MAXIMUS Federal Services

| Case Number: | CM15-0112019 | | |
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| Date Assigned: | 06/18/2015 | Date of Injury: | 06/18/2013 |
| Decision Date: | 09/23/2015 | UR Denial Date: | 06/05/2015 |
| Priority: | Standard | Application Received: | 06/09/2015 |

## 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: Physical Medicine & Rehabilitation

## 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 65 year old female, who sustained an industrial injury on 6/18/13. The injured worker has complaints of low back pain that radiated into the lower extremities. The documentation noted that there is constant pain in the bilateral wrist/hand/thumb right greater than left that is aggravated by repetitive motions, gripping, grasping, pushing, pulling and lifting. The injured worker has difficulty sleeping and has hardware related pain. The documentation noted on examination that there is tenderness over the volar aspect of the wrist and right thumb A1 pulley with triggering and carpometacarpal (CMC). There is diminished sensation in the radial digits and palpable paravertebral muscles tenderness with spasm. The diagnoses have included lumbago and cervicalgia. Treatment to date has included magnetic resonance imaging (MRI) of her cervical and lumbar spine, shoulders and hips; electrodiagnostic studies of her bilateral upper and lower extremities; L4-S1 (sacroiliac) posterior lumbar interbody fusion; two-level laminectomy/discectomy at L4-L5 and L5-S1 (sacroiliac); water therapy; lumbar brace; physical therapy and injections. The request was for Nabumetone (relafen) 750 mg #120 1 pill three times a day; lansoprazole (Prevacid) delayed release capsules, 30 mg #120 1 by mouth every 12 hours as needed; ondansetron 8 mg ODT, #30 1 as needed; cyclobenzaprine hydrochloride tablets 7.5 mg #120 1 PO every 8 hours as needed; tramadol extended release 150 mg #90 once a day as needed for severe pain and eszopiclone tablets 1 mg #30 1 at bedtime as needed for sleep.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Nabumetone (Relafen) 750 mg #120 1 pill TID:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-inflammatory medications Page(s): 22.

**Decision rationale:** This patient presents with constant pain in the low back with radiation in to the lower extremities at 4/10 per progress report 3/17/15. The patient also has pain in the bilateral wrist/hand/thumb right worse than left. The current request is for Nabumetone (Relafen) 750 mg #120 1 pill TID. The listed diagnoses are Lumbago and Cervicalgia. For medication documentation, the treater states, "The patient is to continue taking their medications as directed. They are helping in curing and relieving the patient's symptomatology. They are improving the patient's activities of daily living and making it possible for him to continue working and/or maintain the activities of daily living." Same statement is made on both 3/17/15 and 1/16/15 reports. The UR denial is dated 5/29/15. MTUS page 22, Anti-inflammatory medications states, Anti-inflammatories are the traditional first line of treatment, to reduce pain so activity and functional restoration can resume, but long-term use may not be warranted. (Van Tulder-Cochrane, 2000) A comprehensive review of clinical trials on the efficacy and safety of drugs for the treatment of low back pain concludes that available evidence supports the effectiveness of non-selective nonsteroidal anti-inflammatory drugs (NSAIDs) in chronic LBP and of antidepressants in chronic LBP. In this case, the request would be appropriate. However, the treater does not discuss how this medication is used and with what effectiveness. While the treater has a templated documentation for all medications taken, there is no specific information regarding the use of Relafen and how it's reducing pain and improving function. General statements that are repeated in each progress reports are inadequate documentation. Page 60 of MTUS requires that pain and function must be documented when medications are used for chronic pain. On 5/29/15, the treater provided an explanation of each medication but again, this is a general information regarding indications for the patient. None of the information provided is specific to this patient's response to the medication provided. Given any specific documentation as to how this particular medication is helping the patient, the request is not medically necessary.

**Lansoprazole (Prevacid) delayed release capsules, 30 mg #120 1PO 12H PRN:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms, cardiovascular risk.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular Page(s): 69.

