

<b>Case Number:</b>	CM15-0003950		
<b>Date Assigned:</b>	01/14/2015	<b>Date of Injury:</b>	09/10/2012
<b>Decision Date:</b>	03/13/2015	<b>UR Denial Date:</b>	12/24/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/07/2015

### 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:

The injured worker is a 46 year old male who sustained an industrial injury on 9/10/2012 due to a fall. The diagnoses have included left knee meniscal tear, lumbar spine disc protrusion, lumbar radiculopathy, and ventral hernia. Treatment to date has included physical therapy, chiropractic treatment, acupuncture, shock wave therapy to the lumbar spine and hand, infrared, myofascial release, home exercise program, and pain medications. Submitted documentation includes treatment logs from multiple chiropractic treatments from March to November 2014, with more than 20 visits documented. Per the Primary Treating Physician's Progress Report from 9/4/2014, the injured worker complained of pain to bilateral knees that radiated into feet and bilateral hands with numbness. Medication and therapy helped reduce pain. Objective findings were tenderness to left knee with decreased range of motion, tenderness to abdomen below umbilicus and tenderness to lumbar spine. Urine toxicology screens were included from 5/8/14, 6/18/14, 8/21/14, 9/2/2014, 10/23/14, and 12/4/14 and additional prior dates. Medications as of 10/24/14 included anaprox, prilosec, and tramadol. Per the Primary Treating Physician's Progress Report from 12/4/2014, the injured worker complained of insomnia, fatigue and pain 4-7/10. Objective findings included decreased range of motion of the lumbar spine. Work status was noted as off work and it was documented that the injured worker has not worked since September 2012. Authorization was requested for chiropractic treatment, shockwave to the lumbar spine and right knee, urinalysis for toxicology, medical foods: Theramine, Sentra PM, Sentra AM and Gabadone, acupuncture and prescribed creams. On 12/24/2012 Utilization Review (UR) non-certified a request for Chiropractic Treatment two times a week times four weeks, noting that

there was no clear rationale provided two years after the time of onset of the complaints to provide eight sessions of chiropractic care. UR non-certified a request for Ortho Shockwave for the left knee noting that the doctor provided no medical evaluation and no treatment plan. UR non-certified a request for Urinalysis for toxicology noting that a toxicology screen was ordered on 10/23/2014 with unknown results. UR non-certified a request for Ortho Shockwave for the lumbar spine, noting that there was no rationale provided or specific number of treatments. UR non-certified a request for Medical foods: Theramine, Sentra PM, Sentra AM and Gabadone, noting that there are no quality studies demonstrating the benefits of medical foods in the treatment of chronic pain. UR non-certified a request for Acupuncture Treatment, one time a week times four weeks noting that the injured worker was not undergoing physical rehabilitation nor having surgical intervention. UR non-certified a request for Compound Creams: Flurbiprofen/Capsaicin/Camphor, Ketoprofen/Cyclobenzaprine/lidocaine noting that the physician has not provided any rationale as to medical necessity. The MTUS, ACOEM Guidelines and ODG were cited by Utilization Review.

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

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

**Chiropractic 2 times a week for 4 weeks:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints, Chapter 13 Knee Complaints, Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines

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

**Decision rationale:** The MUTS states that chiropractic care is recommended for chronic pain if caused by musculoskeletal condition of the low back. Chiropractic treatment to the ankle, foot, forearm, wrist, hand, and knee are not recommended. The injured worker has diagnoses of left knee meniscal tear and lumbar spine disc protrusion. The body part to be treated was not specified. Documentation submitted indicates that the injured worker had 13 chiropractic treatments to the lumbar spine in October -November 2014 and multiple prior sessions from March- July 2014, with at least 20 sessions documented. The MTUS notes that chiropractic treatment to the low back is an option, with a trial of 6 visits over 2 weeks, and with evidence of functional improvement, a total of up to 18 visits over 6-8 weeks. Maintenance care is not medically necessary per the MTUS. One to two visits every 4-6 months may be used for recurrences/flareups if return to work is achieved. The injured worker has already received a number of chiropractic treatments in excess of the guidelines, without documentation of functional improvement or return to work. There was no documentation of recurrence/flare of low back pain in the setting of successful return to work. The body part to be treated was not specified as the lumbar spine, and chiropractic treatment to other areas is not recommended. Due to lack of specification of the area to be treated, number of treatments already received with additional treatments requested in excess of the guidelines, and lack of demonstration of functional improvement, the request for Chiropractic 2 times a week for 4 weeks is not medically necessary.

