

<b>Case Number:</b>	CM14-0129933		
<b>Date Assigned:</b>	08/20/2014	<b>Date of Injury:</b>	08/29/2011
<b>Decision Date:</b>	10/24/2014	<b>UR Denial Date:</b>	07/23/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/14/2014

### 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 Orthopedic Surgery, 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:

This 57-year-old male sustained an industrial injury on 8/29/11. Injury occurred when he twisted his back lifting a vacuum. Past surgical history was positive for surgery at L5/S1 in May 2013. He underwent L4/5 and L5/S1 spinal fusion on 3/24/14 and began post-op physical therapy on 5/27/14. The 7/10/14 treating physician report cited grade 5-8/10 low back pain with improved right radicular symptoms. There were complaints of dysesthesia pain, right greater than left. Pain medications were helpful in reducing pain to grade 5/10. Physical exam documented gait with a single point cane, lumbar paraspinal tenderness and muscle spasms, facet pain with extension, and pain over the sacroiliac joints with palpation. There was marked loss of lumbar range of motion with decreased right lateral thigh sensation. There was right greater than left allodynia. Sacroiliac compression tests were positive. The diagnosis was lumbar disc disease and radiculopathy. The treatment plan prescribed a refill on medications including Anaprox DS 550 mg #60, Prilosec DR 20 mg #60, Flexeril 7.5 mg #60, Ketoprofen cream #2, Tramadol ER 150 mg #60, Terocin patch, Theramine, Sentra PM, and Sentra AM. Norco was to continue as prescribed by the spinal surgeon for tapering. Urine drug screen was consistent with medications prescribed. Records indicated that Theramine was prescribed to help absorption of non-steroidal anti-inflammatory drugs. Sentra PM was prescribed to help with sleep and energy and Sentra AM was prescribed to help with alertness and energy. The 7/23/14 utilization review certified the requests for Anaprox, Flexeril, and Tramadol ER. The request for Prilosec was denied as there was no documentation of any upper gastrointestinal symptoms or diagnoses, or risk factors for gastrointestinal side effects. The request for Ketoprofen cream and Terocin patches were not certified as there was no guideline support. Norco was not certified as there was no documentation of dose, frequency or quantity, and it was apparently prescribed by another

physician. Theramine was not certified as there was no documentation to support the nutritional necessity of this medical food. Sentra AM and PM were denied due to lack of guideline support.

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

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

**Prilosec DR 20mg BID #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs with GI symptoms and cardiovascular risk.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69.

**Decision rationale:** The California MTUS guidelines recommend the use of proton pump inhibitors (PPIs), such as Prilosec, for patients at risk for gastrointestinal events. Risk factors include age greater than 65 years, history of peptic ulcer, gastrointestinal bleeding or perforation, concurrent use of ASA, corticosteroids, and/or an anticoagulant, or high dose/multiple NSAID (e.g., NSAID + low-dose ASA). PPIs are reported highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. Guideline criteria for intermediate gastrointestinal risk factors have not been met. There is no evidence in the records provided of any gastrointestinal complaints or past medical history to support the use of Prilosec. Therefore, this request is not medically necessary.

**Ketoprofen cream 20% TID #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 Topical analgesics Page(s): 111-113.

**Decision rationale:** The California MTUS indicates that Ketoprofen is not currently FDA approved for a topical application and has an extremely high incidence of photocontact dermatitis. Guidelines indicate that efficacy in clinical trials of non-steroidal anti-inflammatory agents has been inconsistent and most studies are small and of short duration. Given the absence of guideline support for the topical use of Ketoprofen, this request is not medically necessary.

**Norco:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use, Hydrocodone/acetaminophen Page(s): 76-80, 91.

**Decision rationale:** The California Medical Treatment Utilization Schedule guidelines support the use of opioids on a short term basis for wrist/hand pain. Guidelines recommend Norco for moderate to moderately severe pain on an as needed basis with a maximum dose of 8 tablets per day. Short-acting opioids, also known as "normal-release" or "immediate-release" opioids, are seen as an effective method in controlling both acute and chronic pain. Guideline criteria have not been met for this request. Norco has been prescribed by another physician and is reportedly in the process of tapering. This non-specific request does not provide the dosage, frequency of use, quantity prescribed, or benefit with use to establish medical necessity of continued use. Therefore, this request is not medically necessary.

**Terocin patch with lidocaine 5% 12 hr on and 12 hr off:** 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 does not provide specific recommendations for Terocin patches. Terocin patches include capsaicin, lidocaine, menthol, and methyl salicylate. Lidocaine patches are recommended for localized peripheral pain after a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Capsaicin is supported as an option in patients who have not responded or are intolerant to other treatments. Guideline criteria have not been met for continued use of this medication. There is no clear evidence of neuropathic pain, radicular pain is reported improved. There is no current pain assessment indicating the level of pain or what benefit has been achieved with the use of this medication. There is no current functional assessment or documentation of objective functional benefit with use of this medication. There is no clinical evidence that the patient has failed first-line neuropathic treatment, or has not responded to or is intolerant of other treatments. Therefore, this request is not medically necessary.

**Theramine TID #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation [www.odg-twc.com/odgtwclist.htm](http://www.odg-twc.com/odgtwclist.htm)

**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®<sup>®</sup>, Medical Food

**Decision rationale:** The California MTUS do not address the use of Theramine. Theramine is a medical food from [REDACTED] 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 Official Disability Guidelines state that Theramine is not recommended as there are no high quality studies of the individual ingredients. Therefore,

lacking guideline support for all of the individual ingredients in this compound product, this request is not medically necessary.

**Sentra PM #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation [odg-twc.com/odgtwclist.htm](http://odg-twc.com/odgtwclist.htm)

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

**Decision rationale:** The California MTUS does not provide recommendations for the use of Sentra PM. The Official Disability Guidelines describe Sentra PM as a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan intended for use in management of sleep disorders associated with depression. Guidelines state that Sentra PM is under study for insomnia with no independent unbiased studies supporting use at this time. There is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. Guidelines indicate that glutamic acid is generally used for digestive disorders. Guidelines state that 5-hydroxytryptophan has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity and sleep disorders. There is no documentation that the patient suffers from a choline deficiency. Guidelines do not support all of the individual components of Sentra PM. Therefore, this request is not medically necessary.

**Sentra AM #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation [odg-twc.com/odgtwclist.htm](http://odg-twc.com/odgtwclist.htm)

**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:** The California Medical Treatment Utilization Schedule, Official Disability Guidelines (ODG), and National Guideline Clearinghouse do not provide recommendations for the use of Sentra AM. Sentra AM contains choline and acetylcarnitine. The ODG state there is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. There is no documentation that the patient suffers from a choline deficiency. Guidelines do not support all of the individual components of Sentra AM. Therefore, this request is not medically necessary.