

<b>Case Number:</b>	CM14-0010661		
<b>Date Assigned:</b>	02/21/2014	<b>Date of Injury:</b>	04/21/2006
<b>Decision Date:</b>	08/04/2014	<b>UR Denial Date:</b>	01/08/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/27/2014

### 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 Anesthesiology, has a subspecialty in Pain Management and is licensed to practice in Tennessee. 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 59-year-old male, who has submitted a claim for Stump Pain, right upper quadrant and right elbow sprain/strain; associated with an industrial injury date of April 21, 2006. Medical records from 2006 through 2014 were reviewed, which showed that the patient complained of constant right shoulder pain rated, 7/10 and constant right elbow pain rated at 6-7/10 and hip pain rated 10/10 without medications and 4/10 with medications. Physical examination of the right shoulder showed the following range of motion (ROM): forward flexion at 160; extension at 40; abduction at 140; internal rotation at 60. Impingement was positive on the right with tender acromioclavicular joint. Right elbow range of motion (ROM) was as follows: flexion at 130; extension at 10; supination at 65. There was positive Tinel's sign at the Ulnar Nerve on the right. Tenderness was noted on the right lateral epicondyle. Treatment to date has included amputation of the right hand, terocin, capsaicin, methyl salicylate, menthol, lidocaine, amitriptyline, gabacyclotram, somnicin, genicin, xolindo, Sentra AM and Gabadone. Utilization review from January 8, 2014 denied the request for Xolindo 2%, because there is no other commercially approved topical formulations of lidocaine that are indicated for neuropathic pain. The request for Sentra AM #60 and Gabadone #60 was also denied because there is no documentation to support the presence of choline deficiency secondary to liver deficiency which is contained within both Gabadone and Sentra AM.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Xolindo 2%:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 9792.24.2 Compound Medications Section Page(s): 111-113.

**Decision rationale:** As stated on page(s) 111-113 of Chronic Pain Medical Treatment Guidelines, Ketoprofen, Lidocaine (in creams, lotion or gels), Capsaicin in anything greater than a 0.025% formulation, baclofen, Boswellia Serrata Resin, other muscle relaxants, gabapentin and other antiepilepsy drugs are not recommended for topical applications. In addition, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case, the patient has been prescribed with Xolindo 2% (Lidocaine) since December 10, 2013 (7 months to date). However, records reviewed did not show that the patient had failure of antidepressants or anticonvulsants. In addition, the patient was already prescribed with Lidocaine cream with no documented functional improvement. Likewise, the duration and frequency of the drug was non-specific. Therefore, the request for Xolindo 2% is not medically necessary.

**Sentra AM #60:** 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 Chapter, Medical Food.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Medical Food Section and on the Other Medical Treatment Guideline or Medical Evidence: [ptlcentral/Sentra AM web base](#).

**Decision rationale:** The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, Official Disability Guidelines (ODG) Pain Chapter, Medical Food Section was used instead. ODG states that medical foods are dietary management for a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements. An online search showed that Sentra AM is a medical food that is intended for use in the management of chronic and generalized fatigue, fibromyalgia, post-traumatic stress syndrome (PTSD), neurotoxicity-induced fatigue syndrome, and impaired neurocognitive functions. In this case, the patient was prescribed with Sentra AM. Records reviewed did not indicate the rationale for the prescription of Sentra AM. Moreover, the guideline does not support use of medical food unless there is a nutritional deficiency, which was not found in this case. The medical necessity has not been established. Therefore, the request for SENTRA AM #60 is not medically necessary.

**Gabadone #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

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

**Decision rationale:** The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, ODG was used instead. The Official Disability Guidelines also state that GABAdone is not recommended as it is a medical food. It is a proprietary blend of choline bitartrate, glutamic acid, 5-hydroxytryptophan, and GABA. It is intended to meet the nutritional requirements for inducing sleep, promoting restorative sleep, and reducing snoring in patients who are experiencing anxiety related to sleep disorders. There is no documentation regarding nutritional deficiencies in this patient, or of the conditions as mentioned above. Also, this compound is not recommended for use. Therefore, the request for Gabadone #60 is not medically necessary.