

<b>Case Number:</b>	CM14-0036952		
<b>Date Assigned:</b>	06/25/2014	<b>Date of Injury:</b>	04/13/2006
<b>Decision Date:</b>	07/29/2014	<b>UR Denial Date:</b>	02/25/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/26/2014

### 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 Physical Medicine & Rehabilitation and is licensed to practice in California. 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 27-year-old female with a reported date of injury on 04/30/2006. The mechanism of injury was not submitted within the medical records. Her diagnoses were noted to include cervical spine sprain/strain and left lower extremity lumbar radiculopathy. Her previous treatments were noted to be medications. The progress note dated 02/11/2014 reported the injured worker complained of stabbing low back pain, which radiated down her left lower extremity into her foot rated 7/10 to 8/10 with weakness. The physical examination of the lumbar spine noted decreased sensation over the left lower extremity at L4-5 dermatomes. The provider reported the injured worker had decreased patellar reflexes as well as decreased Achilles reflexes on the left compared to that on the right. There was also decreased motor strength rated 4/5 noted to the left lower extremity. The injured worker continued to have tenderness to palpation in both columns of her lumbar spine, particularly on the left shoulder with sciatic notch tenderness, as well as a strong positive straight leg raise. The request for authorization form dated 02/18/2014 is for topical compounds to reduce pain and oral medication and Xolido for pain.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Terocin 240 mg (one application per month): Upheld**

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

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

**Decision rationale:** The request for Terocin 240 mg (one application per month) is non-certified. Terocin 240 mg is a compounded agent which contains Methyl Salicylate 25%, Capsaicin 0.025%, Menthol 10%, and Lidocaine 2.5%. The California Chronic Pain Medical Treatment Guidelines primarily recommend topical analgesics for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The Guidelines state topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. Any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. The Guidelines state Lidocaine is indicated for neuropathic pain after there has been evidence of a trial of first line therapy (tricyclic or SNRI antidepressants or an AED such as Gabapentin or Lyrica). Topical Lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off label for diabetic neuropathy. No other commercially approved topical formulations of Lidocaine (whether creams, lotions, or gels) are indicated for neuropathic pain. Lidoderm is not recommended for non-neuropathic pain and there is only 1 trial that tested 4% Lidocaine for the treatment of chronic muscle pain, which the results showed there was no superiority over placebo. The Guidelines state capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for postherpetic neuralgia, diabetic neuropathy, and post mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. The Guidelines do not recommend Lidocaine in any formulation other than a Lidoderm patch and capsaicin is not recommended due to lack of documentation of the injured worker not responding or intolerant to other treatments. Therefore, the request for Terocin 240 mg (one application per month) is non-certified.

**Laxacin #100:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MD Consult Drug Monograph.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, initiating therapy Page(s): 77.

**Decision rationale:** The request for Laxacin #100 is non-certified. This medication is a combination of docusate and Senna used together in an oral prevention to treat or prevent constipation. The California Chronic Pain Medical Treatment Guidelines recommend prophylactic treatment of constipation should be initiated when initiating opioid therapy. The request for Vicodin has been non-certified and therefore, Laxacin is not medically warranted at this time. Additionally, the request failed to provide the frequency at which this medication is to be utilized. Therefore, the request for Laxacin #100 is non-certified.

**Flurbiprofen 180 grams:** Upheld

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

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

**Decision rationale:** The request for Flurbiprofen 180 grams is non-certified. Flurbiprofen is a topical NSAID. The California Chronic Pain Medical Treatment Guidelines recommend topical analgesics for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The Guidelines state topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. Any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. The Guidelines state the efficacy and clinical trials for topical NSAIDs 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. Topical NSAIDs are indicated for osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment for short-term use (4 to 12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip, or shoulder and it is not recommended for neuropathic pain, as there is no evidence to support use. The Guidelines recommend topical NSAIDs for short-term use of osteoarthritis of the knee, ankle, or other joints that are amenable to topical treatment; the low back is not indicated. The Guidelines state that any compounded product that contains at least 1 drug that is not recommended is not recommended such as topical Lidocaine in a formulation other than a Lidoderm patch and topical NSAIDS efficacy appears to diminish over time and the injured worker does not have a diagnosis consistent with osteoarthritis. Additionally, the request failed to provide the frequency at which this medication is to be utilized. Therefore, the request for Flurbiprofen 180 grams is non-certified.

**Somnicin #30:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Treatment in Worker's Compensation, Pain Procedure Summary.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Medical Food.

**Decision rationale:** The request for Somnicin #30 is non-certified. Somnicin is a medical food that contains melatonin, 5-HDP, L-tryptophan, vitamin B6, and magnesium. The Official Disability Guidelines recommend medical food based on the following criteria: the product must be food for oral or tube feeding; the product must be labeled for dietary management of a

specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and the product must be used under medical supervision. The ingredient 5-hydroxytryptophan has been found to be possibly effective in the treatment of anxiety disorders, fibromyalgia, obesity, and sleep disorders. It has been found to be effective for depression. In alternative medicine, it has been used for depression, anxiety, insomnia, obesity, aggressive behavior, eating disorders, fibromyalgia, chronic headaches, and various pain disorders. There is a lack of documentation regarding sleep issues and there is no documented specific nutritional deficit that may warrant the need for this medical food. Additionally, the request failed to provide the frequency at which this medication is to be utilized. Therefore, the request for Somnicin #30 is non-certified.

**Vicodin 7.5/325 mg #100:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioid use for chronic pain.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, On-going Management Page(s): 78.

**Decision rationale:** The request for Vicodin 7.5/325 mg #100 is non-certified. The injured worker has been taking this medication since at least 11/2013. According to the California Chronic Pain Medical Treatment Guidelines, the ongoing use of opioid medications may be supported with detailed documentation of pain relief, functional status, appropriate medication use, and side effects. The Guidelines also state the 4 A's for ongoing monitoring including analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors, should be addressed. There is a lack of evidence of decreased pain on a numerical scale. There is a lack of documentation regarding improved functional status while utilizing this medication. There is a lack of documentation regarding side effects and the urine drug screen performed 02/11/2014 was positive for Hydrocodone, Hydromorphone, and Tramadol. Therefore, due to the lack of evidence regarding significant pain relief, increased function, side effects, and with a previous inconsistent urine drug screen, the ongoing use of opioid medications is not supported by the Guidelines. Additionally, the request failed to provide the frequency at which this medication is to be utilized. As such, the request for Vicodin 7.5/325 mg #100 is non-certified.

**Xolido 2% #118:** Upheld

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

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

**Decision rationale:** The request for Xolido 2% #118 is non-certified. Xolido is the equivalent of Lidocaine 2%. The California Chronic Pain Medical Treatment Guidelines primarily recommend topical analgesics for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The Guidelines state topical analgesics are largely experimental in

use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. Any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. The Guidelines state Lidocaine is indicated for neuropathic pain after there has been evidence of a trial of first line therapy (tricyclic or SNRI antidepressants or an AED such as Gabapentin or Lyrica). Topical Lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off label for diabetic neuropathy. No other commercially approved topical formulations of Lidocaine (whether creams, lotions, or gels) are indicated for neuropathic pain. Topical Lidoderm is not recommended for non-neuropathic pain. The Guidelines do not recommend Xolido (Lidocaine) in any formulation other than a Lidoderm patch for neuropathic pain. The Guidelines state any compounded product that contains at least 1 drug that is not recommended is not recommended. Additionally, the request failed to provide the frequency at which this medication is to be utilized. Therefore, the request for Xolido 2% #118 is non-certified.