

<b>Case Number:</b>	CM15-0061256		
<b>Date Assigned:</b>	04/20/2015	<b>Date of Injury:</b>	12/05/2011
<b>Decision Date:</b>	07/17/2015	<b>UR Denial Date:</b>	03/19/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/31/2015

### 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: New York  
 Certification(s)/Specialty: Emergency Medicine

### 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 injured worker is a 60 year old female who has reported multifocal pain after falling on 2/5/11. The diagnoses have included lumbar radiculopathy, herniated lumbar disc, insomnia, and myofascial syndrome. Treatment to date has included injections, physical therapy, chiropractic, Xanax for anxiety/panic attacks, Protonix for acid reflux, Opana, Tylenol, Theramine, Gabadone, lidocaine/gabapentin/menthol/capsaicin/camphor topical, metaxalone for muscle spasm, Elavil for pain related insomnia, and Fioricet for headaches. Reports from the primary treating physician during 2014-2015 reflect high pain levels and poor function. None of the reports discuss the results of drug tests or the results of using any medication. There is no work status. The urine drug qualitative screen on 2/18/15 was positive for barbiturates, oxycodone, opiates, and buprenorphine. Opana and Tylenol #4 were used chronically. The urine drug screen of 1/23/15 was positive for codeine and morphine. At the office visit of 1/22/15 the injured worker was reportedly taking Opana, codeine, Xanax, and Fioricet. The urine drug screen of 12/30/14 was positive for Opana. The urine drug screen of 12/10/14 was positive for oxymorphone, codeine, morphine, and alcohol. Per the report of 3/11/15, there was ongoing, 8/10, multifocal pain. The injured worker wanted to stop narcotics. The urine drug screen of 1/22/15 was positive for codeine and morphine. There was no discussion of the results of using any medication. The medications referred for this Independent Medical Review were listed. There was no work status. There was no discussion of any drug test results. On 3/19/15 Utilization Review non-certified the medications referred for this Independent Medical Review. The MTUS and the Official Disability Guidelines were cited.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Xanax 2mg #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 24. Decision based on Non-MTUS Citation ODG Pain Chapter.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24.

**Decision rationale:** The treating physician has not provided a sufficient account of the indications and functional benefit for this medication. None of the reports address the results of using Xanax. None of the drug tests show any benzodiazepines, and this was not addressed by the treating physician. The MTUS does not recommend benzodiazepines for long term use for any condition. The prescribing has occurred chronically, not short term as recommended in the MTUS. This benzodiazepine is not prescribed according the MTUS, may not even be taken at all, and is not medically necessary.

**Protonix 40mg #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68. Decision based on Non-MTUS Citation ODG Pain Chapter.

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

**Decision rationale:** There are no medical reports which adequately describe the relevant signs and symptoms of possible gastrointestinal disease. There is no examination of the abdomen. This injured worker is not taking NSAIDs or other medications likely to adversely affect the acid milieu of the upper gastrointestinal tract. No reports describe the specific risk factors present in this case, as presented in the MTUS. PPIs are not benign. The MTUS, FDA, and recent medical literature have described a significantly increased risk of hip, wrist, and spine fractures; pneumonia, Clostridium-difficile-associated diarrhea, cardiovascular disease, and hypomagnesemia in patients on proton pump inhibitors. This PPI is not medically necessary based on lack of medical necessity and risk of toxicity.

**Opana 10mg #120:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioid management, Opioids, steps to avoid misuse/addiction, indications, Chronic back pain, Mechanical and compressive etiologies, Medication trials Page(s): 77-81, 94, 80, 81, 60.

Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Alcohol and opioids, Pain chapter, Opioids.

