

<b>Case Number:</b>	CM14-0076013		
<b>Date Assigned:</b>	08/08/2014	<b>Date of Injury:</b>	07/19/2013
<b>Decision Date:</b>	10/15/2014	<b>UR Denial Date:</b>	05/20/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/23/2014

### 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 Georgia. 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 49 year old female who was injured on 08/30/2011. The mechanism of injury is unknown. The patient has been treated conservatively with physical therapy, medications, and chiropractic treatment. Toxicology report dated 03/05/2014 revealed negative results benzodiazepines, amphetamines, opiates, methamphetamines; and marijuana. Tramadol was reported as prescribed which was not detected by GC/MS. Progress report dated 04/01/2014 documented the patient to have complaints of constant neck pain radiating to the upper extremities with numbness and tingling rating the pain as a 2-5/10. She also reported constant low back pain radiating to the lower extremities with numbness and tingling rated as 4/10. She noted her pain with medications is a 2/10 and without medications is an 8/10. The topical analgesics decrease her pain and she is able to walk longer, increase sleep, and decrease oral medications. Objective findings on exam revealed cervical range of motion exhibits flexion to 45; extension to 50; right lateral flexion to 45; left lateral flexion to 30; right rotation to 60; left rotation to 50. There is tenderness to palpation of the cervical spine. Lumbar range of motion revealed flexion to 45; extension to 10; right lateral flexion to 15; and left lateral flexion to T5. Straight leg raise is positive bilaterally. There was tenderness of the lumbar spine as well with decreased sensation of the left upper extremity at C6-C8. Diagnoses are cervical radiculopathy and lumbar radiculopathy. The treatment and plan included Terocin pain patch #20; Methoderm gel #240; Xolindo 2% cream; Theramine #90; Sentra AM #60 and Sentra PM #60 and Gabadone #60; TENS unit 30 day trial; as well as other topical analgesics which are listed below. It is noted the efficacy of this treatment plan will be reviewed upon patient's next visit. On noted dated 05/20/2014, the patient described pain in the back with radiation to the bottom of her left foot. She rated the pain as a 6-7/10 and is moderate to severe. She is noted as taking three medications which are not listed.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Tens unit 30 day trial with supplies:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines electrotherapy-transcutaneous electrical nerve stimulation (TENS u.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TENS, chronic pain (transcutaneous electrical nerve stimulation).

**Decision rationale:** As per CA MTUS guidelines, TENS unit is not recommended as a primary treatment modality, but a one-month home-based TENS trial may be considered as a noninvasive conservative option, if used as an adjunct to a program of evidence-based functional restoration. In this case, the patient continues to have neck and lower back pain radiating to upper and lower extremities associated with numbness and tingling sensation. The diagnosis includes cervical radiculopathy and lumbar radiculopathy. The conservative treatment thus far includes physical therapy, chiropractic treatment and medications. The guidelines indicate that the criteria for use of TENS unit should be there is evidence that other appropriate pain modalities have been tried and failed. However, the progress report dated 04/01/2014 indicates that patient is considering lumbar spine injection. As such, since the patient is still not tried and failed other appropriate pain modalities, the guidelines criteria have not met, and the request for 30-day trial of TENS unit with supplies is not medically necessary at this time.

**Terocin lotion 240 ml-terodoloricin-capsaicin 0.025%-Methyl Salicilate 25% Menthol 10% Lidocaine 2.5%:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines medications for chronic pain: compounded medications.

**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 chronic neuropathic pain. 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 Terocin lotion 240 ml-Terodoloricin-Capsaicin 0.025%-Methyl Salicilate 25% Menthol 10% Lidocaine 2.5% is not medically necessary and non-certified.

**Flurbi (NAP) cream LA (flurbiprofen 20% Lidocaine 5% amitriptyline 4%) 180 gms:**  
Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines medications for chronic pain: compounded medications.

**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 Chapter, 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 chronic neuropathic pain. 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 Flurbi (NAP) cream LA (Flurbiprofen 20% Lidocaine 5% Amitriptyline 4%) 180 gms is not medically necessary and non-certified.

**Gabacyclotram (gabapentin 10% cyclobenzaprine 6% tramadol 10%) 180 gms:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines medications for chronic pain: compounded medications.

