

<b>Case Number:</b>	CM15-0113359		
<b>Date Assigned:</b>	06/19/2015	<b>Date of Injury:</b>	11/26/1997
<b>Decision Date:</b>	09/23/2015	<b>UR Denial Date:</b>	05/16/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/11/2015

### 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:

The 67 year old female injured worker suffered an industrial injury on 11/26/1997. The diagnoses included lumbar disc disease, cervical sprain, spasm of the muscles and lumbago. The diagnostics included lumbar magnetic resonance imaging. The injured worker had been treated with medications and medical foods. On 5/7/2015, the treating provider reported lower back pain, upper back pain and neck pain rated 2 to 2/10 with complaints of difficulty sleeping. On exam there was bilateral tenderness and spasms of the cervical spine along with bilateral tenderness and spasms of the lumbar spine. The cervical and lumbar spine had reduced range of motion. The treatment plan included Norco, Cymbalta, Tramadol, Lidocaine patches, Retrospective Theramine #90 (DOS 5/7/15) and Retrospective Sentra AM/PM.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Norco 5/325mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use Page(s): 80.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain CRITERIA FOR USE OF OPIOIDS Page(s): 60, 61, 76-78, 88, 89.

**Decision rationale:** Based on the 12/14/14 progress report provided by the treating physician, this patient presents with low back pain, upper back pain, and cervical pain, with pain rated 4/10 today. The treater has asked for Norco 5/325mg #60 on 12/14/14. The request for authorization was not included in provided reports. The patient is s/p several lumbar epidurals of unspecified dates per 11/20/14 report. The patient is currently taking Vicodin, Advil, L-thyroxine, Remedex for breast cancer, Cymbalta, Fosamax, and Losartan per 12/14/14 report. The patient had a urine drug screen done on 11/20/14 that showed inconsistent results, as Tramadol was prescribed but not detected. The patient's work status is "permanent work restrictions - avoid lifting more than 15 pounds, and avoid repetitive back motions" per 11/20/14 report. MTUS Guidelines pages 88 and 89 states, "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS page 78 also requires documentation of the 4As (analgesia, ADLs, adverse side effects, and adverse behavior), as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. MTUS p77 states, "function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale." MTUS p90 states, "Hydrocodone has a recommended maximum dose of 60mg/24hrs." In this case, a prescription for Norco is first noted in progress report dated 3/25/14. The patient has been taking the medication consistently at least since then. However, it is not clear when this treatment was initiated. The patient has been able to taper down on Norco with help of medical foods per 12/14/14 report. Although the 3/25/14 report mentions patient "is helped by Norco," the treater does not document a reduction in pain in terms of change in pain scale. No CURES reports are available for review, but a urine drug screen on 11/20/14 was inconsistent, with Tramadol not detected although prescribed. There is no discussion regarding the side effects of Norco as well. MTUS requires a clear documentation regarding impact of Norco on 4As, including analgesia, ADLs, adverse side effects, and aberrant behavior, for continued opioid use. Additionally, MTUS p80, 81 states regarding chronic low back pain: "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited." Long-term use of opiates may be indicated for nociceptive pain as it is "Recommended as the standard of care for treatment of moderate or severe nociceptive pain (defined as pain that is presumed to be maintained by continual injury with the most common example being pain secondary to cancer)." However, this patient does not present with pain that is "presumed to be maintained by continual injury." Hence, the request is not medically necessary.

**Cymbalta 30mg #240:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines SNRIs (serotonin noradrenaline reuptake inhibitors) Page(s): 105.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for Chronic Pain Page(s): 16, 17.

**Decision rationale:** Based on the 12/14/14 progress report provided by the treating physician, this patient presents with low back pain, upper back pain, and cervical pain, with pain rated 4/10 today. The treater has asked for Cymbalta 30mg #240 on 12/14/14. The request for authorization was not included in provided reports. The patient is s/p several lumbar epidurals of unspecified dates per 11/20/14 report. The patient is currently taking Vicodin, Advil, L- thyroxine, Remedex for breast cancer, Cymbalta, Fosamax, and Losartan per 12/14/14 report. The patient had a urine drug screen done on 11/20/14 that showed inconsistent results, as Tramadol was prescribed but not detected. The patient's work status is "permanent work restrictions - avoid lifting more than 15 pounds, and avoid repetitive back motions" per 11/20/14 report. Regarding Cymbalta, the MTUS guidelines page 16-17, Antidepressants for Chronic Pain section, states, "Duloxetine (Cymbalta) is FDA-approved for anxiety, depression, diabetic neuropathy, and fibromyalgia. Used off-label for neuropathic pain and radiculopathy. Duloxetine is recommended as a first-line option for diabetic neuropathy... Trial period: Some relief may occur in first two weeks; full benefit may not occur until six weeks." The patient has been utilizing Cymbalta since at least 3/25/14. Although this patient meets guidelines indications for the use of Cymbalta, recommendation for further use cannot be supported as there is no discussions regarding efficacy. Given this patient has been using this medication chronically, with no documentation of specific efficacy and functional benefit, the request is not medically necessary.

