

<b>Case Number:</b>	CM15-0080607		
<b>Date Assigned:</b>	05/01/2015	<b>Date of Injury:</b>	02/02/1996
<b>Decision Date:</b>	06/29/2015	<b>UR Denial Date:</b>	03/26/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/27/2015

### 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: 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 59-year-old female, who sustained an industrial injury on February 2, 1996. She has reported lower back pain and right leg pain. Diagnoses have included lumbar/lumbosacral degenerative disc disease and lumbago. Treatment to date has included medications and home exercise. A progress note dated March 16, 2015 indicates a chief complaint of an unchanged condition and pain rated at 5/10 numerically. The treating physician documented a plan of care that included medications and an EMS unit.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**EMS unit:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TENS Page(s): 114-121.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of electrical stimulation treatment such as a TENS unit. TENS is not recommended as a primary treatment modality, but a one-month home-based TENS trial may be considered as a noninvasive conservative option, if used as an adjunct to a program of evidence-based functional restoration, for the conditions described below. While TENS may reflect the long-standing accepted standard of care within many medical communities, the results of studies are inconclusive; the published trials do not provide information on the stimulation parameters, which are most likely to provide optimum pain relief, nor do they answer questions about long-term effectiveness. Indications for this type of therapy include: Chronic intractable pain (for the conditions noted above): Documentation of pain of at least three months duration. There is evidence that other appropriate pain modalities have been tried (including medication) and failed. A one-month trial period of the TENS unit should be documented (as an adjunct to ongoing treatment modalities within a functional restoration approach) with documentation of how often the unit was used, as well as outcomes in terms of pain relief and function; rental would be preferred over purchase during this trial. Other ongoing pain treatment should also be documented during the trial period including medication usage. A treatment plan including the specific short- and long-term goals of treatment with the TENS unit should be submitted. In this case, there is insufficient documentation to support the continued use of a TENS unit. There is no evidence in the record to describe the functional outcomes as indicated in the above cited guidelines. There is no documentation on the impact of a TENS unit on medication usage. There is no documented short- and long-term goals as cited above. For these reasons, an EMS unit is not a medically necessary treatment.

**Voltaren gel (unspecified dose and qty):** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of topical analgesic, including Voltaren, as a treatment modality. Topical analgesics are considered as 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. Voltaren is an example of a topical NSAID. Regarding topical NSAIDs, the guidelines state the following: Non-steroidal antiinflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent 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. 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. Neuropathic pain: Not recommended as there is no evidence to support use. FDA-approved agents: 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. In this case, the dose and quantity of Voltaren gel is not specified and therefore it is unclear whether the treatment is consistent with the above-cited MTUS guidelines. Further, the records indicate that Voltaren gel has been used as a long-term treatment strategy for this patient's symptoms. As noted in the above-cited guidelines, long-term use is not recommended. For these reasons, Voltaren gel is not a medically necessary treatment.

**Relafen (unspecified dose and qty):** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67-68.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of NSAIDs, including Relafen, as a treatment modality. NSAIDs are generally recommended as a short-term treatment for acute exacerbations of pain syndromes. Examples are as follows: Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxen being the safest drug). There is no evidence of long-term effectiveness for pain or function. Back Pain - Acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting evidence that NSAIDs are more effective than acetaminophen for acute LBP. For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. (Roelofs-Cochrane, 2008) The addition of NSAIDs or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician. Back Pain Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another. Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in with neuropathic pain. In this case the dose and amount of Relafen is not specified. However, the records suggest that Relafen has been used as a long-term treatment strategy for this patient's pain syndrome. Per the above cited guidelines, long-term use is not recommended. For this reason, Relafen is not considered as a medically necessary treatment.

**Zanaflex (unspecified dose and qty): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants for Chronic Pain Page(s): 63-66.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of muscle relaxants, including Zanaflex, as a treatment modality. These guidelines state that muscle relaxants should be recommend with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. In this case, the dose and quantity of Zanaflex is not provided. However, the records suggest that Zanaflex is being used as a long-term treatment strategy for this patient's symptoms. Long-term use is not recommended per the above cited guidelines. For these reasons, Zanaflex is not considered as a medically necessary treatment.