

<b>Case Number:</b>	CM15-0026762		
<b>Date Assigned:</b>	02/19/2015	<b>Date of Injury:</b>	02/13/2012
<b>Decision Date:</b>	04/08/2015	<b>UR Denial Date:</b>	01/14/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/12/2015

### 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: Pennsylvania  
 Certification(s)/Specialty: Internal 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 47 year-old male has reported mental illness and multifocal pain after an injury on 2/13/12. The diagnoses include status post left foot surgery, foot fracture, bilateral shoulder sprain/strain, left knee sprain/strain, and anxiety and stress. Treatments have included medications, food supplements, physical therapy, chiropractic therapy, electrical stimulation, shoulder injection, and surgery. There are reports from a treating chiropractor during 2013, with no discussion of specific functional improvement. Treatment included prescribing of a home "TENS-EMS" unit. There is a new chiropractor report on 10/22/14. The injured worker was seen for shoulder, knee, hip, and foot pain. There were at least 6 subsequent visits with this chiropractor, and no reports discussing the results and functional improvement resulting from these visits. Reports from the treating physician during 2014 show one episode of dispensing of tramadol and naproxen, in June 2014. There are checklists, generic statements regarding continuation of unspecified medications in order to maintain activities of daily living. Reports show ongoing foot pain, "stress, anxiety, and depression"; shoulder pain, and hip pain. The reports from the primary treating physician are handwritten, difficult to read, and do not provide any discussion of the specific indications or results for the long list of requested treatments. A urine drug screen from 12/8/14 was positive for tramadol and negative for the long list of other drugs assayed, most of which had no apparent indications for testing. A urine drug screen, functional capacity evaluation, interferential stimulation unit, and cold therapy machine, chiropractic, physical therapy, MRIs, electrodiagnostic testing, and topical and oral medications were requested on 8/22/14. Most of these same items were requested again on 10/15/14, 11/11/14, 12/8/14, and

1/6/15. Acupuncture was added to the treatment plan on 11/10/14 and remained so in each subsequent report and Request for Authorization. A "psyche eval per acoem due to chronicity" was requested along with all of the other items on 12/8/14, and a "psych" for depression was requested on 1/6/15. The Utilization Review on 01/14/2015 non-certified Flurbiprofen/Capsaicin/Camphor, Ketoprofen/Cyclobenzaprine/lidocaine, Theramine, Sentra PM, Gabadone, Sentra AM, chiropractic/physiotherapy, acupuncture, urinalysis for toxicology, and a referral to psych. The MTUS and the Official Disability Guidelines were cited.

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

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

**Urinalysis for toxicology:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, drug screens, steps to avoid misuse/addiction; urine drug screen to assess for the use or the presence of illegal drugs; Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control; Opioid contracts: (9) Urine drug screens may be required; Opioids, steps to avoid misuse/addiction: c) Frequent random urine toxicology screens Page(s): 77-80, 94; 43; 77; 78; 89; 94. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain section, Urine Drug Testing and Other Medical Treatment Guidelines Other Medical Treatment Guideline or Medical Evidence: Updated ACOEM Guidelines, 8/14/08, Chronic Pain, Page 138, urine drug screens United States Department of Transportation, 49 CFR Part 40, Drug and Alcohol Regulations.

**Decision rationale:** The treating physician has not provided any specific information regarding the medical necessity for a urine drug screen. No medications were listed, and the need for management via a urine drug screen is not explained. Medical necessity for a urine drug screen is predicated on a chronic opioid therapy program conducted in accordance with the recommendations of the MTUS, or for a few other, very specific clinical reasons. There is no evidence in this case that opioids have been prescribed recently. The treating physician has not listed any other reasons to do the urine drug screen. The test that was performed in December included many unnecessary tests, as many drugs with no apparent relevance for this patient were assayed. The MTUS recommends random drug testing, not at office visits or regular intervals. The details of testing have not been provided. Potential problems with drug tests include: variable quality control, forensically invalid methods of collection and testing, lack of random testing, lack of MRO involvement, unnecessary testing, and improper utilization of test results. Strict collection procedures must be followed, testing should be appropriate and relevant to this patient, and results must be interpreted and applied correctly. Given that the treating physician has not provided details of the proposed testing, the lack of an opioid therapy program in accordance with the MTUS, and that there are outstanding questions regarding the testing process, the urine drug screen is not medically necessary.

**Referral to psych:** Overturned

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ACOEM Occupational Medicine Practice Guidelines, 2nd Edition, 2004, page 127.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 2 General Approach to Initial Assessment and Documentation, Chapter 15 Stress Related Conditions Page(s): 22-23; 391-402.

**Decision rationale:** The ACOEM Guidelines pages 22-33 and 391-397 discuss the evaluation of patients in general, and of patients with possible "stress-related conditions". Important history and physical findings are outlined. At a Qualified Medical Examination (QME) in psychiatry on 8/19/14, the injured worker was noted to have ongoing symptoms of depression, and that he had been briefly treated with Zoloft and lorazepam by his family physician but was no longer taking these medications due to loss of insurance. A diagnosis of major depression was noted, and the examining physician advised referral to a psychiatrist as well as psychotherapy. Per the ACOEM, it is recommendation that individuals with serious conditions such as severe depression and schizophrenia be referred to a specialist. Due to the diagnosis of major depression requiring treatment, the request for psychiatric referral is medically necessary.

