

<b>Case Number:</b>	CM15-0001842		
<b>Date Assigned:</b>	01/13/2015	<b>Date of Injury:</b>	09/23/1997
<b>Decision Date:</b>	03/17/2015	<b>UR Denial Date:</b>	12/27/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/05/2015

### 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: Pennsylvania  
 Certification(s)/Specialty: Internal 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 66 year old female, who sustained an industrial injury on 09/23/1997. The diagnoses have included lumbar radiculopathy, cervical sprain and strain, chronic pain syndrome, chronic pain related insomnia, severe myofascial syndrome, neuropathic pain, prescription narcotic dependence, chronic pain related depression, chronic pain related anxiety, and total body pain. Some progress notes also note a diagnosis of headaches. Work status was noted as permanent and stationary in 2006; work status in 2014 was documented as future medical care/not working. Treatments to date have included physical therapy, chiropractic treatment, biofeedback, psychological therapy, and medications. Use of norco and xanax was documented as far back as 2006. In April 2014, the physician documented that the injured worker found the medication subutex in her house and she took it to relieve her pain, and that she had been placed on idrasil but discontinued taking it because she felt she was having a reaction to the medication. Fioricet was noted to be continued for headaches. Multiple urine drug screens were submitted, some of which were noted to be inconsistent with prescribed medications. Diagnostics to date have included urine drug screen on 10/16/2014 which was positive for butalbital and ethanol and negative for alprazolam and suboxone. Currently, the injured worker complains of pain throughout her body, headaches and dizziness, very low energy, and being tired all the time, with a pain level of 7 out of 10 in severity. The physician noted on several occasions that the injured worker has not been able to get most of her medications and has been in severe pain, it was unclear from the documentation which medications were being utilized by the injured worker as multiple medications were prescribed. Multiple progress notes from 2014

did not contain physical examination findings other than vital signs. Medications as of 10/8/14 were noted as subutex, mobic, fioricet, xanax, prevacid, flexeril, ambien, gabapentin, idrasil, sentra am, sentra pm, and relora. On 12/26/2014, Utilization Review non-certified the above request for Fioricet, Subutex, Mobic, Xanax, Idrasil, Flexeril, Sentra PM, and Relora and modified the request for Gabapentin to Gabapentin 300mg #15. Regarding the Fioricet, Utilization Review (UR) noted that weaning was initiated on 11/26/2012, there is no evidence to support treatment with Fioricet and weaning should be complete. UR noted that with the Subutex, the provider has had time to complete the tapering schedule and the two most recent drug screens did not detect Suboxone, therefore, additional weaning is not warranted. UR noted that with Mobic, the injured worker's pain rating remains unchanged from previous visits and there is no evidence of functional benefit with the use of this medication. UR noted that regarding Xanax that the provided documentation reveals Xanax use as far back as August 2012 and the injured worker has utilized this medication on a chronic basis since at least June 2013, and despite ongoing treatment with Xanax, the provided records fail to demonstrate substantial improvement that can be attributed to its use. UR noted that with Idrasil, cannabinoids are not recommended for management of pain according to guidelines. UR noted regarding Gabapentin, it is appropriate solely for weaning purposes. UR noted that with Flexeril, it does not appear the injured worker is having an acute exacerbation of pain and a review of documentation reveals chronic pain. UR noted that regarding Sentra PM, a review of the provided medical records fails to demonstrate significant clinical findings that might warrant use of a treatment that is under study. UR noted that regarding the Relora, it does not appear there are outstanding clinical findings that might warrant use of a medication that is not supported by guidelines. The MTUS and ODG guidelines were cited. On 1/5/15, an application for independent medical review (IMR) for review of Fioricet 50/325/40mg #60, Subutex 2mg #60, Mobic 7.5mg #60, Xanax 1mg #90, Idrasil 25mg #30, Gabapentin 300mg #30, Flexeril 10mg #90, Sentra PM #60, Relora #60, and Fioricet #60 was submitted.

