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| <b>Case Number:</b>   | CM13-0015391 |                              |            |
| <b>Date Assigned:</b> | 09/23/2013   | <b>Date of Injury:</b>       | 03/12/2003 |
| <b>Decision Date:</b> | 01/10/2014   | <b>UR Denial Date:</b>       | 08/07/2013 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 08/22/2013 |

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Anesthesiology, 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 physician 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 54-year-old male who reported an injury on 03/12/2003. The patient has been seen several times for continued persistent symptomatology in the cervical spine, chronic headaches, tension between the shoulder blades, as well as having migraines. The documentation references the patient having undergone 2 cervical spine surgeries at the C3-4 level. The patient was also noted as having reported constant mid-back with upper extremity pain to include tingling and numbness in the wrist. The patient's previous treatments included oral medications, cervical disc replacement, acupuncture, Toradol injections, and physical therapy. The physician is now currently requesting Genicin 500 mg, Somnicin, Toradol 60 mg, and 1 conservative care B12 injection, which were all ordered through Express Scripts, which is at 1-800-945-595, between the dates of 07/12/2013 and 09/19/2013. &uarr;

### IMR ISSUES, DECISIONS AND RATIONALES

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

#### **90 Genicin 500mg: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines (May 2009.).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines section on Glucosamine (and Chondroitin Sulfate) Page(s): 50.

**Decision rationale:** According to MTUS Chronic Pain Guidelines, Glucosamine is recommended as an option given its low risk in patients with moderate arthritis pain, especially for knee osteoarthritis. Although the patient does suffer with continuous pain, there is no documentation indicating the patient has any complaints of moderate arthritis pain, nor has he been diagnosed with any osteoarthritis. Therefore, taking into consideration the information provided above, regarding the request for Genicin, it is not considered medically necessary or clinically substantiated at this time. The request for 90 Genicin 500mg is not medically necessary and appropriate.

**30 Somnicin:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines section on Topical Analgesics Page(s): 111. Decision based on Non-MTUS Citation Official Disability Guidelines Pain Chapter, section on Melatonin, Medical Food, and Vitamin B.

**Decision rationale:** Somnicin contains (5-hydroxytryptophan, magnesium oxide, melatonin, tryptophan and vitamin B.) Neither the MTUS Guidelines nor the Official Disability Guidelines address this medication. Therefore, the components of the product have been reviewed separately. In regards to compounded medications which include NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists,  $\hat{1}\pm$ -adrenoceptor receptor agonists, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amine, and nerve growth factor; there is little to no research to support the use of many of these agents. The Official Disability Guidelines state repeated administration of melatonin improves sleep. 5-hydroxytryptophan is a supplement that has been found to possibly be effective in treatment of sleep disorders according to the Official Disability Guidelines. The Official Disability Guidelines state a medical food is a "food which is formulated to be consumed or administered internally under the supervision of a physical and which it 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." Vitamin B is not recommended by the Official Disability Guidelines. Furthermore, under MTUS Chronic Pain Guidelines, any compounded product that contains at least 1 drug (or drug class) that is not recommended is therefore not recommended as a whole. Therefore, considering this medication is not considered to be a recommended product for a patient due to containing one of the medications that is not recommended under the guidelines to include Vitamin B, the request cannot be considered medically necessary. The request for 30 Somnicin is not medically necessary and appropriate.

**1 Toradol 60mg:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines (May 2009.).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines section on NSAIDS Page(s): 72.

**Decision rationale:** According to MTUS Chronic Pain Guidelines, ketorolac, otherwise known as Toradol, has a box warning that this medication is not indicated for minor or chronic painful conditions. Therefore, regarding the patient's signs and symptoms as indicated in the documentation which are noted to be chronic, this medication would not be warranted for use at this time. The request for 1 Toradol 60mg is not medically necessary and appropriate.

**1 cc B12 Injection:** 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, Pain Chapter section on Vitamin B, and About.com, <http://altmedicine.about.com/od/herbsupplementguide/a/vitaminb12.htm>.

**Decision rationale:** The Official Disability Guidelines do not recommend Vitamin B, and though it is frequently used for treating peripheral neuropathy, its efficacy is not clear. As noted in the online source, about.com, under alternative medicines, it states that vitamin B12 injections are normally given to people who have trouble absorbing the vitamin. Although some proponents also suggest that vitamin B12 injections can be useful in promoting weight loss, there is no evidence to support this claim. However, regarding the use of it as a sleep aid, this website also does not address the issue. As such, because there is little evidence to support the use of this medication for the intended purpose per the physician's request, the medication cannot be listed as medically necessary at this time. The request for 1 cc B12 injection is not medically necessary and appropriate.