**Decision rationale:** This patient presents with constant pain in the low back with radiation in to the lower extremities at 4/10 per progress report 3/17/15. The patient also has pain in the

bilateral wrist/hand/thumb right worse than left. The current request is for Lansoprazole (Prevacid) delayed release capsules, 30 mg #120 1PO 12H PRN. The listed diagnoses are Lumbago and Cervicalgia. For medication documentation, the treater states, "The patient is to continue taking their medications as directed. They are helping in curing and relieving the patient's symptomatology. They are improving the patient's activities of daily living and making it possible for him to continue working and/or maintain the activities of daily living." Same statement is made on both 3/17/15 and 1/16/15 reports. The UR denial is dated 5/29/15.MTUS p69, NSAIDs, GI symptoms & cardiovascular risk: "Recommend with precautions as indicated below. Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the patient is at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastroduodenal lesions." "Treatment of dyspepsia secondary to NSAID therapy: Stop the NSAID, switch to a different NSAID, or consider H2-receptor antagonists or a PPI." In this case, the request may be appropriate given the patient's NSAID intake. However, the treater does not discuss how this medication is used and with what effectiveness. While the treater has a templated documentation for all medications taken, there is no specific information regarding the use of Prevacid and why this medication is needed. There is no documentation of any GI risk factors, side effects or GERD to warrant the use of this medication. General statements that are repeated in each progress reports are inadequate documentation. Page 60 of MTUS requires that pain and function must be documented when medications are used for chronic pain. On 5/29/15, the treater provided an explanation of each medication but again, this is a general information regarding indications for the patient. None of the information provided is specific to this patient's response to the medication provided. Given any specific documentation as to how this particular medication is helping the patient, the request is not medically necessary.

**Ondansetron 8 mg ODT, #30 1 PRN:** 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), Ondansetron (Zofran).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chapter Chronic pain, under Antiemetics.

**Decision rationale:** This patient presents with constant pain in the low back with radiation in to the lower extremities at 4/10 per progress report 3/17/15. The patient also has pain in the bilateral wrist/hand/thumb right worse than left. The current request is for Lansoprazole (Prevacid) delayed release capsules, 30 mg #120 1PO 12H PRN. The listed diagnoses are Lumbago and Cervicalgia. For medication documentation, the treater states, "The patient is to continue taking their medications as directed. They are helping in curing and relieving the patient's symptomatology. They are improving the patient's activities of daily living and making it possible for him to continue working and/or maintain the activities of daily living." Same statement is made on both 3/17/15 and 1/16/15 reports. The UR denial is dated 5/29/15.

ODG guidelines, Chapter Chronic pain, under Antiemetics (for opioid use): Not recommended for nausea and vomiting secondary to chronic opioid use. "Ondansetron (Zofran): This drug is a serotonin 5-HT3 receptor antagonist. It is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment. It is also FDA-approved for postoperative use. Acute use is FDA-approved for gastroenteritis". In this case, there is no documentation of post-operative nausea, or chemotherapy/radiation therapy induced nausea to warrant the use of this medication. ODG guidelines specifically do not support the use of this medication for opioid induced nausea. The request is not medically necessary.

**Cyclobenzaprine hydrochloride tablets 7.5 mg #120 1 PO Q8H/PRN:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 64.

**Decision rationale:** This patient presents with constant pain in the low back with radiation in to the lower extremities at 4/10 per progress report 3/17/15. The patient also has pain in the bilateral wrist/hand/thumb right worse than left. The current request is for Lansoprazole (Prevacid) delayed release capsules, 30 mg #120 1PO 12H PRN. The listed diagnoses are Lumbago and Cervicalgia. For medication documentation, the treater states, "The patient is to continue taking their medications as directed. They are helping in curing and relieving the patient's symptomatology. They are improving the patient's activities of daily living and making it possible for him to continue working and/or maintain the activities of daily living." Same statement is made on both 3/17/15 and 1/16/15 reports. The UR denial is dated 5/29/15.MTUS page 64, Cyclobenzaprine section has the following: "Recommended for a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant with similar effects to tricyclic antidepressants (e.g. amitriptyline)". "This medication is not recommended to be used for longer than 2-3 weeks". In this case, the treater does not indicate that the medication is to be used for short-term. MTUS does not recommend use of this medication for chronic pain for long-term. The prescription is for #120 suggesting that it is to be used 3-4 tablets per day for a month. The request is not medically necessary.

**Tramadol extended release 150 mg #90 once a day as needed for severe pain:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain criteria for use of opioids Page(s): 60, 61, 76-78, 88, 89.

