

<b>Case Number:</b>	CM14-0170525		
<b>Date Assigned:</b>	10/20/2014	<b>Date of Injury:</b>	02/14/2013
<b>Decision Date:</b>	01/02/2015	<b>UR Denial Date:</b>	10/06/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/15/2014

### 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 Family 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:

This 42-year old man reported injuries to his R knee and L shoulder, after stumbling and falling into a piece of machinery on 2/14/13. Current diagnoses include: status post right knee arthroscopy x2; left knee derivative/compensatory injury; left shoulder impingement syndrome with partial thickness rotator cuff tear, resolved cervical myofascial pain, and substantially resolved lumbar myofascial pain. The patient's past medical history is notable for a previous work injury (8/20/10) with a total hip replacement, and for hypertension. The records contain progress notes from the current primary provider's office dating from 5/13/14 through 10/23/14. Nearly all notes describe ongoing moderate pain in both of the patient's knees, his left shoulder and low back. There is no significant change in pain levels over the documented time period. All notes describe tenderness and decreased range of motion. At every visit naproxen, pantoprazole and a muscle relaxant are dispensed. In the earlier visits the muscle relaxant was Orphenadrine, which was changed to Cyclobenzaprine without explanation. Hydrocodone/APAP was either dispensed or prescribed at every visit. There are records of three urine drug screens performed during this period, all of which are inconsistent: they are negative for hydrocodone and positive for alprazolam. (There is no documentation that the patient was taking Alprazolam.) The screen from 6/27/14 was positive for cotinine, which implies that the patient is a smoker, and which he apparently did not report to his provider. The 10/23/14 screen was negative for both hydrocodone and Cyclobenzaprine, both of which the patient was recorded as taking at the time. There are reports indicating that these results have been thoroughly reviewed, but which do not address the inconsistencies. An MRI of the left shoulder performed 8/27/14 revealed partial tears of the supraspinatus and infraspinatus tendons, and a superior labral tear, and possible subtle subdeltoid bursitis. A subacromial injection of Depo-Medrol and Marcaine was performed on 9/3/14 without a documented rationale. In nearly all visits, the

patient is reported as able to maintain activities of daily living including shopping for groceries, very light household duties, preparing food, grooming and bathing. His activity level does not change across the time span of the visits. The patient's work status is consistently recorded as temporary partial disability with work limitations, which do not change during the period reviewed. It is, however, quite clear that the patient is not working. The 8/19/14 note contains a checked box which states the patient has been off work for months (as part of the justification for obtaining a drug screen).

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Depo-medrol injection:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 9 Shoulder Complaints Page(s): 211-214.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 9 Shoulder Complaints Page(s): 204,213,Chronic Pain Treatment Guidelines Page(s): 10.

**Decision rationale:** The MTUS Chronic Pain Guidelines do not specifically address shoulder injections. However, per page 10 of the Guidelines, when a patient is diagnosed with chronic pain and the treatment for the condition is covered in the clinical topics sections but is not addressed in the chronic pain medical treatment guidelines, the clinical topics section applies to that treatment. Per the ACOEM clinical topics shoulder chapter, if shoulder pain with elevation significantly limits a patient's activities, a subacromial injection with a corticosteroid injection may be indicated. However, it is only indicated after two to three weeks of strengthening exercises and NSAIDs, and the evidence supporting this approach is not overwhelming. Two to three subacromial injections of anesthetic and cortisone over an extended period are recommended as part of an exercise rehabilitation program to treat rotator cuff inflammation, impingement syndrome or small tears. The clinical documentation in this case does not support the performance of a subacromial injection of DepoMedrol and Marcaine. There is no documentation that the patient participated in any strengthening exercise program or exercise rehabilitation program in accordance with the guidelines. Based on the MTUS citations above and on the clinical documentation provided for my review, a subacromial injection of DepoMedrol and Marcaine was not medically necessary, because the prerequisites for performing it were not met: i.e. the patient was not participating in any sort of shoulder exercise program at the time of the injection.

**Marcaine injection:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 9 Shoulder Complaints Page(s): 211-214.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 9 Shoulder Complaints Page(s): 204,213,Chronic Pain Treatment Guidelines Page(s): 10.

**Decision rationale:** The MTUS Chronic Pain Guidelines do not specifically address shoulder injections. However, per page 10 of the Guidelines, when a patient is diagnosed with chronic pain and the treatment for the condition is covered in the clinical topics sections but is not addressed in the chronic pain medical treatment guidelines, the clinical topics section applies to that treatment. Per the ACOEM clinical topics shoulder chapter, if shoulder pain with elevation significantly limits a patient's activities, a subacromial injection with a corticosteroid injection may be indicated. However, it is only indicated after two to three weeks of strengthening exercises and NSAIDs, and the evidence supporting this approach is not overwhelming. Two to three subacromial injections of anesthetic and cortisone over an extended period are recommended as part of an exercise rehabilitation program to treat rotator cuff inflammation, impingement syndrome or small tears. The clinical documentation in this case does not support the performance of a subacromial injection of DepoMedrol and Marcaine. There is no documentation that the patient participated in any strengthening exercise program or exercise rehabilitation program in accordance with the guidelines. Based on the MTUS citations above and on the clinical documentation provided for my review, a subacromial injection of DepoMedrol and Marcaine was not medically necessary, because the prerequisites for performing it were not met: i.e. the patient was not participating in any sort of shoulder exercise program at the time of the injection.

