

<b>Case Number:</b>	CM14-0178291		
<b>Date Assigned:</b>	10/31/2014	<b>Date of Injury:</b>	03/04/2014
<b>Decision Date:</b>	12/08/2014	<b>UR Denial Date:</b>	10/16/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/27/2014

### 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 and Rehabilitation, has a subspecialty in Interventional Spine 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 46 year old female with an injury date of 03/04/14. Based on the 08/27/14 progress report provided by [REDACTED] the patient complains of left elbow and lumbar spine pain. Physical examination revealed tenderness to palpation to the thoracolumbar spine, and range of motion was decreased, especially on flexion 60 degrees. Crossed Straight Leg Raise test was positive at 30 degrees. Examination to the left elbow revealed tenderness on palpation, and decreased range of motion on pronation and supination. Positive tennis elbow test and Tinel's. EMG/NCV revealed abnormality in the upper extremities. The patient is continuing with physical therapy/chiropractic and acupuncture. Sleep Study report dated 08/09/14 revealed that "the patient suffers from a mild pathological sleep breathing respiratory disorder." MRI of the left elbow 08/11/14 Arthroscopy and Medial Meniscectomy (Includes Shaving of chondromalacia) - unremarkable findings, MRI of the lumbar spine 08/08/14, - spondylotic changes are seen at L5-S1, - disc desiccation is noted at L5-S2, - L5-S1: posterior annular tear, 1-2mm posterior disc bulge without evidence of canal stenosis or neural foraminal narrowing. Diagnosis 08/27/14 - thoracic spine sprain/strain, - lumbar spine sprain/strain, rule out herniated disc, - left elbow lateral epicondylitis. The utilization review determination being challenged is dated 10/16/14. The rationale follows: 1) (30) tablets of Somnicin: "Although the preparation does not qualify as a medical food, it is worth noting that "there are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain" 2) (30) Terocin patches (1 patch daily): "the current guidelines provide limited support for compounded medications." 3) (1) container of Flurbiprofen 20%, Lidocaine 5%, and Amitriptyline 5%, 180 grams: "no clear indication that she has failed or is contraindicated to take oral NSAIDs to warrant the topical form." 4) (1) container of Gabapentin 20%, Cyclobenzaprine 6%, and

Tramadol 10%, 180grams: "Gabapentin and Cyclobenzaprine components, these medications are not recommended for topical use." [REDACTED] is the requesting provider and he provided treatment reports from 06/21/14 - 10/14/14.

### IMR ISSUES, DECISIONS AND RATIONALES

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

#### **(30) Tablets of Somnicin: 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 Medications for Chronic Pain Page(s): 60,61. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: <http://www.prlog.org/11964811-hootan-melamed-pharmd-and-los-angeles-based-pharmaceutical-company-alexso-inc-make-announcement.html>, and on the Non-MTUS Official Disability Guidelines (ODG) Pain Chapter, Medical Food.

**Decision rationale:** The patient presents with left elbow and lumbar spine pain. The request is for (30) tablets of Somnicin. The patient's diagnosis dated 08/27/14 includes thoracic and lumbar spine sprain/strain, and left elbow lateral epicondylitis. The patient is continuing with physical therapy/chiropractic and acupuncture. MTUS is silent regarding the request for Somnicin. The following information was found Online.<http://www.prlog.org/11964811-hootan-melamed-pharmd-and-los-angeles-based-pharmaceutical-company-alexso-inc-make-announcement.html>. PRLog - Sep. 2, 2012 - [REDACTED] based pharmaceutical company [REDACTED], [REDACTED]. announced today the release of a new drug designed to relieve insomnia, anxiety and depression, Somnicin. Somnicin was designed by pharmacists and health care professionals to help promote effective sleep through a combination of ingredients that are all naturally-occurring within the body: Melatonin, 5-HTP, L-tryptophan, Vitamin B6, and Magnesium. Individually and as a compound, all are known for their properties to combat insomnia and anxiety. Somnicin is non-habit forming unlike many conventional medications such as Ambien, Lunesta, Flurazepam, or Temazepam, Somnicin. With regards to Medical Foods, ODG guidelines under Pain Chapter states: "Not recommended for chronic pain. Medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. FDA defines a medical food 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." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain." Melatonin: Recommended. See Insomnia treatment. There are also experimental and clinical data supporting an analgesic role of melatonin. In published studies melatonin shows potent analgesic effects in a dose-dependent manner, and melatonin has been shown to have analgesic benefits in patients with chronic pain. Also, the repeated administration of melatonin improves sleep and thereby may reduce anxiety, which leads to lower levels of pain. (Wilhelmsen, 2011) 5-hydroxytryptophan: This supplement has been found to be possibly

