

<b>Case Number:</b>	CM14-0026892		
<b>Date Assigned:</b>	06/13/2014	<b>Date of Injury:</b>	07/16/2010
<b>Decision Date:</b>	07/16/2014	<b>UR Denial Date:</b>	02/21/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/03/2014

### 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, has a subspecialty in Emergency Medicine and is licensed to practice in Florida. 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 patient is a 53 year-old with a date of injury of 07/16/10. A progress report associated with the request for services dated 02/05/14, identified subjective complaints of increased pain and difficulty walking. Objective findings included ataxia. There was tenderness to palpation and decreased range-of-motion of the cervical spine. Diagnoses included cervical cord compression; lumbar radiculopathy; and left knee arthritis. Treatment has included a cervical fusion on 02/10/14. A Utilization Review determination was rendered on 02/24/14 recommending non-certification of urine toxicology, topical compounds - Terocin 240ml, Flurbi 180 grams, Gabacyclotram 180grams, Genetic testing for narcotic risk test, Xolido cream and Somnicin #30 capsules.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**URINE TOXICOLOGY:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 94. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Urine Drug Testing.

**Decision rationale:** This patient is on chronic opioid therapy. The California Medical Treatment Utilization Schedule (MTUS) recommends frequent random urine toxicology screens without specification as to the type. The Official Disability Guidelines (ODG) state that urine drug testing is recommended as a tool to monitor compliance with prescribed substances. The ODG further suggests that in low-risk patients, yearly screening is appropriate. Moderate risk patients for addiction/aberrant behavior are recommended to have point-of-contact screening 2 to 3 times per year. High risk patients are those with active substance abuse disorders. They are recommended to have testing as often as once a month. The record does not document the patient to be moderate or high-risk and therefore no medical necessity for a urine drug screen in February of 2014.

**TOPICAL COMPOUNDS - TEROGIN 240ML, FLURBI 180 GRAMS, GABACYCLOTRAM 180GRAMS: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Compounded Medications.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics; Topical Salicylates Page(s): 105; 111-113; 115. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain: Topical Analgesics; Salicylates Topical, and also updates.pain-topics.org.

**Decision rationale:** Terocin is a compounded agent consisting of menthol, capsaicin (an irritant found in chili peppers), lidocaine (a topical anesthetic) and methylsalicylate (an anti-inflammatory). The MTUS Chronic Pain Guidelines state that topical analgesics are recommended as an option in specific circumstances. However, they do state that they 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. The Guidelines for Chronic Pain state that capsaicin topical is Recommended only as an option in patients who have not responded or are intolerant to other treatments. It is noted that there are positive randomized trials with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific low back pain, but it should be considered experimental at very high doses. The Guidelines further note that although capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in combination with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. The Official Disability Guidelines (ODG) states that neither salicylates nor capsaicin has shown efficacy in the treatment of osteoarthritis. In this case, there is no demonstrated medical necessity for capsaicin in the compound. Lidocaine as a dermal patch has been used off-label for neuropathic pain. However, the guidelines note that no other form (creams, lotions, gels) are indicated. Further, the Guidelines note that lidocaine showed no superiority over placebo for chronic muscle pain. Also, the FDA has issued warnings about the safety of these agents. In this case, there is recommendation and therefore demonstrated medical necessity for lidocaine as a cream in the compound. The Chronic Pain Guidelines do recommend topical salicylates as being significantly better than placebo in chronic pain. In osteoarthritis, salicylates are superior to placebo for the first two weeks, with diminishing effect over another two-week period. The Official Disability Guidelines also recommend topical salicylates as an option and

