

<b>Case Number:</b>	CM15-0188679		
<b>Date Assigned:</b>	09/30/2015	<b>Date of Injury:</b>	05/29/2014
<b>Decision Date:</b>	11/12/2015	<b>UR Denial Date:</b>	08/25/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/24/2015

### 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: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

### 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 female, who sustained an industrial injury on 5-29-2014. The injured worker was being treated for aftercare for surgery of the right shoulder, rotator cuff syndrome of the right shoulder, and bursitis and tendinitis of the left shoulder. Treatment to date has included diagnostics, physical therapy, right shoulder arthroscopic subacromial decompression with debridement of rotator cuff and biceps tenodesis on 12-02-2014), cortisone injections, and medications. A progress report (Initial Evaluation as primary treating physician) dated 3-30-2015 noted complaints of moderate to severe "burning" pain in her bilateral shoulders, with radiation down both arms to the elbows. Her medication use on 3-30-2015 was documented as Effexor, Benazepril, Ibuprofen, and Cyclobenzaprine, without notation of reported side effects. She was prescribed topical compound creams (Ketoprofen 10%, Gabapentin 10%, Lidocaine 6% and Flurbiprofen 15%, Cyclobenzaprine 2%, Baclofen 2%, and Lidocaine 5%). Tried-failed medications were not documented. The progress report (4-15-2015) noted an evaluation only for functional improvement and documented "functional improvement deterioration. Most recently (7-13-2015), the injured worker complains of "constant moderate to severe pain" described as burning, in her bilateral shoulders. She reported that the shoulder pain radiated down both arms to her elbows. Exam noted post surgical scars on her right shoulder, +3 spasm and tenderness to the bilateral rotator cuff muscles and bilateral upper shoulder muscles, and positive Speed's and supraspinatus tests bilaterally. Her work status was modified with restrictions, total temporary disability if unavailable. The treating physician documented that she "has not improved with conservative therapy and her therapy has been

stopped". Her function with activities of daily living was not described. The treatment plan included Ketoprofen 10%, Gabapentin 10%, Lidocaine 6% (DOS: 04/16/2015, 05/21/2015, 07/06/2015) and Flurbiprofen 15%, Cyclobenzaprine 2%, Baclofen 2%, and Lidocaine 5% (DOS: 04/16/2015, 05/21/2015, 07/06/2015). On 8-25-2015 Utilization Review non-certified, the retrospective usage of the requested topical compounded medications.

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

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

**Retrospective topical compounds: Ketoprofen 10%, Gabapentin 10%, Lidocaine 6% (DOS: 04/16/2015, 05/21/2015, 07/06/2015): 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:** Based on the 6/11/15 progress report provided by the treating physician, this patient presents with constant moderate/severe and burning pain in bilateral shoulders, radiating down bilateral arms and stopping at the elbows. The treater has asked for RETROSPECTIVE TOPICAL COMPOUNDS KETOPROFEN 10%, GABAPENTIN 10%, LIDOCAINE 6% (DOS 04/16/2015, 05/21/2015, 07/06/2015) on 6/11/15. The request for authorization was not included in provided reports. The patient is currently using Motrin per 6/11/15 report. The patient is s/p right shoulder arthroscopic subacromial decompression of rotator cuff tear and biceps tenodesis per 1/26/15 report. The patient states that she had compensatory left shoulder pain after work related injury per 3/30/15 report. The patient's work status is temporarily totally disabled until 8/11/15 as of 6/11/15 report. MTUS, Topical Analgesics section, pg. 111: Recommended as an option as indicated below. 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. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (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. MTUS, Topical Analgesics section, pg. 112: 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). The FDA for neuropathic pain has designated topical lidocaine, in the formulation of a dermal patch (Lidoderm) for orphan status. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-

pruritics. MTUS, Topical Analgesics, pg. 113: Baclofen: Not recommended. There is currently one Phase III study of Baclofen-Amitriptyline- Ketamine gel in cancer patients for treatment of chemotherapy-induced peripheral neuropathy. 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. Gabapentin: Not recommended. There is no peer-reviewed literature to support use. The treater does not discuss this request in the reports provided. However, the patient was prescribed an "inflammation topical compound" containing Ketoprofen, Gabapentin, and Lidocaine in 5/7/15 report. The progress reports, however, do not document the efficacy of the topical compound in terms of its impact on the patient's pain and function; neither does it specify which area of the body it is to be applied. MTUS specifically states that Gabapentin is not recommended in any topical formulation. MTUS guidelines also recommend Lidocaine only in the dermal patch form. Additionally, the Guidelines state clearly, "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Hence, this request IS NOT medically necessary.

**Retrospective topical compounds: Flurbiprofen 15%, Cyclobenzaprine 2%, Baclofen 2%, and Lidocaine 5% (DOS: 04/16/2015, 05/21/2015, 07/06/2015): 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:** Based on the 6/11/15 progress report provided by the treating physician, this patient presents with constant moderate/severe and burning pain in bilateral shoulders, radiating down bilateral arms and stopping at the elbows. The treater has asked for RETROSPECTIVE TOPICAL COMPOUNDS FLURBIPROFEN 15%, CYCLOBENZAPRINE 2%, BACLOFEN 2%, AND LIDOCAINE 5% (DOS 04/16/2015, 05/21/2015, 07/06/2015) on 6/11/15. The request for authorization was not included in provided reports. The patient is currently using Motrin per 6/11/15 report. The patient is s/p right shoulder arthroscopic subacromial decompression of rotator cuff tear and biceps tenodesis per 1/26/15 report. The patient states that she had compensatory left shoulder pain after work related injury per 3/30/15 report. The patient's work status is temporarily totally disabled until 8/11/15 as of 6/11/15 report. MTUS, Topical Analgesics section, pg. 111: Recommended as an option as indicated below. 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. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (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. MTUS, Topical Analgesics, pg. 113: Baclofen: Not

recommended. There is currently one Phase III study of Baclofen-Amitriptyline- Ketamine gel in cancer patients for treatment of chemotherapy-induced peripheral neuropathy. 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. Gabapentin: Not recommended. There is no peer-reviewed literature to support use. The treater does not discuss this request in the reports provided. However, the patient was prescribed a "muscular pain topical compound" with Flurbiprofen, Baclofen, Cyclobenzaprine, and Lidocaine in 5/7/15 report. The progress reports, however, do not document the efficacy of the topical compound in terms of its impact on the patient's pain and function; neither does it specify which area of the body it is to be applied. MTUS specifically states that Baclofen and Cyclobenzaprine are not recommended in any topical formulation. MTUS guidelines also recommend Lidocaine only in the dermal patch form. Additionally, the Guidelines state clearly, "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Hence, this request IS NOT medically necessary.