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| Case Number: | CM15-0123526 | | |
| Date Assigned: | 07/15/2015 | Date of Injury: | 08/24/1998 |
| Decision Date: | 10/15/2015 | UR Denial Date: | 06/06/2015 |
| Priority: | Standard | Application Received: | 06/26/2015 |

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: New York
 Certification(s)/Specialty: Pediatrics, Internal 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 56 year old male, who sustained an industrial injury on 8/24/1998. The mechanism of injury is injury from cumulative trauma. The current diagnoses are post laminectomy syndrome, chronic pain syndrome, lumbar radiculopathy, and cervical spondylosis. According to the progress report dated 5/26/2015, the injured worker complains of neck and back pain. The level of pain is not rated. The physical examination of the cervical spine reveals pain with extension and left lateral rotation. Examination of the lumbar spine reveals pain to palpation over the intervertebral spaces. There is pain noted with extension and anterior flexion. The current medications are Promethazine, Imitrex, Flexeril, Naprosyn EC, Amitriptyline, Reglan, Prevacid, Propranolol, Seroquel, Ultram, and Lorazepam. There is documentation of ongoing treatment with these medications since at least 12/1/2014. Treatment to date has included medication management, x-rays, physical therapy, MRI studies, electrodiagnostic testing, and surgical intervention. Per AME notes on 10/17/2013, the injured worker has returned to performing his job activities. A request for Promethazine, Imitrex, Flexeril, Naprosyn EC, Amitriptyline, Reglan, Prevacid, Propranolol, Seroquel, Ultram, and Lorazepam has been submitted.

IMR ISSUES, DECISIONS AND RATIONALES

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

Promethazine 25 milligrams #60 with one refill, 1 tab 2 times a day as needed: 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, Antiemetics.

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

Decision rationale: The CA MTUS/ACOEM Medical Treatment Guidelines is silent regarding the use of Promethazine. However, per the Official Disability Guidelines (ODG), anti-emetics (for opioid nausea) are not recommended for nausea and vomiting secondary to chronic opioid use. Nausea and vomiting is common with use of opioids. These side effects tend to diminish over days to weeks of continued exposure. Studies of opioid adverse effects including nausea and vomiting are limited to short-term duration (less than four weeks) and have limited application to long-term use. If nausea and vomiting remains prolonged, other etiologies of these symptoms should be evaluated for. The differential diagnosis includes gastroparesis (primarily due to diabetes). Current research for treatment of nausea and vomiting as related to opioid use primarily addresses the use of antiemetics in patients with cancer pain or those utilizing opioids for acute/postoperative therapy. Recommendations based on these studies cannot be extrapolated to chronic non-malignant pain patients. There is no high-quality literature to support any one treatment for opioid-induced nausea in chronic non-malignant pain patients. In this case, the ODG does not support Promethazine for nausea and vomiting secondary to chronic opioid use. In addition, the records in this case do not clearly discuss the rationale or indication for its use. Therefore, based on Official Disability Guidelines and submitted medical records, the request for Promethazine is not medically necessary.

Imitrex 100 milligrams #18 with one refill, 1 tab as needed: 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), Head Chapter, Triptans.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG (Head Chapter): Triptans.

Decision rationale: The CA MTUS/ACOEM Medical Treatment Guidelines are silent regarding the use of Imitrex. However, per the Official Disability Guidelines (ODG), Imitrex is recommended for migraine sufferers. At marketed doses, all oral triptans (e.g., sumatriptan, brand name Imitrex) are effective and well tolerated. Differences among them are in general relatively small, but clinically relevant for individual patients. In this case, the submitted medical records failed to provide documentation regarding history of headaches and/or a diagnosis of migraines that would support the use of Imitrex. Therefore, based on Official Disability Guidelines and submitted medical records, the request for Imitrex is not medically necessary.

Flexeril 10 milligrams #60 with one refill, 1 tab 2 times per day as needed: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

Decision rationale: Per CA MTUS Chronic Pain Medical Treatment Guidelines, Cyclobenzaprine (Flexeril) is a skeletal muscle relaxant and a central nervous system (CNS) depressant. Guidelines recommend Cyclobenzaprine (Flexeril) be used as an option, using a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. (Browning, 2001) Treatment should be brief. Furthermore, muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. The addition of cyclobenzaprine to other agents is not recommended. In this case, there was no documentation of muscle spasms to necessitate the use of a muscle relaxant. In addition, the guidelines only recommend use of this medication for a short duration, and not longer than 2-3 weeks. There is documentation of ongoing treatment with Flexeril since at least 12/1/2014, and continuation for any amount of time does not comply with the recommended guidelines. Therefore, based on CA MTUS guidelines and submitted medical records, the request for Flexeril is not medically necessary.

EC-Naprosyn DR 375 milligrams #60 with one refill, 1 tab 2 times per day as needed: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

Decision rationale: Per the CA MTUS Chronic Pain Medical Treatment Guidelines, Naprosyn (Naproxen) is a non-steroidal anti-inflammatory drug (NSAID) for the relief of the signs and symptoms of osteoarthritis. The guidelines recommended NSAIDs at the lowest dose for the shortest period in patients with moderate to severe pain. Additionally, NSAIDs can be used as an option for short-term symptomatic relief of chronic low back pain. The guidelines indicate that analgesics should show effects within 1-3 days, and that a record of pain and function with the medication should be recorded. In this case, there is documentation of ongoing treatment with Naprosyn since at least 12/1/2014. The guidelines recommend NSAIDs for short-term symptomatic relief, and continuation for any amount of time does not comply with the recommended guidelines. Therefore, based on CA MTUS guidelines and submitted medical records, the request for Naprosyn is not medically necessary.

