

Case Number:	CM15-0121652		
Date Assigned:	07/09/2015	Date of Injury:	06/07/2009
Decision Date:	09/16/2015	UR Denial Date:	06/16/2015
Priority:	Standard	Application Received:	06/23/2015

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: Iowa, Illinois, Hawaii

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine, Public Health & General Preventive 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 32 year-old female who sustained an industrial injury on 06/07/09. She reported right shoulder, low back, and right knee pain after falling. Initial diagnoses are not available. Initial treatment included chiropractic care. Currently, the injured worker complains of low back pain. MRI performed in 2013 results were described by the treating physician as findings compatible with central canal stenosis at L3-4, and bilateral facet arthropathy at L3-L4 as well as L4-L5 and L5-S1; MRI of the shoulder and right knee does not show any operative lesions. Current physical examination is remarkable for decreased lumbar spine range of motion with pain. She walks slowly and crouched at the waist. Right shoulder shows diffuse pain with range of motion; she is unable to fully place her hand behind her head or behind her back. Right knee shows diffuse pain to patella compression with patella motion. She has had no treatment for many years. Plan of care includes conservative care with pain management, appropriate injections, naproxen 550mg, 60 tablets, zaleplon 10mg, 30 tablets, cyclobenzaprine 10mg, 60 tablets, omeprazole 20mg, 60 tablets, and Tramadol 37.5/325mg, 60 tablets. The injured worker's disability status is not available. Date of Utilization review: 06/16/15.

IMR ISSUES, DECISIONS AND RATIONALES

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

Naproxen 550mg, 60 Tablets: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67-73. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Naproxen, NSAIDs (non-steroidal anti-inflammatory drugs).

Decision rationale: MTUS specifies four recommendations regarding NSAID use: 1) Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. 2) Back Pain - Acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting evidence that NSAIDs are more effective than acetaminophen for acute LBP. 3) Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. 4) Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in with neuropathic pain. The medical documents do not indicate that the patient is being treated for osteoarthritis. Additionally, the treating physician does not document failure of primary (Tylenol) treatment. Progress notes do not indicate how long the patient has been on naproxen, but the MTUS guidelines recommend against long-term use. Additionally, the treating physician has not provided documentation of objective functional improvement with the use of Naproxen. As such, the request for Naproxen 550mg, 60 Tablets is not medically necessary.

Zaleplon 10mg, 30 Tablets: Upheld

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

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

Decision rationale: The CA MTUS is silent regarding this topic. ODG states regarding insomnia, "Recommend correcting deficits, as nonrestorative sleep is one of the strongest predictors for pain." ODG additional details specific components of sleep hygiene, such as "a) Wake at the same time every day; (b) Maintain a consistent bedtime; (c) Exercise regularly (not within 2 to 4 hours of bedtime); (d) Perform relaxing activities before bedtime; (e) Keep your bedroom quiet and cool; (f) Do not watch the clock; (g) Avoid caffeine and nicotine for at least six hours before bed; (h) Only drink in moderation; & (i) Avoid napping." Medical documents also do not include results of these first line treatments, if they were used in treatment of the patient's insomnia. ODG additionally states; "The specific component of insomnia should be addressed: (a) Sleep onset; (b) Sleep maintenance; (c) Sleep quality; & (d) Next-day functioning." Medical documents provided do not detail these components. ODG states, "Zaleplon (Sonata) reduces sleep latency. Side effects: headache, drowsiness, dizziness, fatigue, confusion, abnormal

thinking. Sleep-related activities have also been noted such as driving, cooking, eating and making phone calls. Abrupt discontinuation may lead to withdrawal. Dosing: 10 mg at bedtime (5 mg in the elderly and patients with hepatic dysfunction). (Morin, 2007) Because of its short half-life (one hour), may be re-administered upon nocturnal waking provided it is administered at least 4 hours before wake time. (Ramakrishnan, 2007) This medication has a rapid onset of action. Short-term use (7-10 days) is indicated with a controlled trial showing effectiveness for up to 5 weeks." The medical records has indicated that the patient has been on this medication exceeding the 5 week effectiveness recommendation. The medical documents also do not detail the specific complaints of insomnia, diagnosis of insomnia, and what conservative therapy was trialed and the results of those conservative therapy. As such, the request for Zaleplon 10mg, 30 Tablets is not medically necessary.

Cyclobenzaprine 10mg, 60 Tablets,: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants Page(s): 43.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine, Medications for chronic pain, Antispasmodics Page(s): 41-42, 60-61, 64-66. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Cyclobenzaprine (Flexeril®) and Other Medical Treatment Guidelines UpToDate, Flexeril.

Decision rationale: MTUS Chronic Pain Medical Treatment states for Cyclobenzaprine, "Recommended as an option, using a short course of therapy. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. (Browning, 2001) Treatment should be brief." "The medication is not recommended to be used for longer than 2-3 weeks." The medical documents indicate that patient is far in excess of the initial treatment window and period. Additionally, MTUS outlines, "Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity. Before prescribing any medication for pain the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005)" Uptodate "Flexeril" also recommends; "Do not use longer than 2-3 weeks". Medical documents do not fully detail the components outlined in the guidelines above and do not establish the need for long term/chronic usage of cyclobenzaprine. ODG states regarding cyclobenzaprine, "Recommended as an option, using a short course of therapy. The addition of cyclobenzaprine to other agents is not recommended." Several other pain medications are being requested, along with cyclobenzaprine, which ODG recommends against. As such, the request for Cyclobenzaprine 10mg, 60 Tablets is not medically necessary.

Omeprazole 20mg, 60 Tablets: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 68.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), NSAIDs, GI symptoms & cardiovascular risk.

Decision rationale: MTUS and ODG states, "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)." And "Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 mg four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44)." The medical documents provided do not establish the patient has having documented GI bleeding, perforation, peptic ulcer, high dose NSAID, or other GI risk factors as outlined in MTUS. As such, the request for Omeprazole 20mg, 60 Tablets is not medically necessary.

Tramadol 37.5/325mg, 60 Tablets: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 91.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Tramadol, Ultram Page(s): 74-96, 113, 123. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) - Medications for acute pain (analgesics), Tramadol (Ultram®).

Decision rationale: Tramadol is classified as a central acting synthetic opioids. MTUS states regarding Tramadol that "A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals." ODG further states, "Tramadol is not recommended as a first-line oral analgesic because of its inferior efficacy to a combination of Hydrocodone/ acetaminophen." MTUS states "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 treating physician did not provide sufficient documentation that the patient has failed a trial of non-opioid analgesics at the time of prescription or in subsequent medical notes. Additionally, no documentation was provided which discussed the setting of goals for the use of Tramadol prior to the initiation of this medication. The treating physician does not fully document the least reported pain over the period since last assessment, intensity of pain after taking opioid, pain relief, increased level of function, or improved quality of life. As such, the request for Tramadol #180 is not medically necessary.