance is medically necessary.

**Right L4-5 and L5-S1 lumbar epidural steroid injection with fluoroscopic guidance:**

Overtured

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Epidural steroid injections (ESIs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Epidural steroid injections (ESIs).

**Decision rationale:** Per the MTUS, Epidural Steroid Injections are recommended as an option for the treatment of radicular pain. Radiculopathy must be documented by physical examination and corroborated by imaging studies and /or electrodiagnostic testing. The purpose of the ESI is to reduce pain and inflammation, restoring range of motion and thereby facilitating progress in more active treatment programs and avoiding surgery. The treatment alone offers no significant long-term functional benefit. In the therapeutic phase, repeat blocks should be based on continued objective documented pain and functional improvement, including at least 50% pain relief with associated reduction of medication use for six to eight weeks with a general recommendation of no more than 4 blocks per region per year. It is reported that this injured worker had a 50% improvement in symptoms for six weeks with prior ESI. Based on the injured workers favorable clinical response to prior ESI the request for Right L4-5 and L5-S1 lumbar epidural steroid injection with fluoroscopic guidance is medically necessary.

**P-Stim x 4:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain / P-Stim/ Auricular electroacupuncture.

**Decision rationale:** The MTUS did not address the use of P-Stim therefore other guidelines were consulted. Per the ODG, P-Stim is not recommended. The evidence is insufficient to evaluate the effect of auricular electroacupuncture on acute and chronic pain. In the only published RCT, use of the P-Stim device was not associated with improved pain management. Auricular electrostimulation or ear-acupuncture is a type of ambulatory electrical stimulation of acupuncture points on the ear. Devices, including the P-Stim and E-pulse, have been developed to provide continuous or intermittent stimulation over a period of several days. This type of electrostimulation is being evaluated for a variety of conditions, including pain, depression, and anxiety. Both the P-Stim [REDACTED] and the E-pulse [REDACTED] devices have received marketing clearance through the FDA abbreviated 510(k) process for use in treating acute or chronic pain by a qualified practitioner of acupuncture. Unfortunately this treatment modality is not supported by the guidelines, and the injured workers medical records do not show that the injured workers has exhausted all other recommended treatment options, therefore the request for P-Stim x 4 is not medically necessary.

**Urine drug test:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, steps to avoid misuse/addiction.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Drug testing. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) / Urine Drug testing.

**Decision rationale:** Per the MTUS, Drug testing is recommended as an option, using a urine drug screen to assess for the use or the presence of illegal drugs before a therapeutic trial of opioids, during ongoing management and to avoid misuse/ addiction. Per the ODG, frequency of urine drug testing should be based on documented evidence of risk stratification including use of a testing instrument. A review of the injured workers medical records reveal that this injured worker has chronic pain with narcotic dependency, regular urine drug testing is appropriate, therefore the request for Urine drug test is medically necessary.

**H-wave unit with supplies:** 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): Topical Analgesics.

**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 reveal that she has tried and failed several recommended first line therapies including TENS, Given the chronicity of her clinical presentation and the history of narcotic dependency a trial of H-wave stimulation is appropriate, therefore the request for H-Wave unit with supplies is medically necessary.

**Omeprazole 20mg #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

**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)." Unfortunately a review of the injured workers medical records do not reveal any past or current gastrointestinal complaints that would indicate that the injured worker is at increased risk for a gastrointestinal event, the injured worker does not meet the guideline requirement for prophylaxis therefore the request for Omeprazole is not medically necessary.

**Flurbiprofen 25%/ Dextromethorphan 10% in lipoderm base 180gm:** Upheld

**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. Unfortunately this compounded product is not supported by the guidelines. A review of the injured workers medical records that are available to me does not show an exhaustive trial of recommended first line agents that have failed, therefore the request for Flurbiprofen 25%/ Dextromethorphan 10% in lipoderm base 180gm is not medically necessary.

**Gabapentin 10%, Ketoprofen 10%, Tramadol 5%, Cyclobenzaprine 2% in lipoderm base 180gm:** Upheld

**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. Unfortunately this compounded product is not supported by the guidelines. A review of the injured workers medical records that are available to me does not show an exhaustive trial of recommended first line agents that have failed, therefore the request for Gabapentin 10%, Ketoprofen 10%, Tramadol 5%, Cyclobenzaprine 2% in lipoderm base 180gm is not medically necessary.

**Terocin patches #30:** 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): 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. Topical lidocaine is approved for use in the formulation of a dermal patch. Given the chronicity of the injured workers symptoms and her history of narcotic dependency, the use of topical lidocaine in the form of a patch as an adjunct to her treatment is appropriate, therefore the request for Terocin patches #30 is medically necessary.

**Duragesic patches #10:** Upheld

**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): 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 reveal ongoing complaints of worsening pain, She does not appear to be having a favorable response to the use of Duragesic, continued use is not appropriate, therefore the request for Duragesic patches #10 is not medically necessary.