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| <b>Case Number:</b>   | CM15-0171586 |                              |            |
| <b>Date Assigned:</b> | 09/11/2015   | <b>Date of Injury:</b>       | 01/15/2015 |
| <b>Decision Date:</b> | 10/16/2015   | <b>UR Denial Date:</b>       | 08/18/2015 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 08/31/2015 |

### 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, District of Columbia, Maryland  
 Certification(s)/Specialty: Anesthesiology, Pain Management

### 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 65 year old female, who sustained an industrial injury on 1-15-2015. She reported injury to the left wrist from a fall and subsequently diagnosed with a fracture. Diagnoses include left wrist closed fracture distal radius and ulna, status post left wrist severe closed injury, rule out left scaphoid and lunate fracture and rule out carpal ligament injuries, left MCP extension contractures, and status post Open Reduction Internal Fixation (ORIF) of the left wrist on 4-2-15. Treatments to date include activity modification, soft cast, and medication therapy. Currently, she complained of pain on the topside of the left hand with flexion, stiffness in the fingers, and swelling of the left forearm. On 7-24-15, the physical examination documented near complete extension, limited range of motion in the wrist, and decreased overall edema and in duration of scar. The plan of care included prescriptions for transdermal topical compound creams. The appeal requested authorization for HMPC2 - Flurbiprofen 20% + Baclofen 10% + Dexamethasone - micro 0.2% + Hyaluronic Acid 0.2% in cream base 240 grams; and HNPCI - Amitriptyline 10% + Gabapentin 10% + Bupivacaine 5% - Hyaluronic. The Utilization Review dated 8-18-15, denied the request based on California Medical Treatment Utilization Guidelines that state, "Any compounded product that contains at least one drug that is not recommended is not recommended."

### IMR ISSUES, DECISIONS AND RATIONALES

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

**HMPC2- Flurbiprofen 20%-Baclofen 10%-Dexamthasome-Micro-0.2%-Hyaluronic acid 0.2% in cream base 240gms: 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:** Per MTUS with regard to Flurbiprofen (p 112), "These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder." Flurbiprofen may be indicated. Capsaicin may have an indication for chronic lower back pain in this context. Per MTUS p 112 "Indications: There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy." Per MTUS p 113 with regard to topical baclofen, "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." Baclofen is not indicated. The CA MTUS, ODG, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the topical application of dexamethasone or hyaluronic acid. It is the opinion of this IMR reviewer that a lack of endorsement, a lack of mention, inherently implies a lack of recommendation, or a status equivalent to "not recommended." Since multiple agents are not medically indicated, then the overall product is not indicated per MTUS as outlined below. Note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of multiple medications, MTUS p 60 states "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually. The request is not medically necessary.

**HNPCI - Amitriptyline 10%/Gabapentin 10%/Bupivacaine 5%-Hyaluronic:** 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:** Per MTUS p 113 with regard to topical gabapentin: "Not recommended. There is no peer-reviewed literature to support use." Note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The MTUS is silent on the use of topical Bupivacaine, however, topical lidocaine is only recommended for neuropathic 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). There is no documentation that the injured worker has failed trial of these first-line therapies. Per the article "Topical Analgesics in the Management of Acute and Chronic Pain" published in Mayo Clinic Proceedings (Vol 88, Issue 2, p 195-205), "Studies in healthy volunteers demonstrated that topical amitriptyline at concentrations of 50 and 100 mmol/L produced a significant analgesic effect ( $P < .05$ ) when compared with placebo and was associated with transient increases in tactile and mechanical nociceptive thresholds." Amitriptyline may be indicated. The CA MTUS, ODG, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the topical application of hyaluronic acid. It is the opinion of this IMR reviewer that a lack of endorsement, a lack of mention, inherently implies a lack of recommendation, or a status equivalent to "not recommended". Regarding the use of multiple medications, MTUS p 60 states "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others". Therefore, it would be optimal to trial each medication individually. As gabapentin is not recommended, the compound is not recommended. The request is not medically necessary.