**Flurbiprofen/Capsaicin/Camphor 10/0.25%/2%/1% 120gm:** 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 Medications for chronic pain; Topical Medications Page(s): 60; 111-113. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Up-to-date: camphor and menthol: drug information. In Up-to-date, edited by Ted. W. Post, published by Up-to-date in Waltham, MA, 2015.

**Decision rationale:** No physician reports discuss the specific indications and medical evidence in support of the topical medications prescribed in this case. The treating physician has not discussed the ingredients of this topical agent and the specific indications for this injured worker. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. The MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Per the MTUS, topical non-steroidal anti-inflammatory drugs (NSAIDs) for short term pain relief may be indicated for pain in the extremities caused by osteoarthritis or tendonitis. There is no good evidence supporting topical NSAIDs for shoulder or axial pain. The treating physician has not discussed the specific body parts to be treated, and there are no reports of the specific benefit from using this topical compound. Note that topical flurbiprofen is not FDA approved, and is therefore experimental and cannot be presumed as safe and efficacious. Non-FDA approved medications are not medically necessary. Capsaicin has some indications, in

the standard formulations readily available without custom compounding. It is not clear what the indication is in this case, as the injured worker does not appear to have the necessary indications per the MTUS. The MTUS also states that capsaicin is only recommended when other treatments have failed. This injured worker has not received adequate trials of other, more conventional treatments. The treating physician did not discuss the failure of other, adequate trials of other treatments. Capsaicin is not medically necessary based on the lack of indications per the MTUS. The MTUS is silent with regards to camphor. It may be used for relief of dry, itchy skin. This agent carries warnings that it may cause serious burns. The topical agents prescribed are not medically necessary based on the MTUS, lack of medical evidence, and lack of FDA approval.

**Ketoprofen/Cyclobenzaprine/Lidocaine 10%/3%/5% 120gm:** 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 Medications for chronic pain; Topical Medications Page(s): 60; 111-113.

**Decision rationale:** No physician reports discuss the specific indications and medical evidence in support of the topical medications prescribed in this case. The treating physician has not discussed the ingredients of this topical agent and the specific indications for this injured worker. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. The MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical lidocaine, only in the form of the Lidoderm patch, is indicated for neuropathic pain (which is not present in this case). The MTUS states that the only form of topical lidocaine that is recommended is Lidoderm. The topical lidocaine prescribed in this case is not Lidoderm. Topical anesthetics like the ones dispensed are not indicated per the FDA, are not FDA approved, and place injured workers at an unacceptable risk of seizures, irregular heartbeats and death. Two topical NSAIDs were prescribed simultaneously (ketoprofen and flurbiprofen), which is duplicative and unnecessary, as well as possibly toxic. Note that topical ketoprofen is not FDA approved, and is not recommended per the MTUS. Cyclobenzaprine is a muscle relaxant. Per the MTUS citation, there is no good evidence in support of topical muscle relaxants; these agents are not recommended. The topical agents prescribed are not medically necessary based on the MTUS, lack of medical evidence, FDA directives, and inappropriate prescribing.

**Theramine #90:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Pain (updated 12/30/14) Theramine.

**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, theramine and Other Medical Treatment Guidelines Other Medical Treatment Guideline or Medical Evidence: FDA Definition of medical foods: Defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)).

**Decision rationale:** Theramine is medical food intended for use in the management of chronic pain syndromes which contains 5-hydroxytryptophan 95%, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine, gamma-aminobutyric acid (GABA), whey protein concentrates, grape seed extract 85%, cinnamon, and cocoa (theobromine 6%). Per the ODG, theramine is not recommended for the treatment of chronic pain. There are no physician reports which provided specific medical evidence in support of amino acid supplements for the treatment of this patient. Medical foods, per the FDA definition, are for treatment of specific dietary conditions and deficiencies. No medical reports have established any specific dietary deficiencies. The MTUS does not address "medical food". The Official Disability Guidelines have several recommendations and indications (such as liver deficiency, achlorhydria), per the citation above. This injured worker does not meet any of the indications in the Official Disability Guidelines, and the treating physician has not identified any specific indications for the ingredients in Theramine. Theramine is not medically necessary based on the lack of any indications in this injured worker and the recommendations of the guidelines and the FDA.

**Sentra PM #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Pain (updated 12/30/14) Sentra PM.

**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 food, sentra pm, insomnia treatment and Other Medical Treatment Guidelines Other Medical Treatment Guideline or Medical Evidence: FDA Definition of medical foods: Defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)).

**Decision rationale:** Sentra PM is a medical food intended for use in management of sleep disorders associated with depression. It is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan, hawthorn berry, cocoa, ginkgo biloba, and acetyl L-carnitine. The MTUS does not address the use of hypnotics other than benzodiazepines. The ODG states that medical food is not recommended for the treatment of chronic pain. The ODG specifies that pharmacologic agents for the treatment of insomnia should only be used after careful evaluation of potential causes of sleep disturbance. No physician reports describe the specific criteria for a sleep disorder. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. There is no evidence of that in this case. Per the ODG, Sentra PM is not recommended.

