

<b>Case Number:</b>	CM15-0123739		
<b>Date Assigned:</b>	07/08/2015	<b>Date of Injury:</b>	06/23/2012
<b>Decision Date:</b>	08/24/2015	<b>UR Denial Date:</b>	06/15/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/26/2015

### 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:

The injured worker is a 45 year-old male, who sustained an industrial injury on 6/23/12. The injured worker was diagnosed as having cervical radiculopathy, cervical spine sprain/strain, cephalgia, lumbar disc displacement with radiculopathy, lumbar radiculopathy, lumbar spine sprain/strain, shoulder rotator cuff syndrome, and shoulder sprain/strain. Treatment to date has included left shoulder decompression with acromioplasty, Toradol injections, trigger point injections, and medication including Hydrocodone, Naproxen, Cyclobenzaprine, and topical medication. Currently, the injured worker complains of pain in the neck, low back, and left shoulder. The treating physician requested authorization for shockwave therapy for the lumbar spine x7 visits, shockwave therapy for the cervical spine x3 visits, Flurbiprofen 20%/Baclofen 5%/Camphor 2%/Menthol 2%/Dexamethasone Micro 0.2%/Capsaicin 0.025%/Hyaluronic acid 0.2%, and Amitriptyline HCL 10%/Gabapentin 10%/Bupivacaine. The patient sustained the injury due to fall from a ladder. The medication list include Anaprox, Xanax, Omeprazole and Cyclobenzaprine. Per the note dated 3/12/15 the patient had complaints of pain I cervical and lumbar region at 9/10. Physical examination of the cervical spine revealed limited range of motion, C 5 radiculopathy and weakness. The patient has had positive Spurling sign. Physical examination of the lumbar spine on 3/2/15 revealed muscle spasm, tenderness on palpation, limited range of motion, and positive SLR. The patient has had MRI of the cervical and lumbar spine revealed disc protrusions, foraminal narrowing, and degenerative changes. The patient had received an unspecified number of the PT and acupuncture visits for this injury.

## IMR ISSUES, DECISIONS AND RATIONALES

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

### **Shockwave therapy, lumbar, seven visits: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Low Back Complaints.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines Treatment in Workers' Comp., online Edition Chapter: Knee & Leg (updated 07/10/15) Extracorporeal shock wave therapy (ESWT) Official Disability Guidelines, current online version Shoulder (updated 08/06/15) Extracorporeal shock wave therapy (ESWT).

**Decision rationale:** Request Shockwave therapy, lumbar, seven visits ACOEM and CA-MTUS guidelines do not address shock wave therapy. Per the cited guidelines, extracorporeal shockwave treatment is "Under study for patellar tendinopathy and for long-bone hypertrophic non-unions". extracorporeal shockwave therapy (ESWT) is ineffective for treating patellar tendinopathy, compared to the current standard of care emphasizing multimodal physical therapy focused on muscle retraining, joint mobilization, and patellar taping. "Per the cited guidelines extracorporeal shockwave treatment is under study" compared to the current standard of care emphasizing multimodal physical therapy. The patient had received an unspecified number of the PT visits for this injury. The response to prior conservative treatments including physical therapy or chiropractic therapy was not specified in the records provided. The records submitted contain no accompanying current PT evaluation for this patient. The medical necessity of the request for Shockwave therapy, lumbar, and seven visits is not fully established for this patient.

### **Shockwave therapy, cervical, three visits: 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) Elbow (updated 06/23/15) Extracorporeal shockwave therapy (ESWT) Shoulder (updated 08/06/15) Extracorporeal shock wave therapy (ESWT).

**Decision rationale:** Shockwave therapy, cervical, three visits ACOEM and CA-MTUS guidelines do not address shock wave therapy. Per the cited guidelines, extracorporeal shockwave treatment is "Not recommended. High energy ESWT is not supported, but low energy ESWT may show better outcomes without the need for anesthesia, but is still not recommended. Trials in this area have yielded conflicting results..." Per the cited guidelines, extracorporeal shockwave treatment is "Recommended for calcifying tendinitis but not for other 'disorders'." As per cited guideline extracorporeal shockwave treatment is not recommended. Per the cited guidelines there was no high grade scientific evidence to support the use of

extracorporeal shockwave treatment for this diagnosis. Patient has received an unspecified number of PT visits for this injury. The response to prior conservative treatments including physical therapy or chiropractic therapy was not specified in the records provided. The notes from the previous conservative treatments sessions were not specified in the records provided. The medical necessity of the request for Shockwave therapy, cervical, three visits is not fully established in this patient.

