

<b>Case Number:</b>	CM14-0191595		
<b>Date Assigned:</b>	11/25/2014	<b>Date of Injury:</b>	11/06/2012
<b>Decision Date:</b>	01/09/2015	<b>UR Denial Date:</b>	11/03/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	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 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 36-year old man reported sustaining a right shoulder, neck and back injury on 11/16/12. There is no described mechanism in the available records. His past medical history is notable for Hepatitis C with elevated liver function tests. Treatment has included medications, chiropractic manipulation, physical therapy, acupuncture, cervical epidural steroid injections, a steroid injection of the right shoulder, and a right shoulder arthroscopic surgery on 9/15/14. Cervical spine surgery has been authorized, but the patient wished to defer it until after his shoulder surgery. He has been followed by two treating orthopedists, one who treats his shoulder and another who treats his spine. Prior to his shoulder surgery, his documented medications consisted of topical ketoprofen, topical Lidopro, oral Prilosec, and occasional low-dose oral Norco (5/325 once per day). On 8/6/14, the spine orthopedist increased his dose of Norco to 7.5/325 mg for severe pain, and apparently dispensed 30 tablets of this medication. At the time of his surgery (9/15/14), the shoulder orthopedist had the patient begin Norco 5/325 one to two every four hours for pain, as well as Keflex, Ambien and Zofran. It does not appear that Prilosec was continued. On 9/18/14 the shoulder orthopedist notes that the patient is taking 6 Norco per day, and continues to use Lidopro cream and take Ambien, Keflex and Zofran. The 9/25/14 note by the same provider states that the patient continues to take 6 Norco per day, as well as to take Ambien at night and use Lidopro cream. He has discontinued Keflex and Zofran. The provider apparently dispensed Norco 10/325 #90 to be taken once per day as needed, and Prilosec 20 mg #60 to be taken once per day as needed. A 10/1/14 note by the spine orthopedist states that the patient is taking Norco 10/325 4 per day, and Prilosec 2 per day for stomach pain, and that he continues to use Lidopro. Neither provider addresses the patient's functional status or documents any functional goals. Neither provider documents concerns about the patient's liver functions. Neither provider seems to be aware that the other is prescribing Norco. There are several

postoperative PT notes which do address the patient's level of function and functional goals. Over the period of 10/3/14 to 10/12/14 the patient remains unable to use his right upper extremity to assist with self-grooming or to dress himself without severe pain. No progress is documented toward the goals of being able to actively elevate his shoulder to over 120 degrees in order to be able to wash and groom his hair, or of being able to don and doff a jacket. No change in his shoulder range of motion is documented.

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

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

#### **Hydrocodone/APAP 10/325mg #90: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 79-81. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain, page 60; Criteria for use of Opioids, pages 76-77; Opioids, pain . Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Up to Date, an online, evidence-based review service for practitioners ([www.uptodate.com](http://www.uptodate.com)), Hydrocodone and acetaminophen: Drug information.

**Decision rationale:** Hydrocodone/APAP is sold under the brand name of Norco, among others. Hydrocodone is an opioid analgesic and APAP 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 MTUS 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 functional goals should be set, and continued use of opioids should be contingent on meeting these goals. Opioids should be discontinued if there is no improvement in function or if there is a decrease in function. A pain contract is recommended for chronic use of opioids. Among other items, it should include goals of therapy, statements that only one provider gives prescriptions and one pharmacy dispenses them, and that opioids may be discontinued if their use is not effective. The Up to Date reference states that acetaminophen is potentially hepatotoxic, and that this risk increases with pre-existing liver disease. Chronic daily dosing has resulted in liver damage in some patients. The available clinical documentation does not support the ongoing use of hydrocodone/APAP in this case. There is no documentation of any evaluation of the patient's current pain and its causes, of his current functional status, or of any evaluation for risk factors of abuse. There is no documentation that functional goals have been set or are being monitored for its use. This patient has Hepatitis C with elevated liver enzymes. It is particularly concerning in this case that the patient is being followed by two providers who adjust and dispense medications independently, neither of whom appears to be monitoring his liver status. Their progress notes are not in agreement as to how much of this medication he is taking. The patient's functional level does not appear to be improving, which

should have resulted in a reassessment by at least one of the providers, with discontinuation of the patient's hydrocodone/APAP. This has not occurred. Based on the clinical information provided for my review and on the evidence-based citations above, Hydrocodone/APAP 10/325 #90 is not medically necessary. It is not medically necessary because no appropriate evaluation of the patient prior to beginning it is documented, because no functional goals were set and are being followed for its use, because there is no documentation of a pain contract, and because two physicians appear to be dispensing it without coordination with each other and without monitoring the patient's pre-existing liver disease.