**Gabadone #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Pain (updated 12/30/14) GABAdone.

**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, gabadone and Other Medical Treatment Guidelines Other Medical Treatment Guideline or Medical Evidence: FDA Definition of medical foods: Defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)).

**Decision rationale:** Gabadone is a medical food that is a proprietary blend of choline bitartrate, glutamic acid, 5-hydroxytryptophan, GABA, grape seed extract, griffonia extract, whey protein, valerian extract, ginkgo biloba and cocoa. It is intended to meet the nutritional requirements for sleep disorders and sleep disorders associated with insomnia. The ODG specifies that pharmacologic agents for the treatment of insomnia should only be used after careful evaluation of potential causes of sleep disturbance. The MTUS does not address the use of hypnotics other than benzodiazepines. No physician reports describe the specific criteria for a sleep disorder. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. There is no evidence of that in this case. Per the ODG, Gabadone is not recommended for sleep disorders based on limited available research. The ODG states that medical food is not recommended for the treatment of chronic pain. As this agent is not recommended by the guidelines, the request for gabadone 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 ODG Pain (updated 12/30/14) 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 section, Medical food and Other Medical Treatment Guidelines Other Medical Treatment Guideline or Medical Evidence: FDA Definition of medical foods: Defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)).

**Decision rationale:** Sentra AM is a medical food intended for use in the management of chronic and generalized fatigue, fibromyalgia, post-traumatic stress syndrome (PTSD), neurotoxicity-induced fatigue syndrome, and cognitive impairment involving arousal, alertness, and memory. The ODG states that 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. There are no physician reports which provided specific medical evidence in support of medical food for the treatment of this patient. Medical foods, per the FDA definition, are for treatment of specific dietary conditions and deficiencies. No medical reports have established any specific dietary deficiencies. The MTUS does not address "medical food". The Official Disability Guidelines have several recommendations and indications (such as liver deficiency, achlorhydria), per the citation above. This injured worker does not meet any of the indications in the Official Disability Guidelines, and the treating physician has not identified any specific indications for the ingredients in Sentra AM. This medical food is not medically necessary based on the lack of any indications in this injured worker and the recommendations of the guidelines and the FDA.

## **Chiropractic/Physiotherapy 2 times a week for 4 weeks: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 58-59.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Manual therapy & manipulation Page(s): 58-60.

**Decision rationale:** Per the MTUS for Chronic Pain, the purpose of manual medicine is functional improvement, progression in a therapeutic exercise program, and return to productive activities (including work). Per the MTUS, chiropractic manipulation is not recommended for the "Ankle & Foot, Carpal tunnel syndrome, Forearm, Wrist, & Hand, Knee". Per the MTUS for Chronic Pain, a trial of 6 visits of manual therapy and manipulation may be provided over 2 weeks, with any further manual therapy contingent upon functional improvement. The primary treating physician has been prescribing chiropractic care for months, without specific indications or discussion of results. It appears that treatment has been given for the foot and ankle. The number of visits to date is not discussed in the records but there have been at least 6 visits. The MTUS states that maintenance manipulation is not recommended. Care in this case is prescribed at each visit, which implies maintenance care rather than care for flare-ups, which would occur infrequently and unpredictably. The treating physician has stated that the patient is temporarily totally disabled. This is evidence of no functional improvement. The treating physician has not provided any evidence of functional improvement to date. There are no reports from the treating chiropractor or the primary treating physician who describes specific functional improvement as defined in the MTUS. No additional manual and manipulative therapy is medically necessary based on the lack of functional improvement after an initial trial of at least 6 visits, ongoing maintenance care, and because chiropractic treatment has been provided for body parts for which chiropractic care is not recommended.

## **Acupuncture once a week for four weeks: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Acupuncture Treatment Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Acupuncture Treatment Guidelines.

**Decision rationale:** The prescription for acupuncture is evaluated in light of the MTUS recommendations for acupuncture. Per the MTUS, acupuncture is used as an option when pain medication is reduced or not tolerated, it may be used as an adjunct to physical rehabilitation and/or surgical intervention to hasten functional recovery. The treating physician has not provided the specific indications for acupuncture as listed in the MTUS. There is no discussion of issues with pain medications, or functional recovery in conjunction with surgery and physical rehabilitation. Given the cursory nature of the medical reports, it is not clear if the injured worker has already been attending acupuncture visits, as acupuncture is listed in the treatment plan over many months. Given that the focus of acupuncture is functional improvement, function (including work status or equivalent) must be addressed as a starting point for therapy and as a measure of progress. As discussed in the MTUS, chronic pain section, the goal of all treatment

for chronic pain is functional improvement, in part because chronic pain cannot be cured. The injured worker remains on temporarily totally disabled status. This implies a failure of all treatment, including acupuncture. An initial or follow-up course of acupuncture is not medically necessary based on the lack of specific indications per the MTUS and the lack of emphasis on functional improvement.