**Cyclobenzaprine 7.5mg QTY: 20:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain; Muscle Relaxants Page(s): 60,63-66.

**Decision rationale:** Cyclobenzaprine is a sedating muscle relaxant. Its 7.5 mg form is long-acting, and its common trade name is Fexmid. Per the first reference cited above, medications should be trialed one at a time while other treatments are held constant, with careful assessment of function, and there should be functional improvement with each medication in order to continue it. Per the second reference, non-sedating muscle relaxants are recommended with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain. In most low back pain patients, they show no benefit. There is no additional benefit if they are used in combination with NSAIDs. Efficacy appears to diminish over time. Cyclobenzaprine is only recommended for a short course of therapy, as there is no evidence to support its long-term use. Its greatest effect appears to occur within the first four days of treatment. Side effects include drowsiness, urinary retention, dry mouth and headaches. Its use should be avoided in patients with arrhythmias, heart block, heart failure and recent myocardial infarction. The clinical documentation in this case does not support the use of Cyclobenzaprine. Various rationales are given for its use in different notes, including that the patient has muscle spasm that is refractory to multiple modalities, and that it is given to improve activity, exercise and range of motion, that its structure resembles that of a tricyclic antidepressant, and that it is not addictive. However, there is no muscle spasm documented on exam, and no documented significant improvement in function or range of motion. In addition, the patient appears to have been on muscle relaxants for months to years, which would mean that

any current muscle spasm he is experiencing would not be acute. The prescription for Cyclobenzaprine clearly extends beyond the four days that it is likely to be effective. Finally, Fexmid is long-acting and sedating, particularly when combined with an opioid such as hydrocodone. It actually may make it more difficult for this patient to increase his level of activity and thus interfere with his recovery. Based on the MTUS citations above and on the clinical records provided for my review, Cyclobenzaprine 7.5 mg #20 is not medically necessary. It is not medically necessary because there has been no functional improvement as a result of taking it, because there is no other evidence to support its short or long-term use and because its side effects may in fact interfere with this patient's recovery. Incidentally, the drug screen results of 10/23/14 make it appear that this patient is not taking Cyclobenzaprine at all, in which case it certainly should not be dispensed.

**Pantoprazole 20mg QTY: 90: 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 Other Medical Treatment Guideline or Medical Evidence: UptoDate, an evidence-based online review service for clinicians, ([www.uptodate.com](http://www.uptodate.com)) , Pantoprazole: drug information

**Decision rationale:** Pantoprazole is a proton pump inhibitor, or PPI. The first guideline cited above states that clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. They should determine if the patient is at risk for GI events. Risk factors include age over 65 years; history of peptic ulcer, GI bleeding or perforation; concurrent use of aspirin, corticosteroids, or an anticoagulant; or high-dose or multiple NSAIDs, or an NSAID combined with aspirin. Patients with no GI risk factors and no cardiovascular disease may be prescribed a non-selective NSAID. Those at intermediate risk for GI disease should receive a non-selective NSAID plus a proton pump inhibitor (PPI) or misoprostol; or a Cox-2 selective NSAID. Patients at high GI risk should receive a Cox-2 selective NSAID and a PPI if an NSAID is absolutely necessary. This reference notes that long-term PPI use has been shown to increase the risk of hip fracture. The UptoDate reference cited above lists the indications for pantoprazole as active duodenal ulcer, gastric ulcer, erosive esophagitis, helicobacter pylori eradication, pathological hypersecretory conditions (such as Zollinger-Ellison syndrome), frequent heartburn, GERD or other acid-related disorders, NSAID-induced ulcer treatment, NSAID-induced ulcer prophylaxis, and stress ulcer prophylaxis in ICU patients. Several of these indications are off label in the US. Risks of long-term (usually over one year) use include atrophic gastritis, increased incidence of gastric carcinoid tumors, clostridium difficile-associated diarrhea, increased incidence of osteoporosis-related fractures of the hip, spine, or wrist; hypomagnesemia and Vitamin B12 deficiency. The clinical documentation in this case does not support the provision of pantoprazole to this patient. The provider has again documented several rationales for dispensing this medication, including that the patient is at intermediate risk for GI events, that taking the PPI omeprazole "was ineffective, as adverse effects did remain, frequency and severity", and that the patient experienced "GI upset" with NSAID use which resolved due to taking a PPI. There is no actual documentation of what factors put the patient at intermediate

risk for GI events. "GI upset" is a vague term that would include nausea and constipation, for neither of which a PPI is indicated. There is no documentation of any other condition likely to require a PPI prescription or of any symptoms suggestive of such a condition. It does appear likely that the patient has been taking a PPI for at least a year, which would put him at risk for the side effects listed above, many of which could be life threatening. According to the evidence-based citations above and to the clinical documentation provided for my review, pantoprazole 20 mg #90 is not medically necessary for this patient. It is not medically necessary because there is no documentation of any GI risk or other condition that would require its use, and because its use places the patient at unacceptable risk for serious adverse side effects.

