

<b>Case Number:</b>	CM14-0085894		
<b>Date Assigned:</b>	08/08/2014	<b>Date of Injury:</b>	11/18/1997
<b>Decision Date:</b>	11/20/2014	<b>UR Denial Date:</b>	05/15/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/09/2014

### 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 Physical Medicine and Rehabilitation 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 patient is a who was injured on 11/18/1997 when he was involved in a motor vehicle accident and felt a sharp pull in his upper back radiating to his lower back. Prior treatment history has included chiropractic therapy, acupuncture, and physical therapy. Progress report dated 02/04/2014 states the patient presented with complaints of pain to his low back and radiates to the mid center. The patient explained he is unable to perform physical activities without difficulty. On exam, range of motion of the lumbar spine revealed flexion to 20; extension to 05; right lateral bending to 05; and left lateral bending to 05. Straight leg raise is positive bilaterally as well as Kemp's test. He is recommended for acupuncture treatments to the lumbar spine twice a week for 4 weeks; chiropractic manipulation to the lumbar spine twice a week for 4 weeks and physical therapy to the lumbar spine twice a week for 4 weeks to improve range of motion and increase strength. Progress report dated 04/01/2014 states the patient complained of low back pain radiating to the right lower extremity with numbness and tingling rated as an 8/10. He rated his pain as an 8/10 without medications and with medications a 5/10. He reported topical creams and patches decrease his pain and increase his sleep. On exam, the lumbar spine range of motion revealed flexion to 35; extension to 5; right lateral flexion to 10; and left lateral flexion to 10. Straight leg raise and femoral stretch are positive bilaterally. There is tenderness to palpation over the lumbar spine with spasm. Sensation is decreased in the right lower extremity at L5-S1. He is diagnosed with lumbar radiculopathy, lumbar disc protrusion, and lumbar facet syndrome. The patient is given a prescription for Ibuprofen 800 mg, Norco 5/325, Cyclobenzaprine Hydrochloride 7.5 mg, Omeprazole 20 mg, Terocin pain patch Sentra AM 360, Sentra PM #60; Gabadone #60 and compounded topical creams. Prior utilization review dated 05/15/2014 states the request for Topical compound: Terocin 120mg Capsaicin 0.025%-Methyl Saicylate 25%-Menthol 10%-Lidocaine 2.5%, Apply 3-4 times a day; Topical

compound: Flurbi (NAP) Cream-LA 180gms-Flubiprofen 20%-Lidocaine 5%-Amitriptyline 4%, Apply 2-3 time a day; Topical compound: Gabacyclotram 180mg: Gabapentin 10%-Cyclobezaprine 6%- Tramadol 10%, Apply 2-3 times a day as needed; Xolindo 2% cream; Methoderm Gel #240; Theramine #990; Sentra AM #60; Gabadone #60; Acupuncture 2 X 4; Chiropractic manipulation 2 X 4; Physical Therapy 2x4.

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

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

**Topical compound: Terocin 120mg Capsaicin 0.025%-Methyl Saicylate 25%-Menthol 10%-Lidocaine 2.5%, Apply 3-4 times a day: 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 per CA MTUS guidelines, topical analgesics are "recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." In this case, this patient has a chronic lower back pain radiating into left lower extremity with numbness and tingling. The guidelines indicate that topical Lidocaine is recommended in the formulation of a dermal patch for neuropathic pain. No other commercially approved topical formulations of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Further guidelines indicate that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Thus, the request for Topical compound: Terocin 120mg Capsaicin 0.025%-Methyl Saicylate 25%-Menthol 10%-Lidocaine 2.5%, Apply 3-4 times a day is not medically necessary and non-certified.

**Topical compound: Flurbi (NAP) Cream-LA 180gms-Flubiprofen 20%-Lidocaine 5%-Amitriptyline 4%, Apply 2-3 time a day: 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 per CA MTUS guidelines, topical analgesics are "recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." In this case, this patient has a chronic lower back pain radiating into left lower extremity with numbness and tingling. The guidelines indicate that topical Lidocaine is recommended in the formulation of a dermal patch for

neuropathic pain. No other commercially approved topical formulations of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Further guidelines indicate that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Thus, the request for Topical compound: Flurbi (NAP) Cream-LA 180gms-Flubiprofen 20%-Lidocaine 5%-Amitriptyline 4%, Apply 2-3 times a day is not medically necessary and non-certified.

**Topical compound: Gabacyclotram 180mg: Gabapentin 10%-Cyclobezaprine 6%-Tramadol 10%, Apply 2-3 times a day as needed: 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 per CA MTUS guidelines, topical analgesics are "recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." In this case, this patient has a chronic lower back pain radiating into left lower extremity with numbness and tingling. The guidelines indicate that there is no peer-reviewed literature to support use of topical Gabapentin. Further guidelines indicate that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Thus, the request for Topical compound: Gabacyclotram 180mg: Gabapentin 10%-Cyclobezaprine 6%- Tramadol 10%, Apply 2-3 times a day as needed is not medically necessary and non-certified.

**Xolindo 2% cream: 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 based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Lidoderm® (lidocaine patch)

**Decision rationale:** As per CA MTUS guidelines, topical analgesics are "recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." In this case, this patient has a chronic lower back pain radiating into left lower extremity with numbness and tingling. Xolindo contains Lidocaine Hydrochloride and the guidelines indicate that topical Lidocaine is recommended in the formulation of a dermal patch for neuropathic pain. No other commercially approved topical formulations of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Thus, the request for Xolindo 2% cream is not medically necessary and appropriate.

