

<b>Case Number:</b>	CM14-0183379		
<b>Date Assigned:</b>	11/12/2014	<b>Date of Injury:</b>	03/31/2001
<b>Decision Date:</b>	12/19/2014	<b>UR Denial Date:</b>	10/28/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/04/2014

### 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 Emergency 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 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 injured worker is a 59-year-old female who reported an injury on 06/05/1998 due to an unknown mechanism. The physical examination on 10/21/2014 was handwritten and very illegible. Other clinical notes that were sent in by the same provider were also illegible and handwritten. Diagnoses were displacement of lumbar intervertebral disc without myelopathy, tear of medial cartilage or meniscus of knee current, and other affections of shoulder region not elsewhere classified. The injured worker complained their pain was at 7/10. Examination of the lumbar spine was positive for spasm. The injured worker was recommended arthroscopy for the knee. Medications were medical foods, Theramine, and Centrum. The rationale and Request for Authorization were not submitted.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Chiropractic therapy 3 x week for 4 weeks, per 10/21/14 RFA: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 58-60.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Manual Therapy Page(s): 58-59.

**Decision rationale:** The California Medical Treatment Utilization Schedule states that manual therapy and manipulation is recommended for chronic pain if caused by musculoskeletal conditions. For low back, therapy is recommended initially in a therapeutic trial of 6 sessions, and with objective functional improvement, a total of up to 18 visits over 6 to 8 weeks may be appropriate. Treatment for flare ups requires a need for reevaluation of prior treatment success. Treatment is not recommended for the ankle and foot, carpal tunnel syndrome, the forearm, wrist, or hand or knee. If chiropractic treatment is going to be effective, there should be some outward sign of subjective or objective improvement within the first 6 visits. Treatment beyond 4 to 6 visits should be documented with objective improvement in function. The maximum duration is 8 weeks, and at 8 weeks, 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. The physical examination dated 10/21/2014 was handwritten and illegible. Pertinent information may not have been reported. The clinical documentation did not reveal evidence of objective functional deficits. It is unknown how many visits the injured worker had of chiropractic treatments. The clinical information submitted for review does not provide evidence to justify the decision for chiropractic therapy 3 x weeks for 4 weeks, per 10/21/14 RFA. Therefore, this request is not medically necessary.

**Urinalysis test for toxicology:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Urine Drug Test Page(s): 43.

**Decision rationale:** The decision for urinalysis test for toxicology is not medically necessary. The California Medical Treatment Utilization Schedule Guidelines recommend a urine drug test as an option to assess for the use or the presence of illegal drugs. It may also be used in conjunction with a therapeutic trial of opioids for ongoing management and as a screening for risk of misuse and addiction. The documentation provided did not indicate that the injured worker displayed any aberrant behaviors, drug seeking behavior, or whether the injured worker was suspected of illegal drug use. The clinical documentation submitted for review did not indicate what medications the injured worker was taking. Therefore, this request is not medically necessary.

**Ortho shockwave for the lumbar spine:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 300. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back, Shock Wave Therapy

**Decision rationale:** The decision for extracorporeal shockwave therapy sessions is not medically necessary. The Official Disability Guidelines state that it is not recommended. The available evidence does not support the effectiveness of ultrasound or shockwave for treating low back pain. In the absence of such evidence, the clinical use of these forms of treatment is not justified, and should be discouraged. The guidelines do not support the use of extracorporeal shockwave therapy. Therefore, the request is not medically necessary.

**Theramine #90:** Upheld

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

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

**Decision rationale:** The Official Disability Guidelines state that Theramine is not recommended for the treatment of chronic pain. 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. Furthermore, the request does not indicate a frequency for the medication. The medical guidelines do not support the use of medical foods. There were no other significant factors provided to justify use outside of current guidelines. Therefore, this request 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 (ODG) Pain Procedure

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

**Decision rationale:** The Official Disability Guidelines state that Sentra PM is a medical food from [REDACTED], intended for use the management of sleep disorders associated with depression that is a proprietary blend of choline bitartrate, glutamate, and 5 hydroxy tryptophan. The medical guidelines state that medical food is not recommended for chronic pain. Medical foods are not recommended for the treatment of chronic pain, as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The FDA defines a medical food as 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. There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. There were no other significant factors provided to justify the use outside of current guidelines. Furthermore, the request does not indicate a frequency for the medication. Therefore, this request 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 (ODG) Pain Procedure

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Official Disability Guidelines (ODG) Pain, Gabadone, Medical Food.