**Tramadol ER 150mg #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use Page(s): 80.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain CRITERIA FOR USE OF OPIOIDS Page(s): 60, 61, 76-78, 88, 89.

**Decision rationale:** Based on the 12/14/14 progress report provided by the treating physician, this patient presents with low back pain, upper back pain, and cervical pain, with pain rated 4/10 today. The treater has asked for Tramadol ER 150mg #30 on 12/14/14. The request for authorization was not included in provided reports. The patient is s/p several lumbar epidurals of unspecified dates per 11/20/14 report. The patient is currently taking Vicodin, Advil, L- thyroxine, Remedex for breast cancer, Cymbalta, Fosamax, and Losartan per 12/14/14 report. The patient had a urine drug screen done on 11/20/14 that showed inconsistent results, as Tramadol was prescribed but not detected. The patient's work status is "permanent work restrictions - avoid lifting more than 15 pounds, and avoid repetitive back motions" per 11/20/14 report. MTUS Guidelines Criteria For Use of Opioids (Long-Term Users of Opioids) Section, Pages 88-89 states: "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS page 78 under Criteria For Use of Opioids - Therapeutic Trial of Opioids, also requires documentation of the 4As, analgesia, ADLs, adverse side effects, and adverse behavior, as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. In this case, the treater has requested Tramadol. MTUS requires appropriate discussion of all the 4A's. The 3/25/14 report states that "with meds, able to do ADLs such as cooking, driving, and house work

such as cleaning." However, no validated instrument is used to show the analgesia with medications and without medications. There is no CURES and no opioid contract provided in the provided progress reports. A urine drug screen on 11/20/14 did not detect Tramadol, although it was being prescribed. Given the lack of documentation as required by MTUS, the request does not meet the specifications given by the guidelines. Therefore, the request is not medically necessary.

**Lidocaine patches #30: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 112.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (lidocaine patch) Page(s): 57.

**Decision rationale:** Based on the 12/14/14 progress report provided by the treating physician, this patient presents with low back pain, upper back pain, and cervical pain, with pain rated 4/10 today. The treater has asked for Lidocaine patches #30 on 12/14/14 "for allodynia and dysesthesia pain." The request for authorization was not included in provided reports. The patient is s/p several lumbar epidurals of unspecified dates per 11/20/14 report. The patient is currently taking Vicodin, Advil, L-thyroxine, Remedex for breast cancer, Cymbalta, Fosamax, and Losartan per 12/14/14 report. The patient had a urine drug screen done on 11/20/14 that showed inconsistent results, as Tramadol was prescribed but not detected. The patient's work status is "permanent work restrictions - avoid lifting more than 15 pounds, and avoid repetitive back motions" per 11/20/14 report. MTUS Guidelines, Lidoderm (lidocaine patch), page 57 states, "Topical lidocaine may be recommended for a localized peripheral pain after there has been evidence of a trial of first-line therapy (tricyclic or SNRI antidepressants, or an AED such as gabapentin or Lyrica)." MTUS Guidelines, under Lidocaine, page 112 also states, "Lidocaine indication: Neuropathic pain, recommended for localized peripheral pain." ODG Guidelines, Pain (Chronic) Chapter, under Lidoderm (Lidocaine Patch) specifies that the Lidoderm patches are indicated as a trial if there is "evidence of localized pain that is consistent with a neuropathic etiology." ODG further requires documentation of the area for treatment, trial of a short-term use with outcome, documenting pain and function. MTUS page 60 required recording of pain and function when medications are used for chronic pain. The patient has been using Lidoderm patches as early as 10/2/14 report. In this case, the patient does not have any documentation of localized neuropathic pain as required by MTUS Guidelines. Furthermore, review of the reports provided does not indicate how Lidoderm patches have impacted the patient's pain and function. Due to a lack of documentation of efficacy, the requested Lidoderm patch is not medically necessary.

**Retrospective Theramine #90 (DOS 5/7/15): 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, 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 (Chronic) Chapter, under Medical Foods.