Amitriptyline 100 milligrams #60 with one refill, 2 tab every night: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

Decision rationale: Per the CA MTUS Chronic Pain Medical Treatment Guidelines, Tricyclic medications are recommended, and 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. The guidelines recommend Amitriptyline for neuropathic pain: The starting dose may be as low as 10-25 mg at night, with increases of 10-25 mg once or twice a week up to 100 mg/day. (ICSI, 2007) The lowest effective dose should be used (Dworkin, 2007). In this case, the guidelines support the use of Amitriptyline: however, the recommended daily dose is up to a maximum 100 mg/day. The rationale for a 200 mg dosage is not supported by the CA MTUS guidelines. Therefore, based on CA MTUS guidelines and submitted medical records, the request for Amitriptyline is not medically necessary.

Reglan 10 milligrams #120 with one refill, 1 tab 4 times per day: 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), Antiemetics (for opioid nausea).

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

Decision rationale: The CA MTUS/ACOEM Medical Treatment Guidelines is silent regarding the use of Reglan (Metoclopramide). However, per the Official Disability Guidelines, antiemetics (for opioid nausea) are not recommended for nausea and vomiting secondary to chronic opioid use. Current research for treatment of nausea and vomiting as related to opioid use primarily addresses the use of antiemetics in patients with cancer pain or those utilizing opioids for acute/postoperative therapy. Recommendations based on these studies cannot be extrapolated to chronic non-malignant pain patients. There is no high-quality literature to support any one treatment for opioid-induced nausea in chronic non-malignant pain patients. In this case, the ODG does not support Reglan for nausea and vomiting secondary to chronic opioid use. Therefore, based on Official Disability Guidelines and submitted medical records, the request for Reglan is not medically necessary.

Prevacid DR 30 milligrams #60 with one refill, 1 tab 2 times per day: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

Decision rationale: The CA MTUS Chronic Pain Medical Treatment Guidelines recommend proton pump inhibitors be used with precautions. The clinicians should weigh the indications for NSAIDs against gastrointestinal risk factors. Factors determining if a patient is at risk for gastrointestinal events include: age greater than 65 years, history of peptic ulcer, GI (gastrointestinal) bleeding, or perforation, concurrent use of aspirin, corticosteroids, and/or anticoagulant or high dose/multiple NSAID use. In this case, there is no documentation that the injured worker is at risk for gastrointestinal events or cardiovascular complications to support the use of proton-pump inhibitors. Therefore, based on CA MTUS guidelines and submitted medical records, the request for Prilosec is not medically necessary.

Propranolol 20 milligrams #90 with one refill, 1 tab 3 times a day: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Food and Drug Administration.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/016418s080,016762s017,017683s00081bl.pdf.

Decision rationale: The CA MTUS, ACOEM, and Official Disability Guidelines are silent regarding the use of Propranolol. Propranolol is FDA approved for treatment of Hypertension, Angina Pectoris Due to Coronary Atherosclerosis, Atrial Fibrillation, Myocardial Infarction, Migraine, Essential Tremor, Hypertrophic Subaortic Stenosis and Pheochromocytoma. There is no documentation of the indication for treatment with the propranolol nor the IW's response to the medication. The request is not medically necessary and appropriate.

Seroquel 300 milligrams #60 with one refill, 2 tab every night: 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), Mental Illness and Stress, Quetiapine (Seroquel).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness & Stress - Quetiapine (Seroquel).

Decision rationale: The CA MTUS/ACOEM Medical Treatment Guidelines are silent regarding the use of Seroquel. However, according to the Official Disability Guidelines (ODG), Seroquel is not recommended as a first-line treatment. There is insufficient evidence to recommend atypical antipsychotics (eg, quetiapine, risperidone) for conditions covered in ODG. In this case, the submitted medical records failed to provide a clear rationale as to why this medication would be indicated. Therefore, based on ODG and submitted medical records, the request for Seroquel is not medically necessary.

Ultram 50 milligrams #300, 1 tab 4 times a day as needed for 60 days: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids (Classification), Opioids, California Controlled Substance Utilization Review and Evaluation System (CURES) [DWC], Opioids, criteria for use, Opioids for chronic pain, Opioids for neuropathic pain, Opioids for osteoarthritis, Opioids, cancer pain vs. nonmalignant pain, Opioids, dealing with misuse & addiction, Opioids, differentiation: dependence & addiction, Opioids, dosing, Opioids, indicators for addiction, Opioids, long-term assessment.

Decision rationale: Per the CA MTUS Chronic Pain Medical Treatment Guidelines, Tramadol (Ultram) is a centrally acting synthetic opioid analgesic and it is not recommended as a first-line oral analgesic. The guidelines indicate continued use of opioids requires 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 non-adherent) 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. In this case, the treating physician did not document the least reported pain over the period since last assessment, average pain, and intensity of pain after taking the opioid, how long it takes for pain relief, how long pain relief lasts, improvement in pain, and improvement in function. These are necessary to meet the CA MTUS guidelines. Furthermore, there is no documentation 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 as a result. Therefore, based on CA MTUS guidelines and submitted medical records, the request for Tramadol is not medically necessary.

Lorazepam 1 milligram #21, with one refill, 1 tab once a day: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Benzodiazepines.

Decision rationale: Per the CA MTUS Chronic Pain Medical Treatment Guideline, Benzodiazepines are 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. In this case, Benzodiazepines are not recommended for long-term use. Most guidelines limit use up to 4 weeks. However, there is documentation of ongoing treatment with Loreazepam since at least 12/1/2014, and continuation for any amount of time does not comply with the recommended guidelines. Therefore, based on CA MTUS guidelines and submitted medical records, the request for Lorazepam is not medically necessary.