**Decision rationale:** There is insufficient evidence that the treating physician is prescribing opioids according to the MTUS, which recommends prescribing according to function, with specific functional goals, return to work, random drug testing, opioid contract, and there should be a prior failure of non-opioid therapy. None of these aspects of prescribing are in evidence. The prescribing physician does not specifically address function with respect to prescribing opioids. Work status is not addressed. This fails the "return-to-work" criterion for opioids in the MTUS, and represents an inadequate focus on functional improvement. There is no evidence of significant pain relief or increased function from the opioids used to date. Pain levels remain high. The MTUS recommends random urine drug screens for patients with poor pain control and to help manage patients at risk of abuse. There is a high rate of aberrant opioid use in patients with chronic back pain. There is no record of a urine drug screen program performed according to quality criteria in the MTUS and other guidelines. The injured worker has failed multiple drug screens, and none of the results were discussed by the treating physician and prescribing did not change. The injured worker stated that she wanted to stop narcotics and this was not addressed; opioids continued regardless. The Official Disability Guidelines, chronic pain, opioid section states: "Extreme caution is required for any opioid use in patients with the following: (1) Individuals with a high risk for misuse or diversion; (2) Individuals with evidence of substance abuse issues; "The risk of overdose increases when opioids are used with other drugs (such as benzodiazepines, cocaine, and/or heroin) or alcohol". "Recommend that if a patient exhibits aberrant behaviors these concerns should be addressed immediately. It has been suggested that most chronic pain problems will not resolve while there is active and ongoing alcohol, illicit drug, or prescription drug abuse". The alcohol use was never addressed in this injured worker. As currently prescribed, this opioid does not meet the criteria for long term opioids as elaborated in the MTUS and is therefore not medically necessary. This is not meant to imply that some form of analgesia is contraindicated; only that the opioids as prescribed have not been prescribed according to the MTUS and that the results of use do not meet the requirements of the MTUS.

**Tylenol #4 #25:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioid management, Opioids, steps to avoid misuse/addiction, indications, Chronic back pain, Mechanical and compressive etiologies, Medication trials Page(s): 77-81, 94, 80, 81, 60. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Alcohol and opioids, Pain chapter, Opioids.

**Decision rationale:** There is insufficient evidence that the treating physician is prescribing opioids according to the MTUS, which recommends prescribing according to function, with specific functional goals, return to work, random drug testing, opioid contract, and there should be a prior failure of non-opioid therapy. None of these aspects of prescribing are in evidence. The prescribing physician does not specifically address function with respect to prescribing opioids. Work status is not addressed. This fails the "return-to-work" criterion for opioids in the MTUS, and represents an inadequate focus on functional improvement. There is no evidence of significant pain relief or increased function from the opioids used to date. Pain levels remain high. The MTUS recommends random urine drug screens for patients with poor pain control and to help manage patients at risk of abuse. There is a high rate of aberrant opioid

use in patients with chronic back pain. There is no record of a urine drug screen program performed according to quality criteria in the MTUS and other guidelines. The injured worker has failed multiple drug screens, and none of the results were discussed by the treating physician and prescribing did not change. The injured worker stated that she wanted to stop narcotics and this was not addressed; opioids continued regardless. The Official Disability Guidelines, chronic pain, opioid section states: Extreme caution is required for any opioid use in patients with the following: (1) Individuals with a high risk for misuse or diversion; (2) Individuals with evidence of substance abuse issues; "The risk of overdose increases when opioids are used with other drugs (such as benzodiazepines, cocaine, and/or heroin) or alcohol". "Recommend that if a patient exhibits aberrant behaviors these concerns should be addressed immediately. It has been suggested that most chronic pain problems will not resolve while there is active and ongoing alcohol, illicit drug, or prescription drug abuse." The alcohol use was never addressed in this injured worker. As currently prescribed, this opioid does not meet the criteria for long term opioids as elaborated in the MTUS and is therefore not medically necessary. This is not meant to imply that some form of analgesia is contraindicated; only that the opioids as prescribed have not been prescribed according to the MTUS and that the results of use do not meet the requirements of the MTUS.

**Theramine #120:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation 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 section, Medical food, Theramine and Other Medical Treatment Guidelines Other Medical Treatment Guideline or Medical Evidence: FDA Definition of medical foods: Defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)).

**Decision rationale:** Medical foods, per the FDA definition, are for treatment of specific dietary conditions and deficiencies. No medical reports have established any specific dietary deficiencies. The MTUS does not address "medical food". The Official Disability Guidelines have several recommendations and indications (such as liver deficiency, achlorhydria), per the citation above. This injured worker does not meet any of the indications in the Official Disability Guidelines, and the treating physician has neither defined the ingredients nor identified any specific indications for the ingredients in this medical food. The Official Disability Guidelines specifically recommend against Theramine for chronic pain. This medical food is not medically necessary based on the lack of any indications in this injured worker and the recommendations of the guidelines and the FDA.

**Gabadone:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation FDA, National Guideline Clearinghouse.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain section, Medical food and Other Medical Treatment Guidelines Other Medical Treatment Guideline or Medical Evidence: FDA Definition of medical foods: Defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)).

