

<b>Case Number:</b>	CM15-0008267		
<b>Date Assigned:</b>	01/23/2015	<b>Date of Injury:</b>	08/10/2011
<b>Decision Date:</b>	03/13/2015	<b>UR Denial Date:</b>	01/12/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/14/2015

### 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: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

### 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 49 year old female was injured 8/10/11 in an industrial accident. She complains of persistent neck, low back and residual pain in the right shoulder. Her overall pain intensity without medications is 7/10 and with medications is 5-6/10. Current medications include Tramadol, Omeprazole and Gabapentin and these are helpful in relieving her pain. In addition to her medications she's had post-operative physical therapy. Diagnostic evaluations included right shoulder MRI's (2011, 2012. Diagnoses include cervical and lumbar spine herniated nucleus pulposus; right shoulder impingement syndrome/ tendinitis; status post right shoulder surgery (4/24/14) and status post lap band procedure. On 1/12/15 Utilization Review non-certified Urinalysis for toxicology based on lack of rationale to support the test; Flurbiprofen/ capsaicin/ Camphor #129 grams; Ketoprofen/ Cyclobenzaprine/ Lidocaine #120 grams based on lack of support for using topical creams over oral medications; Theramine; Sentra AM # 60; gabadone # 60; Sentra PM # 60 based on lack of evidence of a nutritional deficiency. Guidelines referenced were MTUS; MTUS Topical Analgesics and ODG respectively.

### 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 Opioids, steps to avoid misuse/addiction. Decision based on Non-MTUS Citation Official Disability Guidelines, (ODG) Pain Chapter, (UDT)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Drug Testing, page 43.

**Decision rationale:** Per MTUS Guidelines, urine drug screening is recommended as an option before a therapeutic trial of opioids and for on-going management to differentiate issues of abuse, addiction, misuse, or poor pain control; none of which apply to this patient who has been prescribed long-term opioid this chronic injury. Presented medical reports from the provider have unchanged chronic severe pain symptoms with unchanged clinical findings of restricted range and tenderness without acute new deficits or red-flag condition changes. Treatment plan remains unchanged with continued medication refills without change in dosing or prescription for chronic pain. There is no report of aberrant behaviors, illicit drug use, and report of acute injury or change in clinical findings or risk factors to support frequent UDS. Documented abuse, misuse, poor pain control, history of unexpected positive results for a non-prescribed scheduled drug or illicit drug or history of negative results for prescribed medications may warrant UDS and place the patient in a higher risk level; however, none are provided. The Urinalysis for toxicology is not medically necessary and appropriate.

**Flurbiprofen/Capsaicin/Camphor 10/0.025% 2% 1% #120gm: 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:** Per MTUS Chronic Pain Guidelines, the efficacy in clinical trials for topical analgesic treatment modality has been inconsistent and most studies are small and of short duration. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. There is little evidence to utilize topical compound analgesic over oral NSAIDs or other pain relievers for a patient with spinal and multiple joint pain without contraindication in taking oral medications. Submitted reports have not adequately demonstrated the indication or medical need for this topical analgesic for this chronic injury without documented functional improvement from treatment already rendered. The Flurbiprofen/Capsaicin/Camphor 10/0.025% 2% 1% #120gm is not medically necessary and appropriate.

**Ketoprofen/Cyclobenzaprine/Lidocaine 10% 3% 5% # 120gm: 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:** Per MTUS Chronic Pain Guidelines, the efficacy in clinical trials for topical analgesic treatment modality has been inconsistent and most studies are small and of short duration. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. There is little evidence to utilize topical compound analgesic over oral NSAIDs or other pain relievers for a patient with spinal and multiple joint pain without contraindication in taking oral medications. Submitted reports have not adequately demonstrated the indication or medical need for this topical analgesic to include a compounded NSAID and muscle relaxant over oral formulation for this chronic injury without documented functional improvement from treatment already rendered. It is also unclear why the patient is being prescribed 2 concurrent anti-inflammatories, topical Flurbiprofen and topical compounded Ketoprofen posing an increase risk profile without demonstrated extenuating circumstances and indication. Guidelines do not recommend long-term use of NSAID without improved functional outcomes attributable to their use. The Ketoprofen/Cyclobenzaprine/Lidocaine 10% 3% 5% # 120gm is not medically necessary and appropriate.

