

<b>Case Number:</b>	CM15-0209111		
<b>Date Assigned:</b>	10/28/2015	<b>Date of Injury:</b>	10/13/2014
<b>Decision Date:</b>	12/15/2015	<b>UR Denial Date:</b>	10/06/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/23/2015

### 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: Texas, California

Certification(s)/Specialty: Family Practice

### 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 39 year old male patient, who sustained an industrial injury on 10-13-14. The diagnoses include lumbar radiculopathy, lumbar sprain-strain, right hip sprain-strain, loss of sleep, insomnia, anxiety and depression. Per the doctor's note dated 9-23-15, he had complains of dull, aching pain of low back rated 6 out of 10 without medications and 4 out of 10 with medications and associated with radiation, tingling and numbness to right more than left lower extremities; dull, aching pain of right hip rated 7 out of 10 without medications and 4 out of 10 with medications and also complains of loss of sleep and anxiety and depression. He is not working currently. Physical exam performed on 9-23-15 revealed decreased and painful lumbar range of motion with tenderness to palpation of lumbar paravertebral muscles with spasm of lumbar paravertebral muscles and decreased range of motion of right hip with tenderness to palpation of anterior hip, lateral hip and posterior hip. The medications list includes Prilosec, Tramadol-acetaminophen, anaprox, Cyclobenzaprine and topical compound creams. MRI of lumbar spine performed on 2-11-15 revealed small nodules in cauda equine and slightly more prominent nodule on dorsal surface of left psoas muscle, small nodular structure medial to right S1 nerve root sleeve within the spinal canal at level of upper portion of S1 vertebral body and associated degenerative disc changes L4-5 and L5-S1. Treatment to date has included oral medications including Prilosec, Tramadol and Cyclobenzaprine; physical therapy, home exercise program, back brace and activity modifications. The treatment plan included solace stimulation unit, Flurbiprofen 20%, Baclofen 10%, Dexamethasone 2%, Panthenol 0.5% in salt stable LS base 240gm and Dextromethorphan 10%, Gabapentin 10%, Bupivacaine 5%, Camphor 2%, Menthol

2%, in salt stable LS base 240gm. On 10-6-15 request for Solace stimulation unit, Flurbiprofen 20%, Baclofen 10%, Dexamethasone 2%, Panthenol 0.5% in salt stable LS base 240gm and Dextromethorphan 10%, Gabapentin 10%, Bupivacaine 5%, Camphor 2%, Menthol 2%, in salt stable LS base 240gm was non-certified by utilization review.

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

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

**Solace Stim Unit, quantity: 1: Upheld**

**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:** Solace Stim Unit is a kind of TENS unit. According to the cited guidelines, TENS is not recommended as a primary treatment modality, but a one-month home-based TENS trial may be considered as a noninvasive conservative option, if used as an adjunct to a program of evidence-based functional restoration, for the conditions described below. While TENS may reflect the long-standing accepted standard of care within many medical communities, the results of studies are inconclusive; the published trials do not provide information on the stimulation parameters which are most likely to provide optimum pain relief, nor do they answer questions about long-term effectiveness. Recommendations by types of pain: A home-based treatment trial of one month may be appropriate for neuropathic pain and CRPS II (conditions that have limited published evidence for the use of TENS as noted below), and for CRPS I (with basically no literature to support use). Per the MTUS chronic pain guidelines, there is no high grade scientific evidence to support the use or effectiveness of electrical stimulation for chronic pain. The patient does not have any objective evidence of CRPS I and CRPS II that is specified in the records provided. Evidence of diminished effectiveness of medications or intolerance to medications is not specified in the records provided. The request for Solace Stim Unit, quantity: 1 is not medically necessary or established for this patient.

**Flurbiprofen 20%, Baclofen 10%, Dexamethasone 2%, Panthenol 0.5% in salt stable LS base 240gm, quantity: 1: 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:** Flurbiprofen is an NSAID and baclofen is a muscle relaxant. The cited Guidelines regarding topical analgesics state, "Largely experimental in use with few randomized controlled trials to determine efficacy or safety, 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 (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants,...)". (Argoff, 2006) There is little to no research to support the use of many of these agents. "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended". Topical NSAIDs- There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use: Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. "Baclofen: Not recommended". There is no peer-reviewed literature to support the use of topical baclofen. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product. The cited guidelines recommend topical analgesics for neuropathic pain only when trials of antidepressants and anticonvulsants have failed to relieve symptoms. Failure of antidepressants and anticonvulsants for this injury is not specified in the records provided. Intolerance to oral medication is not specified in the records provided. In addition, as cited above, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Flurbiprofen and baclofen are not recommended by the cited guidelines for topical use as cited, because of the absence of high grade scientific evidence to support their effectiveness. The request for Flurbiprofen 20%, Baclofen 10%, Dexamethasone 2%, Panthenol 0.5% in salt stable LS base 240gm, quant....is not medically necessary or fully established for this patient.

**Dextromethorphan 10%, Gabapentin 10%, Bupivacaine 5%, Camphor 2%, Menthol 2%, in salt stable LS base 240gm, quantity: 1: 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:** The cited Guidelines regarding topical analgesics state, "Largely experimental in use with few randomized controlled trials to determine efficacy or safety, 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 (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants,...)". (Argoff, 2006) There is little to no research to support the use of many of these agents. "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended". "Topical NSAIDs- There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use". Gabapentin: Not recommended. There is no peer-reviewed literature to support use. The cited guidelines recommend topical analgesics for neuropathic pain only when trials of antidepressants and anticonvulsants have failed to relieve symptoms. Failure of antidepressants and anticonvulsants for this injury is not specified in the records provided. Intolerance to oral medication is not specified in the records provided. In addition, as cited above, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Gabapentin is not recommended by the cited guidelines for topical use as cited above because of the absence of high grade scientific evidence to support

their effectiveness. There is no high grade clinical evidence to support the effectiveness of topical menthol in lotion form. The request for Dextromethorphan 10%, Gabapentin 10%, Bupivacaine 5%, Camphor 2%, Menthol 2%, in salt stable LS base is not medically necessary or fully established for this patient.