**Decision rationale:** Based on the 12/14/14 progress report provided by the treating physician, this patient presents with low back pain, upper back pain, and cervical pain, with pain rated 4/10 today. The treater has asked for Retrospective Theramine #90 (DOS 5/7/15) but the requesting progress report is not included in the provided documentation. The request for authorization was not included in provided reports. The patient is s/p several lumbar epidurals of unspecified dates per 11/20/14 report. The patient is currently taking Vicodin, Advil, L-thyroxine, Remedex for breast cancer, Cymbalta, Fosamax, and Losartan per 12/14/14 report. The patient had a urine drug screen done on 11/20/14 that showed inconsistent results, as Tramadol was prescribed but not detected. The patient's work status is "permanent work restrictions - avoid lifting more than 15 pounds, and avoid repetitive back motions" per 11/20/14 report. MTUS and ACOEM guidelines are silent regarding Theramine. ODG guidelines, Pain (Chronic) Chapter, under Medical Foods, state: Not recommended for chronic pain. Medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. As per [nutrientpharmacology.com/PDFs/monographs/theramine-monograph.pdf](http://nutrientpharmacology.com/PDFs/monographs/theramine-monograph.pdf). Theramine is a medical food containing a proprietary formulation of neurotransmitter precursors (L-arginine, L- glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan), neurotransmitters (gamma- aminobutyric acid [GABA]), and a neuromodulator (L-serine); polyphenolic antioxidants (grape seed extract, cinnamon bark, cocoa); anti-inflammatory and immunomodulatory peptides (whey protein hydrolysate); and adenosine antagonists (cocoa, metabromine). While the ODG guidelines do not discuss every ingredient found in Theramine, ODG does state that L-arginine is "not indicated in current references for pain or 'inflammation.'" Regarding L-serine, the guidelines state "There is no indication in Micromedex, Clinical Phamacology, or AltMedDex for the use of this supplement." Regarding GABA, the guidelines state that "This supplement is indicated for epilepsy, spasticity and tardive dyskinesia. There is no high quality peer-reviewed literature that suggests that GABA is indicated for treatment of insomnia. Adverse reactions associated with treatment include hypertension, increased heart rate and anxiety." Additionally, ODG guidelines do not recommend medical foods for the treatment of chronic pain. The treater has not provided a medical rationale to prescribe a medical food that contains ingredients not supported by the ODG. Therefore, the request is not medically necessary.

**Retrospective Sentra AM/PM (DOS 5/7/15) #1:** 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, 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 Chapter under Sentra PM.

**Decision rationale:** Based on the 12/14/14 progress report provided by the treating physician, this patient presents with low back pain, upper back pain, and cervical pain, with pain rated 4/10 today. The treater has asked for Retrospective Sentra AM/PM (DOS 5/7/15) #1 but the requesting progress report is not included in the provided documentation. The request for authorization was not included in provided reports. The patient is s/p several lumbar epidurals of unspecified dates per 11/20/14 report. The patient is currently taking Vicodin, Advil, L-thyroxine, Remedex for breast cancer, Cymbalta, Fosamax, and Losartan per 12/14/14 report. The patient had a urine drug screen done on 11/20/14 that showed inconsistent results, as Tramadol was prescribed but not detected. The patient's work status is "permanent work restrictions - avoid lifting more than 15 pounds, and avoid repetitive back motions" per 11/20/14 report. ODG Guidelines, Pain Chapter under Medical Foods states: "Medical food: Intended for a specific dietary management of a disease or condition for which distinctive nutritional requirements are established by medical evaluation. To be considered, the product must 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, (3) The product must be used under medical supervision...Not recommended for chronic pain." ODG Guidelines, Pain Chapter under Sentra PM: Sentra PM is a medical food from [REDACTED], intended for use in management of sleep disorders associated with depression, which is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. ODG Pain Chapter under choline: there is no known medical need for choline supplementation. ODG Pain Chapter under glutamic acid: this supplement is used for treatment of hypochlorhydria and achlorhydria. Treatment indications include those for impaired intestinal permeability, short bowel syndrome, cancer, and critical illnesses. It is generally used for digestive disorders and complementary medicine. ODG Pain Chapter under 5-hydroxytryptophan: the supplement has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity, and sleep disorders. It has been found to be effective for depression. The patient has been taking Docuprene for constipation in reports dated 3/25/14, 6/5/14, and 11/20/14. It is not clear when Sentra AM/PM was initiated. It appears to be an initial request. Sentra AM/PM consists of choline bitartrate, glutamate, and 5-hydroxytryptophan. Both choline and glutamic acid are not supported by ODG Guidelines. The treater has not provided a medical rationale to prescribe a medical food that contains ingredients not supported by ODG. Therefore, the request is not medically necessary.