**Flurbiprofen 20%/Baclofen 5%/Camphor 2%/Menthol 2%/Dexamethasone Micro 0.2%/Capsaicin 0.025%/Hyaluronic Acid 0.2%: Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints, Chapter 9 Shoulder Complaints, Chapter 12 Low Back Complaints, Chronic Pain Treatment Guidelines Pain (Chronic) Section. Decision based on Non-MTUS Citation Pain, Suffering, And The Restoration of Function Chapter (ACOEM Practice Guidelines, 2nd Edition (2004), Chapter 6) , as well as the Official Disability Guidelines (ODG).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain - Topical Analgesics, pages 111-112 Topical Analgesics.

**Decision rationale:** Flurbiprofen 20%/Baclofen 5%/Camphor 2%/Menthol 2%/Dexamethasone Micro 0.2%/Capsaicin 0.025%/Hyaluro. According to the MTUS Chronic Pain Guidelines regarding topical analgesics state that the use of topical analgesics is "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". There is little to no research to support the use of many of these agents. "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. Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photo contact dermatitis". "Lidocaine Indication: Neuropathic pain 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). Non-neuropathic pain" MTUS guidelines recommend topical analgesics for neuropathic pain only when trials of antidepressants and anticonvulsants have failed to relieve symptoms. Any trial of antidepressants and anticonvulsants for these symptoms were not specified in the records provided. Any intolerance or contraindication to oral medications was not specified in the records provided. Any evidence of diminished effectiveness of medications was not specified in the records provided. Flurbiprofen is NSAID. "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended Non-steroidal anti-inflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration" Baclofen is a muscle relaxant. Per the cited guidelines, "Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." "Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments". There is also no evidence that menthol is recommended by the CA, MTUS, Chronic pain treatment guidelines. There is no evidence that menthol is recommended by the CA, MTUS, chronic pain treatment guidelines. In addition, as cited above, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The topical Flurbiprofen,

Menthol, Capsaicin and Baclofen are not recommended by MTUS. The medical necessity of the medication Flurbiprofen 20%/Baclofen 5%/Camphor 2%/Menthol 2%/Dexamethasone Micro 0.2%/Capsaicin 0.025%/Hyaluro is not fully established in this patient.

**Amitriptyline HCL 10%/Gabapentin 10%/Bupivacaine:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 9 Shoulder Complaints, Chapter 8 Neck and Upper Back Complaints, Chapter 12 Low Back Complaints, Chronic Pain Treatment Guidelines Pain (Chronic) Section. Decision based on Non- MTUS Citation Pain, Suffering, And The Restoration of Function Chapter (ACOEM Practice Guidelines, 2nd Edition (2004), Chapter 6), as well as the Official Disability Guidelines (ODG).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain - Topical Analgesics, pages 111-112 Topical Analgesics.

**Decision rationale:** Amitriptyline HCL 10%/Gabapentin 10%/Bupivacaine. According to the MTUS Chronic Pain Guidelines regarding topical analgesics state that the use of topical analgesics is "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". 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." "Gabapentin: Not recommended. There is no peer-reviewed literature to support use. Ketamine: Under study: Only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatment has been exhausted..." MTUS guidelines recommend topical analgesics for neuropathic pain only when trials of antidepressants and anticonvulsants have failed to relieve symptoms. Any trial of antidepressants and anticonvulsants for these symptoms were not specified in the records provided. Any intolerance or contraindication to oral medications was not specified in the records provided. As per cited guideline "Gabapentin: Not recommended. There is no peer-reviewed literature to support use." Topical Gabapentin is not recommended in this patient for this diagnosis as cited. Amitriptyline is an antidepressant. Per the cited guidelines, "Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants. There is little to no research to support the use of many of these agents". Therefore, topical amitriptyline is not recommended by the cited guidelines. Per the cited guidelines, "any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Topical Gabapentin and amitriptyline are not recommended in this patient for this diagnosis as cited. The medical necessity of the request for Amitriptyline HCL 10%/Gabapentin 10%/Bupivacaine is not fully established in this patient.