

<b>Case Number:</b>	CM14-0085934		
<b>Date Assigned:</b>	08/15/2014	<b>Date of Injury:</b>	09/12/2003
<b>Decision Date:</b>	09/29/2014	<b>UR Denial Date:</b>	05/08/2014
<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 Anesthesiology, has a subspecialty in Pain 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:

A 57 year old female injured worker with date of injury 9/12/03 with related shoulder pain. Per progress report dated 11/18/13, the injured worker complained of right shoulder pain rated 6-7/10 in intensity, and right wrist pain with numbness and tingling rated at 8/10. Pain without medications was rated 10/10 and 4-5/10 with medications. Medications allowed for increased ability to do chores, increased sleep, and topicals medications decrease the need for oral medications. On examination, right wrist range of motion was decreased in all planes with 4/5 strength, tender right wrist, and right upper extremity sensation was decreased over C8. Imaging studies were not available for review. Treatment to date has included injections, acupuncture, physical therapy, and medication management. The date of UR decision was 1/17/14.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Soma 350mg #90:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines CARISOPRODOL Page(s): 29.

**Decision rationale:** MTUS Guidelines state Soma is not recommended. This medication is not indicated for long-term use. Carisoprodol is a commonly prescribed, centrally acting skeletal muscle relaxant whose primary active metabolite is meprobamate (a schedule-IV controlled substance). Carisoprodol is now scheduled in several states but not on a federal level. It has been suggested that the main effect is due to generalized sedation and treatment of anxiety. Abuse has been noted for sedative and relaxant effects. In regular abusers the main concern is the accumulation of meprobamate. Carisoprodol abuse has also been noted in order to augment or alter effects of other drugs. As this medication is not recommended by MTUS, it is not medically necessary.

**Ambien 10mg #30:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. 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 Official Disability Guidelines (ODG) Pain (Chronic), Zolpidem (Ambien).

**Decision rationale:** With regard to Ambien, the ODG Guidelines state Zolpidem is a prescription short-acting non-benzodiazepine hypnotic, which is approved for the short-term (usually two to six weeks) treatment of insomnia. Proper sleep hygiene is critical to the individual with chronic pain and often is hard to obtain. Various medications may provide short-term benefit. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit-forming, and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term. The documentation submitted for review does not contain information regarding sleep onset, sleep maintenance, sleep quality, and next-day functioning. It was not noted whether simple sleep hygiene methods were tried and failed. The request is not medically necessary.

**Norco 10/325mg #180:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines OPIOIDS Page(s): 78, 91.

**Decision rationale:** Documentation of pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug related behaviors are criteria necessary in the on-going management of opioids. The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. Review of the available medical records reveals no documentation to support the medical necessity of norco nor any documentation addressing the specified criteria. Specifically, the notes do not appropriately

review and document pain relief, functional status improvement, appropriate medication use, or side effects. Furthermore, efforts to rule out aberrant behavior are necessary to assure safe usage and establish medical necessity. There is no documentation comprehensively addressing this concern in the records available for review. As MTUS recommends to discontinue opioids if there is no overall improvement in function, the request is not medically necessary.

**Terocin pain patch box of 10 patches:** 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): 25, 60, 105, 111-113.

**Decision rationale:** Terocin is a compound product that is comprised of capsaicin, lidocaine, menthol, methyl salicylate, and boswellia serrata. Per MTUS Guidelines, there are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. Terocin patches contain menthol. Guidelines provide no evidence-based recommendations regarding the topical application of menthol. A lack of endorsement, and a lack of mention, implies a lack of recommendation, or a status equivalent to not recommended. Guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended for use. Since menthol is not medically indicated, then the overall product is not indicated per MTUS Guidelines. As such, the request is not medically necessary.

**Menthoderm Gel #240:** Upheld

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

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

**Decision rationale:** Menthoderm is comprised of methyl salicylate and menthol. MTUS Guidelines provide no evidence-based recommendations regarding the topical application of menthol. A lack of endorsement, and a lack of mention, implies a lack of recommendation, or a status equivalent to not recommended. Since menthol is not medically indicated, then the overall product is not indicated per MTUS Guidelines. As such, 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 Chapter.

