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| <b>Case Number:</b>   | CM14-0036060 |                              |            |
| <b>Date Assigned:</b> | 07/25/2014   | <b>Date of Injury:</b>       | 06/27/2012 |
| <b>Decision Date:</b> | 10/02/2014   | <b>UR Denial Date:</b>       | 03/03/2014 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 03/24/2014 |

### 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 41-year-old male who has submitted a claim for lumbar disc protrusion, lumbar spinal stenosis, hypertension, and obstructive sleep apnea associated with an industrial injury date of June 27, 2012. Medical records from 2012 to 2014 were reviewed. The patient complained of low back pain radiating to the lower extremities, left worse than right. Physical examination showed tenderness and spasm at the paracervical and paralumbar muscles. Range of motion was restricted. Spurling test was positive, as well as straight leg raise test. Sensation was diminished at C5 to C7 and L5 to S1 dermatomes. There was weakness of knee extensors, extensor hallucis longus and ankle dorsiflexors bilaterally. Achilles reflexes were absent. The patient ambulated with assistance of a cane. Treatment to date has included right inguinal hernia repair in 2012, trigger point injections, epidural steroid injection, physical therapy, and medications such as gabapentin, Norco, glucosamine sulfate (since 2013), Klonopin, Xanax, omeprazole, tramadol, cyclobenzaprine, naproxen, Terocin patch (since 2013), and ondansetron (since 2013). Utilization review from March 3, 2014 modified the request for Cyclobenzaprine Hydrochloride 7.5mg, #60 into #20 for the purpose of weaning because long-term use was not recommended; denied Omeprazole 20mg #60 because there were no gastrointestinal complaints; denied Theramine #120 and Trepadone #120 because there was no clear evidence of nutritional deficits that would require supplementation; denied Ondansetron 4mg #30 because of no complaints of nausea and vomiting; denied Terocin Patch #20 because there was no evidence of failed trial of antidepressants and anticonvulsants to warrant such; denied Flurbi NAP Cream LA 180gms and Gabacyclotam 180gms because of lack of published studies concerning its efficacy and safety; and denied Genicin Capsules #90 and Somnicin Capsules #30 because of no evidence of subjective or functional benefit.

## IMR ISSUES, DECISIONS AND RATIONALES

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

### **Cyclobenzaprine Hydrochloride (7.5mg, #60): Overturned**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41-42.

**Decision rationale:** According to the Chronic Pain Medical Treatment Guidelines, sedating muscle relaxants are recommended with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain. In this case, there was no prior use of cyclobenzaprine based on the records submitted. The most recent physical examination showed evidence of paracervical and paralumbar muscle spasm. The medical necessity has been established. Therefore, the request for Cyclobenzaprine Hydrochloride is medically necessary.

### **Omeprazole (20mg, #60): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI Symptoms, and Cardiovascular Risk Page(s): 68.

**Decision rationale:** As stated in the Chronic Pain Medical Treatment Guidelines, clinicians should weigh the indications for NSAIDs against both GI and cardiovascular risk factors: age > 65 years, history of peptic ulcer, GI bleeding or perforation; concurrent use of ASA, corticosteroids, or anticoagulant; or on high-dose/multiple NSAIDs. Patients with intermediate risk factors should be prescribed proton pump inhibitors (PPI). In this case, there was no prior use of omeprazole. However, there was no subjective report of heartburn, epigastric burning sensation or any other gastrointestinal symptoms that may corroborate the necessity of this medication. Furthermore, patient did not meet any of the aforementioned risk factors. The guideline criteria were not met. Therefore, the request for Omeprazole is not medically necessary.

### **Theramine (#120): Upheld**

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

**Decision rationale:** The California MTUS Guidelines do not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, the Official Disability Guidelines, Pain section was used instead. The Official Disability Guidelines state that Theramine is a medical food that is a proprietary blend of GABA (gamma-aminobutyric acid) and choline bitartrate, L-arginine and L-serine that is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain and inflammatory pain. However, it remains not recommended by the guidelines. In this case, there was no prior use of Theramine. However, there was no documented indication for this medication despite not being recommended by the guidelines. Therefore, the request for Theramine is not medically necessary.

**Trepadone (#120): Upheld**

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

**Decision rationale:** The California MTUS Guidelines do not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, the Official Disability Guidelines was used instead. Trepadone is a medical food that is a proprietary blend of L-arginine, L-glutamine, choline bitartrate, L-serine, and GABA. It is intended for use in the management of joint disorders associated with pain and inflammation. Regarding GABA, there is no high quality peer-reviewed literature that suggests that GABA is indicated; regarding choline, there is no known medical need for choline supplementation; regarding L-Arginine, this medication is not indicated in current references for pain or inflammation; and regarding L-Serine, there is no indication for the use of this product. In this case, there was no prior use of Trepadone. However, there was no documented indication for this medication despite not being recommended by the guidelines. Therefore, the request for Trepadone is not medically necessary.

