

<b>Case Number:</b>	CM15-0015134		
<b>Date Assigned:</b>	02/03/2015	<b>Date of Injury:</b>	09/08/2011
<b>Decision Date:</b>	03/31/2015	<b>UR Denial Date:</b>	01/12/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/27/2015

### 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: 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 35 year old female with an industrial injury dated 09/08/2011 while lifting a toddler weighing 25-35 pounds. Her diagnoses include disc disorder of the lumbar spine, status post right L4-L5 laminectomy and discectomy, lumbar radiculopathy, lumbar facet arthropathy, rule out lumbar discogenic pain, and depression and anxiety syndrome. Recent diagnostic testing has included and x-ray of the lumbar spine (date unknown) showing no significant degenerative disc disease, and a nerve conduction study/electrodiagnostic testing of the lower extremities (07/21/2014) which was normal. She has been treated with diagnostic facet block at L4-S1, right transforaminal epidural steroid injection, medications, activity restrictions, physical therapy, and conservative care. In a progress note dated 11/13/2014, the treating physician reports constant low back pain described as sharp with radiation of pain into the lower extremities, and rated as 8/10 in severity. The objective examination revealed tenderness to the paravertebral muscles with spasms, positive seated nerve root test, guarded and restricted range of motion in the lumbar spine, and numbness and tingling in the L5-S1 dermatomal patterns. The treating physician is requesting multiple medications which were denied by the utilization review. On 01/12/2015, Utilization Review non-certified a prescription for tramadol ER 150mg once daily as needed #90, noting the lack of documented information about whether the injured worker had experienced any side effects from use, lack of documented benefit and functional improvement from use of this medication. The MTUS Guidelines were cited. On 01/12/2015, Utilization Review non-certified a prescription for Eszopiclone tablets 1mg at bedtime as needed #30, noting the absence of documented benefit from use and the non-recommendation for long

term use. The MTUS Guidelines were cited. On 01/12/2015, Utilization Review non-certified a prescription for cyclobenzaprine HCL 7.5mg by mouth every 8 hours as needed #120, noting the absence of recommendation for the long term use and that the injured worker had been on this medication for more than 3 weeks. The MTUS Guidelines were cited. On 01/12/2015, Utilization Review non-certified a prescription for Omeprazole 20mg by mouth 12 hours as needed #120, noting the injured worker was not at intermediate risk for gastrointestinal events. The MTUS Guidelines were cited. On 01/12/2015, Utilization Review non-certified a prescription for ondansetron 8mg ODT as needed #30, noting that the medication was not recommended for nausea and vomiting secondary to opioid use. The ODG Guidelines were cited. On 01/12/2015, Utilization Review non-certified a prescription for Fenoprofen Calcium 400mg three times daily #120, noting the absence of documented benefit from use of this medication. The MTUS Guidelines were cited. On 01/27/2015, the injured worker submitted an application for IMR for review of tramadol ER 150mg once daily as needed #90, Eszopiclone tablets 1mg at bedtime as needed #30, cyclobenzaprine HCL 7.5mg by mouth every 8 hours as needed #120, Omeprazole 20mg by mouth 12 hours as needed #120, ondansetron 8mg ODT as needed #30, and Fenoprofen Calcium 400mg three times daily #120.

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

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

**Tramadol ER 150mg, Once A Day As Needed, #90 NDC# 776218-0708-05: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids section, Weaning of Medications section Page(s): 74-95, 124.

**Decision rationale:** Tramadol is a central acting synthetic opioid that exhibits opioid activity with a mechanism of action that inhibits the reuptake of serotonin and norepinephrine with side effects similar to traditional opioids. The MTUS Guidelines do not recommend the use of opioid pain medications, in general, for the management of chronic pain. There is guidance for the rare instance where opioids are needed in maintenance therapy, but the emphasis should remain on non-opioid pain medications and active therapy. Long-term use may be appropriate if the patient is showing measurable functional improvement and reduction in pain in the absence of non-compliance. Functional improvement is defined by either significant improvement in activities of daily living or a reduction in work restriction as measured during the history and physical exam. The medical records do not indicate that the injured worker is experiencing significant reduction in pain with associated objective functional improvement as a result of chronic use of tramadol. Medical necessity of this request has not been established within the recommendations of the MTUS Guidelines. It is not recommended to discontinue opioid treatment abruptly, as weaning of medications is necessary to avoid withdrawal symptoms when opioids have been used chronically. This request however is not for a weaning treatment, but to continue treatment. The request for Tramadol ER 150mg, Once A Day As Needed, #90 NDC# 776218-0708-05 is determined to not be medically necessary.

