

Case Number:	CM14-0100718		
Date Assigned:	08/06/2014	Date of Injury:	12/05/2011
Decision Date:	09/17/2014	UR Denial Date:	06/03/2014
Priority:	Standard	Application Received:	06/30/2014

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 & Rehabilitation has a subspecialty in Pain Medicine and is licensed to practice in Texas and Ohio. 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 injured worker is a 59-year-old female who reported injury on 12/05/2011 after sustaining a gastrointestinal injury while at work. The injured worker complained of sharp pain to the lower back, with the pain radiating down the right leg with numbness to the bilateral feet. The diagnoses included myoligamentous strain of the lumbar spine with radiation symptoms. The nerve conduction studies done on 09/24/2013 revealed bilateral active L4-5 and L5-S1 lumbar radiculopathy. The objective findings dated 05/27/2014 to the thoracolumbosacral spine and lower extremities included range of motion with a flexion of 65 degrees, extension of 20 degrees, and bilateral bending of 25 degrees. Straight leg raise in the sitting position was 90 degrees with supine position at 45 degrees, tenderness of the erector spinae mass musculature bilaterally, midline lumbar at the L3-S1 and the right sacroiliac joint. No past treatments were available for review. The medication included Metaxalone 800 mg, Opana IR 10 mg, Protonix 40 mg, Bupropion 100 mg, Buspar 10 mg, Duexis 800/26.6 mg, Theramine, Xanax 2 mg, Gabadone, Percura, Fioricet, B12 IM, and topical cream. The request for authorization dated 08/06/2014 was submitted with the documentation. The rationale for the medications was not provided.

IMR ISSUES, DECISIONS AND RATIONALES

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

Metaxalone 800mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Non-Sedating Muscle Relaxants Page(s): 63.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines ANTISPASMODICS Page(s): 64-65.

Decision rationale: The request for metaxalone 800 mg, 1 three times a day # 90 is denied. The California MTUS Guidelines indicate that metaxalone is reported to be a relatively non-sedating muscle relaxant. The exact mechanism of action is unknown, but the effect is presumed to be due to general depression of the central nervous system. Metaxalone was approved by the FDA in 1964 and data to support approval were published in the mid-1960s. The side effects include dizziness and drowsiness, although less than that compared to other skeletal muscle relaxants. Other side effects include headache, nervousness, nausea, vomiting, and GI upset. A hypersensitivity reaction (rash) has been reported. Use with caution in patients with renal and/or hepatic failure. Per the documentation provided, the clinical note dated 05/04/2014 indicated that the injured worker had an episode where she did not know where she was at where the injured worker lost consciousness. Per the clinical notes the injured worker was noted for pain 10/10, showing no efficacy with the use of this medication. Side effects include dizziness and drowsiness. The injured worker fell out of her bed, hitting her head. As such, the request is Metaxalone 800mg #90 Metaxalone 800mg #90 is not medically necessary.

Opana IR 10mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain, On-Going Management Page(s): 79-80, 81. Decision based on Non-MTUS Citation American Pain Society and the American Academy of Pain Medicine, Opioid Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic pain Page(s): 78, 86 & 93.

Decision rationale: Ongoing Monitoring including analgesia, activities of daily living, adverse side effects and aberrant drug taking behavior. Recommend that dosing not exceed 120 mg oral morphine equivalents per day, and for patients taking more than 1 opioid, the morphine equivalent doses of the different opioids must be added together to determine the cumulative dose. Use the appropriate factor below to determine the Morphine Equivalent Dose (MED) for each opioid. In general, the total daily dose of opioid should not exceed 120 mg oral morphine equivalents. Rarely, and only after pain management consultation, should the total daily dose of opioid be increased above 120 mg oral morphine equivalents. There are other guidelines to consider, and actual maximum safe dose will be patient-specific and dependent on current and previous opioid exposure, as well as on whether the patient is using such medications chronically. Per the clinical notes the injured worker rates her pain a 10/10 however the vitals remain within normal limits with B/P 140/76, P. 86 and Resp. 19. The documentation was not evident of the efficacy of the medication or the rate of pain with the medication and the length of time the medication is effective in relieving the pain. Safety should be a concern for the injured

worker with documentation that she had fallen and appeared to lose a bit of time. As such, the request is not medically necessary.

Protonix 40mg #80: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter FDA (Omeprazole).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 67-68.