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

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

**1 prescription for Fioricet 50/325/40mg, #60: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines barbiturate-containing analgesic agents Page(s): p.23. Decision based on Non-MTUS Citation chronic pain chapter: fioricet, barbiturate-containing analgesic agents

**Decision rationale:** Per the MTUS and ODG, Fioricet is not recommended. Barbiturate-containing analgesics have a high potential for drug dependence and no evidence exists to show a clinically important enhancement of analgesic efficacy of barbiturate containing analgesics due to the barbiturate constituents. Fioricet is commonly used for acute headache, with some data to support it, but there is a risk of medication overuse as well as rebound headache. The physician documented that the injured worker had headaches, and fioricet has been prescribed chronically for months. The injured worker has a history of prescription medication dependence and

noncompliance. As Fioricet is not recommended and as there is a history of prescription medication dependence with attendant risk of overuse, the request for Fioricet is not medically necessary.

**1 prescription for Subutex 2mg, #60: 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 buprenorphine.

**Decision rationale:** Subutex contains buprenorphine. Chronic Pain Medical Treatment Guidelines state that buprenorphine is indicated for the treatment of addiction. It is also recommended as an option for chronic pain, especially after detoxification in patients who have a history of opiate addiction. Within the documentation available for review, there is no indication that the medication is improving the injured worker's function or pain, no documentation regarding side effects, and no discussion regarding aberrant use. This is in spite of the fact that multiple urine drug screens were inconsistent with prescribed medications, and the injured worker has a history of prescription narcotic medication dependence. Buprenorphine was not detected in urine drug screen in spite of prescription of this medication. Additionally, there is no documentation that the patient is being actively treated for addiction. As such, there is no clear indication for ongoing use of the medication. The request for Subutex is not medically necessary.

**1 prescription for Mobic 7.5mg #60: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): p. 67-73.

**Decision rationale:** Per the MTUS, nonsteroidal anti-inflammatory drugs (NSAIDs) are recommended as a second line treatment after acetaminophen for treatment of acute exacerbations of chronic back pain. NSAIDs are noted to have adverse effects including gastrointestinal side effects and increased cardiovascular risk; besides these well-documented side effects of NSAIDs, NSAIDs have been shown to possibly delay and hamper healing in all the soft tissues including muscles, ligaments, tendons, and cartilage. NSAIDs can increase blood pressure and may cause fluid retention, edema, and congestive heart failure; all NSAIDs are relatively contraindicated in patients with renal insufficiency, congestive heart failure, or volume excess. They are recommended at the lowest dose for the shortest possible period in patients with moderate to severe pain. The MTUS does not recommend chronic NSAIDs for low back pain, NSAIDs should be used for the short term only. The documentation indicates that the injured worker was prescribed Voltaren, another NSAID, for months without documentation of functional improvement, and the plan to change to Mobic did not include discussion of the rationale for use of a different NSAID. Systemic toxicity is possible with NSAIDs. The FDA

and MTUS recommend monitoring of blood tests and blood pressure. There is no evidence that the prescribing physician is adequately monitoring for toxicity as recommended by the FDA and MTUS. Due to the lack of functional improvement as a result of prior NSAID use, the chronic use of NSAIDs not in accordance with the guidelines, and the lack of documentation of laboratory monitoring, the request for mobic is not medically necessary.

**1 prescription for Xanax 1mg #90: Upheld**

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

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

**Decision rationale:** Per the MTUS, benzodiazepines are not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long term use may actually increase anxiety. The MTUS states that a more appropriate treatment for anxiety disorder is an antidepressant. The MTUS does not recommend benzodiazepines for long term use for any condition. The MTUS does not recommend benzodiazepines as muscle relaxants. The injured worker has a diagnosis of anxiety and chronic pain. Xanax has been documented as prescribed in multiple progress notes throughout 2014 and the documentation notes that it was in use as far back as 2006. There was no documentation of functional improvement as a result of treatment with xanax. Benzodiazepines should not be abruptly discontinued, but there is no provision to modify the current request to allow tapering. Due to the long-term use which is not in accordance with the guidelines, the request for xanax is not medically necessary.

**1 prescription for Idrasil 25mg, #30: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines cannabinoids Page(s): p. 28.

**Decision rationale:** Idrasil is medical cannabis in pill form. The MTUS states that cannabinoids are not recommended for the treatment of chronic pain. The FDA and other agencies report that no scientific studies support the medicinal use of cannabis. Psychoactive effects and decline in cognitive performance have been seen. In addition, the injured worker has a history of prescription narcotic medication dependence and medication non-compliance with multiple urine drug screens inconsistent with prescribed medications. Due to the lack of quality controlled clinical data and the MTUS recommendation against its use, idrasil is not medically necessary.

