

<b>Case Number:</b>	CM14-0102950		
<b>Date Assigned:</b>	08/04/2014	<b>Date of Injury:</b>	06/27/2012
<b>Decision Date:</b>	10/07/2014	<b>UR Denial Date:</b>	06/09/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/03/2014

### 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 Nevada. 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 records, presented for review, indicate that this 41-year-old individual was reportedly injured on June 27, 2012. The mechanism of injury was noted as a trip and fall type event. The most recent progress note, dated April 28, 2014, indicated that there were ongoing complaints of low back and lower extremity pains. The physical examination demonstrated the lumbar spine examination to be unchanged. There was tenderness to palpation, a decreased range of motion of lumbar spine, slight weakness in the extensor hallucis longus, and an absent Achilles tendon reflex. Diagnostic imaging studies objectified degenerative disc disease, disc desiccation, a posterior bulge of the proximal 4 mm and foraminal stenosis. Previous treatment included multiple medications, physical therapy, conservative care and pain management interventions. A request had been made for multiple medications and was not certified in the pre-authorization process on June 9, 2014.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flurbi (NAP) Cream LA (flurbiprofen 20%, lidocaine 5%, and amitriptyline 4%) 180gms:**  
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:** The California MTUS guidelines state that topical analgesics are "largely experimental," and that "any compound product, that contains at least one drug (or drug class), that is not recommended, is not recommended". Additionally, topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Furthermore, there is no indication for a topical muscle relaxant this far out from the date of injury. As such, this request is not considered medically necessary.

**GabaCycloTram 180gms (gabapentin 10%, cyclobenzaprine 6%, and tramadol 10%):**  
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:** The California MTUS guidelines state that topical analgesics are "largely experimental," and that "any compound product, that contains at least one drug (or drug class), that is not recommended, is not recommended". Additionally, topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Furthermore, there is no indication for a topical muscle relaxant this far out from the date of injury. As such, this request is not considered medically necessary.

**Genicin (glucosamine sodium, 500mg, #90):** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate) Page(s): 50.

**Decision rationale:** The California MTUS chronic pain guidelines support glucosamine and chondroitin sulfate as an option, given the low risk in patients with moderate knee osteoarthritis. Review, of the available medical records, fails to document a diagnosis or imaging studies demonstrating osteoarthritis of the knees. Therefore, based on the incomplete clinical information presented for review, this request is not medically necessary.

**Somnicin (Melatonin 2mg, 5-HTP 50mg, L-Tryptophan 100mg, Pyridoxine 10mg, and Magnesium 50mg):** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MD Consult Drug Monograph

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications; Vitamins Page(s): (Electronically Cited).

**Decision rationale:** Somnicin is a preparation of melatonin, 5-HTP, L tryptophan, pyridoxine, and magnesium. This medication is considered a nutritional supplement and is not directly address by the California MTUS Guidelines. However, the ACOEM Practice Guidelines specifically recommends against the use of complementary and alternative treatments including dietary supplements for the management of chronic pain. As such, the requested medication is considered not medically necessary.

**Terocin 240ml (capsaicin 0.025%, methyl salicylate 25%, menthol 10% and lidocaine 2.5%):** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate topicals and Topical Analgesics Page(s): 105, 112.

**Decision rationale:** The California MTUS guidelines support the use of topical lidocaine for individuals with neuropathic pain that have failed treatment with first-line therapy including antidepressants or anti-epilepsy medications. Review, of the available medical records, fails to document signs or symptoms consistent with neuropathic pain or a trial of first-line medications. As such, this request is not medically necessary.

**Terocin Pain Patches (#20):** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate topicals and Topical Analgesics Page(s): 105, 112.

**Decision rationale:** The California MTUS guidelines support the use of topical lidocaine for individuals with neuropathic pain that have failed treatment with first-line therapy including antidepressants or anti-epileptic medications. Review, of the available medical records, fails to document signs or symptoms consistent with neuropathic pain or a trial of first-line medications. As such, this request is not medically necessary.

**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 Salicylate topicals Page(s): 105.

**Decision rationale:** According to the California Chronic Pain Medical Treatment Guidelines, the only recommended topical analgesic agents are those including anti-inflammatories, lidocaine, or capsaicin. There is no peer-reviewed evidence-based medicine to indicate that any other compounded ingredients have any efficacy. For this reason, this request for Mentherm is not medically necessary.

**Xolido Cream (2%):** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (lidocaine patch), Topical Analgesics Page(s): 56-57, 112.

**Decision rationale:** The California MTUS guidelines support the use of topical lidocaine for individuals with neuropathic pain that have failed treatment with first-line therapy including antidepressants or anti-epileptic medications. Based on the clinical documentation provided, the claimant is noted of ongoing complaints of pain; however, there is no noted efficacy or utility with the previous use of this preparation. As such, the request is considered 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 ODG-TWC Pain Procedure Summary.

**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, updated September 2014

**Decision rationale:** This is noted to be a medical food from a proprietary distributor in the Southern California area. The California MTUS Guidelines and the ACOEM Practice Guidelines do not address this type of product. The parameters noted in the Official Disability Guidelines were applied. There are no high quality peer-reviewed literature citations to support this concoction. Therefore, the medical necessity has not been established.

**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-TWC Pain Procedure Summary.

**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, updated September 2014

**Decision rationale:** This is noted as a medical food. Sentra AM is a proprietary blend of neurotransmitters and neurotransmitter precursors (choline bitartrate, L-glutamate); activators of precursor utilization (acetyl-L-carnitine, L-glutamate, cocoa powder); polyphenolic antioxidants (cocoa powder, grape-seed extract, hawthorn berry); an adenosine antagonist (cocoa powder); and an inhibitor of the attenuation of neurotransmitter production associated with precursor administration (grape-seed extract). The California MTUS Guidelines and the ACOEM Practice Guidelines do not address this type of product. However, as outlined in the Official Disability Guidelines, there are no double blinded, peer-reviewed literature citations to support this endeavor. Therefore, the medical necessity for this preparation has not been established.

**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-TWC Pain Procedure Summary.

**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, updated September 2014

**Decision rationale:** This is noted as a medical food. Sentra AM is a proprietary blend of neurotransmitters and neurotransmitter precursors (choline bitartrate, L-glutamate); activators of precursor utilization (acetyl-L-carnitine, L-glutamate, cocoa powder); polyphenolic antioxidants (cocoa powder, grape-seed extract, hawthorn berry); an adenosine antagonist (cocoa powder); and an inhibitor of the attenuation of neurotransmitter production associated with precursor administration (grape-seed extract). The California MTUS Guidelines and the ACOEM Practice Guidelines do not address this type of product. However, as outlined in the Official Disability Guidelines, there are no double blinded, peer-reviewed literature citations to support this endeavor. Therefore, the medical necessity for this preparation has not been established.

**GABAdone (#60): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG-TWC Pain Procedure Summary.

**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, updated September 2014

**Decision rationale:** This combination is a medical food that includes GABA. The California MTUS Guidelines and the ACOEM Practice Guidelines do not address this type of product. The parameters noted in the Official Disability Guidelines were applied. There is no literature presented to support the medical necessity of this proprietary food.

**Trepadone (#90): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG-TWC Pain Procedure Summary.

**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, updated September 2014

**Decision rationale:** This combination is a medical food that includes GABA. It is noted that the MTUS and ACOEM guidelines do not address this item. The parameters noted in the Official Disability Guidelines were applied. There is no literature presented to support the medical necessity of this proprietary food.