

<b>Case Number:</b>	CM14-0177496		
<b>Date Assigned:</b>	10/30/2014	<b>Date of Injury:</b>	03/01/2013
<b>Decision Date:</b>	12/08/2014	<b>UR Denial Date:</b>	10/13/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/27/2014

### 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 Family Medicine 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:

This 50-year-old dishwasher reported a left elbow injury due to striking his elbow on a metal table on 3/1/13. Injuries to the left shoulder and wrist have subsequently been added. The most recent progress note in the records, dated 9/18/14, states that the patient has constant left shoulder, elbow, wrist and hand pain. Examination is notable for tenderness of the entire left upper extremity, with extremely limited range of motion of the shoulder, elbow and wrist. Diagnoses included left rotator cuff sprain, and tear, left elbow internal derangement and sprain, left wrist sprain and left hand sprain. Medications include Ibuprofen, Prilosec, Ultram, Neurontin, Theramine, Sentra AM and Sentra PM. Plan includes urine toxicology, acupuncture, consult with an orthopedist, and MRIs of the left shoulder and elbow. Apparently topical creams were dispensed to this patient in early 2014, and a retroactive request for two of them was non-certified in UR on 10/13/14. There are no progress notes in the available records from the physician who actually prescribed the creams. There is a single undated medical necessity form in the records signed by the current treater, which lists topical creams with different ingredients than the creams involved in this review, and which has a checked box giving "manage/reduce pain" as the rationale for prescribing the creams. Otherwise there is no information in the records regarding the provider's reasoning for dispensing the creams.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**RETRO: Flurbiprofen 25%, Cyclobenzaprine 02% - 240gm (DOS: 1-9-14): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines compound medications Page(s): 111, 112-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain; Medications for Chronic Pain Page(s): 60; 111-113.

**Decision rationale:** The requested medication is a topical compounded cream which contains flurbiprofen (an NSAID) and cyclobenzaprine (a muscle relaxant). The first reference cited above states that medications should be started individually while other treatments are held constant, with careful assessment of function. There should be functional improvement with each medication in order to continue it. The second guideline states that 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. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Note that topical flurbiprofen is not FDA approved, and is therefore experimental and cannot be presumed as safe and efficacious. Non-FDA approved medications are not medically necessary. Baclofen: Not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product. The clinical documentation in this case does not support the use of topical flurbiprofen and cyclobenzaprine. Using this medication means that two medications are being started simultaneously. The medications cannot be monitored individually and it would be impossible to tell which medication caused any side effect or any functional improvement that might result. For this reason alone, this cream is not indicated. In addition, topical flurbiprofen is not FDA-approved, and there is no medical evidence to support the use of topical muscle relaxants, of which cyclobenzaprine is one. Based on the MTUS citations above and on the clinical information provided for my review, topical flurbiprofen 25% with cyclobenzaprine 02% is not medically necessary. It is not medically necessary because its use means that two medications are being started simultaneously, because flurbiprofen is not FDA-approved for topical use, and because there is no evidence to support the use of topical cyclobenzaprine.

**RETRO: Gabapentin 10%, Lidocaine 5%, Tramadol 15% - 240 gm (DOS: 1-9-14):** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines compound medications Page(s): 111, 112-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain; Topical analgesics Page(s): 60; 111-113.

**Decision rationale:** The requested medication is a topical compounded cream which contains gabapentin (an anti-epileptic drug), lidocaine (a local anesthetic), and tramadol (an opioid analgesic). The first reference cited above states that medications should be started individually while other treatments are held constant, with careful assessment of function. There should be functional improvement with each medication in order to continue it. The second guideline states that 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. Any compounded product that contains at

least one drug (or drug class) that is not recommended is not recommended. Gabapentin is not recommended. There is no peer-reviewed literature to support its use. Lidocaine is indicated for localized neuropathic pain if there is evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Only FDA-approved products are indicated, and no other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Topical lidocaine is not indicated for non-neuropathic pain. The clinical documentation in this case does not support the use of topical gabapentin, lidocaine and tramadol. Using this medication means that three medications are being started simultaneously. The medications cannot be monitored individually and it would be impossible to tell which medication caused any side effect or any functional improvement that might result. For this reason alone, this cream is not indicated. In addition, the MTUS guideline cited above states that topical gabapentin is not recommended, and that only FDA-approved forms of topical lidocaine are indicated for neuropathic pain. This patient's pain does not appear to be neuropathic, and the form of lidocaine requested is not Lidoderm, which is the only FDA-approved topical lidocaine preparation. Based on the MTUS citations above and on the clinical information available for my review, topical gabapentin 10%, lidocaine 5%, tramadol 15% cream is not medically necessary because its use means that three medications are being started simultaneously and because two of its ingredients (gabapentin and lidocaine) are not recommended.