

<b>Case Number:</b>	CM14-0066623		
<b>Date Assigned:</b>	07/11/2014	<b>Date of Injury:</b>	08/17/2011
<b>Decision Date:</b>	10/30/2014	<b>UR Denial Date:</b>	04/11/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/09/2014

### 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 Internal Medicine, and is licensed to practice in District of Columbia & Virginia. 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 is a 30 year old patient who sustained injury on Aug 17 2011. On Dec 6 2011 MRI of the L spine showed mild degenerative changes of the lumbar spine and L4-5 and moderate bilateral foraminal narrowing. MRI of the C spine showed mild scattered degenerative changes with mild foraminal narrowing. EMG/NCV of the bilateral upper and lower extremities was normal for the upper extremities and bilateral sacral radiculopathy with some active denervation. He was diagnosed with lumbar and lumbar spine radiculitis. The patient had an MRI of the cervical spine on May 2 2012 showing central disc protrusion and a right sided disc bulge. He was also diagnosed with lumbar sprain and elbow sprain and knee sprain. He was prescribed compound creams.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Compound Cream: FLURBI 20%; TRAMA 20%; CYCLO 4%: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 72,20, 111.

**Decision rationale:** This compound contains Flurbiprofen. Per MTUS, Flurbiprofen (A NSAID, generic available): 50, 100 mg. Dosing: Osteoarthritis and mild to moderate pain: 200-300mg per day at intervals of 2 to 4 divided doses. The maximum daily doses 300 mg/day and the maximum divided dose is 100 mg (for instance, 100 mg twice a day). Oral NSAIDs: One intermediate-quality study (patients with symptoms of 10 or less days) was reviewed that randomized Flurbiprofen vs. piroxicam<sup>28</sup> and found that "Flurbiprofen was significantly superior to Piroxicam with regard to relief of pain at day 28, pain on active movement at days 14 and 28, pain on passive movement at days 7, 14 and 28 and pain, as measured by a visual analogue scale, at day 14." Two low-quality studies evaluated Diflunisal and Naproxen. The first found no significant differences between the groups (patients with symptoms for at least 6 or 7 days prior to evaluation) and therefore, concluded that Diflunisal and naproxen are "equivalent in providing relief of pain and tenderness due to tennis elbow."<sup>29</sup> The second study (patients' duration of symptoms not indicated) concluded that "Diflunisal and naproxen significantly reduce pain...however; Diflunisal provided more effective pain relief in the group studied."<sup>30</sup> Lastly, one high-quality study (43.3% of patients had symptoms for less than 6 weeks and 44.1% had symptoms for more than 6 months) evaluated Diclofenac (150 mg) versus placebo, with the results indicating that a "statistically and clinically significant reduction of pain was associated with Diclofenac, but no clinically significant difference in grip strength or functional improvement could be detected between the 2 groups."<sup>31</sup> The authors concluded that it is "difficult to recommend these of Diclofenac in the treatment of lateral epicondylalgia at the dosage used in this study." In regards to topical medication: Non-steroidal anti-inflammatory 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. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) 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. (Biswal, 2006) 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. 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 lends 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. (Voltaren package insert) For additional adverse effects: See NSAIDs, GI symptoms and cardiovascular risk; & NSAIDs, hypertension and renal function. Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photo contact dermatitis. Absorption of the drug depends on the base it is delivered in. Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. This is not recommended, per MTUS guidelines, therefore it is not medically indicated.

**Compound Cream: GABA 10%; AMITRIP 10%; EXTRO 10%:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 16-17.

**Decision rationale:** Per MTUS, topical Gabapentin, one of the components of this compound, is recommended for neuropathic pain (pain due to nerve damage). There is a lack of expert consensus on the treatment of neuropathic pain in general due to heterogeneous etiologies, symptoms, physical signs and mechanisms. Most randomized controlled trials (RCTs) for the use of this class of medication for neuropathic pain have been directed at postherpetic neuralgia and painful polyneuropathy (with diabetic polyneuropathy being the most common example). There are few RCTs directed at central pain and none for painful radiculopathy. The choice of specific agents reviewed below will depend on the balance between effectiveness and adverse reactions. See also specific drug listings below: Gabapentin (Neurontin); Pregabalin (Lyrica); Lamotrigine (Lamictal); Carbamazepine (Tegretol); Oxcarbazepine (Trileptal); Phenytoin (Dilantin); Topiramate (Topamax); Levetiracetam Zonisamide (Zonegran); & Tiagabine (Gabitril) Outcome: A "good" response to the use of AEDs has been defined as a 50% reduction in pain and a "moderate" response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response of this magnitude may be the "trigger" for the following: (1) a switch to a different first-line agent (TCA, SNRI or AED are considered first-line treatment); or (2) combination therapy if treatment with a single drug agent fails. After initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. AEDs are associated with teratogenicity, so they must be used with caution in woman of childbearing age. Preconception counseling is recommended for anticonvulsants (due to reductions in the efficacy of birth control pills). Per MTUS, topical analgesia is not recommended for patients with neuropathic pain when trials of antidepressants and anticonvulsants have failed. Therefore it is not medically indicated.

