

<b>Case Number:</b>	CM14-0021448		
<b>Date Assigned:</b>	05/07/2014	<b>Date of Injury:</b>	02/23/2012
<b>Decision Date:</b>	07/09/2014	<b>UR Denial Date:</b>	02/07/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/20/2014

### 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, has a subspecialty in Pain Medicine 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 patient is a 43-year-old female who was injured on 02/23/2012. Mechanism of injury is unknown. Prior treatment history included acupuncture and medication. Progress note dated 02/18/2014 documents the patient with complaints of decreased low back pain, which she rates 4/10. She complains of tenderness over the lower part area, which is kind of discomfort. On 01/21/2014, she had bilateral L4 through S1 facet rhizotomy. She got relief right after the procedure. She got 80% relief post procedure. She was able to bend and squat. She was able to decrease her medications. She is taking her medications regularly. She has not seen any doctor since her last visit. There have been no changes in her medical history as documented in her last appointment. Objective findings one exam revealed a wide based gait. Heel-to walk was performed with difficulty secondary to low back pain. There is a diffuse tenderness noted over the paraspinal musculature. There is slight facet tenderness noted L4 to S1. There was trace Kemp's test. Straight leg raise elicits pain only. Lumbar spine range of motion lateral bending was 25 degrees on right and 30 degrees on left. Flexion was 70 degrees bilaterally and extension 15 degrees to the right and 20 degrees to the left. Ankle range of motion was normal. Lower extremity muscle testing was 5/5 in all muscle groups. Sensation is intact to pain, temperature, light touch, vibration and two-point discrimination in all dermatomes. Lower extremities muscle testing was 5/5. Lower extremity reflexes were 2+ bilaterally. Assessment revealed Lumbar facet syndrome. UR report dated 02/07/2014 denied the request for Terocin patch. Considering the records, given the absence of documented neuropathy and based on guideline recommendations regarding the use of Lidocaine and menthol; it appears that the use of a Terocin patch was not medically indicated for this patient. Terocin Topical was denied considering the records, given the absence of documented neuropathy and based on guideline recommendations regarding the use of capsaicin and menthol; it appears that the use of a topical

Terocin was not medically indicated for this patient. The request for Somnicin was denied. Although there may be some evidence supporting the use of some of the ingredients in Somnicin for treatment of insomnia, evidence-based guidelines and research-based literature do not support the use of vitamin B6 or L-tryptophan and guidelines caution against 5-HTP-(5-hydroxytryptophan) stating this product is linked to a contaminant that causes eosinophilia-myalgia.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

#### **30 TEROGIN LOTION PATCH BETWEEN 11/21/2013 AND 11/21/2013: 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:** Terocin patch contains Lidocaine, Capsaicin, methyl salicylate, and menthol. According to the CA MTUS guidelines, Lidocaine is recommended for neuropathic pain, recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica. The patient's diagnosis is lumbar facet syndrome. The medical do not establish a diagnosis of diabetic neuropathy or neuropathic pain. Furthermore, Capsaicin is appropriate and medically necessary for patients that are intolerant to first-line therapies, which is not the case for this patient. The guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The medical records do not establish this compounded topical product is appropriate or medically indicated. The medical necessity of Terocin patch is not established. The request is not medically necessary.

#### **1 PRESCRIPTION FOR NEW TEROGIN LOTION 240GM BETWEEN 11/21/13 AND 11/21/13: Upheld**

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

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

**Decision rationale:** Terocin patch contains Lidocaine, Capsaicin, methyl salicylate and menthol. According to the CA MTUS guidelines, Lidocaine is recommended for neuropathic pain, recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an anti-epilepsy drugs (AED) such as gabapentin or Lyrica. The patient's diagnosis is lumbar facet syndrome. The medical do not establish a diagnosis of diabetic neuropathy or neuropathic pain. Furthermore, Capsaicin is appropriate and medically necessary for patients that are intolerant to first-line therapies, which is not the case for

this patient. The guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The medical records do not establish this compounded topical product is appropriate or medically indicated. The medical necessity of Terocin patch is not established. The request is not medically necessary.

### **30 SOMNICIN BETWEEN 11/21/13 AND 11/21/13: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic), Insomnia Treatment.

**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 and <http://sales.advancedrxmgt.com/sales-content/uploads/2012/04/Somnicin-Patient-Info-Sheet.pdf>.

**Decision rationale:** CA MTUS guidelines do not discuss the issue in dispute. The Official Disability Guidelines (ODG) recommends the following for Medical Food as indicated below. Definition: Defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." To be considered the product must, at a minimum, meet the following criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision. According to the referenced literature, this is a product by [REDACTED], that contains Melatonin, 5-HTP, L-tryptophan, Vitamin B6 and Magnesium, "This particular drug aims to cure certain conditions like insomnia, anxiety and depression." This product is not recognized by the FDA. The medical records do not establish the patient has a medical condition that necessitates this product as treatment. In reference to the Official Disability Guidelines, Somnicin is not recommended, as it does not meet the criteria set by the guidelines. The medical records do not establish this patient has a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements. The medical records do not establish this product is labeled as intended for the specific dietary management of a disorder, disease or condition for which a distinctive nutritional requirement exists, and has been established by a medical evaluation. The medical necessity of Somnicin is not established. The request is not medically necessary.