**Decision rationale:** Medical foods, per the FDA definition, are for treatment of specific dietary conditions and deficiencies. No medical reports have established any specific dietary deficiencies. The MTUS does not address "medical food". The Official Disability Guidelines have several recommendations and indications (such as liver deficiency, achlorhydria), per the citation above. This injured worker does not meet any of the indications in the Official Disability Guidelines, and the treating physician has neither defined the ingredients nor identified any specific indications for the ingredients in this medical food. This medical food is not medically necessary based on the lack of any indications in this injured worker and the recommendations of the guidelines and the FDA.

**Lidocaine/Gabapentin/Menthol/Capsaicin/Camphor Compounded Ointment transdermally:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Topical Medications Page(s): 60, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Topical analgesics.

**Decision rationale:** No physician reports discuss the specific indications and medical evidence in support of the topical medications prescribed in this case. The treating physician has not discussed the ingredients of this topical agent and the specific indications for this injured worker. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. The Official Disability Guidelines state that "Custom compounding and dispensing of combinations of medicines that have never been studied is not recommended, as there is no evidence to support their use and there is potential for harm". The compounded topical agent in this case is not supported by good medical evidence and is not medically necessary based on this Official Disability Guidelines recommendation. The MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical lidocaine, only in the form of the Lidoderm patch, is indicated for neuropathic pain (which is not present in this case). The MTUS states that the only form of topical lidocaine that is recommended is Lidoderm. The topical lidocaine prescribed in this case is not Lidoderm. Per the MTUS citation, there is no good evidence in support of topical gabapentin and it is not recommended Capsaicin has some

indications, in the standard formulations readily available without custom compounding. It is not clear what the indication is in this case, as the injured worker does not appear to have the necessary indications per the MTUS. The MTUS also states that capsaicin is only recommended when other treatments have failed. This injured worker has not received adequate trials of other, more conventional treatments. The treating physician did not discuss the failure of other, adequate trials of other treatments. Capsaicin is not medically necessary based on the lack of indications per the MTUS. Menthol and camphor are not discussed specifically in the MTUS. The topical compounded medication prescribed for this injured worker is not medically necessary based on the MTUS, the Official Disability Guidelines, lack of medical evidence, and lack of FDA approval.

**Metaxalone 800 #90:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines muscle relaxants Page(s): 63-66.

**Decision rationale:** The MTUS for Chronic Pain does not recommend muscle relaxants for chronic pain. Non-sedating muscle relaxants are an option for short term exacerbations of chronic low back pain. The muscle relaxant prescribed in this case is sedating. This injured worker has chronic pain with no evidence of prescribing for flare-ups. Prescribing has occurred consistently for months at minimum. The quantity prescribed implies long term use, not a short period of use for acute pain. No reports show any specific and significant improvements in pain or function as a result of prescribing muscle relaxants. Per the MTUS, this muscle relaxant is not indicated and is not medically necessary.

**Elavil 25mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 13-16.

**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, Insomnia treatment.

**Decision rationale:** Elavil is stated to be prescribed for insomnia. The MTUS does not address the use of hypnotics other than benzodiazepines. The Official Disability Guidelines were used instead. The Official Disability Guidelines recommend the short term use of hypnotics like zolpidem (less than two months), discuss the significant side effects, and note the need for a careful evaluation of the sleep difficulties. No physician reports describe the specific criteria for a sleep disorder. The treating physician has not addressed major issues affecting sleep in this patient, including the use of other psychoactive agents like opioids and alcohol, which significantly impair sleep architecture. This injured worker has been prescribed this hypnotic chronically. The reports do not show specific and significant benefit of Elavil over time. Elavil is not medically necessary based on prolonged use contrary to guideline recommendations, lack of benefit, and lack of sufficient evaluation of the sleep disorder.

**Fioricet #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 23. Decision based on Non-MTUS Citation <http://www.drugs.com/pro/fiorinal.html>.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Barbiturate-containing analgesic agents (BCAs) Page(s): 23.

**Decision rationale:** The MTUS recommends against analgesics containing barbiturates. There are several significant, and negative, side effects. Other analgesics listed in the MTUS are available for treating chronic pain. There are no reports from the treating physician which address the specific benefits and ongoing medical necessity for this medication. None of the reports address the failed drug tests. The barbiturate-containing analgesic in this case is not medically necessary based on the MTUS.