**Decision rationale:** The decision for Gabadone #60 is not medically necessary. The Official Disability Guidelines state that Gabadone is not recommended. Gabadone is a medical food from [REDACTED] that is a proprietary blend of choline bitartrate, glutamic acid, 5 hydroxy tryptophan, 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. The guidelines state that medical food is not recommended for chronic pain. Medical foods are not recommended for the treatment of chronic pain, as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The FDA defines a medical food as 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. There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. Therefore, the request 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 (ODG) Pain Procedure

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

**Decision rationale:** This medication is a medical food. The Official Disability Guidelines state that medical foods medical food is not recommended for chronic pain. Medical foods are not recommended for the treatment of chronic pain, as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The FDA defines a medical food as 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. There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. The medical guidelines do not support the use of medical foods. There were no other significant factors provided to justify use outside of current guidelines. Furthermore, the request does not indicate a frequency for the medication. Therefore, this request is not medically necessary.

**Flurbiprofen/Capsaicin/Camphor 10/0.025%/2%/1% (120gm): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Flurbiprofen, Topical Analgesic, Capsaicin, Salicylates Page(s): 72, 111, 28, 105.

**Decision rationale:** The California Medical Treatment Utilization Schedule Guidelines indicate that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety. The guidelines primarily recommend topical analgesics for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least 1 drug (or drugs class) that is not recommended is not recommended. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with diminishing effect over another 2 week period. This agent is not currently approved for topical application. FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. A search of the National Library of Medicine National Institute of Health database demonstrated no high quality human studies evaluating the safety and efficacy of this medication through dermal patches or topical administration. Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. The guidelines support the use of topical salicylates. The efficacy of this medication was not reported. The medical guidelines do not support the use of compounded topical analgesics. Furthermore, the request does not indicate a frequency for the medication. The clinical information submitted for review does not provide evidence to justify continued use. Therefore, this request is not medically necessary.

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

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Ketoprofen, Cyclobenzaprine Page(s): 111-112, 41.

**Decision rationale:** The decision for Ketoprofen/Cyclobenzaprine/Lidocaine 10%/3%/5% (120gm) is not medically necessary. The California Medical Treatment Utilization Schedule Guidelines indicate that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety. The guidelines primarily recommend topical analgesics for

neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least 1 drug (or drugs class) that is not recommended is not recommended. Ketoprofen is not currently FDA approved for topical application. The guidelines do not recommend the topical use of cyclobenzaprine as a topical muscle relaxant, as there is no evidence for use of any other muscle relaxant as a topical product. The addition of cyclobenzaprine to other agents is not recommended. The medical guidelines do not support the use of Ketoprofen or Cyclobenzaprine as a topical analgesic. Furthermore, the request does not indicate a frequency for the medication. The clinical information submitted for review does not provide evidence to justify continued use. Therefore, this request is not medically necessary.

**Chiropractic therapy 1 week x 4 weeks:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 58-60.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Manual Therapy Page(s): 58-59.

**Decision rationale:** The decision for chiropractic therapy 1 week x 4 weeks is not medically necessary. The California Medical Treatment Utilization Schedule states that manual therapy and manipulation is recommended for chronic pain if caused by musculoskeletal conditions. For the low back, therapy is recommended initially in a therapeutic trial of 6 sessions, and with objective functional improvement, a total of up to 18 visits over 6 to 8 weeks may be appropriate. Treatment for flare ups requires a need for reevaluation of prior treatment success. Treatment is not recommended for the ankle and foot, carpal tunnel syndrome, the forearm, wrist, or hand or knee. If chiropractic treatment is going to be effective, there should be some outward sign of subjective or objective improvement within the first 6 visits. Treatment beyond 4 to 6 visits should be documented with objective improvement in function. The maximum duration is 8 weeks, and at 8 weeks, 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. The physical examination dated 10/21/2014 was handwritten and illegible. Pertinent information may not have been reported. There were previous chiropractic progress notes submitted for review to show objective functional improvement. It is unknown how many visits the injured worker had of chiropractic treatments. The clinical information submitted for review does not provide evidence to justify the decision for chiropractic therapy 1 week x 4 weeks. Therefore, this request is not medically necessary.