effective in 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." Provider has not documented reason for the request. Sleep Study report dated 08/09/14 revealed that "the patient suffers from a mild pathological sleep breathing respiratory disorder." Somnicin which is constituted of Melatonin and 5-hydroxytryptophan may be indicated for sleep disorders based on ODG. However, in review of medical records the provider does not discuss the patient's sleep issues and does not document how this medication in particular, is helping. MTUS page 60 require recording of pain and function when medications are used for chronic pain. Furthermore, medical foods are not recommended for chronic pain. Therefore, the medication is not medically necessary and appropriate.

**(30) Terocin Patches: 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 Lidoderm Patches; Topical Analgesic Page(s): 56,57,111-113.

**Decision rationale:** The patient presents with left elbow and lumbar spine pain. The request is for (30) Terocin patches (1 patch daily). The patient's diagnosis dated 08/27/14 includes thoracic and lumbar spine sprain/strain, and left elbow lateral epicondylitis. The patient is continuing with physical therapy/chiropractic and acupuncture. MTUS guidelines page 57 states, "topical lidocaine may be 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)." MTUS Page 112 also states, "Lidocaine Indication: Neuropathic pain. Recommended for localized peripheral pain." When reading ODG guidelines, it specifies that lidoderm patches are indicated as a trial if there is "evidence of localized pain that is consistent with a neuropathic etiology." ODG further requires documentation of the area for treatment, trial of a short-term use with outcome documenting pain and function. In review of medical records, provider has not documented reason for the request, how the patches will be used, nor area of treatment. The patient has left elbow pain and a diagnosis of left elbow epicondylitis, for which topical Lidocaine patch may be indicated. However, the provider does not discuss how it is used with what efficacy. Therefore, the medication is not medically necessary and appropriate

**(1) Container of Flurbiprofen 20%, Lidocaine 5% and Amitriptyline 5% 180 grams: 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.

**Decision rationale:** The patient presents with left elbow and lumbar spine pain. The request is for (1) container of Flurbiprofen 20%, Lidocaine 5%, and Amytriptyline 5%, 180 grams. The

patient's diagnosis dated 08/27/14 includes thoracic and lumbar spine sprain/strain, and left elbow lateral epicondylitis. The patient is continuing with physical therapy/chiropractic and acupuncture. MTUS has the following regarding topical creams (page 111, chronic pain section): "Topical Analgesics: 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." Review of reports does not show documentation that patient presents with osteoarthritis. Also, NSAID cream is to be used for short duration of 2 weeks. Requested cream is not inline with MTUS indication. Therefore, the medication is not medically necessary and appropriate.

**(1) Container of Gabapentin 20%, Cyclobenzaprine 6%, and Tramadol 10% 180 grams:**  
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.

**Decision rationale:** The patient presents with left elbow and lumbar spine pain. The request is for (1) container of Gabapentin 20%, Cyclobenzaprine 6%, and Tramadol 10%, 180grams. The patient's diagnosis dated 08/27/14 includes thoracic and lumbar spine sprain/strain, and left elbow lateral epicondylitis. The patient is continuing with physical therapy/chiropractic and acupuncture. The MTUS has the following regarding topical creams (p111, chronic pain section): "Topical Analgesics: Recommended as an option as indicated below. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. 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. Gabapentin: Not recommended. Baclofen: Not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product. "" The requested compounded creams contain Gabapentin and Cyclobenzaprine, which are not indicated by guidelines. Therefore, the medication is not medically necessary and appropriate.