

<b>Case Number:</b>	CM14-0187559		
<b>Date Assigned:</b>	11/17/2014	<b>Date of Injury:</b>	04/13/2014
<b>Decision Date:</b>	01/06/2015	<b>UR Denial Date:</b>	10/23/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/10/2014

### 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 Occupational Medicine, and is licensed to practice in Montana. 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:

The injured worker is a nurse's aide with a date of injury of 4/13/14. The injury was a slip and fall at work with injury to the head, low back and bilateral lower extremities. She continues to have complaint of low back pain radiating into the lower extremities with numbness and tingling. Treatment has included medications, physical therapy and epidural steroid injection. The records note that chiropractic treatment and acupuncture were requested but it is not clear whether those were performed. Current diagnoses include cervical and lumbar strains with cervical and lumbar radiculopathy, bilateral shoulder pain with rotator cuff syndrome and bilateral knee pain. The treating physician has requested 2 compounded topical analgesic medications.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flurbiprofen 10%, Capsaicin 0.05%, Menthol 2.5%, Camphor 2.5%, Hyaluronic Acid 0.2%,:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 49, Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

**Decision rationale:** The MTUS, in the ACOEM guidelines, states that, for initial treatment, topical medications are not recommended. The Chronic Pain Medical Treatment Guidelines note that topical analgesics are 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. This topical analgesic contains Flurbiprofen, which is a non-steroidal anti-inflammatory medications (NSAIDs). The MTUS states that topical non-steroidal anti-inflammatory agents have not been shown to be effective in long-term studies. Topical non-steroidal anti-inflammatory agents have shown inconsistent efficacy in clinical trials and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. 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). Voltaren Gel 1% (Diclofenac): Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. Maximum dose should not exceed 32 g per day (8 g per joint per day in the upper extremity and 16 g per joint per day in the lower extremity). The most common adverse reactions were dermatitis and pruritus. Topical treatment can result in blood concentrations and systemic effects comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. The MTUS does not recommend use of topical hyaluronic acid, camphor or menthol. It states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case the request for Flurbiprofen 10%, Capsaicin 0.05%, Menthol 2.5%, Camphor 2.5%, Hyaluronic Acid 0.2% is not supported by the MTUS and is not medically necessary.

**Diclofenac 10%, Gabapentin 10%, Lidocaine 5%, Hyaluronic Acid 0.2%:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 49, Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

**Decision rationale:** The MTUS, in the ACOEM guidelines, states that, for initial treatment, topical medications are not recommended. The Chronic Pain Medical Treatment Guidelines note that topical analgesics are 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. This topical analgesic contains diclofenac, which are non-steroidal anti-inflammatory medications (NSAIDs). The MTUS states that topical non-steroidal anti-inflammatory agents have not been shown to be effective in long-term studies. Topical non-steroidal anti-inflammatory agents have shown inconsistent efficacy in clinical trials

and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. 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). Voltaren Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. Maximum dose should not exceed 32 g per day (8 g per joint per day in the upper extremity and 16 g per joint per day in the lower extremity). The most common adverse reactions were dermatitis and pruritus. Topical treatment can result in blood concentrations and systemic effects comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. The MTUS states that topical use of Gabapentin is not recommended, with no peer-reviewed literature to support use. There is also no recommendation for use of topical hyaluronic acid. The MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case the request for Diclofenac 10%, Gabapentin 10%, Lidocaine 5%, and Hyaluronic Acid 0.2% is not supported by the MTUS and is not medically necessary.