**Ondansetron (4mg, #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 Pain Procedure Summary Antiemetics

**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, Antiemetics (for opioid nausea) and Ondansetron

**Decision rationale:** The California MTUS Guidelines do not address ondansetron specifically. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, the Official Disability Guidelines (ODG), Pain Chapter, Antiemetics (for opioid nausea) and Ondansetron was used instead. The ODG states that ondansetron is indicated for prevention of nausea and vomiting caused by cancer chemotherapy, radiation therapy and surgery. It is not recommended for nausea and vomiting secondary to chronic opioid use. In this case, there was no prior intake of ondansetron. However, patient has no subjective complaints of nausea or vomiting. Patient is not in post-operative state. He is not receiving any chemotherapy or radiation therapy to necessitate this medication. There is no clear indication for this request. Therefore, the request for Ondansetron is not medically necessary.

**Terocin Patches (#20):** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lidocaine Patch Page(s): 56-57. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Section, Topical Salicylate

**Decision rationale:** Terocin patch contains both lidocaine and menthol. The Chronic Pain Medical Treatment Guidelines state that 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). Regarding the Menthol component, California MTUS Guidelines do not cite specific provisions, but the Official Disability Guidelines (ODG) Pain Chapter states that the FDA has issued an alert in 2012 indicating that topical over the counter (OTC) pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns. In this case, patient's manifestation of low back pain radiating to the lower extremities was consistent with neuropathic pain. Patient was previously prescribed gabapentin; however, symptoms persisted warranting adjuvant Terocin patch since 2013. However, there was no documentation concerning pain relief and functional improvement derived from its use. The medical necessity cannot be established due to insufficient information. Therefore, the request for Terocin Pain Patches is not medically necessary.

**Flurbi NAP Cream LA (180gms):** 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:** As noted in the Chronic Pain Medical Treatment Guidelines, there is little to no research as for the use of flurbiprofen in compounded products. Topical formulations of lidocaine (whether creams, lotions or gels) are not indicated for neuropathic or non-neuropathic pain complaints. Amitriptyline is a tricyclic antidepressant considered first-line agents, but there is no discussion regarding topical application of this drug. In this case, topical cream is prescribed as adjuvant therapy to oral medications. However, the prescribed medication contains flurbiprofen, amitriptyline, and lidocaine, which are not recommended for topical use. Guidelines state that any compounded product that contains a drug class, which is not recommended, is not recommended. Therefore, the request for Compound Flurbi (NAP) Cream - LA is not medically necessary.

**GabaCycloTram (180gms):** 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:** As stated in the Chronic Pain Medical Treatment Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. Gabapentin is not recommended for use as a topical analgesic. Likewise, cyclobenzaprine has no evidence for use as a topical product. The topical formulation of tramadol does not show consistent efficacy. In this case, topical cream is prescribed as adjuvant therapy to oral medications. However, the prescribed medication contains gabapentin, cyclobenzaprine, and tramadol, which are not recommended for topical use. Guidelines state that any compounded product that contains a drug class, which is not recommended, is not recommended. Therefore, the request for Compound GabaCycloTram is not medically necessary..

**Genicin Capsules (#90):** Upheld

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

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

**Decision rationale:** As stated in the Chronic Pain Medical Treatment Guidelines, Glucosamine is recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. In this case, patient has been on Genicin since 2013 without evidence of subjective and objective functional improvement. There was no complaint of knee pain. Moreover, progress report from April 1, 2014 specifically cited that there was no evidence

of hip arthritis. There is no clear indication for this medication. Guideline criteria were not met. Therefore, the request for Genicin capsules is not medically necessary.

**Somnicin Capsules (#30): 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 last updated 11/6/11

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

**Decision rationale:** The California MTUS Guidelines do not specifically address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers Compensation, the Official Disability Guidelines (ODG), Pain Section was used instead. Somnicin contains Melatonin, 5-hydroxytryptophan, L-tryptophan, Magnesium, and vitamin B-6. The ODG states that medical foods are formulated 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. 5-Hydroxytryptophan has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity, depression, and sleep disorders. The FDA states that specific requirements for the safety or appropriate use of medical foods have not yet been established. In this case, there was no prior intake of Somnicin. There was a note of obstructive sleep apnea in 2013; however, there was no recent complaint of sleep disturbances. There was likewise no discussion concerning sleep hygiene. The medical necessity cannot be established due to insufficient information. Therefore, the request for Somnicin Capsules is not medically necessary.