

<b>Case Number:</b>	CM14-0024863		
<b>Date Assigned:</b>	06/11/2014	<b>Date of Injury:</b>	09/10/2009
<b>Decision Date:</b>	07/18/2014	<b>UR Denial Date:</b>	02/21/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/26/2014

### 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 Physical Medicine and Rehabilitation 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:

The injured worker is a 50-year-old male who reported an injury on 09/10/2009 with the mechanism of injury not cited within the document provided. In the clinical note dated 02/05/2014, the injured worker complained of intermittent headaches, constant severe pain in cervical spine that radiated down into his hands, thoracic spine pain described as aching and sharp, lumbar spine pain described as sharp and aching, right shoulder pain, right elbow pain, right wrist and hand pain, and bilateral knee pain. The physical examination of the cervical spine revealed +4 spasm and tenderness to the bilateral paraspinal muscles from C4-7, bilateral suboccipital muscles and bilateral upper shoulder muscles. An axial compression test was positive bilaterally for neurological compromise. The physical examination of the thoracic spine noted +3 spasm and tenderness to the bilateral thoracic paraspinal muscles from T4-11. The physical examination of the lumbar spine revealed +3 spasm and tenderness to the bilateral lumbar paraspinal muscles from L2-S1, multifidus and bilateral piriformis muscles. A straight leg raise test was positive bilaterally and the right patellar reflex, right hamstring reflex, and right Achilles reflex were all decreased. The physical examination of the shoulders revealed there was +3 spasm and tenderness to the right upper shoulder muscles and right rotator cuff muscles. The physical examination of the elbows revealed a +4 spasm and tenderness to the right lateral epicondyle and right medial epicondyle. The physical examination of the wrist and hands revealed there was a +4 spasm and tenderness to the right wrist flexors, right wrist extensors and right anterior wrist. A Tinel's, Guyon's and Bracelet test were positive on the right. The physical examination of the knees revealed +4 spasm and tenderness to the bilateral anterior joint lines. Diagnostic impressions included cervical disc herniation with myelopathy, lumbar spondylosis with myelopathy, thoracic spondylosis without myelopathy, sacroiliitis, carpal tunnel syndrome (median nerve entrapment at the right wrist), tear of medial meniscus of the bilateral knees,

partial tear of rotator cuff tendon of the right shoulder, medial epicondylitis of the right elbow, lateral epicondylitis of the right elbow, headache (tension), and sleep disorder. Prior treatments included chiropractic therapy, an EMG/NCV, and an MRI. The treatment plan included a prescription for inflammation topical compound (lidocaine 6%, gabapentin 10%, tramadol 10%) to apply a thin layer to affected area twice daily as directed by physician quantity 180 grams with 2 refills, muscular pain topical compound (flurbiprofen 15%, cyclobenzaprine 2%, baclofen 2%, lidocaine 5%) to apply a thin layer to affected area twice daily as directed by physician quantity 180 grams with 2 refills, tramadol 50 mg 1 capsule by mouth as needed for pain 4 to 5 as needed quantity 90, and naproxen sodium 550 mg to take 1 capsule by mouth every 12 hours with food quantity 90. An orthopedic surgical consult was requested and an MRI 3D of the bilateral knees and right shoulder was requested. It was also annotated that the injured worker was taught a series of home exercises as part of the patient education plan. It was noted that proper form, duration, and number of repetitions for the exercise plan was reviewed. It was noted that the injured worker understood the responsibilities for self-management of the injuries. The Request for Authorization for tramadol 50 mg #90, topical compound lidocaine 6% gabapentin 10% and tramadol 10% 180 grams, topical compound flurbiprofen 15% cyclobenzaprine 2% baclofen 2% and lidocaine 5% 180 grams, and naproxen sodium 550 mg #90 with rationale was not submitted.