**Ortho shockwave for the left knee: Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints, Chapter 13 Knee Complaints, Chronic Pain Treatment Guidelines. 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 knee chapter: extracorporeal shock wave therapy

**Decision rationale:** Per the ODG, shock wave therapy is under study for patellar tendinopathy and for long-bone hypertrophic nonunions. New data suggests that extracorporeal shockwave therapy is ineffective for treating patellar tendinopathy, compared to the current standard of care emphasizing multimodal physical therapy focused on muscle retraining, joint mobilization, and patellar taping. The injured worker has a diagnosis of left knee meniscal tear with continued knee pain. There was no diagnosis of patellar tendinopathy or long-bone nonunion. Due to lack of indication and lack of evidence for effectiveness of the requested treatment, the request for Ortho shockwave for the left knee is not medically necessary.

**Urinalysis for toxicology: Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints, Chapter 13 Knee Complaints, Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guideline

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines drug testing, opioids Page(s): 43, 77-78, 89, 94. Decision based on Non-MTUS Citation chronic pain chapter: urine drug testing

**Decision rationale:** Per MTUS chronic pain medical treatment guidelines, urine drug screens are recommended as an option to assess for the use or the presence of illegal drugs, in accordance with a treatment plan for use of opioid medication, and as a part of a pain treatment agreement for opioids. Per the ODG, urine drug testing is recommended as a tool to monitor compliance with prescribed substances, identify use of undisclosed substances, and uncover diversion of prescribed substances. Urine drug testing is recommended at the onset of treatment when chronic opioid management is considered, if the patient is considered to be at risk on addiction screening, or if aberrant behavior or misuse is suspected or detected. Ongoing monitoring is recommended if a patient has evidence of high risk of addiction and with certain clinical circumstances. Frequency of urine drug testing should be based on risk stratification. Patients with low risk of addiction/aberrant behavior should be tested within six months of initiation of therapy and on a yearly basis thereafter. Patients at moderate risk for addiction/aberrant behavior should be tested 2-3 times per year. Patients at high risk of adverse outcomes may require testing as often as once a month. Random collection is recommended. Results of testing should be documented and addressed. The injured worker has been prescribed tramadol for chronic pain. There was no documentation of an opioid treatment plan in accordance with MTUS. Urine drug screens have been performed monthly for over 6 months. No discussion of results was present in the

documentation submitted. The progress notes do not include any evidence of risk stratification for aberrant behavior for this injured worker. There was no documentation that the injured worker was at high risk of addiction/aberrant behavior to warrant monthly urine drug testing. The request for urinalysis for toxicology did not indicate the frequency of testing requested. The most recent urine drug test was performed December 4, 2014. Due to lack of documentation of a need for frequent urine drug testing, the request for Urinalysis for toxicology is not medically necessary.

**Ortho shockwave for lumbar spine:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Acupuncture Treatment Guidelines, Chronic Pain Treatment Guidelines. 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 low back chapter: shock wave therapy

**Decision rationale:** Per the ODG, low back chapter, shock wave therapy is not recommended. The available evidence does not support the effectiveness of ultrasound or shock wave for treating low back pain. The injured worker had diagnoses of lumbar spine disc protrusion and lumbar radiculopathy. The documentation submitted indicates that he had prior shock wave treatment to the lumbar spine in April 2014, without documentation of functional improvement as a result of this treatment. As shock wave therapy is not recommended, and as there was no functional improvement as a result of prior treatment with this modality, the request for Ortho shockwave for lumbar spine is not medically necessary.

**Theramine #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. 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 chronic pain chapter: theramine

**Decision rationale:** Theramine is a medical food that 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%). It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. Although the injured worker does have report of ongoing pain issues, per the ODG, Theramine is not recommended for the treatment of chronic pain. For this reason, the request for theramine #90 is not medically necessary.

**Sentra PM #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. 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 chronic pain chapter: insomnia treatment

**Decision rationale:** Sentra PM is a medical food from [REDACTED], [REDACTED], 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 specifies that pharmacologic agents for the treatment of insomnia should only be used after careful evaluation of potential causes of sleep disturbance. The treating physician documented that the injured worker had insomnia, and on 3/14/14 the injured worker underwent a preliminary evaluation and assessment of pulmonary/respiratory disorders and sleep disordered breathing, with documentation of suspicion of obstructive sleep apnea, but further testing/results was not included in the documentation submitted. 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. Furthermore, per the ODG, Sentra PM is not recommended. The request for Sentra PM #60 is not medically necessary.

**Sentra AM #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. 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 chronic pain chapter: medical food

**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. For this reason the request for Sentra AM #60 is not medically necessary.

