

<b>Case Number:</b>	CM14-0206848		
<b>Date Assigned:</b>	01/30/2015	<b>Date of Injury:</b>	07/22/2013
<b>Decision Date:</b>	03/04/2015	<b>UR Denial Date:</b>	11/03/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/10/2014

### 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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: Hawaii, California

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This 34 year old female was a retail associate when she sustained an injury on July 22, 2013. The injured worker fell 3-4 feet off of a ladder. She reported back and left shoulder pain. The diagnoses and results of the injury included left shoulder contusion and back pain. Initial treatment included x-rays of the chest, left shoulder, and left humerus, arm sling, and pain and non-steroidal anti-inflammatory medication. The x-rays were unremarkable. Additional past treatments included cold therapy, activity modifications, MRI, left shoulder steroid injection, physical therapy, chiropractic therapy, medical foods, and oral and topical pain and non-steroidal anti-inflammatory medications. On August 19, 2013, left shoulder x-rays revealed no fractures, dislocations, masses, or arthritic changes. On September 9, 2013, an MRI revealed no rotator cuff tear and was essentially unremarkable. On October 21, 2014, the treating orthopedic physician noted insomnia, fatigue, and pain over all areas. The physical exam of the left shoulder revealed decreased range of motion of the cervical and lumbosacral spine, and left shoulder impingement. Diagnoses were cervical spine sprain, lumbar spine sprain/strain, left shoulder impingement, and left neck pain. The physician recommended medical foods, chiropractic/physiotherapy, a topical compound cream, a neurological consult, and a follow-up visit in 4 weeks. The injured worker's current work status was temporarily totally disabled. On November 3, 2014, Utilization Review non-certified a request for 1 Neurologic Consultation and 1 Follow-up visit with an Orthopedic Surgeon requested on October 25, 2014. The Neurologic Consultation and the Follow-up visit with an Orthopedic Surgeon was non-certified based on the injured worker's medication regimen was previously denied and the lack of evidence of red-flag

conditions or existence of a surgical lesion to support the request. The MRI of the shoulder showed no rotator cuff tear and was noted to be essentially unremarkable. The California Medical Treatment Utilization Schedule (MTUS), ACOEM (American College of Occupational and Environmental Medicine), Occupational Medicine Guidelines, Second edition (2004), Chapter 9 and the Official Disability Guidelines (ODG) for Office Visits were cited.

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

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

**Neurologic consultation:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 9 Shoulder Complaints Page(s): 209-210.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 179-180. Decision based on Non-MTUS Citation Neck and Upper Back, Office Visits

**Decision rationale:** ODG states concerning office visits, recommended as determined to be medically necessary. Evaluation and management (E&M) outpatient visits to the offices of medical doctor(s) play a critical role in the proper diagnosis and return to function of an injured worker, and they should be encouraged. The need for a clinical office visit with a health care provider is individualized based upon a review of the patient concerns, signs and symptoms, clinical stability, and reasonable physician judgment. The determination is also based on what medications the patient is taking, since some medicines such as opiates, or medicines such as certain antibiotics, require close monitoring. As patient conditions are extremely varied, a set number of office visits per condition cannot be reasonably established. The determination of necessity for an office visit requires individualized case review and assessment, being ever mindful that the best patient outcomes are achieved with eventual patient independence from the health care system through self-care as soon as clinically feasible. The treating physician requests consultation for neurology, but does not document what specific issues or questions he has for consulting physician. There appears to be a wide possible range of medical issues (pain, ortho, headaches, etc) and specificity is needed in consulting specialists. As such, the request for Neurologic consultation is not medically necessary.

**Follow up visit with an orthopedic surgeon:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Treatment Index, 11th Edition, 2014, Low Back, Office Visits

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints, Chapter 9 Shoulder Complaints Page(s): 177, 208-209, 289, 296. Decision based on Non-MTUS Citation Neck and Upper Back, Office Visits

**Decision rationale:** ACOEM states for a shoulder injury, referral for surgical consultation may be indicated for patients who have: Red-flag conditions (e.g., acute rotator cuff tear in a young worker, glenohumeral joint dislocation, etc), Activity limitation for more than four months, plus existence of a surgical lesion, Failure to increase ROM and strength of the musculature around the shoulder even after exercise programs, plus existence of a surgical lesion, Clear clinical and imaging evidence of a lesion that has been shown to benefit, in both the short and long term, from surgical repair. ACOEM states for neck and upper back injuries. The presence of a herniated cervical or upper thoracic disk on an imaging study, however, does not necessarily imply nerve root dysfunction. Studies of asymptomatic adults commonly demonstrate intervertebral disk herniations that apparently do not cause symptoms. Referral for surgical consultation is indicated for patients who have: Persistent, severe, and disabling shoulder or arm symptoms, Activity limitation for more than one month or with extreme progression of symptoms, Clear clinical, imaging, and electrophysiologic evidence, consistently indicating the same lesion that has been shown to benefit from surgical repair in both the short- and long-term, Unresolved radicular symptoms after receiving conservative treatment. ACOEM states concerning low back complaints: Assessing Red Flags and Indications for Immediate Referral Physical-examination evidence of severe neurologic compromise that correlates with the medical history and test results may indicate a need for immediate consultation. The examination may further reinforce or reduce suspicions of tumor, infection, fracture, or dislocation. A history of tumor, infection, abdominal aneurysm, or other related serious conditions, together with positive findings on examination, warrants further investigation or referral. A medical history that suggests pathology originating somewhere other than in the lumbosacral area may warrant examination of the knee, hip, abdomen, pelvis or other areas. The treating physician has not provided documentation to meet the above ACOEM guidelines for referral to an orthopedic specialist for shoulder, neck, and/or low back complaints. As such the request for an ORTHOPEDIC REFERRAL is not medically necessary.

