

Case Number:	CM15-0147051		
Date Assigned:	08/10/2015	Date of Injury:	05/12/2006
Decision Date:	10/02/2015	UR Denial Date:	06/22/2015
Priority:	Standard	Application Received:	07/28/2015

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: Arizona, Michigan

Certification(s)/Specialty: Preventive Medicine, Occupational 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 46 year old female who sustained an industrial injury on 05-12-2006 resulting in injury to multiple body parts. Treatment provided to date has included: injections, medications, and conservative therapies and care. Diagnostic testing was reported to have included x-rays and MRI scan; however, these reports were no available for review, and details were not discussed. Although there were no noted comorbidities or other dates of injury noted, it was noted that the injured worker is prescribed 2 different insulins. On 05-29-2015, physician progress report noted complaints of low back pain, thoracic pain, cervical pain and bilateral arms and wrist pain. The pain was rated 5 out of 10 in severity, and was described as constant, sharp, aching, numbing, pressure like, shooting, stabbing, throbbing, tingling, tightness, stiffness, soreness and electrical. Additional complaints included migraines, involuntary loss of bowel and bladder control, difficulty sleeping, muscle tightness and spasms. Current medications include Flector transdermal patches, Novolog and Lantus insulin, Abilify, Relpax, Duexis, Cymbalta, Dilaudid, Duragesic transdermal patches, Klonopin, Lyrica, and Soma. The injured worker reported that current medications are somewhat effective in controlling her pain. The physical exam revealed no acute distress, poor hygiene, poor dentition, obesity with a BMI of 38, full active range of motion in the cervical spine, negative Spurling's test, decreased internal rotation of the shoulders bilaterally, negative impingement test bilaterally, decreased deep tendon reflexes in the bilateral brachial and triceps, slightly decreased opposing strength bilaterally, bilateral grip strength full and equal, normal sensation in C5-T1, hyper-abduction negative bilaterally, negative Addison's bilaterally, negative osteoclavicular bilaterally, negative Tinel's

test bilaterally, negative Phalen's maneuver bilaterally, negative Finklestein's test bilaterally, and bilateral elbow flexion of 150°. The provider noted diagnoses of cervical intervertebral disc displacement without myelopathy, cervical spondylosis without myelopathy, anxiety state, and depressive disorder not elsewhere classified lumbosacral spondylosis without myelopathy, and degeneration of cervical intervertebral disc. Random urine drug screenings with signed opioid agreement were reported. Plan of care includes continuation of current medications, and follow-up in 30 days. The injured worker's work status was noted as "return as previous"; however, all reports state the same status. Work status is unclear and unchanged. The request for authorization and IMR (independent medical review) includes: Cymbalta tablets 60mg #60, Lyrica tablets 225mg #90, Duexis tablets 800-26.6mg #60, Replax tablets 40mg #60, Duragesic patches 50mcg per hour #25, Dilaudid tablets 4mg #180, Klonopin tablets 0.5mg #90, and Soma tablets 350mg #90.

IMR ISSUES, DECISIONS AND RATIONALES

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

Cymbalta tablets 60 mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain Page(s): 13-16.

Decision rationale: According to the MTUS in regards to Cymbalta (duloxetine), anti-depressants are recommended as a first line option in treating neuropathic pain, and a possible choice for non-neuropathic pain. Decrease in pain generally occurs within a few days to a week. Assessment of effectiveness of the treatment should include not just pain conclusions, but also an evaluation of function, changes in use of other analgesic medication, sleep quality and duration, and psychological assessment. Duloxetine is FDA-approved for anxiety, depression, diabetic neuropathy, and fibromyalgia, but used off-label for neuropathic pain and radiculopathy. Although Duloxetine is recommended as a first-line option for diabetic neuropathy; there is insufficient evidence to support the use of duloxetine for lumbar radiculopathy with more studies needed to determine the efficacy of duloxetine for other types of neuropathic pain. Side effects include: central nervous system symptoms of dizziness, fatigue, somnolence, drowsiness, anxiety and insomnia, gastrointestinal symptoms, and weight loss. In this case, there was clear evidence in the medical records that the injured worker had been prescribed this medication for several months; however, there is insufficient evidence of ongoing reduction in pain or improvement in function with the use of this medication as the injured worker reported that her medications were only somewhat effective in controlling her pain. Additionally, there has been an inadequate assessment of the effectiveness of this medication. Due to the lack of ongoing improvement in pain levels or functional improvement, and possible side-effects, medical necessity has not been established. The request for Cymbalta 60mg #60 is not medically necessary.