note that they are significantly better than placebo in acute and chronic pain. They further note however, that neither salicylates nor capsaicin have shown significant efficacy in the treatment of osteoarthritis. Flurbiprofen is an NSAID being used as a topical analgesic. The MTUS Guidelines note that the efficacy of topical NSAIDs in clinical trials has been inconsistent and most studies are small and of short duration. Recommendations primarily relate to osteoarthritis where they have been shown to be superior to placebo during the first two weeks of treatment, but either not afterward, or with diminishing effect over another two week period. The Guidelines also state that there is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. They are indicated for relief of osteoarthritis pain in joints that lend themselves to treatment (ankle, elbow, foot, hand, knee, and wrist). In neuropathic pain, they are not recommended as there is no evidence to support their use. The Official Disability Guidelines (ODG) also does not recommend them for widespread musculoskeletal pain. The only FDA approved topical NSAID is Diclofenac. The MTUS Guidelines state that Gabapentin is not recommended. There is no peer-reviewed literature to support use. The Guidelines further state: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, there is no documented medical necessity for the addition of Gabapentin in the topical formulation for this patient. The MTUS Guidelines state that there is no specific evidence for Baclofen or any other muscle relaxant as a topical product. The Guidelines further state any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, there is no necessity for the addition of Cyclobenzaprine in the topical formulation for this patient. The efficacy of topical Tramadol is not specifically addressed in the MTUS or the Official Disability Guidelines (ODG). There is some data that topical Tramadol has efficacy directly at an acute postsurgical site. However, there is insufficient data to assure that significant systemic absorption does not occur. Lacking definitive data on the efficacy of topical Tramadol, the medical record does not document neuropathic pain that has failed antidepressant or anticonvulsant therapy. Therefore, medical necessity for topical Tramadol has not been established. The Guidelines further state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, in this case, there is no documentation of the failure of conventional therapy, documented functional improvement, or recommendation for all the ingredients of the compound and therefore the medical necessity of the compounded formulation Terocin, Flurbiprofen, or combination of cycl/gaba/tram.

#### **GENETIC TESTING FOR NARCOTIC RISK TEST: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Pain procedure Summary.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, screening for risk of addiction (tests) Page(s): 90-91. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Genetic Testing For Potential Opioid Abuse.

**Decision rationale:** The Medical Treatment Utilization Schedule (MTUS) recommends the CAGE Questionnaire, Cyr-Wartman Screen, Skinner Trauma Screen, SOAPP, and/or Opioid Risk Tool as screens for addiction. The Official Disability Guide (ODG) states that genetic

testing is not recommended. The record does not document any recommended screening and therefore does not document the medical necessity for genetic testing for narcotic risk.

**XOLIDO FOR CREAM:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Topical Analgesics.

**Decision rationale:** Xolido (Lidocaine cream) is a topical analgesic. The Medical Treatment Utilization Schedule (MTUS) Chronic Pain Guidelines state that topical analgesics are recommended as an option in specific circumstances. However, they do state that they 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. Lidocaine as a dermal patch has been used off-label for neuropathic pain. However, the guidelines note that no other form (creams, lotions, gels) are indicated. Further, the Guidelines note that Lidocaine showed no superiority over placebo for chronic muscle pain. Also, the FDA has issued warnings about the safety of these agents. The Guidelines further state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, in this case there is no demonstrated medical necessity for Lidocaine with this type of formulation. Likewise, there is no documentation of the failure of conventional therapy or documented functional improvement for the medical necessity of Xolido (Lidocaine cream).

**SOMNICIN #30 CAPSULES:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Mental Illness & Stress; Insomnia Treatment, Melatonin.

**Decision rationale:** The Medical Treatment Utilization Schedule (MTUS) Guidelines do not specifically address hypnotics or these agents. The Official Disability Guidelines (ODG) state that treatment should be based upon etiology and only after careful evaluation of the potential causes of sleep disturbance. They do not specifically address all the agents in Somnicin nor affirm their efficacy. They do recommend melatonin as an option. Additionally, Somnicin contains agents that are available at recommended levels in a normal diet. Therefore, in this case, the medical record does not document the medical necessity for Somnicin.