

Case Number:	CM13-0062082		
Date Assigned:	12/30/2013	Date of Injury:	03/05/2010
Decision Date:	05/07/2014	UR Denial Date:	11/20/2013
Priority:	Standard	Application Received:	12/06/2013

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. The expert reviewer is Board Certified in Physical Medicine & Rehabilitation, has a subspecialty in Pain Medicine and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 42-year-old female with a date of injury of March 5, 2010. The covered body regions include the left knee. The current disputed request includes Prilosec, Ultram, and transdermal pain medication consisting of gabapentin, ketoprofen, and lidocaine. A utilization review determination on November 20, 2013 had noncertified these requests. The stated rationale for the denial of Prilosec was that gastrointestinal risk factors were not identified in this patient. The denial of Ultram was related to "no documentation of subjective or objective benefit from use of this medication." The transdermal cream was denied because no documentation of trials of antidepressants or anticonvulsants, which have failed in this patient, was noted.

IMR ISSUES, DECISIONS AND RATIONALES

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

60 PRILOSEC 20MG, 1 EVERY 12 HOURS: 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 Risk , Page(s): 68-69.

Decision rationale: The Chronic Pain Medical Treatment Guidelines on page 68-69 states the following regarding the usage of proton pump inhibitors (PPI): "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. Recommendations: Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g., ibuprofen, naproxen, etc.) 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 µg 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). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardioprotection) and a PPI. If cardiovascular risk is greater than GI risk, the suggestion is naproxen plus low-dose aspirin plus a PPI. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007) (Laine, 2007)". It is noted that some of the progress notes in this case are handwritten and difficult to decipher. Perusal of the records fails to reveal any indication that the patient has gastrointestinal risk factors. The mere usage of anti-inflammatory medications does not warrant a proton pump inhibitor use. This request is recommended for non-certification.

120 ULTRAM 50MG, 1 FOUR TIMES A DAY: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol, Page(s): 94.

Decision rationale: The Chronic Pain Medical Treatment Guidelines on page 94 states the following regarding tramadol: "Tramadol is a synthetic opioid affecting the central nervous system. Tramadol is not classified as a controlled substance by the DEA. Side Effects: Dizziness, nausea, constipation, headache, somnolence, flushing, pruritus, vomiting, insomnia, dry mouth, and diarrhea. Tramadol may increase the risk of seizure especially in patients taking SSRIs, TCAs and other opioids. Do not prescribe to patients that at risk for suicide or addiction. Warning: Tramadol may produce life-threatening serotonin syndrome, in particular when used concomitantly with SSRIs, SNRIs, TCAs, and MAOIs, and triptans or other drugs that may impair serotonin metabolism. Analgesic dose: Tramadol is indicated for moderate to severe pain. The immediate release formulation is recommended at a dose of 50 to 100mg PO every 4 to 6 hours (not to exceed 400mg/day). This dose is recommended after titrating patients up from 100mg/day, with dosing being increased every 3 days as tolerated. For patients in need of immediate pain relief, which outweighs the risk of non-tolerability the initial starting dose, may be 50mg to 100mg every 4 to 6 hours (max 400mg/day). Ultram ER®: Patient currently not on immediate release tramadol should be started at a dose of 100mg once daily. The dose should be titrated upwards by 100mg increments if needed (Max dose 300mg/day). Patients currently on immediate release tramadol calculate the 24-hour dose of IR and initiate a total daily dose of ER

rounded to the next lowest 100mg increment (Max dose 300mg/day). (Product information, Ortho-McNeil 2003) (Lexi-Comp, 2008)". Since tramadol is an opioid, it is subject to the ongoing monitoring requirements as stated in the Chronic Pain Medical Treatment Guidelines, which specify on pages 78-79 the following: "On-Going Management. Actions Should Include: (a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy. (b) The lowest possible dose should be prescribed to improve pain and function. (c) Office: 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 nonadherent) 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. (Passik, 2000)" In the case of this injured worker, there is documentation of urine drug testing with a specimen collected on April 25, 2013. However, there is no documentation of objective functional benefit attributable to tramadol. This request is recommended for noncertification.

TRANSDERMAL PAIN GKL/CAP: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Page(s): 111-113.

Decision rationale: On page 113 of the Chronic Pain Medical Treatment Guidelines, the following is stated: "Gabapentin: Not recommended. There is no peer-reviewed literature to support use." Therefore, topical gabapentin is recommended for non-certification. The guidelines also specify that if one Final Determination Letter for IMR Case Number [REDACTED] drug or drug class of a compounded topical mixture is not recommended, then the entire mixture is not recommended. Given this, this request is recommended for noncertification.