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

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

#### **TRAMADOL 50 MG # 90: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, specific drug list Page(s): 80, 93-94.

**Decision rationale:** The request for tramadol 50 mg #90 is non-certified. The California MTUS Guidelines state that opioids appears to be efficacious but limited for short term pain relief, and long term efficacy is unclear (greater than 16 weeks), and also appears limited. Failure to respond to a time limited course of opioids has led to the suggestion of the assessment and consideration of alternative therapy. Tramadol is indicated for moderate to severe pain. The immediate release formulation is recommended at a dose of 50 to 100 mg by mouth every 4 to 6 hours (not to exceed 400 mg per day). In the clinical notes provided for review, there is a lack of documentation of the injured worker's pain level status as well as the injured worker's prescribed medication regimen. It is also noted that the injured worker had been prescribed Tramadol since 8/2013. Also, the request lacks the frequency and duration at which tramadol is to be taken. Therefore, the request for tramadol 50 mg #90 is non-certified.

#### **TOPICAL COMPOUND LIDOCAINE 6 %, GABAPENTIN 10 % AND TRAMADOL 10 % 180 GRAMS: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

**Decision rationale:** The request for topical compound lidocaine 6%, gabapentin 10%, and tramadol 10%, 180 grams is non-certified. The California MTUS Guidelines state topical analgesics 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. 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. Lidocaine is recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Gabapentin is not recommended for topical application. In the clinical notes provided for review, there is a lack of documentation of the injured worker having used antidepressants and anticonvulsants or other prescribed pain medications and their efficacy. There is also a lack of documentation of the injured worker's failed specific conservative therapies. There is also a lack of documentation of the injured worker's pain level. Furthermore, the guidelines do not recommend the use of any compounded product that contains at least 1 drug (or drug class) that is not recommended, as lidocaine in a cream for and gabapentin are not recommended, the medication would not be indicated. Therefore, the request for topical compound lidocaine 6%, gabapentin 10% and tramadol 10% 180 grams is non-certified.

**TOPICAL COMPOUND FLURBIPROFEN 15 %, CYCLOBENZAPRINE 2 %, BACLOFEN 2 % AND LIDOCAINE 5 % 180 GRAMS:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

**Decision rationale:** The request for topical compound flurbiprofen 15%, cyclobenzaprine 2%, baclofen 2%, and lidocaine 5% 180 grams is non-certified. The California MTUS Guidelines state topical analgesics 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. 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. Lidocaine is recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Topical lidocaine (in the formulation

of a dermal patch) has been designated for orphan status by the FDA for neuropathic pain. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Baclofen 2% and cyclobenzaprine 2% are not recommended for topical application. With the use of topical NSAIDs, the efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. In the clinical notes provided for review, there is a lack of documentation of the injured worker trying antidepressants or anticonvulsants or other prescribed pain medications and their efficacy. There is also a lack of documentation of the injured worker's pain level status. The guidelines state that they do not recommend a compounded product that contains at least 1 drug or drug class that is not recommended, as lidocaine in a cream and gabapentin. Furthermore, the guidelines state that the use of topical analgesic NSAIDs efficacy are inconsistent. Therefore, the request for topical compound flurbiprofen 15%, cyclobenzaprine 2%, baclofen 2%, and lidocaine 5%, 180 grams is non-certified.

**NAPROXEN SODIUM 550 MG # 90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 68.

**Decision rationale:** The request for naproxen sodium 550 mg #90 is non-certified. The California MTUS Guidelines state that NSAIDs (nonsteroidal anti-inflammatory drugs) are recommended for osteoarthritis (including knee and hip pain at the lowest dose for the shortest period in injured worker's with moderate to severe pain. Acetaminophen may be considered for initial therapy for injured worker's with mild to moderate pain, and in particular injured workers with gastrointestinal, cardiovascular, or renovascular risk factors. In the clinical notes provided for review, there is a lack of documentation of the injured worker's pain level along with the injured worker's prescribed medication regimen or lack thereof. The request also lacks the frequency at which the naproxen sodium is to be taken. Furthermore, the clinical notes also lack documentation of the rationale for the prescription of naproxen sodium. Therefore, the request for naproxen sodium 550 mg #90 is non-certified.