Decision rationale: The request for Protonix 40mg, one a day for acid reflex and GI upset # 80 is denied. The California MTUS indicate that non-steroidal anti-inflammatory agents have limited demonstrated efficacy in clinical trials and have been inconsistent with most studies being small and of short duration. They have been found in studies to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. However, again the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. The documentation provided indicated that the injured worker had exceeded the recommended time for taking this medication. The injured worker was instructed on a low fat, low acid diet. No followup was evident in the documentation. Per the clinical notes dated 03/06/2014 indicated that the injured workers abdominal pain had improved. Per the clinical notes dated 05/27/2014, the injured worker had no complaints of gastrointestinal issues; however, the gastrointestinal concern was at the time of injury. Per the clinical notes, that is no longer a concern. The Guidelines indicate no more than 4 to 12 weeks. As such, the request is not medically necessary.

Bupropion 100mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants Page(s): 13-14. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Bupropion (Wellbutrin) Page(s): 27.

Decision rationale: The request for Bupropion 100 mg 1 po BID # 60 is denied. The California MTUS Guidelines recommend as an option after other agents. While Bupropion has shown some efficacy in neuropathic pain there is no evidence of efficacy in patients with non-neuropathic chronic low back pain. Furthermore, Bupropion is generally a third-line medication for diabetic neuropathy and may be considered when patients have not had a response to a tricyclic or SNRI. See antidepressants for chronic pain for general guidelines, as well as specific Bupropion listing for more information and references. The Guidelines indicate that Bupropion is indicated for neuropathic pain with no evidence of efficacy in patients with non-neuropathic

chronic lower back pain. The documentation was not evident that the injured worker had diabetic neuropathy. As such, the request is not medically necessary.

Buspar 10mg #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 (ODG).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines SPECIFIC ANTIDEPRESSANTS Page(s): 15.

Decision rationale: The request for Buspar 10mg # 60 is denied. The California MTUS Guidelines recommend Buspar as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. Tricyclics are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. Analgesia generally occurs within a few days to a week, whereas antidepressant effect takes longer to occur. Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep quality and duration, and psychological assessment. Side effects, including excessive sedation (especially that which would affect work performance) should be assessed. It is recommended that these outcome measurements should be initiated at one week of treatment with a recommended trial of at least 4 weeks. The optimal duration of treatment is not known because most double-blind trials have been of short duration (6 to 12 weeks). It has been suggested that if pain is in remission for 3 to 6 months, a gradual tapering of anti-depressants may be undertaken. Long-term effectiveness of anti-depressants has not been established. The effect of this class of medication in combination with other classes of drugs has not been well the reciprocal value of the response rate on active and placebo) has been used to calculate efficacy of the different classes of antidepressants. Per the clinical notes the injured worker is awaiting a psychiatric evaluation, however the clinical notes did not indicate that the injured worker had a diagnosis of depression. The clinical notes did not address the efficacy while being prescribed this BuSpar. As such, the request is not medically necessary.

Duexis 26.6 mg: 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).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: www.drugs.com.

Decision rationale: The request for Duexis (800 Motrin/Famotidine) is denied. The www.Drugs.com indicate that Duexis contains a combination of famotidine and ibuprofen. Famotidine is a histamine blocker. Famotidine works by decreasing the amount of acid the stomach produces. Ibuprofen is a nonsteroidal anti-inflammatory drug (NSAID). Ibuprofen works by reducing hormones that cause inflammation and pain in the. The generic name is ibuprofen and famotidine is a coated tablet. Gastrointestinal Risk NSAIDs cause an increased risk of serious

gastrointestinal adverse reactions including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These reactions can occur at any time. Per the clinical notes the injured worker had had a history of gastrointestinal upset and Duexis would not be recommended. The clinical notes did not address the efficacy of the medication. As such, the request is not medically necessary.

Ibuprofen / Famotidine #30: 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).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: www.drugs.com.

Decision rationale: The request for Duexis (800 Motrin/Famotidine) is denied. The www.drugs.com indicate that Duexis contains a combination of famotidine and ibuprofen. Famotidine is a histamine blocker. Famotidine works by decreasing the amount of acid the stomach produces. Ibuprofen is a nonsteroidal anti-inflammatory drug (NSAID). Ibuprofen works by reducing hormones that cause inflammation and pain in the. The generic name is ibuprofen and famotidine is a coated tablet. Gastrointestinal Risk NSAIDs cause an increased risk of serious gastrointestinal adverse reactions including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These reactions can occur at any time. Per the clinical notes the injured worker had had a history of gastrointestinal upset and Duexis would not be recommended. The clinical notes did not address the efficacy of the medication. As such, the request is not medically necessary.

Theramine #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 (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) Head, Medical Foods.

Decision rationale: The retrospective request for 4 prescriptions for Theramine #90 is denied. The Official Disability Guidelines do not recommend Theramine. Theramine is a medical food from physician therapeutics that is a posterity blend of gamma aminobutyric acid and choline bitartrate. It is intended for the use and management of pain syndrome that include acute pain, chronic pain, fibromyalgia, neuropathic pain and inflammatory pain. There was no indication for the use of this product. In a manufacture study comparing Theramine to Naproxen, Theramine appeared to be effective in relieving back pain without causing significant side effects, however until there is higher quality study of the ingredients in Theramine, it is not recommended. The documentation provided did not indicate if the Theramine had been effective for pain control.