**Gabadone #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. 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 chronic pain chapter: gabadone

**Decision rationale:** GABAdone is a Medical food from [REDACTED], [REDACTED], 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 MTUS does not address the use of hypnotics other than benzodiazepines. 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 treating physician documented that the injured worker had insomnia, and on 3/14/14 the injured worker underwent a preliminary evaluation and assessment of pulmonary/respiratory disorders and sleep disordered breathing, with documentation of suspicion of obstructive sleep apnea, but further testing/results was not included in the documentation submitted. 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 request for Gabadone #60 is not medically necessary.

**Acupuncture treatment 1x 4 weeks:** Upheld

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

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

**Decision rationale:** 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 MTUS recommends an initial trial of 3-6 visits of acupuncture. Frequency of treatment of 1-3 times per week with an optimum duration of 1-2 months is specified by the MTUS. Medical necessity for any further acupuncture is considered in light of functional improvement. Acupuncture treatments may be extended if functional improvement is documented. The documentation indicates that the injured worker had acupuncture in February 2014; only one note was provided and the number of treatments completed was not specified. There was no documentation of functional improvement as a result of the prior acupuncture treatment. The injured worker remains off work, which is evidence of lack of a treatment plan focused on functional recovery. There was no documentation of reduction or intolerance to pain medication. The injured worker had undergone prior physical therapy including treatment in October 2014, but there was no documentation that the injured worker was currently undergoing physical therapy and no recent or planned surgical intervention was discussed. For these reasons, the request for Acupuncture treatment 1x 4 weeks is not medically necessary.

**Flurbiprofen/Capsaicin/Camphor 10/0.25%/2%/1% (120grams):** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): p. 111-113.

**Decision rationale:** Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. Flurbiprofen is a nonsteroidal anti-inflammatory agent. Per the MTUS, topical nonsteroidal anti-inflammatory medications (NSAIDs) for short term pain relief may be indicated for pain in the extremities caused by osteoarthritis or tendonitis. There is no documentation of diagnoses of osteoarthritis or tendonitis for this injured worker. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip, or shoulder, and topical NSAIDs are not recommended for neuropathic pain. There should be no concurrent use of an oral and topical NSAID. The only FDA approved topical NSAID is voltaren gel (diclofenac). Capsaicin is recommended as an option in patients who have not responded or are intolerant to other treatments. The MTUS and ODG are 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 documentation submitted does not indicate that trial of antidepressants or anticonvulsant oral medication has been used and failed. The injured worker was prescribed oral naproxen and a request was submitted for topical ketoprofen, making therapy duplicative and potentially toxic. Due to the lack of recommendation for flurbiprofen and the potential for toxicity of this compounded product, the request for Flurbiprofen/Capsaicin/Camphor 10/0.25%/2%/1% (120grams) is not medically necessary.

**Ketoprofen/Cyclobenzaprine/lidocaine 10%/3% 5% (120 gm): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): p. 111-113.

**Decision rationale:** Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. Ketoprofen is not currently FDA approved for topical application. It has a high incidence of photocontact dermatitis. Per the MTUS, topical nonsteroidal anti-inflammatory medications (NSAIDs) for short term pain relief may be indicated for pain in the extremities caused by osteoarthritis or tendonitis. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip, or shoulder. There is no documentation of diagnoses of osteoarthritis or tendonitis for this injured worker. Topical NSAIDs are not recommended for neuropathic pain. There should be no concurrent use of an oral and topical NSAID. The only FDA approved topical NSAID is voltaren gel (diclofenac). Cyclobenzaprine is a muscle relaxant. The MTUS notes that there is no evidence for use of muscle relaxants as topical products. Topical lidocaine is recommended for localized peripheral pain after there has been evidence of a trial of first line therapy with tricyclic or serotonin/norepinephrine reuptake inhibitor antidepressants or an antiepileptic drug such as gabapentin or Lyrica. Topical lidocaine in dermal patch form (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain, and further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Topical lidocaine other than Lidoderm is not recommended per the

MTUS. No other commercially approved topical formulations of lidocaine (whether creams, lotions, or gels) are indicated for neuropathic pain. The documentation submitted does not indicate that trial of antidepressants or anticonvulsant oral medication has been used and failed. The injured worker was prescribed oral naproxen and a request was submitted for topical flurbiprofen, making therapy duplicative and potentially toxic. Due to the lack of recommendation for flurbiprofen and the potential for toxicity of this compounded product, and the lack of recommendation for cyclobenzaprine topical and lidocaine in non-dermal patch form, the request for Ketoprofen/Cyclobenzaprine/lidocaine 10%/3% 5% (120 gm) is not medically necessary.