

Case Number:	CM14-0214049		
Date Assigned:	01/06/2015	Date of Injury:	09/01/2012
Decision Date:	03/03/2015	UR Denial Date:	11/25/2014
Priority:	Standard	Application Received:	12/22/2014

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 & Gen Prev Med

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This is a 46 year old patient with date of injury of 09/01/2012. Medical records indicate the patient is undergoing treatment for shoulder pain, internal derangement knee. Subjective complaints include constant pain in right knee, pain rated 6/10; left shoulder pain described as burning, rated 8/10. Objective findings include tenderness at knee joint line, patellar grind test positive, McMurray positive, crepitus with painful range of motion; shoulder palpation tenderness around anterior glenohumeral region and subacromial space, Hawkins and impingement signs are positive, extension and flexion are guarded and restricted. Treatment has consisted of surgical intervention, brace, Nalfon, Cyclobenzaprine, Sumatriptan, Ondasetron, Omeprazole, Lunesta, Tramadol, Cidaflex, Ketoprofen, Norco, Levofloxacin, Mentherm, Terocin patch and Neurontin. The utilization review determination was rendered on 11/25/2014 recommending non-certification of Fenoprofen Calcium 400 mg# 120, Omeprazole 20 mg # 120 and Onadasteron 8 mg # 30, Cyclobenzaprine HCL 7.5 mg # 120, Tramadol ER 150 mg # 90 and Eszopiclone 1 mg # 30.

IMR ISSUES, DECISIONS AND RATIONALES

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

Fenoprofen Calcium 400 mg# 120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67-72. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Fenoprofen (Nalfon®).

Decision rationale: MTUS recommends the use of NSAIDS for the acute exacerbation of back pain at the lowest effective dose for the shortest amount of time due to the increased cardiovascular risk, renal, hepatic and GI side effects associated with long term use. Fenoprofen (Nalfon, generic available): 200, 600 mg. Dosing: osteoarthritis; (off-label use for ankylosing spondylitis); 300 - 600mg by mouth 3 to 4 times per day (Max daily dose is 3200mg). Improvement may take as long as 2 to 3 weeks. Mild to moderate pain (off-label use for bone pain): 200mg by mouth every 4 to 6 hours as needed. The patient does have documented back pain. Medical records do indicate that the patient has been on NSAID for some time and would not be considered shortest amount of treatment time. Additionally, the medical records do not subjectively define the pain well and does not subjectively or objectively annotate improvement. As such, the request Fenoprofen Calcium 400 mg# 120 is not medically necessary.

Omeprazole 20 mg # 120: Upheld

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

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 g 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 as having documented GI bleeding/perforation/peptic ulcer or other GI risk factors as outlined in MTUS. As such, the request for Omeprazole 20 mg # 120 is not medically necessary.

Ondansetron 8 mg # 30: 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 Procedure Summary

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines antidepressants, NSAIDs, GI symptoms, opioids Page(s): 68-69, 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, Antiemetics (for opioid nausea).

Decision rationale: Ondansetron (Zofran) is an antiemetic used to decrease nausea and vomiting. Nausea is a known side effect of chronic opioid use and some Serotonin-norepinephrine reuptake inhibitors (SNRIs). ODG does not recommend use of antiemetic for "nausea and vomiting secondary to chronic opioid use". Additionally, "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." There is no evidence that patient is undergoing chemotherapy/radiation treatment or postoperative. MTUS is specific regarding the gastrointestinal symptoms related to NSAID usage. If criteria are met, the first line treatment is to discontinue usage of NSAID, switch NSAID, or consider usage of proton pump inhibitor. There is no documentation provided that indicated the discontinuation of NSAID or switching of NSAID occurred. Additionally, ondansetron is not a proton pump inhibitor and is not considered first line treatment. As such, the request for Ondansetron 8 mg # 30 is not medically indicated.

Cyclobenzaprine HCL 7.5 mg # 120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Muscle Relaxants

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®). Other Medical Treatment Guideline or Medical Evidence: 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. Treatment should be brief." The medical documents indicate that patient is far in excess of the initial treatment window and period. Additionally, MTUS outlines that "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." Other pain medications are being requested, along with cyclobenzaprine, which ODG recommends against. As such, the request for Cyclobenzaprine HCL 7.5 mg # 120 is not medically necessary.

Tramadol ER 150 mg # 90: Upheld

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

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: Ultram is the brand name version of tramadol, which is classified as 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." "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 original utilization review recommended weaning and modified the request, which is appropriate. As such, the request for Tramadol ER 150 mg # 90 is not medically necessary.

Eszopiclone 1 mg # 30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Med Lett Drugs Ther. 2005 Feb 25;47 (1203): 17-9 Eszopiclone (Lunesta)

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

Decision rationale: MTUS is silent specifically regarding eszopiclone (Lunesta), therefore other guidelines were utilized. ODG states regarding Eszopiclone, "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." For insomnia ODG recommends that

"Pharmacological agents should only be used 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. Secondary insomnia may be treated with pharmacological and/or psychological measures. The specific component of insomnia should be addressed: (a) Sleep onset; (b) Sleep maintenance; (c) Sleep quality; & (d) Next-day functioning." Medical records do not indicate patient's sleep hygiene or the need for variance from the guidelines, such as "a) Wake at the same time everyday; (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 indicate that the patient has been on Eszopiclone in excess of guideline recommendations. Additionally, medical records do not indicate what components of insomnia have been addressed, treated with conservative measures, and the results of those conservative treatments. As such, the request for Eszopiclone 1 mg # 30 is not medically necessary.