There was no evidence of any other medications or a VAS scale given. There was no frequency given. As such, the request is not medically necessary.

Xanax 2mg #30: 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 Benzodiazepines Page(s): 24.

Decision rationale: The request for Xanax 2 mg po bid PRN #30 is denied. The California MTUS do not recommend for long term use. 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. Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. The 2014 clinical note indicated the mental status was appropriate. No suicidal or homicidal ideations, or auditory or visual hallucinations. The use of Xanax is for short term use. The exact amount that the injured worker was taking daily was not addressed. The efficacy of the medication was not addressed. As such, the request is not medically necessary.

Gabadone #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 (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 Pain (Chronic) GABA done.

Decision rationale: The retrospective request for Gabadone two at bedtime for insomnia #60 is denied. The Official Disability Guidelines do not recommend the use of Gabadone it is a medical food from Physician Therapeutics, Los Angeles, CA, that is a proprietary blend of Choline Bitartrate, Glutamic Acid, 5-Hydroxytryptophan, and GABA. It is intended to meet the nutritional requirements for inducing sleep, promoting restorative sleep and reducing snoring in patients who are experiencing anxiety related to sleep disorders. Choline, Glutamic Acid, 5-hydroxytryptophan, and Gamma-aminobutyric acid (GABA). Per the guidelines Gabadone is not recommended. As such, the request is not medically necessary.

Percura #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 (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 (Chronic) Medical Foods.

Decision rationale: The retrospective request for 4 prescriptions for Theramine #90 is denied. The Official Disability Guidelines do not recommend Theramine. Theramine is a medical food from physician therapeutics that is a posterity blend of gamma aminobutyric acid and choline bitartrate. It is intended for the use and management of pain syndrome that include acute pain, chronic pain, fibromyalgia, neuropathic pain and inflammatory pain. There was no indication for the use of this product. In a manufacture study comparing Theramine to Naproxen, Theramine appeared to be effective in relieving back pain without causing significant side effects, however until there is higher quality study of the ingredients in Theramine, it is not recommended. The documentation provided did not indicate if the Theramine had been effective for pain control. There was no evidence of any other medications or a VAS scale given. There was no frequency given. As such, the request is not medically necessary.

Fioricet #30: 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 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 (Chronic) Barbiturates.

Decision rationale: The request for Fioricet 2 po q 8 hours is denied. The California MTUS Guidelines do not recommended Fioricet for chronic pain. The potential for drug dependence is high and no evidence exists to show a clinically important enhancement of analgesic efficacy of BCAs 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. Per the clinical notes the injured worker complained of a headache and rated her pain 10/10, the use of Fioricet has a rebound effect when there is a risk of overuse. The clinical notes did not address the efficacy or if the medication was being used for the pain or headache. Fioricet has a high risk for dependence. As such, the request is not medically necessary.

Vitamin B12: 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).

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) Vitamin B.

Decision rationale: The request for B12 IM 2cc x1 is denied. The California MTUS Guidelines do not recommend. Vitamin B is frequently used for treating peripheral neuropathy but its efficacy is not clear. A recent meta-analysis concluded that there are only limited data in randomized trials testing the efficacy of vitamin B for treating peripheral neuropathy and the evidence is insufficient to determine whether vitamin B is beneficial or harmful. In the comparison of vitamin B with placebo, there was no significant short-term benefit in pain intensity while there is a small significant benefit in vibration detection from oral benfotiamine, a derivative of thiamine. In comparing different doses of vitamin B complex, there was some evidence that higher doses resulted in a significant short-term reduction in pain and improvement in paraesthesiae, in a composite outcome combining pain, temperature and vibration, and in a composite outcome combining pain, numbness and paraesthesiae. There was some evidence that vitamin B is less efficacious than alpha-lipoic acid, cilostazol or cytidine triphosphate in the short-term improvement of clinical and nerve conduction study outcomes. Vitamin B is generally well-tolerated. Per the guidelines B12 is not recommended. As such, the request is not medically necessary.

Gabapentin 6%/ Lidocaine2%/ Capsaicin0.375%/Menthol 0.5%/Camphor 0.5% #240 gram: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: The request for Gabapentin 6 %/ Lidocaine 2%/ Capsaicin 0.375% / Menthol 0.5%/ Camphor 0.5% # 240 is denied. The CA/ MTUS states that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety; also, that they are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control; however, there is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended, therefore, is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. Gabapentin is not recommended. There is no peer-reviewed literature to support use. Per the guidelines any compounded product that contains at least one drug that is not recommended, therefore it is not recommended. As such, the request is not medically necessary.