Lyrica tablets 225 mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 16-22.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs) & Pregabalin (Lyrica) Page(s): 16-20 & 99.

Decision rationale: MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. Lyrica is an Anti-Epilepsy drug (AED) used to treat diabetic painful neuropathy and postherpetic neuralgia. According to California MTUS Guidelines, AEDs are a first-line treatment for neuropathic pain; however, the MTUS also states that there is insufficient evidence to recommend for or against antiepileptic drugs for axial low back pain. Lyrica is FDA approved for diabetic neuropathy and post-herpetic neuralgia and has been used effectively for the treatment of other neuropathic pain. The guidelines indicate a good to moderate response to the use of Lyrica is a 30-50% reduction in pain. The MTUS states, "A 'good' response to the use of AEDs has been defined as a 50% reduction in pain and a 'moderate' response as a 30% reduction. A lack of response of this magnitude may indicate the need for the following: (1) a switch to a different first-line agent (TCA, SNRI or AED are considered first-line treatment); or (2) combination therapy if treatment with a single drug agent fails." Although there is no established trial period, the onset of action is thought to be less than 1 week. Lyrica is also known to have side effects including edema, CNS depression, weight gain, and blurred vision. It is recommended that this drug be avoided if the patient has a problem with weight gain. In regards to the current request for Lyrica, the injured worker has been taking Lyrica, in addition to narcotic analgesics, for several months with no significant measurable improvement in pain or function documented. Without evidence of improvement, the guidelines recommend changing to a different first-line agent (TCA, SNRI or AED) or a combination of therapy. In addition, the injured worker is noted to have obesity with a BMI of 38 for which this drug is not recommended. Medical necessity for Lyrica has not been established. Therefore, the current request for Lyrica 225mg #90 is not medically necessary.

Duexis tablets 800/26.6 mg #60: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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; Duexis® (ibuprofen & famotidine).

Decision rationale: MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. Duexis (ibuprofen & famotidine) is used in the treatment of pain caused by arthritis in patients who might have stomach problems caused by pain medicines, and is a combination of a non-steroidal anti-inflammatory drug (NSAID) and an H2-blocker that helps protect against ulcers in the stomach or intestines. The MTUS is silent in regards to Duexis; therefore alternative guidelines were referenced in the review and decision of this medication. The ODG states that Duexis is not recommended as a first-line drug, but has been recommended for rheumatoid arthritis and osteoarthritis. The ODG also states: "Ibuprofen (eg, Motrin, Advil) and famotidine (eg, Pepcid) are also available in multiple strengths OTC (over the counter), and other strategies are recommended to prevent stomach ulcers in patients taking NSAIDS. With less benefit and higher cost, using Duexis as a first-line therapy is not justified." In this case, there is no diagnoses of rheumatoid arthritis or osteoarthritis and no clinical evidence of

arthritis. Additionally, there were no complaints of gastrointestinal issues. Furthermore, it is unclear how long the injured worker has been prescribed Duexis and there is no assessment of the effectiveness of this medication. As such the medical necessity of Duexis is not established. Therefore the requested Duexis tablets 800-26.6mg #60 is not medically necessary.

Replax tablets 40 mg #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.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UpToDate / Relpax (Eletriptan).

Decision rationale: The MTUS/ ACOEM did not address the use of triptans therefore other guidelines were consulted. Per UpToDate serotonin 1b/1d agonists (triptans) are effective for the acute treatment of migraine. The triptans are considered to be "specific" therapies for acute migraine since, in contrast to analgesics, they act at the pathophysiologic mechanism of the headache [1,2]. However, triptan responsiveness should not be considered diagnostic of migraine, as secondary headaches may also improve with triptan treatment. Unfortunately a review of the injured workers medical records did not reveal any documentation of pain or functional improvement with the use of Relpax, without this information it is not possible to determine medical necessity, therefore the request for Relpax is not medically necessary.

Duragesic patches 50 mcg/hr #15: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 44.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Duragesic (fentanyl transdermal system) & Opioids Page(s): 44 & 74-96.