**Omeprazole 20mg #60: 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 Chapter

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Up to Date, an evidence-based online review service for clinicians, ([www.uptodate.com](http://www.uptodate.com)), Omeprazole: drug information

**Decision rationale:** Omeprazole is a proton pump inhibitor (PPI) which is sold under the brand name of Prilosec, among others. 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 Up to Date reference cited above lists the indications for omeprazole 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. The last three indications are off label. Significant side effects include hepatic disease and hepatic failure. 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 usual dosing for omeprazole is 20 mg once daily. The clinical documentation in this case does not support the use of Prilosec for this patient. Although the 10/1/14 progress note from the spine orthopedist documents that the patient is taking omeprazole twice daily for stomach pain, the shoulder orthopedist, who actually dispensed the omeprazole, documented that he is to take it once per day and does not record that it is for stomach pain. The records do not contain documentation of any evaluation for abdominal pain or discussion of its cause. There is no documentation of a diagnosis or of symptoms of a diagnosis that would necessitate omeprazole use. There is no clear documentation

of symptoms of gastritis or of an assessment of the patient's risk factors for GI events. The patient does not even appear to taking an NSAID at this point, which would make evaluation for GI risk unnecessary. This patient has existing liver disease and is taking a medication which contains acetaminophen. The addition of another potentially hepatotoxic drug, especially if it is being taken at twice its usual dosage, is medically risky and unnecessary. Based on the clinical information provided for my review and the evidence-based citations above, omeprazole 20 mg #60 is not medically necessary. It is not medically necessary because the provider has not documented any diagnosis or any symptoms compatible with a condition that would require its use, because the provider has not documented any risk factors for GI events that would require its use, because it appears to be being prescribed at twice the usual dosage, and because it is potentially hepatotoxic and the patient has pre-existing liver disease and is already taking a potentially hepatotoxic medication.

**Norco 10/325mg #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 81. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain, Criteria for use of Opioids, Opioids, pain treatment agreement Page(s): 60, 67. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Up to Date, an online, evidence-based review service for practitioners ([www.uptodate.com](http://www.uptodate.com)), Hydrocodone and acetaminophen: Drug information

**Decision rationale:** Norco is brand-name hydrocodone/APAP Hydrocodone is an opioid analgesic and APAP 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 MTUS 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 in 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 functional goals should be set, and continued use of opioids should be contingent on meeting these goals. Opioids should be discontinued if there is no improvement in function or if there is a decrease in function. A pain contract is recommended for chronic use of opioids. Among other items, it should include goals of therapy, statements that only one provider gives prescriptions, and one pharmacy dispenses them, and that opioid may be discontinued if their use is not effective. The Up to Date reference states that acetaminophen is potentially hepatotoxic, and that this risk increases with pre-existing liver disease. Chronic daily dosing has resulted in liver damage in some patients. The available clinical documentation does not support the ongoing use of Norco in this case. There is no documentation of any evaluation of the patient's current pain and its causes, of his current functional status, or of any evaluation for risk factors of abuse. There is no documentation that functional goals have been set or are being monitored for its use. This patient has Hepatitis C with elevated liver enzymes. It is particularly concerning in this case that the patient is being followed by two providers who adjust and dispense medications independently, neither of whom appears to be monitoring his liver status. They also do not agree as to how

much of this medication he is taking. The patient's functional level does not appear to be improving, which should have resulted in a reassessment by at least one of the providers, with discontinuation of the patient's Norco. This has not occurred. Based on the clinical information provided for my review and on the evidence-based citations above, Norco 10/325 #90 is not medically necessary. It is not medically necessary because no appropriate evaluation of the patient prior to beginning it is documented, because no functional goals were set and are being followed for its use, because there is no documentation of a pain contract, and because two physicians appear to be dispensing it without coordination with each other and without monitoring the patient's pre-existing liver disease.

**Prilosec 20mg #60: 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 Chapter

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Up to Date, an evidence-based online review service for clinicians, ([www.uptodate.com](http://www.uptodate.com)), Omeprazole: drug information

**Decision rationale:** Prilosec is brand-name omeprazole, which is a proton pump inhibitor (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 Up to Date reference cited above lists the indications for omeprazole 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. The last three indications are off label. Significant side effects include hepatic disease and hepatic failure. 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 usual dosing for Prilosec is 20 mg once daily. The clinical documentation in this case does not support the use of Prilosec for this patient. Although the 10/1/14 progress note from the spine orthopedist documents that the patient is taking Prilosec twice daily for stomach pain, the shoulder orthopedist, which actually dispensed the Prilosec, documents that he is to take it once per day and does not record that it is for stomach pain. The records do not contain documentation of any evaluation for abdominal pain or discussion of its cause. There is no clear documentation of symptoms of gastritis or of an assessment of the

patient's risk factors for GI events. The patient does not even appear to taking an NSAID at this point, which would make evaluation for GI risk unnecessary. This patient has existing liver disease and is taking a medication which contains acetaminophen, the addition of another potentially hepatotoxic drug, especially if it is being taken at twice its usual dosage, is medically risky and unnecessary. Based on the clinical information provided for my review and the evidence-based citations above, Prilosec 20 mg #60 is not medically necessary. It is not medically necessary because the provider has not documented any diagnosis or symptoms of a diagnosis of a condition that necessitates its use, because the provider has not documented any risk factors for GI events that would require its use, because it appears to be being prescribed at twice the usual dosage, and because it is potentially hepatotoxic and the patient has pre-existing liver disease and is already taking a potentially hepatotoxic medication.