**1 prescription for Gabapentin 300mg 30: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-Epilepsy Drug (AEDs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines antiepilepsy drugs Page(s): p. 16-22.

**Decision rationale:** Per the MTUS, antiepilepsy drugs (AEDs) are recommended for neuropathic pain due to nerve damage. Gabapentin has been shown to be effective for treatment of diabetic neuropathy and postherpetic neuralgia and has been considered a first line treatment for neuropathic pain. The injured worker does have a history of lumbar radiculopathy. However, there has been no documentation of functional improvement as a result of gabapentin use in spite of ongoing use for many months. The injured worker is noted to be not working; there was no discussion of activities of daily living. There has been no reduction in medication use or frequency of office visits. Due to the lack of functional improvement as a result of treatment with gabapentin, the request for gabapentin is not medically necessary.

**1 prescription for Flexeril 10mg #90:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines flexeril p. 41-42, muscle relaxants p. 63-33 Page(s): p. 41-42, 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. The 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 for a short period of use for acute pain. No reports show any specific and significant improvement in pain or function as a result of prescribing muscle relaxants. Per the MTUS chronic pain medical treatment guidelines, cyclobenzaprine (Flexeril, fexmid) is a skeletal muscle relaxant and a central nervous system depressant. It is recommended as an option for a short course of therapy, with greatest effect in the first four days of treatment. Guidelines state that treatment should be brief. The addition of cyclobenzaprine to other agents is not recommended. Limited, mixed evidence does not allow for a recommendation for chronic use. Due to the continued long term use not in accordance with the guidelines, and lack of functional improvement, the request for flexeril is not medically necessary.

**1 prescription for Sentra PM #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Mental Illness & Stress

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation chronic pain chapter: insomnia treatment, sentra PM

**Decision rationale:** Sentra PM is a medical food from Targeted Medical Pharma Inc., Los Angeles, CA, intended for use in management of sleep disorders associated with depression. It is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan, hawthorn berry, cocoa, ginkgo biloba, and acetyl L-carnitine. The MTUS does not address the use of hypnotics other than benzodiazepines. The ODG specifies that pharmacologic agents for the treatment of insomnia should only be used after careful evaluation of potential causes of sleep disturbance. The treating physician documented that the injured worker had chronic pain related insomnia, but no evaluation of the potential causes of sleep disturbance was documented. No physician reports describe the specific criteria for a sleep disorder. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. There is no evidence of that in this case. Per the ODG, Sentra PM is not recommended. The request for Sentra PM #60 is not medically necessary.

**1 prescription for Relora #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation ODG and National Guideline Clearinghouse

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation chronic pain chapter: medical food

**Decision rationale:** Relora is a proprietary blend of Magnolia officinalis and Phellodendron amurense bark extracts marketed as a dietary supplement to alleviate stress, promote weight management, and balance cortisol levels. Per the ODG, 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. The FDA defines a medical food as "a food which is formulated to be consumed or administered enterally 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." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. There is no documentation of a specific nutritional deficiency which would be expected to be improved with Relora. As there is no indication for this product in the treatment of chronic pain, the request for Relora is not medically necessary.

**1 prescription for Fioricet #60: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines barbiturate- containing analgesics Page(s): p. 23. Decision based on Non-MTUS Citation chronic pain chapter: fioricet, barbiturate-containing analgesic agents

**Decision rationale:** Per the MTUS and ODG, Fioricet is not recommended. Barbiturate-containing analgesics have a high potential for drug dependence and no evidence exists to show

a clinically important enhancement of analgesic efficacy of barbiturate containing analgesics due to the barbiturate constituents. Fioricet is commonly used for acute headache, with some data to support it, but there is a risk of medication overuse as well as rebound headache. The physician documented that the injured worker had headaches, and fioricet has been prescribed chronically for months. The injured worker has a history of prescription medication dependence and noncompliance. As fioricet is not recommended and as there is a history of prescription medication dependence with attendant risk of overuse, the request for fioricet is not medically necessary.