**Menthoderm Gel #240: 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 based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG), PAIN, TOPICAL ANALGESICS

**Decision rationale:** As per CA MTUS guidelines, topical analgesics are "recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." In this case, this patient has a chronic lower back pain radiating into left lower extremity with numbness and tingling. Mentoderm contains Methyl Salicylate 15% and Menthol 10%. As per CA MTUS guidelines, topical NSAIDs for treatment of the spine, hip or shoulder is not recommended. This patient has chronic neuropathic pain and topical NSAIDs are not recommended as there is no evidence to support use. Thus, the request for Mentoderm Gel #240 cream is not medically necessary and appropriate.

**Theramine #990: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**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

**Decision rationale:** CA MTUS guideline is silent regarding this request. As per ODG, Theramine is a medical food "which is formulated to be consumed or administered internally 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." The medical records provided for review do not provide any clinical documentation to indicate its use, benefit, or clinical response. There is no evidence that the patient has distinctive nutritional requirements. There is no documentation of efficacy with regard to decrease in rate of pain or increase in objective functional improvement based on its prior use. Thus, the request for Theramine #990 is not medically necessary and appropriate.

**Sentra AM #60: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**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

**Decision rationale:** CA MTUS guideline is silent regarding this request. Sentra AM is a medical food. As per ODG, medical food is formulated to be consumed or administered internally 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." Further ODG indicates that Sentra AM is intended for use in management of sleep disorders associated with depression that is a proprietary blend of Choline Bitartrate, Glutamate, and 5-Hydroxytryptophan. The medical records provided for review do not provide any clinical documentation to indicate its use, benefit, or clinical response. There is no evidence that the patient has distinctive nutritional requirements. There is no documentation of efficacy with regard to decrease in rate of pain or increase in objective functional improvement based on its prior use. Thus, the request for Sentra AM #60 is not medically necessary and appropriate.

**Sentra PM #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**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

**Decision rationale:** CA MTUS guideline is silent regarding this request. Sentra PM is a medical food. As per ODG, medical food is formulated to be consumed or administered internally 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." Further ODG indicates that Sentra PM is intended for use in management of sleep disorders associated with depression that is a proprietary blend of Choline Bitartrate, Glutamate, and 5-hydroxytryptophan. The medical records provided for review do not provide any clinical documentation to indicate its use, benefit, or clinical response. There is no evidence that the patient has distinctive nutritional requirements. There is no documentation of efficacy with regard to decrease in rate of pain or increase in objective functional improvement based on its prior use. Thus, the request for Sentra PM #60 is not medically necessary and appropriate.

**Gabadone #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**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

**Decision rationale:** CA MTUS guideline is silent regarding this request. Gabadone is a medical food. As per ODG, medical food is formulated to be consumed or administered internally 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." Further ODG indicates that Gabadone 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. The medical records provided for review do not provide any clinical documentation to indicate its use, benefit, or clinical response. There is no evidence that the patient has distinctive nutritional requirements. There is no documentation of efficacy with regard to decrease in rate of pain or increase in objective functional improvement based on its prior use. Thus, the request for Gabadone #60 is not medically necessary and appropriate.

**Acupuncture 2 X 4:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Acupuncture Treatment Guidelines. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG), BACK, ACUPUNCTURE

**Decision rationale:** As per CA MTUS guidelines, 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. Further guidelines indicate that acupuncture can be used to reduce pain, reduce inflammation, increase blood flow, increase range of motion, decrease the side effect of medication-induced nausea, promote relaxation in an anxious patient, and reduce muscle spasm. In this case, this patient has a chronic lower back pain radiating into left lower extremity with numbness and tingling, 8-9/10. This patient has been treated with acupuncture in the past but there is no documentation of objective functional improvement, reduction in pain level or reduction in medication usage with the previous treatment provided. Thus, the request for acupuncture 2x4 is not medically necessary and appropriate.

**Chiropractic manipulation 2 X 4:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines MANUAL THERAPY & MANIPULATION Page(s): 58-60. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Low Back - Lumbar & Thoracic, Manipulation

**Decision rationale:** As per CA MTUS guidelines, Manual Therapy is widely used in the treatment of musculoskeletal pain. The guidelines recommend an initial trial of 6 visits over 2 weeks, with evidence of objective functional improvement, In this case, this patient has a chronic lower back pain radiating into left lower extremity with numbness and tingling, 8-9/10. This patient has been treated with chiropractic treatment in the past, but there is no documentation of objective functional improvement or reduction in pain level with the previous treatment provided. Thus, the request for chiropractic 2x4 (8 visits) is not medically necessary and appropriate.

**Physical Therapy 2x4:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines PHYSICAL MEDICINE Page(s): 98-99. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Back, Physical therapy of the Lumbar guidelines

**Decision rationale:** According to the CA MTUS guidelines, physical medicine is based on the philosophy that therapeutic exercise and/or activity are beneficial for restoring flexibility, strength, endurance, function, range of motion, and can alleviate discomfort. In this case, this patient has a chronic lower back pain radiating into left lower extremity with numbness and tingling, 8-9/10. This patient has been treated with physical therapy in the past, but there is no documentation of objective functional improvement or reduction in pain level with the previous treatment provided. Thus, the request for physical therapy 2x4 (8 visits) is not medically necessary and appropriate.