

<b>Case Number:</b>	CM14-0034910		
<b>Date Assigned:</b>	07/23/2014	<b>Date of Injury:</b>	01/09/2013
<b>Decision Date:</b>	09/24/2014	<b>UR Denial Date:</b>	02/20/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/20/2014

### 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, has a subspecialty in Neuromuscular Medicine and is licensed to practice in Maryland. 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 67 year old female with a work injury dated 1/9/13. The diagnoses include headache; cervical disc protrusion; cervical spondylosis; thoracic sprain/strain; lumbar sprain/strain; lumbar disc protrusion. Under consideration is a request for Terocin Pain Patch #20, Tramadol 150mg #60, Theramine #90, Trepadone # 120, Sentra AM #60, Sentra PM #60, GABAdone #60, and Methoderm Gel 120mg. There is a primary treating physician report dated 12/20/13 that states that the patient complains of frequent headaches. 7/10; constant neck pain. 7-8/10; constant mid back pain. 5/10: constant low back pain radiating to the right lower extremity with numbness and tingling. 8/10. Oral/topical medications - no side effects. On exam there is decreased cervical range of motion. The cervical Compression & Shoulder Depression positive on left. Tender cervical spine with spasms. Lumbar range of motion: flexion 30; extension 5; rt. Lateral flexion 10; lt. lateral flexion 10. The straight leg raise test is positive on right. Tender lumbar spine with spasms. The treatment plan included compounded medications. The patient was given a prescription for Tramadol 150mg #60, Theramine #90, Trepadone #120, Sentra AM #60, Sentra PM #60 and GABAdone #60, to be taken as directed. The patient was provided Terocin Pain Patch Box, which is a topical analgesic medication to be taken as directed for the treatment of minor aches and muscle pains and Methoderm gel 120mg, to be applied as directed. An 11/6/13 document states that the patient complains of occasional headaches, 6/10: constant neck pain, 7-8/10: constant mid back pain, 7/10: constant low back pain, 9/10. Oral/topical medications - no side effects. Pain without medications 9/10, with medications 6-7/10. Topicals - increase sleep, decrease pain. The patient was given a prescription for Tramadol 150mg #60, to be taken as directed. An 8/30/13 EMG/NCV indicated I. Moderate to severe

bilateral carpal tunnel syndrome.2. Right L5 radiculopathy. 3. There is no electrophysiological evidence of C5-T I radiculopathy on either side.

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

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

#### **Terocin Patch Quantity 20: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (lidocaine patch) Salicylate topical ; Topical analgesics Page(s): 56, 105, 111-112.

**Decision rationale:** Terocin Patch Quantity 20 is not medically necessary per the MTUS Chronic Pain Medical Treatment Guidelines. A Terocin patch contains: Menthol 4%; Lidocaine 4%. In regards to the Lidoderm patch the MTUS guidelines state that ". Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia" Per MTUS guidelines, topical Lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI antidepressants or an AED. Topical Analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Additionally, the MTUS guidelines state, "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Although Menthol is not specifically addressed in the MTUS menthol is present in Ben Gay which is recommended by the MTUS. Due to the fact that documentation submitted does not show evidence of failure of oral first line therapy for peripheral pain such as antidepressants or anticonvulsants, and that patient does not have post herpetic neuralgia, Terocin patches are not medically necessary.

#### **Tramadol 150 mg Quantity 60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol Page(s): 113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol Opioids, criteria for use Page(s): 76-80, 93-94.

**Decision rationale:** Tramadol 150mg quantity 60 is not medically necessary per the MTUS Chronic Pain Medical Treatment Guidelines. Tramadol is a synthetic opioid affecting the central nervous system. Documentation submitted is not clear on patient's ongoing review and documentation of pain relief, functional status and on-going medication management or treatment plan. This would include appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. The MTUS guidelines state to discontinue opioids if there is no overall improvement in function and pain there is no indication that the medication has improved patient's pain or

functioning to a significant degree since the patient started this medication therefore Tramadol 150mg quantity 60 is not medically necessary.

**Theramine Quantity 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 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) Chronic Pain-Theramine.

**Decision rationale:** Theramine quantity 90 is not medically necessary. The MTUS does not address Theramine. The ODG states that Theramine is a medical food that is a proprietary blend of gamma-aminobutyric acid [GABA] and Choline Bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. The ODG states in regards to Gamma-aminobutyric acid (GABA) that "There is no high quality peer-reviewed literature that suggests that GABA is indicated". In regards to Choline, the ODG states that "There is no known medical need for choline supplementation". In regards to L-Arginine, the ODG states that "This medication is not indicated in current references for pain or inflammation"; & for L-Serine, guidelines state that, "There is no indication for the use of this product." The ODG states that until there are higher quality studies of the ingredients in Theramine, it remains not recommended. The documentation does not indicate a nutritional deficiency of why this patient requires this supplement. The request for Theramine quantity 90 is not medically necessary.

**Trepadone Quantity 120:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines 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 Foods.

**Decision rationale:** Trepadone quantity 120 is not medically necessary per ODG guidelines. The MTUS is silent on this issue. Trepadone is a medical food that is a proprietary blend of L-arginine, L-glutamine, Choline Bitartrate, L-serine and Gammaaminobutyric acid [GABA]. It is intended for use in the management of joint disorders associated with pain and inflammation. Documentation submitted does not reveal a clear rationale why the patient requires this supplement. The request for Trepadone quantity 120 is not medically necessary.

**Sentra AM Quantity 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 Medical Food.

**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 Foods.

**Decision rationale:** Sentra AM #60 is not medically necessary per the ODG. The MTUS is silent on this issue. Sentra AM is considered a medical food. The ODG states that medical foods are not 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 documents submitted reveal no evidence that the patient's condition requires any particular nutritional requirements. The request for Sentra AM #60 is not medically necessary.

**Sentra PM Quantity 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 Medical Food.

**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 Foods.

**Decision rationale:** Sentra PM Quantity 60 is not medically necessary per the ODG. The MTUS is silent on this issue. Sentra AM is considered a medical food. The ODG states that medical foods are not 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 documents submitted reveal no evidence that the patient's condition necessitates any particular nutritional requirements. The request for Sentra PM Quantity 60 is not medically necessary.

**Gabadone Quantity 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 Medical Food.

**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 Foods.

**Decision rationale:** Gabadone quantity 60 is not medically necessary per the ODG. The MTUS is silent on this issue. Gabadone is considered a medical food. The ODG states that medical foods are not 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 documents submitted reveal no evidence that the patient's condition necessitates any particular nutritional requirements. The request for Gabadone quantity 60 is not medically necessary.

**Methoderm Gel 120mg:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate topicals; Topical analgesics Page(s): 105, 111-113. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence:  
<http://www.physiciansproducts.net/joomla/index.php/topical-pain-creams/72-menthoderm>.

**Decision rationale:** Menthoderm Gel 120mg is not medically necessary per the MTUS guidelines. Menthoderm is a topical analgesic used for the temporary relief of minor aches and muscle pains associated with arthritis, simple backache, strains, muscle soreness and stiffness. The active ingredients are Methyl Salicylate 15.00% and Menthol 10.00%. The MTUS states that salicylate topical is significantly better than placebo in chronic pain. Menthol is an ingredient in Ben Gay which is a topical salicylate. The MTUS states that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is no evidence of intolerance to oral medications necessitating the need for this topical analgesic. The request for Menthoderm Gel 120mg is not medically necessary.