### **8 chiropractic treatments for cervical/lumbar spine and left shoulder: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Manual Therapy and Manipulation Page(s): 58.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Manual therapy & manipulation Page(s): 58-60. Decision based on Non-MTUS Citation Low Back - Lumbar & Thoracic (Acute & Chronic), Chiropractic, Manipulation

**Decision rationale:** MTUS states, recommended for chronic pain if caused by musculoskeletal conditions, MTUS additionally quantifies, b. Frequency: 1 to 2 times per week the first 2 weeks, as indicated by the severity of the condition. Treatment may continue at 1 treatment per week for the next 6 weeks. c. Maximum duration: 8 weeks. At week 8, patients should be reevaluated. Care beyond 8 weeks may be indicated for certain chronic pain patients in whom manipulation is helpful in improving function, decreasing pain and improving quality of life. In these cases, treatment may be continued at 1 treatment every other week until the patient has reached plateau and maintenance treatments have been determined. Extended durations of care beyond what is considered maximum may be necessary in cases of re-injury, interrupted continuity of care, exacerbation of symptoms, and in those patients with comorbidities. ODG writes regarding

cervical treatment, it would not be advisable to use beyond 2-3 weeks if signs of objective progress towards functional restoration are not demonstrated. Additionally, MTUS states Low back: Recommended as an option. Therapeutic care, Trial of 6 visits over 2 weeks, with evidence of objective functional improvement, total of up to 18 visits over 6-8 weeks. Elective /maintenance care, not medically necessary. Recurrences/flare-ups, need to reevaluate treatment success, if RTW achieved then 1-2 visits every 4-6 months. The request for 8 sessions is excessive for a trial therapy. The treating physician does not indicate extenuating circumstances that would warrant exception to the guideline initial trial recommendations. As such, the request for 8 chiropractic treatments for cervical/lumbar spine and left shoulder is not medically necessary.

**Topical compound cream (Flurbiprofen, Capsaicin, Camphor 10%/0.025%/2%/1% 120grams): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin, Topical Analgesics Page(s): 28, 111-113. Decision based on Non-MTUS Citation Pain, Compound creams

**Decision rationale:** MTUS and ODG recommend, usage of topical analgesics as an option, but also further details primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, there is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. MTUS recommends topical capsaicin only as an option in patients who have not responded or are intolerant to other treatments. There is no indication that the patient has failed oral medication or is intolerant to other treatments. Additionally, ODG states Topical OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns, a new alert from the FDA warns. MTUS states that the only FDA- approved NSAID medication for topical use includes diclofenac, which is indicated for relief of osteoarthritis pain in joints. Flurbiprofen would not be indicated for topical use in this case. ACOEM and MTUS are silent regarding the use of camphor. This request compound has multiple components that are not recommended. As such, the request for Topical compound cream (Flurbiprofen, Capsaicin, Camphor 10%/0.025%/2%/1% 120 grams is not medically necessary.

**Topical compound cream: Cyclobenzaprine/ Lidocaine 10%/3%/5% 120 grams): Upheld**

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

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

**Decision rationale:** MTUS and ODG recommends, usage of topical analgesics as an option, but also further details primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, there is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. MTUS states regarding topical muscle relaxants, other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product. Topical cyclobenzaprine is not indicated for this usage, per MTUS. ODG also states that topical lidocaine is appropriate in usage as patch under certain criteria, but that no other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. MTUS states regarding lidocaine, 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). MTUS indicates Lidocaine Non-neuropathic pain: Not recommended. The medical records do not indicate failure of first-line therapy for neuropathic pain and lidocaine is also not indicated for non-neuropathic pain. ODG states regarding Lidocaine topical patch, this is not a first-line treatment and is only FDA approved for post-herpetic neuralgia. Medical documents do not document the patient as having post-herpetic neuralgia. This request compound has multiple components that are not recommended. As such, the request for Topical compound cream: Cyclobenzaprine/ Lidocaine 10%/3%/5% 120 grams is not medically necessary.

