

Case Number:	CM15-0004501		
Date Assigned:	01/15/2015	Date of Injury:	01/23/2001
Decision Date:	03/13/2015	UR Denial Date:	12/08/2014
Priority:	Standard	Application Received:	01/08/2015

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: North Carolina
 Certification(s)/Specialty: Family Practice

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 35 year old female, who sustained an industrial injury on January 23, 2001. The diagnoses have included cervical radiculopathy, cervical pain, C5-C7 fusion, shoulder pain, and mood disorder. Treatment to date has included a C5-C7 fusion, psychological therapy, physical therapy, acupuncture, and medications. Currently, the injured worker complains of poor sleep quality with axial cervical pain that radiates to the upper back. The Primary Treating Physician's report dated November 20, 2014, noted the injured worker's pain level had increased since the previous visit. Physical examination was noted to show cervical spine paravertebral muscles, spasm, tenderness, and trigger point noted on both sides. Motor testing was limited by pain. On December 8, 2014, Utilization Review modified the requests for Percocet 10/325 mg #120 with one refill, Dilaudid 4mg #7 with one refill, and Celebrex 200mg #30 with one refill. The UR Physician modified the request for Percocet 10/325 mg #120 with one refill to Percocet 10/325 mg up to #90 with no refills, with the remaining #30 and one refill recommended non-certified, citing the MTUS Chronic Pain Medical Treatment Guidelines. The UR Physician noted the use of Dilaudid was reasonable and congruent with current guideline recommendations, however, only one prescription was substantiated, therefore the request for Dilaudid 4mg #7 with one refill, was modified to approve Dilaudid 4mg #7, with the remaining one refill non-certified, citing the MTUS Chronic Pain Medical Treatment Guidelines. The UR Physician noted the continued use of Celebrex was reasonable and congruent with current guideline recommendations, therefore the request for Celebrex 200mg #30 with one refill was modified to approve Celebrex 200mg #30, with the remaining one refill non-certified, citing the Chronic Pain

Medical Treatment Guidelines. On January 8, 2015, the injured worker submitted an application for IMR for review of Percocet 10/325 mg #120 with one refill, Dilaudid 4mg #7 with one refill, and Celebrex 200mg #30 with one refill.

IMR ISSUES, DECISIONS AND RATIONALES

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

Percocet 10/325 mg # 120 with one refill: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use, Ongoing Management, Opioids, specific d.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines opioids
Page(s): 76-84.

Decision rationale: The California chronic pain medical treatment guidelines section on opioids states for ongoing management: 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. When to Continue Opioids(a) If the patient has returned to work(b) If the patient has improved functioning and pain(Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/DoD, 2003) (Maddox-AAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004)- Chronic back pain: Appears to be efficacious but limited for short-term pain relief, and long term efficacy is unclear (>16 weeks), but also appears limited. Failure to respond to a time limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy. There is no evidence to recommend one opioid over another. In patients taking opioids for back pain, the prevalence of

lifetime substance use disorders has ranged from 36% to 56% (a statistic limited by poor study design). Limited information indicated that up to one-fourth of patients who receive opioids exhibit aberrant medication-taking behavior. (Martell-Annals, 2007) (Chou, 2007) The long-term use of this medication class is not recommended per the California MTUS unless there documented evidence of benefit with measurable outcome measures and improvement in function. The most recent progress reports do not mention the patient's work status. The patient has an improvement in VAS scores from a 10/10 without medications to a 7/10 with medications. However there is no mention of objective functional improvement. For these reasons the criteria set forth above of ongoing and continued used of opioids have not been met. Therefore the request is not certified.

One prescription of Dilaudid 4 mg # 7 with one refill: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Opioids, criteria for use, Ongoing Management, Opioids, specific drug list

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines opioids Page(s): 76-84.

Decision rationale: The California chronic pain medical treatment guidelines section on opioids states for ongoing management: 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. When to Continue Opioids(a) If the

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One prescription of Celebrex 200 mg # 30 with one refill: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 65-69.

Decision rationale: The California chronic pain medical treatment guidelines section on NSAID use and proton pump inhibitors (PPI) states: 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. Cardiovascular disease: A non-pharmacological choice should be the first option in patients with cardiac risk factors. It is then suggested that acetaminophen or aspirin be used for short term needs. An opioid also remains a

short-term alternative for analgesia. Major risk factors (recent MI, or coronary artery surgery, including recent stent placement): If NSAID therapy is necessary, the suggested treatment is naproxyn plus low-dose aspirin plus a PPI. Mild to moderate risk factors: If long-term or high-dose therapy is required, full-dose naproxen (500 mg twice a day) appears to be the preferred choice of NSAID. If naproxyn is ineffective, the suggested treatment is (1) the addition of aspirin to naproxyn plus a PPI, or (2) a low-dose Cox-2 plus ASA. Cardiovascular risk does appear to extend to all non-aspirin NSAIDs, with the highest risk found for the Cox-2 agents. (Johnsen, 2005) (Lanas, 2006) (Antman, 2007) (Laine,2007)Use with Aspirin for cardioprotective effect: In terms of GI protective effect: The GI protective effect of Cox-2 agents is diminished in patients taking low-dose aspirin and a PPI may be required for those patients with GI risk factors. (Laine, 2007)In terms of the actual cardioprotective effect of aspirin: Traditional NSAIDs (both ibuprofen and naproxen) appear to attenuate the antiplatelet effect of enteric-coated aspirin and should be taken 30 minutes after ASA or 8 hours before. (Antman, 2007) Cox-2 NSAIDs and diclofenac (a traditional NSAID) do not decrease anti-platelet effect. (Laine, 2007)Per the California MTUS guidelines, Cox-2 agents like Celebrex are indicated for patients at intermediate or high gastrointestinal risk. While the patient has had non-specific GI complaints, there are no documented risk factors that place the patient at intermediate or high risk as set forth above. Therefore the medication does not meet criteria and is not certified.