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

**Decision rationale:** Theramine is a medical food that is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. There is no high quality peer-reviewed literature that suggests the use of this product for the patient's current diagnoses. Theramine is not recommended by the ODG Guidelines, and is therefore 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 Chapter.

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

**Decision rationale:** ODG Guidelines say medical foods are not considered medically necessary except in those cases in which the patient has a medical disorder, disease or condition for which there are distinctive nutritional requirements. The records submitted for review do not include evidence that the injured worker has any distinctive nutritional requirements. The 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 Chapter.

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

**Decision rationale:** ODG Guidelines states that medical foods are not considered medically necessary except in those cases in which the patient has a medical disorder, disease or condition for which there are distinctive nutritional requirements. The records submitted for review do not include evidence that the injured worker has any distinctive nutritional requirements, nor have they addressed the injured worker's sleep hygiene. The 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 Chapter.

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

**Decision rationale:** GABAdone is a medical food that 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 ODG Guidelines state that this product is not recommended, and the request is therefore not medically necessary.

**Terocin 240ml: Capsaicin 9.25%-Menthol salicylate 25%-Menthol 10%-Lidocaine 2.5%:**  
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): 25, 60, 105, 111-113.

**Decision rationale:** Terocin is a compound product that is comprised of capsaicin, lidocaine, menthol, methyl salicylate, and boswellia serrata. Per MTUS Guidelines, there are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. Terocin patches contain menthol. Guidelines provide no evidence-based recommendations regarding the topical application of menthol. A lack of endorsement, and a lack of mention, implies a lack of recommendation, or a status equivalent to not recommended. Guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended for use. Since menthol is not medically indicated, then the overall product is not indicated per MTUS Guidelines. As such, the request is not medically necessary.

**Flurbi NAP cream-LA 180gms; Flurbiprofen 20%-Lidocaine5%-Amitriptyline 4%:**  
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): 111-112.

**Decision rationale:** The MTUS Chronic Pain Medical Treatment Guidelines state that topical medications are 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. These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended for use. Because lidocaine is not indicated, the compound is not recommended. This request is not medically necessary.

**Gabacyclotram 180grams Gabapentin 10%-Cyclobenzaprine 6%-Tramadol 10%:** 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): 111-113.

**Decision rationale:** There is no evidence for use of any muscle relaxant as a topical product. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended for use. MTUS Guidelines state that topical Gabapentin is not recommended. As such, the request is not medically necessary.

**Genicin #90: Glucosamine sodium 500mg:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines GLUCOSAMINE Page(s): 50.

**Decision rationale:** Genicin contains glucosamine. The MTUS Guidelines state glucosamine is recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. However, the documentation submitted for review contains no evidence of arthritis pain. The request is not medically necessary.

**Somnicin #30: Melatonin 2mg-5HTP 50mg-L Tryptophan 100mg-Pyridoxine 10mg-Magnesium 50mg:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG) PAIN (CHRONIC) INSOMNIA TREATMENT.

**Decision rationale:** Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve in a 7 to 10 day period may indicate a psychiatric and/or medical illness. Primary insomnia is generally addressed pharmacologically. Secondary insomnia may be treated with pharmacological and/or psychological measures. The specific component of insomnia should be addressed: (a) Sleep onset; (b) Sleep maintenance; (c) Sleep quality; and (d) Next-day functioning. The documentation submitted for review does not provide information regarding sleep onset, sleep maintenance, sleep quality or next day functioning to support the medical necessity of a sleep aid. The request is not medically necessary.

**Drug Screen:** Overturned

**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.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines OPIOIDS Page(s): 87.

**Decision rationale:** MTUS Chronic Pain guidelines recommend random drug screening for patients to avoid the misuse of opioids, particularly for those at high risk of abuse. The last urine drug screen was authorized on 10/21/13. The results of that testing are not included in the documentation submitted for review. The request is medically necessary to assure safe and appropriate medication usage.