**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 neuropathic pain. 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 Gabacyclotram (Gabapentin 10% Cyclobenzaprine 6% Tramadol 10%) 180 gms is not medically necessary and non-certified.

**Genecin (glucosamine 500 mg) #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate) Page(s): 50. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Glucosamine

**Decision rationale:** As per CA MTUS guidelines, Glucosamine is recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. In this case, this patient has neck and lower back pain radiating down the upper and lower extremities associated with numbness and tingling sensation. The patient is diagnosed with cervical and lumbar radiculopathy. The submitted records do not support the medical necessity for the use of this medication, and hence the request is non-certified.

**Somnicin (melatonin 2 mg, 5HTP 50 mg, L-tryptophan 100 mg, pyridoxine 10mg, magnesium 50mg) #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Insomnia Treatment; Melatonin; & Vitamin B

**Decision rationale:** CA MTUS guideline is silent regarding this request. Somnicin is comprised of Melatonin 2 mg, 5-HTP (5-hydroxytryptophan) 50 mg, L-tryptophan 100 mg, Vitamin B6 (pyridoxine) 10 mg, Magnesium 50 mg and is noted to be used for patients with insomnia and depression. The ODG noted vitamin B is not recommended. Vitamin B is frequently used for treating peripheral neuropathy but its efficacy is not clear. A recent meta-analysis concluded that there are only limited data in randomized trials testing the efficacy of vitamin B for treating peripheral neuropathy and the evidence is insufficient to determine whether vitamin B is beneficial or harmful. The ODG noted Melatonin is recommended in treating sleep disorder post-traumatic brain injury (TBI). The provider noted the employee had a score of 6 out of 24 on the Epworth Sleepiness Scale. Per the provided medical records, it did not appear the employee had significant insomnia or depression. Additionally, the guidelines do not recommend the use of vitamin B (which is part of the medication Somnicin) as its efficacy is unclear. Additionally, the guidelines recommend melatonin (which is a component of the medication Somnicin) in treating a sleep disorder post TBI. Per the provided documentation, it did not appear the patient experienced a TBI. The request for Somnicin is not medically necessary and appropriate.

**Xolindo 20% cream:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain.

**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 chapter, 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 neuropathic pain. Xolido 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 Xolido 20% cream is not medically necessary and appropriate.

**Menthoderm gel #240:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medication for chronic pain.

**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." 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 #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines-Pain Chapter-Medical Foods

**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:** 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. Thus, the request for Theramine #90 is not medically necessary and appropriate.

**Sentra AM #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines-Pain Chapter-Medical Foods

**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:** 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. Thus, the request for Sentra AM #60 is not medically necessary and appropriate.

**Sentra PM #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines-Pain Chapter-Medical Foods

**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:** 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. Thus, the request for Sentra PM #60 is not medically necessary and appropriate.

**Gabadone #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines-Pain Chapter-Medical Foods

**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. Thus, the request for Gabadone #60 is not medically necessary and appropriate.

**Follow up visits:** Overturned

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

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 303. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Office visits

**Decision rationale:** As per CA MTUS/ACOEM guidelines, "patients with potentially work-related low back complaints should have follow-up every three to five days by a midlevel practitioner or physical therapist who can counsel the patient about avoiding static positions, medication use, activity modification, and other concerns." As per ODG, "evaluation and management (E&M) outpatient visits to the offices of medical doctor(s) play a critical role in the proper diagnosis and return to function of an injured worker, and they should be encouraged." In this case, the patient is having neck and lower back pain radiating down the upper and lower extremities and lumbar spine injection is being considered. As such, the medical necessity for follow-up visit is established and the requested is certified.

**Urine drug screen:** 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 Drug Testing Page(s): 43. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Urine Drug Testing

**Decision rationale:** As per CA MTUS and ODG, urine drug testing is recommended as a tool to monitor compliance with prescribed substances and to assess for the use or the presence of illegal drugs. As per ODG, patients at "low risk" of addiction/aberrant behavior should be tested within six months of initiation of therapy and on a yearly basis thereafter. There is no reason to perform confirmatory testing unless the test is inappropriate or there are unexpected results. In this case, this patient had urine drug screening done on 02/05/2014 and 03/05/2014 and there is documentation that the patient is compliant with the medications. As such, the request for another urine drug screen is not medically necessary and appropriate at this time.