**Theramine #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, Treatment Index, 2014, Pain, Medical Foods, Theramine

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pain (Chronic), Theramine and medical food

**Decision rationale:** ODG states that a medical food is 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. ODG comments on Theramine directly, not recommended. Theramine is a medical food from [REDACTED], that is a proprietary blend of gamma-aminobutyric acid [GABA] and choline bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. See Medical food, Gamma-aminobutyric acid (GABA), where it says, there is no high quality peer-reviewed literature that suggests that GABA is indicated; Choline, where it says, there is no known medical need for choline supplementation; L-Arginine, where it says, this medication is not indicated in current references for pain or inflammation; & L-Serine, where it says, there is no indication for the use of this product. In this manufacturer study comparing Theramine to Naproxen; Theramine appeared to be effective in relieving back pain without causing any significant side effects. (Shell, 2012) Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. The ODG guidelines do

not support the use of Theramine. As such the request for Theramine #60 is not medically necessary.

**Sentra PM #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, Treatment Index, 2014, Pain, Medical Foods, Sentra PM

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pain, Medical Food

**Decision rationale:** MTUS is silent regarding Sentra PM. ODG states that Sentra PM is a medical food from [REDACTED], intended for use in management of sleep disorders associated with depression that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. In addition ODG states that a medical food is by 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 eternally 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. ODG specifically states Choline is a precursor of acetylcholine. There is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. Medical records do not indicate that the patient meets these criteria. The medical records do not indicate the specific dietary disease or condition for which there is a distinctive nutritional requirement that the medication would be used for. Additionally, there is a component of this medication that is not recommended per guidelines. As such, the request for Sentra PM #60, 1 bottle 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, Treatment Index, 2014, Pain, Medical Foods

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pain (Chronic), Gabadone and Medical Food

**Decision rationale:** MTUS is silent concerning Gabadone. ODG states that a medical food is a food which is formulated to be consumed or administered eternally 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. ODG comments on Gabadone directly, not recommended. Gabadone is a medical food from [REDACTED], that 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. (Shell, 2009) See Medical food, Choline, Glutamic Acid, 5-hydroxytryptophan, and Gamma-aminobutyric acid (GABA). The ODG guidelines do not support the use of Gabadone. As such the request for Gabadone #60 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, Treatment Index, 2014, Pain, Medical Foods, Sentra AM

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pain, Medical Food

**Decision rationale:** Sentra AM is a medical food that contains choline and acetylcarnitine as in intended to maintain production of acetylcholine in the central and peripheral nervous system. MTUS and ODG are silent specifically regarding Sentra AM. In addition ODG states that a medical food is by 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 eternally 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. ODG specifically states Choline is a precursor of acetylcholine. There is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. Medical records do not indicate that the patient meets these criteria. The medical records do not indicate the specific dietary disease or condition for which there is a distinctive nutritional requirement that the medication would be used for. Additionally, there is a component of this medication that is not recommended per guidelines. As such, the request for Sentra AM #60 is not medically necessary.

**Tramadol 150mg #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 76-77.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Tramadol, Ultram Page(s): 74-96, 113, 123. Decision based on Non-MTUS Citation Pain (Chronic) - Medications for acute pain (analgesics), Tramadol (Ultram®)

**Decision rationale:** Tramadol is classified as central acting synthetic opioids. MTUS states regarding tramadol that a therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals. ODG further states, Tramadol is not recommended as a first-line oral analgesic because of its inferior efficacy to a combination of Hydrocodone/ acetaminophen. The treating physician did not provide sufficient documentation that the patient has failed a trial of non-opioid analgesics at the time of prescription or in subsequent medical notes. Additionally, no documentation was provided which discussed the setting of goals for the use of Tramadol prior to the initiation of this medication. As such, the request for Tramadol 150mg #60 is not medically necessary.

**Naproxen 550mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67-73. Decision based on Non-MTUS Citation Pain (Chronic), Naproxen, NSAIDs (non-steroidal anti-inflammatory drugs)

**Decision rationale:** MTUS specifies four recommendations regarding NSAID use: 1) Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. 2) Back Pain - Acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting evidence that NSAIDs are more effective than acetaminophen for acute LBP. 3) Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. 4) Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in with neuropathic pain. The medical documents do not indicate that the patient is being treated for osteoarthritis. Additionally, the treating physician does not document failure of primary (Tylenol) treatment. Progress notes do not indicate how long the patient has been on naproxen, but the MTUS guidelines recommend against long-term use. The other components of the guideline's criteria were not met. As such, the request for Naproxen 550mg #60 is not medically necessary.

**Omeprazole 20mg #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Pain (Chronic), NSAIDs, GI symptoms & cardiovascular risk

**Decision rationale:** MTUS and ODG states, "Determine if the patient is at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA)." And "Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44)." The medical documents provided do not establish the patient has having documented GI bleeding, perforation, peptic ulcer, high dose NSAID, or other GI risk factors as outlined in MTUS. As such, the request for Omeprazole 20mg #60 is not medically necessary.