

Case Number:	CM15-0204202		
Date Assigned:	10/21/2015	Date of Injury:	08/10/2011
Decision Date:	12/28/2015	UR Denial Date:	09/23/2015
Priority:	Standard	Application Received:	10/17/2015

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: 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 36 year old male who sustained an industrial injury on 8-10-11. The injured worker reported pain in the low back and left lower extremity. A review of the medical records indicates that the injured worker is undergoing treatments for displacement of lumbar intervertebral disc and lumbar post-laminectomy syndrome. Provider documentation dated 9-15-15 noted the work status as maximally medically improved. Treatment has included status post lumbar disc depression (2-16-12), home exercise program, Etodolac since at least April of 2015, Melatonin since at least April of 2015, Nortriptyline since at least April of 2015, and Tramadol since at least April of 2015. Objective findings dated 9-15-15 were notable for a "normal gait" and "normal posture." The original utilization review (9-23-15) partially approved a request for Nortriptyline 25mg capsule, 1 every night at bedtime, #30 with 2 refills, Melatonin ER (extended release) 3mg tablets, 1 every night at bedtime, #30 with 2 refills, Tramadol 50mg, 1-2 every day as needed, #45 with 2 refills and Etodolac 300mg capsule every day as needed, #30 with 2 refills.

IMR ISSUES, DECISIONS AND RATIONALES

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

Nortriptyline 25mg capsule, 1 every night at bedtime, #30 with 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antidepressants for chronic pain.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antidepressants for chronic pain.

Decision rationale: The request is for nortriptyline, which is a tricyclic antidepressant that may also be used for treatment of pain. The MTUS guidelines recommended tricyclic antidepressants as a first-line option for neuropathic pain, especially if pain is accompanied by insomnia, anxiety, or depression. For non-neuropathic pain, it is recommended as an option in depressed patients, but effectiveness is limited. A systematic review indicated that tricyclic antidepressants have demonstrated a small to moderate effect on chronic low back pain (short-term pain relief), but the effect on function is unclear. In the treatment of radiculopathy, antidepressants are an option, but there are no specific medications that have been proven in high quality studies to be efficacious for treatment of lumbosacral radiculopathy. For osteoarthritis, no studies have specifically studied the use of antidepressants to treat pain from osteoarthritis, but improving depression symptoms was found to decrease pain and improve functional status. 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 (6-12 weeks). It has been suggested that if pain is in remission for 3-6 months, a gradual tapering of anti-depressants may be undertaken. Continued treatment would require clear documentation of a decrease in pain, a decrease in utilization of other medications, a functional improvement, and/or a return to work. Documentation suggests the injured worker has not decreased use of other medications despite use of nortriptyline for more than 12 weeks, nor has had a clear improvement in pain. While tricyclics are considered a first-line medication, 3 months of use without reassessment would far exceed the MTUS guidelines recommended duration of use. Consideration may be made with closer reassessment. However, the request as submitted is not supported by the MTUS guidelines and therefore is not medically necessary.

Melatonin ER (extended release) 3mg tablets, 1 every night at bedtime, #30 with 2 refills:
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-TWC), Insomnia treatment; Therapeutic Options for Sleep-Maintenance and Sleep-Onset Insomnia - Anna K. Morin, Pharm.D., Courtney I. Jarvis, Pharm.D., Ann M. Lynch, Pharm.D.; www.medscape.com.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Melatonin.

Decision rationale: The request is for melatonin, an analog of a naturally occurring hormone use for the treatment of insomnia. The MTUS guidelines do not clearly discuss melatonin. The Official Disability Guidelines (ODG) recommends the use of melatonin for delayed sleep phase syndrome and rapid eye movement sleep behavior disorders. There is also some suggestion that

it can have an analgesic effect, but current research is largely in the experimental phases. The literature reporting treatment of chronic insomnia disorder with melatonin remains inconclusive. Regarding the injured worker, documentation does not contain clear discussion of a sleep latency disorder, nor is there a discussion of sleep hygiene. Furthermore, long-term treatment for a sleep disorder is better aimed at the underlying cause, which may be chronic pain, but is not clearly addressed within the documentation. Therefore, the request as submitted is of unclear medical benefit, and is not medically necessary.

Tramadol 50mg, 1-2 every day as needed, #45 with 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation ACOEM, Chapter 7: Independent Medical Examinations and Consultations.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

Decision rationale: The request is for tramadol, an opioid used for the acute treatment of moderate to severe pain. The chronic use of opioids requires the 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. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. The MTUS guidelines support the chronic use of opioids if the injured worker has returned to work and there is a clear overall improvement in pain and function. The treating physician should consider consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psychiatric consult if there is evidence of depression, anxiety or irritability. Consider an addiction medicine consult if there is evidence of substance misuse. Opioids appear to be efficacious for the treatment of low back pain, but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited. Failure to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy. In regards to the injured worker, there is poor documentation of an improvement in pain, no clear functional improvement, no decrease in medication use, and no return to work. There is incomplete fulfillment of the criteria for use based upon the MTUS guidelines. Therefore, the request as written may not have medical benefit and is not medically necessary.

Etodolac 300mg capsule every day as needed, #30 with 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, specific drug list & adverse effects.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs).

Decision rationale: The request is for etodolac, a non-steroidal anti-inflammatory drug (NSAID) used for the treatment of acute pain. Non-steroidal anti-inflammatory drugs are recommended as an option for short-term symptomatic relief of acute exacerbation of chronic low back pain. However, non-steroidal anti-inflammatory drugs appear to be no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. Non-steroidal anti-inflammatory drugs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In general, non-steroidal anti-inflammatory drugs are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Studies have shown that when non-steroidal anti-inflammatory drugs are used for more than a few weeks, they can retard or impair bone, muscle, and connective tissue healing and perhaps cause hypertension. Therefore, they should be used only acutely. In regard to the injured worker, etodolac has been a part of the treatment regimen for far longer than the recommended duration, and the risk may outweigh the benefit. The request does not comply with the MTUS guidelines. Therefore, the request with 2 refills, for another 3 months of use, is not medically necessary.