**Hydrocodone/APAP 10/325mg QTY: 60: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain, Criteria for use of Opioids, Opioids, Ongoing Management Page(s).

**Decision rationale:** Hydrocodone is an opioid analgesic. In this case it is combined with APAP, which is acetaminophen. According to the first guideline cited above, medications should be started individually while other treatments are held constant, with careful assessment of function. There should be functional improvement with each medication in order to continue it. The remaining guidelines state that opioids should not be started without an evaluation of the patient's current status in terms of pain control and function. An attempt should be made to determine if the patient's pain is nociceptive or neuropathic. Red flags indicating that opioid use may not be helpful should be identified, as should risk factors for abuse. Specific goals should be set, and continued use of opioids should be contingent on meeting these goals. The section on ongoing management of opioid use recommends that regular assessment for aberrant drug taking behavior should be performed. Opioids should be discontinued if there is no improvement in function or if there is a decrease in function. Opioids are not recommended as first-line therapy for neuropathic pain. The response of neuropathic pain to drugs may depend on the cause of the pain. There are very limited numbers of studies that involve opioid treatment for chronic lumbar root pain. A recent study found that chronic radicular lumbar pain did not respond to opioids in doses that have been effective for painful diabetic neuropathy and postherpetic neuralgia. The clinical findings in this case do not support the provision of hydrocodone/APAP to this patient. There is no documentation that it was introduced individually, with ongoing careful assessment of function. There is no documentation of evaluation of whether or not the patient's pain is nociceptive or neuropathic. No assessment is documented as to whether or not opioid use was likely to be helpful in this patient, or of his potential for abuse. No specific functional goals were set or followed. Opioids were not discontinued when it became clear that it has not produced any functional improvement. The patient remains off work, and there is no documentation of any significant increase in function due to the use of hydrocodone/APAP. Finally, three drug screens performed on this patient while hydrocodone was being provided to him were negative for hydrocodone or hydrocodone metabolites. This makes it unlikely that the patient is taking the drug, and possible that he is diverting it. Based on the evidence-based guidelines cited above,

and the clinical documentation provided for my review, hydrocodone/APAP 10/325 #60 is not medically necessary for this patient. It is not medically necessary because of the lack of appropriate documentation of the patient's status prior to beginning it, because of the failure to set and monitor functional goals, because of the failure to discontinue it when it became clear that it has not produced any functional recovery, and because of the failure to respond appropriately to multiple drug tests which show the patient is not taking this medication and may be diverting it.

**Naproxen 550mg QTY: 90: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain; NSAIDs (non-steroidal anti-inflammatory drugs); NSAIDs, Hypertensi.

**Decision rationale:** Naproxen is an NSAID. Per the first reference cited above, medications should be trialed one at a time while other treatments are held constant, with careful assessment of function, and there should be functional improvement with each medication in order to continue it. The NSAID references state that NSAIDs are recommended at the lowest dose for the shortest period possible for patients with moderate to severe pain due to osteoarthritis. There is no evidence to recommend one drug over another in terms of efficacy or pain relief. Cardiovascular risk occurs with all NSAIDs, and there is no evidence of long-term effectiveness for pain or function. NSAIDs are recommended as an option for short-term symptomatic relief of chronic low back pain. There is inconsistent evidence to support their use for neuropathic pain. All NSAIDs have the potential to raise blood pressure in susceptible patients. The greatest risk appears to occur in patients taking ACE inhibitors, ARBs, beta-blockers or diuretics. The clinical documentation in this case does not support the use of naproxen. This patient has been taking naproxen for at least 5 months, and probably for much longer. This is not short-term use of an NSAID for chronic back pain. The patient has hypertension and is probably a smoker, which puts him at risk for cardiac disease. No blood pressure is in the records, which is concerning. Any patient who is taking an NSAID should be monitored for high blood pressure. There is no documentation of any functional improvement in response to naproxen use. Based on the MTUS citations above and on the clinical records provided for my review, Naprosyn 550 #90 is not medically necessary. It is not medically necessary because the patient has clear risk factors for cardiac disease and his risk is increased with NSAID use, because his blood pressure is not being monitored, because the use of Naproxen has obviously exceeded the lowest dose for the shortest period possible, and because there is no documentation of functional improvement in response to its use.