**Decision rationale:** This patient presents with constant pain in the low back with radiation in to the lower extremities at 4/10 per progress report 3/17/15. The patient also has pain in the bilateral wrist/hand/thumb right worse than left. The current request is for Tramadol extended

release 150 mg #90 once a day as needed for severe pain. The listed diagnoses are Lumbago and Cervicalgia. For medication documentation, the treater states, "The patient is to continue taking their medications as directed. They are helping in curing and relieving the patient's symptomatology. They are improving the patient's activities of daily living and making it possible for him to continue working and/or maintain the activities of daily living." Same statement is made on both 3/17/15 and 1/16/15 reports. The UR denial is dated 5/29/15. For chronic opiates use, MTUS guidelines p88, 89; Long-term users of opioids section require specific documentations regarding pain and function. Page 78 of MTUS requires "Pain Assessment' that requires 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". Furthermore, “The 4 A's for ongoing monitoring" are required that include analgesia, ADL's, adverse side effects and aberrant drug-seeking behavior. MTUS p80, 81 also states regarding chronic low back pain: "Appears to be efficacious but limited for short-term pain relief and long-term efficacy is unclear (>16 weeks), but also appears limited". Long-term use of opiates may be indicated for nociceptive pain per MTUS, stating, "Recommended as the standard of care for treatment of moderate or severe nociceptive pain (defined as pain that is presumed to be maintained by continual injury with the most common example being pain secondary to cancer)". However, this patient does not present with pain that is presumed to be maintained by continual injury. In this case, there is no documentation of the four A's, no UDS, no discussion regarding the patient's side effects, and no outcome measures. No before and after scales are provided on any of the reports. On 5/29/15, the treater provided an explanation of each medication but again, this is a general information regarding indications for the patient. None of the information provided is specific to this patient's response to the medication provided. Given any specific documentation as to how this particular medication is helping the patient, the request is not medically necessary.

**Eszopiclone tablets 1 mg #30 1 at bedtime as needed for sleep:** 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), Eszopicolone (Lunesta) mental chapter.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Stress Chapter, under Lunest.

**Decision rationale:** This patient presents with constant pain in the low back with radiation in to the lower extremities at 4/10 per progress report 3/17/15. The patient also has pain in the bilateral wrist/hand/thumb right worse than left. The current request is for Eszopiclone tablets 1 mg #30 1 at bedtime as needed for sleep. The listed diagnoses are Lumbago and Cervicalgia. For medication documentation, the treater states, "The patient is to continue taking their medications as directed. They are helping in curing and relieving the patient's symptomatology. They are improving the patient's activities of daily living and making it possible for him to continue working and/or maintain the activities of daily living." Same statement is made on both 3/17/15 and 1/16/15 reports. The UR denial is dated 5/29/15. ODG guidelines Chapter Stress, under Lunesta section: Not recommended for long-term use, but recommended for short-term

use. See Insomnia treatment. See also the Pain Chapter. Recommend limiting use of hypnotics to three weeks maximum in the first two months of injury only, and discourage use in the chronic phase. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit-forming, and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term. In this study, eszopicolone (Lunesta) had a Hazard ratio for death of 30.62 (C.I., 12.90 to 72.72), compared to zolpidem at 4.82 (4.06 to 5.74). In general, receiving hypnotic prescriptions was associated with greater than a threefold increased hazard of death even when prescribed less than 18 pills per year. (Kripke, 2012) The FDA has lowered the recommended starting dose of eszopiclone (Lunesta) from 2 mg to 1 mg for both men and women. Previously recommended doses can cause impairment to driving skills, memory, and coordination as long as 11 hours after the drug is taken. Despite these long-lasting effects, patients were often unaware they were impaired. (FDA, 2014) In this case, there is no documentation as to how this medication is used on a daily basis. ODG does not support long-term use of this medication and only short-term use is supported. There is concern of increased pain and depression over the long-term. The treater does not raise these concerns and there is no documentation in any of the reports whether or there is any efficacy. On 5/29/15, the treater provided an explanation of each medication but again, this is a general information regarding indications for the patient. None of the information provided is specific to this patient's response to the medication provided. Given any specific documentation as to how this particular medication is helping the patient, the request is not medically necessary.