**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 Chapter, Teramine

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Chapter, page 136-137, on COMPLEMENTARY, ALTERNATIVE TREATMENTS, OR DIETARY SUPPLEMENT.

**Decision rationale:** Per MTUS Treatment Guidelines, Theramine is classified as medical food containing products that are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The provider has not documented any nutritional deficiency or medical conditions that would require nutritional supplementation as it relates to this patient's musculoskeletal injuries. The Theramine # 90 is not medically necessary and appropriate.

**Sentra AM # 60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://marvistahealthcenter.com/medicalfoods/SentraAMProductMonograph.pdf>

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medical Food, pages 758-760

**Decision rationale:** Sentra is a medical food supplement in alternative medicine. MTUS is silent on its use; however, ODG states to be considered, the product must, at a minimum, meet the following criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision. Based on a review of the available medical reports, there is no evidence to suggest that this patient has any type of condition to warrant the investigational use of this supplement. Senna is not medically necessary and appropriate. The provider has not provided any documentation of medical necessity consistent with evidence-based, peer-reviewed, nationally recognized treatment guideline for Senna or any other alternative supplements. Absent medical necessity, certification cannot be granted. The request for Sentra AM # 60 is not medically necessary and appropriate.

**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 Chapter, GABAdone, Medical food section

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pain, Medical food, Gabadone, pages 729, 758-759

**Decision rationale:** Gabadone is a Medical Food product that provides amino acids, precursors to the neurotransmitters that have been depleted due to certain disease states or as a result of certain drug side effects. This Medical Food stimulates the body to produce the neurotransmitters that induce sleep, promote restorative sleep, and reduce snoring. Patients with sleep disorders frequently experience a nutritional deficiency of tryptophan and choline. Patients with sleep disorders frequently show reduced blood levels of serotonin and 5-hydroxytryptophan. Choline deficiency has also been associated with sleep disorders, particularly those associated with sleep apnea syndromes. Gabadone aids in the nutritional management of serotonin, acetylcholine and GABA production deficiencies in patients with sleep disorders and anxiety. Gabadone is considered a medical food, used for the treatment of disease states with known nutritional deficiencies. Based on a review of the available medical reports, there is no evidence to suggest that this patient has any type of nutritional deficiency. According to the FDA website, “specific requirements for the safety or appropriate use of medical foods have not yet been established”. Also per the FDA Gabadone are not FDA approved for any indication. Therefore, the use of any medical food or medical food combination would be considered experimental. Guidelines state this formulated food may be recommended for specific dietary management of a disease or condition for which distinctive nutritional requirements have been established by medical evaluation based on scientific principles. The provider had not documented the indication, clinical findings, diagnoses or medical necessity consistent with evidence-based, peer-reviewed, nationally recognized treatment guideline for this medical food. The Gabadone # 60 is not medically necessary and appropriate.

**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 Chapter, Sentra PM

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medical Food, pages 758-760

**Decision rationale:** Sentra is a medical food supplement in alternative medicine. MTUS is silent on its use; however, ODG states to be considered, the product must, at a minimum, meet the following criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision. Based on a review of the available medical reports, there is no evidence to suggest that this patient has any type of condition to warrant the investigational use of this supplement. Senna is not medically necessary and appropriate. The provider has not provided any documentation of medical necessity consistent with evidence-based, peer-reviewed, nationally recognized treatment guideline for Senna or any other alternative supplements. Absent medical necessity, certification cannot be granted. The request for Sentra PM # 60 is not medically necessary and appropriate.