

<b>Case Number:</b>	CM15-0180965		
<b>Date Assigned:</b>	09/22/2015	<b>Date of Injury:</b>	04/06/2013
<b>Decision Date:</b>	11/09/2015	<b>UR Denial Date:</b>	08/19/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/14/2015

### 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 57 year old female, who sustained an industrial injury on 4-6-13. Medical record indicated the injured worker is undergoing treatment for bursitis and tendinitis of the right shoulder, bicipital tenosynovitis, partial tear of rotator cuff tendon, and medial and lateral epicondylitis of right elbow and olecranon bursitis of right elbow. Treatment to date has included right shoulder surgery on 9/13/14, post-operative physical therapy, and home exercise program and activity modifications. Currently on 8-6-15, the injured worker complains of moderate to severe right shoulder pain described as tender, right elbow frequent, minimal pain described as heavy with reported numbness over the elbow and intermittent slight pain described as throbbing and aching with numbness that radiated into her right arm. Work status is noted to be temporarily totally disabled. Physical exam performed on 8-6-15 revealed spasm and tenderness to bilateral cervical paraspinal muscles from C2-7, right upper shoulder muscles and right upper trapezius; surgical scars on right shoulder with spasm and tenderness to bilateral rotator cuff muscles and right upper shoulder muscles, exam of elbows revealed numbness post-surgery of right shoulder with spasm and tenderness to the bilateral lateral epicondyles and right olecranon and exam of wrists and hands revealed spasm and tenderness to the bilateral wrist extensors and bilateral wrist flexors. The treatment plan included requests for Lidocaine 6%, Gabapentin 10%, Ketoprofen 10% cream, Flurbiprofen 15%, Cyclobenzaprine 2%, Baclofen 2%, Lidocaine 5% cream and Flexeril 10mg #60 with 2 refills and a functional improvement measure. On 8-19-15, utilization review non-certified a request for Lidocaine 6%, Gabapentin 10%, Ketoprofen 10% cream and Flurbiprofen 15%, Cyclobenzaprine 2%, Baclofen 2%, Lidocaine 5% cream noting guidelines state any topical compounded product that contains

at least one drug that is not recommended is not recommended; Lidocaine is recommended for localized peripheral pain after there has been evidence of trial of first line therapy, topical NSAIDs (non-steroidal anti-inflammatory drugs) are not recommended as there is no evidence to support use in neuropathic pain, Ketoprofen is not currently FDA approved for topical application, Gabapentin is not recommended and there is no peer reviewed literature to support the use of topical Baclofen; and Flexeril 10mg #60 with 2 refills was modified to #60 with 0 refills noting it is not recommended for use longer than 2-3 weeks. The patient has had EMG of bilateral upper extremity that revealed CTS. The medication list includes Relafen, Norco, Tylenol#3, Naproxen and Tramadol.

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

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

**Lidocaine 6%, Gabapentin 10%, Ketoprofen 10%, 180gm, 2 refills: Upheld**

**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): Topical Analgesics.

**Decision rationale:** Request: Lidocaine 6%, Gabapentin 10%, Ketoprofen 10%, 180gm, 2 refills. 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 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." 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: Gabapentin: Not recommended. There is no peer-reviewed literature to support use. MTUS guidelines recommend topical analgesics for neuropathic pain only when trials of antidepressants and anticonvulsants have failed to relieve symptoms. Trial of antidepressants and anticonvulsants for these symptoms were not specified in the records provided. Intolerance or contraindication to oral medications was not specified in the records provided. Evidence of diminished effectiveness of 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. Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. In addition, as cited above, any compounded product that contains at least one drug (or drug class) that is not

recommended is not recommended. Topical Ketoprofen and Gabapentin are not recommended by MTUS. The medical necessity of the request for Lidocaine 6%, Gabapentin 10%, Ketoprofen 10%, 180gm, 2 refills is not fully established in this patient.

**Flurbiprofen 15%, Cyclobenzaprine 2%, Baclofen 2%, Lidocaine 5%, 180gm, 2 refills:**  
Upheld

**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): Topical Analgesics.

**Decision rationale:** Flurbiprofen 15%, Cyclobenzaprine 2%, Baclofen 2%, Lidocaine 5%, 180gm, 2 refills. 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. Trial of antidepressants and anticonvulsants for these symptoms were not specified in the records provided. Intolerance or contraindication to oral medications was not specified in the records provided. 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. Cyclobenzaprine and Baclofen are muscle relaxants. Per the cited guidelines: Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product. In addition, as cited above, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical Flurbiprofen, Cyclobenzaprine and Baclofen are not recommended by MTUS. The medical necessity of the medication Flurbiprofen 15%, Cyclobenzaprine 2%, Baclofen 2%, Lidocaine 5%, 180gm, 2 refills is not fully established in this patient.

**Flexeril 10mg #60, 2 refills:** 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): Cyclobenzaprine (Flexeril).

**Decision rationale:** Flexeril 10mg #60, 2 refills. According to CA MTUS guidelines cited below, "Recommended as an option, using a short course of therapy. Cyclobenzaprine (Flexeril) is more effective than placebo in the management of back pain." The patient has had right shoulder surgery on 9/13/14. Currently on 8-6-15, the injured worker complains of moderate to severe right shoulder pain described as tender, right elbow frequent, minimal pain described as heavy with reported numbness over the elbow and intermittent slight pain described as throbbing and aching with numbness that radiated into her right arm. Physical exam performed on 8-6-15 revealed spasm and tenderness to bilateral cervical paraspinal muscles from C2-7, right upper shoulder muscles and right upper trapezius; surgical scars on right shoulder with spasm and tenderness to bilateral rotator cuff muscles and right upper shoulder muscles, exam of elbows revealed numbness post-surgery of right shoulder with spasm and tenderness to the bilateral lateral epicondyles and right olecranon and exam of wrists and hands revealed spasm and tenderness to the bilateral wrist extensors and bilateral wrist flexors. The patient has evidence of muscle spasm on objective examination. The patient also has chronic conditions with abnormal objective findings. These conditions are prone to intermittent exacerbations. Therefore with this, it is deemed that, the use of the muscle relaxant Flexeril 10mg #60, 2 refills is medically appropriate and necessary in this patient.