

Case Number:	CM14-0192023		
Date Assigned:	11/25/2014	Date of Injury:	01/06/2013
Decision Date:	01/12/2015	UR Denial Date:	11/06/2014
Priority:	Standard	Application Received:	11/17/2014

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. The expert reviewer is Board Certified in Internal Medicine and is licensed to practice in New York. 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 reported date of injury of 01/06/2013. The mechanism of injury was mentioned as cumulative trauma injuries. The injury results include neck pain, bilateral shoulder pain, upper back pain, right elbow pain, bilateral wrist pain, anxiety, depression, insomnia, and nervousness. The diagnoses include chronic overuse syndrome of the bilateral shoulders, bilateral elbows, bilateral wrists, and bilateral hands; right lateral epicondylitis; anxiety; and insomnia. Treatments have include pain medications, MRI of the right elbow, x-rays of the right elbow, physical therapy, and platelet rich plasma (PRP) injection for the right shoulder, which did not provide relief. The MRI and x-ray reports were not included in the medical records provided for review. The medical report dated 10/23/2014 indicated that the injured worker complained of continued pain in her right elbow, mild neck pain, mild left shoulder pain, moderate right shoulder pain, mild right wrist pain, and mild mid-back pain. She admitted to feeling better under medication. The injured worker refused her therapy and topical creams. It was noted that she took the Naprosyn 550mg, Tylenol #3, and Prilosec 20mg, as needed. An examination of the right elbow showed full range of motion and tenderness on the lateral epicondyle. It was noted that the injured worker denied wanting steroid injections and surgery. The treating physician felt that without the topical creams, steroid injections, and surgery, the injured worker may be disabled much longer. The injured worker's work status was temporarily totally disabled for six (6) weeks. On 11/06/2014, Utilization Review (UR) denied the request for topical compounded creams of Ketoprofen, Gabapentin, and Tramadol; Naprosyn (Aleve DS, Naproxen) 550mg, #60; and Tylenol #3 (Tylenol/Codeine) #90. A modified approval was provided for the request for Prilosec (Omeprazole) 20mg #90. The UR physician cited the MTUS Chronic Pain Guidelines, the ODG Guidelines, and the Food and Drug Administration. The UR physician noted that each of the requested topical medications have not

been approved for transdermal use, and that documentation indicated that the injured worker had to discontinue the use of oral gabapentin due to systemic side effects; documentation was not clear regarding the functional benefits obtained with the continued use of narcotic medications, no documented visual analog scale score, and no recent opioid risk assessment; there was no documentation indicating that the injured worker could not use readily available over-the-counter non-steroidal anti-inflammatory drugs (NSAIDs); and documentation indicated that the injured worker had a history of prolonged NSAIDs and narcotics use, which would have a potential for gastric irritation and need for protection.

IMR ISSUES, DECISIONS AND RATIONALES

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

Topical CMPD creams of Ketoprofen, Gabapentin, and Tramadol: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 70.

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

Decision rationale: Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. [Note: Topical analgesics work locally underneath the skin where they are applied. These do not include transdermal analgesics that are systemic agents entering the body through a transdermal means. See Duragesic (fentanyl transdermal system).] Non-steroidal anti-inflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study the effect appeared to diminish over time.... Ketoprofen is an NSAID. Also Gabapentin is not recommended as a topical analgesic. Thus, the compound is not recommended.

Naprosyn (Aleve DS, Naproxen) 550mg, #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 70, 111. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 67-68.

Decision rationale: NSAIDs (non-steroidal anti-inflammatory drugs) Specific recommendations: Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with Naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. (Chen, 2008) (Laine, 2008). Long term use of NSAIDS in this case is not consistent with MTUS guidelines.

Tylenol #3 (Tylenol/Codeine) #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 77, 111. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, On-going Management Page(s): 78-79.

Decision rationale: According to Chronic Pain Medical Treatment Guidelines 8 C.C.R. 9792.20 - 9792.26 MTUS (Effective July 18, 2009) Page 78 : 4) 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) (d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management. (e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control. (f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion). (g) Continuing review of overall situation with regard to nonopioid means of pain control. (h) Consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Consider an addiction medicine consult if there is evidence of substance misuse. Codeine is an opiate and the clinical documentation does not meet the above criteria for continued on-going opiate management.

Prilosec (Omeprazole) 20mg #90: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain, Proton Pump Inhibitors (PPIs)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI symptoms and Cardiovascular Risks Page(s): 68-69.

Decision rationale: 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. 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 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). 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. This patient does not have a high GI risk (under 65 years of age, no history of GI bleed or peptic ulcer disease) and further NSAIDS treatment was denied. There is no documented indication for Omeprazole 20 mg daily.