Decision rationale: MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. Fentanyl (duragesic patch) is a long-acting opioid and is a highly potent form of opiate analgesic. According to the California MTUS Guidelines (2009), topical duragesic patches, are indicated for the management of persistent chronic pain, which is moderate to severe requiring continuous, around-the-clock opioid therapy and should only be used in patients who are currently on opioid therapy for which tolerance has developed. The MTUS discourages long term usage unless there is evidence of "ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life." The MTUS also recommends the discontinuation of opioids when there is no overall improvement in function, unless there are extenuating circumstances. Weaning should occur under direct ongoing medical supervision as a slow taper except for the below mentioned possible indications for immediate discontinuation. Upon review of the submitted documentation, it is clear that the injured worker has been prescribed duragesic patches for several months. However, the progress reports demonstrate that the treating physician did not document: 1) the least reported pain over the period since last assessment; 2) intensity of

pain after taking the opioid; 3) how long it takes for pain relief; 4) how long pain relief lasts; 5) improvement in pain; or 6) improvement in function. Additionally, there is no documented evidence of monitoring for misuse as there was no urine toxicology testing results available. Despite the use of this medication, the injured worker has continued to report ongoing high levels of pain. As such, duragesic patches 50mcg per hour #25 are not medically necessary.

Dilaudid tablets 4 mg #180: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 74-82.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96. Decision based on Non-MTUS Citation Pain (Chronic); Opioids, specific drug list.

Decision rationale: MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. Hydromorphone (Dilaudid) is a short-acting opioid drug that is used to treat severe chronic pain, and is often used for intermittent or breakthrough pain. The MTUS discourages long term usage unless there is evidence of "ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life." The MTUS also recommends ongoing assessment of appropriate use of opioids and side effects, and the discontinuation of opioids when there is no overall improvement in function, unless there are extenuating circumstances. Weaning should occur under direct ongoing medical supervision as a slow taper except for the below mentioned possible indications for immediate discontinuation. Upon review of the submitted documentation, it is clear that the injured worker has been prescribed Dilaudid for several months. However, the progress reports demonstrate that the treating physician did not document: 1) the least reported pain over the period since last assessment; 2) intensity of pain after taking the opioid; 3) how long it takes for pain relief; 4) how long pain relief lasts; 5) improvement in pain; or 6) improvement in function. Additionally, there is not documented evidence of monitoring for misuse as there was no urine toxicology testing results available. As such, Dilaudid tablets 4mg #180 is not medically necessary.

Klonopin tablets 0.5 mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 24.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 44.

Decision rationale: MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. Klonopin (clonazepam) is classified as a benzodiazepine. According to the MTUS, benzodiazepines are not recommended for long-term use because long-term efficacy is

not proven, and due to the high risk of dependence with guidelines limiting use to 4 weeks. The documented range of action includes sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant effects. Additionally, chronic use of benzodiazepines is the treatment of choice in very few conditions. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. Therefore, antidepressant medications are considered more appropriate in the treatment of anxiety disorders. In this case, the injured worker has been prescribed Klonopin for several months. Although, there are diagnoses of depression and anxiety, there are no complaints of anxiety noted in the reports, and insufficient evidence that the injured worker has been seen by a psychiatrist or had a psychological evaluation for the treatment of anxiety and depression. Furthermore, benzodiazepines (Klonopin in this case) are not recommended for use longer than 4 weeks due to the high risk of dependence and the long-term use can lead to increased anxiety. As such, the request for Klonopin tablets 0.5mg #90 is not medically necessary.

Soma tablets 350 mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 63-66.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Carisoprodol (Soma) & Muscle relaxants (for pain) Page(s): 29 & 63-66.

Decision rationale: MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. Carisoprodol (Soma) is a centrally acting skeletal muscle relaxant whose primary active metabolite is meprobamate (a schedule-IV controlled substance). According to the MTUS, Soma (carisoprodol) is not recommended and is not indicated for long-term use (more than 2-3 weeks). The MTUS recommends non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP (low back pain) as they can reduce pain from muscle tension and possibly increase mobility. However, in most cases involving LBP, they provide no more benefit beyond NSAIDs in pain and overall improvement. Skeletal muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. In this case, clinical notes show that the injured worker has been prescribed Soma for several months with insufficient evidence of reduction in pain, reduction in muscle spasms, and/or improvement in function. Additionally, there was no evidence of muscle spasms on any of the exams available for review. Furthermore, the MTUS does not recommend or support the long-term use of Soma for more than 2-3 weeks. Therefore, Soma 350mg #90 is not medically necessary.