

<b>Case Number:</b>	CM14-0152545		
<b>Date Assigned:</b>	09/22/2014	<b>Date of Injury:</b>	02/11/2009
<b>Decision Date:</b>	12/19/2014	<b>UR Denial Date:</b>	09/05/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/18/2014

### 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 65- year old woman reported injuries to her neck and back with date of injury 2/11/09. The records available to me do not describe the mechanism of injury, and contain a single progress note from the secondary treater, dated 8/26/14. There is no other available clinical documentation, and much of the information contained in this report was gleaned from the utilization review report of 9/5/14. There is no description of previous treatments, except for medications and a recent cervical epidural steroid injection. The 8/26/14 progress note from the secondary treater, a pain specialist, states that the patient has worsening constant low back pain radiating to the left leg. She is tripping due to foot drop. She also has neck pain radiating to both upper extremities, which has improved since an epidural steroid injection. She is taking multiple medications and her current pain level is 4/10. Exam findings include tenderness and spasm, decreased range of motion of neck and back, decreased sensation in a C5 dermatomal distribution (side not specified) and in the left lateral thigh. Diagnoses include cervical disc degeneration and displacement, cervical radiculitis, low back pain, lumbar disc displacement and lumbar radiculopathy. Treatment plan includes sufficient Norco 10/325, Naprosyn 550 mg, Neurontin 600 mg, and Protonix 40 mg for one month. A lower extremity EMG/NCV is requested. The patient is advised to continue therapy with her primary treater. The UR report of 8/26/14 states that a previous UR dated 6/17/14 certified Naprosyn, omeprazole and tramadol with the stipulation that future certification depends upon appropriate documentation of subjective and functional benefit, and upon documentation of appropriate evaluation for use of omeprazole and of requirements for ongoing use of tramadol. None of this documentation is contained in the available records. The patient's functional status is not addressed, except to state that she is "retired". Requests for Norco 10/325, Naprosyn 550 mg, and Protonix 40 mg were non-certified in the 9/5/14 UR.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Norco 10/325mg #90:** 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 for neuropathic pain; Opioid.

**Decision rationale:** Norco is brand-name hydrocodone with acetaminophen. Hydrocodone is an opioid analgesic. 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. 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. Opioid dosing should not exceed 120 oral morphine equivalents per day. Patients taking opioids sometimes develop abnormal pain, a change in pain pattern, or persistence in pain at higher levels than expected, which are actually a result of taking opioids. This is called opioid hyperalgesia. Opioid hyperalgesia should be screened for, as it actually may require weaning off opioids rather than increasing doses. The clinical findings in this case do not support the provision of Norco to this patient. There is no documentation that Norco 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. Many of the documented symptoms as well as diagnoses (cervical and lumbar radiculopathy) and treatments (gabapentin and epidural injections) make it appear that the patient's pain is neuropathic. Neuropathic pain does not necessarily respond well to opioids. No assessment was made of whether or not opioid use was likely to be helpful in this patient, or of her potential for abuse. No specific functional goals were set or followed. No evaluation for opioid hyperalgesia has been made. Most importantly, 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 Norco. Based on the evidence-based guidelines cited above, and the clinical documentation provided for my review, Norco 10/325 #90 is not medically necessary for this patient. Norco 10/325 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 evaluate for opioid hyperalgesia, and because of the failure to discontinue it when it became clear that it has not produced any functional recovery.

**Naproxen 550mg #60:**

**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:** Naprosyn is brand-name naproxen, which 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 two months, and probably for much longer. This is not short-term use of an NSAID for chronic back pain. Since the patient is 65, she may well have cardiac risk factors or even cardiac disease, but there is no documentation regarding the presence or absence of these conditions. No blood pressure is recorded on the sole report in the records, which is concerning. Any patient who is taking an NSAID should be monitored for high blood pressure. The patient's pain appears to be primarily neuropathic, which often does not respond well to NSAIDs. 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 #60 is not medically necessary. It is not medically necessary because there is no documentation of the patient's risk factors for NSAID use or of monitoring for side effects, because it is not recommended for long-term treatment of chronic back pain, because it may not be useful for neuropathic pain, and because there is no documentation of functional improvement in response to its use.

**Protonix 40mg, #30:** 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 and 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:** Protonix is brand-name pantoprazole, which is a 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. It is impossible to guess from the available clinical records why pantoprazole is being prescribed for this patient. There is no documentation of her risk for GI events. There is no documentation of any 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 her 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, Protonix 40 mg #30 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.