**Eszopiclone Tablets 1mg, At Bedtime As Needed, #30 NDC# 00054-0290-13: Upheld**

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

**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 section

**Decision rationale:** The MTUS Guidelines do not address pharmacologic sleep aids. Per the Official Disability Guidelines, pharmacological agents should only be used for insomnia management after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve in a 7 to 10 day period may indicate a psychiatric and/or medical illness. Primary insomnia is generally addressed pharmacologically whereas secondary insomnia may be treated with pharmacological and/or psychological measures. Eszopiclone (Lunesta) has demonstrated reduced sleep latency and sleep maintenance. It is the only benzodiazepine-receptor agonist FDA approved for use longer than 35 days. A randomized, double blind, controlled clinical trial with 830 primary insomnia patients reported significant improvement in the treatment group when compared to the control group for sleep latency, wake after sleep onset, and total sleep time over a 6-month period. Side effects: dry mouth, unpleasant taste, drowsiness, dizziness. Sleep-related activities such as driving, eating, cooking and phone calling have occurred. Withdrawal may occur with abrupt discontinuation. The medical records provided for review do not well describe the injured worker's insomnia or the history of evaluation and treatment for insomnia. Medical necessity for the use of pharmacologic sleep aids has not been established. The request for Eszopiclone Tablets 1mg, At Bedtime As Needed, #30 NDC# 00054-0290-13 is determined to not be medically necessary.

**Cyclobenzaprine HCL 7.5mg, po every 8 hours PRN, #120 NDC#76218-1219-01: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 64.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine section, Muscle Relaxants (for pain) section Page(s): 41, 42, 63, 64.

**Decision rationale:** Cyclobenzaprine is recommended by the MTUS Guidelines for short periods with acute exacerbations, but not for chronic or extended use. These guidelines report that the effect of cyclobenzaprine is greatest in the first four days of treatment. Cyclobenzaprine is associated with a number needed to treat of three at two weeks for symptoms improvement in low back pain and is associated with drowsiness and dizziness. The injured worker is not reported to have an acute exacerbation that may benefit from short term use of cyclobenzaprine. This request is also for 60 or more days of treatment, which is excess of the recommendations of the MTUS Guidelines. Chronic use of cyclobenzaprine may cause dependence, and sudden discontinuation may result in withdrawal symptoms. Discontinuation should include a tapering dose to decrease withdrawal symptoms. This request however is not for a tapering dose. The

request for Cyclobenzaprine HCL 7.5mg, po every 8 hours PRN, #120 NDC#76218-1219-01 is determined to not be medically necessary.

**Omeprazole 20mg, PO 12hourse PRN #120, NDC# 60505-0065-01: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risk section Page(s): 68, 69.

**Decision rationale:** Proton pump inhibitors, such as omeprazole are recommended by the MTUS Guidelines when using NSAIDs if there is a risk for gastrointestinal events. There is no indication that the injured worker has had a gastrointestinal event or is at increased risk of a gastrointestinal event, which may necessitate the use of omeprazole when using NSAIDs. The medical reports indicate that the injured worker experiences occasional dyspepsia. This reason alone is not an indication for twice a day treatment with omeprazole as recommended by the MTUS Guidelines. The request for omeprazole 20mg, PO 12 hours PRN #120, NDC# 60505-0065-01 is determined to not be medically necessary.

**Ondansetron 8mg ODT, PRN #30, NDC# 65862-0391-10: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Ondansetron

**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, Antiemetics (for opioid nausea)

**Decision rationale:** The MTUS Guidelines do not address the use of ondansetron. The ODG does not recommend the use of antiemetics for nausea and vomiting secondary to chronic opioid use. Ondansetron is FDA approved for use with nausea as a result of chemotherapy or radiation treatments, post-operative nausea, and acutely in gastroenteritis. The medical records indicate that the injured worker has occasional dyspepsia. Medical necessity of this request has not been established within the recommendations of the ODG. The request for Ondansetron 8mg ODT, PRN #30, NDC# 65862-0391-10 is determined to not be medically necessary.

**Fenoprofen Calcium 400mg, TID #120, NDC# 76186-1215-09: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs section Page(s): 67-71.

**Decision rationale:** The use of NSAIDs are recommended by the MTUS Guidelines with precautions. NSAIDs are recommended to be used secondary to acetaminophen, and at the lowest dose possible for the shortest period in the treatment of acute pain or acute exacerbation of chronic pain as there are risks associated with NSAIDs and the use of NSAIDs may inhibit the healing process. The injured worker has chronic injuries with no change in pain level and no acute injuries reported. The medical records do not indicate that the injured worker has an acute injury or acute exacerbation, and is not diagnosed with osteoarthritis. The medical records do not indicate that the injured worker has significant pain reduction with objective functional improvement as a result of this medication. Medical necessity of this request has not been established within the recommendations of the MTUS Guidelines. The request for Fenoprofen Calcium 400mg, TID #120, NDC# 76186-1215-09 is determined to not be medically necessary.