

Case Number:	CM14-0189768		
Date Assigned:	11/20/2014	Date of Injury:	04/22/2005
Decision Date:	01/09/2015	UR Denial Date:	11/04/2014
Priority:	Standard	Application Received:	11/13/2014

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 49-year old inspector reported injuries to her low back, neck, upper back, bilateral shoulders, left elbow, right wrist, left hip and thigh, abdomen and bilateral knees due to a fall on 4/12/05 as well as to cumulative trauma from her work. In addition she attributes depression, headaches, increased blood pressure and weight gain to consequences from her injuries. Treatment has included medications, physical therapy, chiropractic manipulation, TENS, and a right shoulder arthroscopy on 10/23/13. Currently her primary provider is a chiropractor, and a secondary provider who is an orthopedist also follows her. She has remained at total disability since at least 2008. Her current diagnoses include right shoulder impingement/rotator cuff syndrome; lumbosacral sprain, facet arthropathy and radiculopathy; cervical sprain, left knee internal derangement and right carpal tunnel syndrome. An orthopedic AME report dated 12/17/13 notes that the patient is taking Naproxen, Tramadol and Nizatidine, which is the earliest mention of specific medications in the available records. The first available note from her secondary provider is dated 3/24/14. It states that she is currently taking Prilosec, Relafen, Gabapentin, and Norco 5, and that she does not need refills. The secondary provider's notes on 5/12/14, 6/23/14 and 8/8/14 state that the medications were not authorized by the insurance carrier, but do not state whether or not they had been dispensed or were being taken. A note dated 9/29/14 again notes requests for Prilosec, Relafen, Norco 2.5 and Gabapentin. A request for authorization for the same medications followed on 10/14/14. A pain medicine consultation performed 6/11/14 notes that the patient is taking only over the counter medications, and recommends that she start Naproxen, Flexeril and Tramadol. There are multiple notes in the records from the patient's primary provider which state that the patient's liver function tests are "enlarged" beginning 5/14/14. The primary provider attributes this problem to the patient's medications, which he states should be discontinued. Some of the available notes from the

various providers document that the patient has significant disabilities, such as being unable to sit for more than 20 minutes or walk for more than 45 minutes. None of them documents any functional goals. Urine drug screens performed 3/17/14, 4/21/14 and 4/30/14 were all completely negative, which would suggest that the patient was not taking Norco. UR performed 11/4/14 denied Prilosec on the basis that the patient's risk for GI events had not been documented; denied Relafen on the basis that there was no documentation of its efficacy and that the frequency of dosage was not specified; and denied Norco on the basis that appropriate questions had not been addressed in regards to opioid use, that there was no current pain assessment, and that frequency of dosage was not specified. Neurontin was certified in UR on 10/29/14.

IMR ISSUES, DECISIONS AND RATIONALES

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

Prilosec 20mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 58.

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) , 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 UptoDate 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 3/24/14 progress note documents the reasons for Prilosec use as "for gastritis and stomach protection", the records do not contain documentation of symptoms of gastritis or of an

assessment of the patient's risk factors for GI events. The primary provider in this case documented concerns about elevated liver function tests multiple times, of which the secondary provider appears to be unaware. Although the secondary provider does not specify dosage for the current request, he documents the dosage as 20 mg twice per day on 3/24/14. This is a higher than usual dose, which would be doubly concerning as a possible cause of the patient's liver dysfunction. Based on the clinical information provided for my review and the evidence-base citations above, Prilosec 20 mg #60 is not medically necessary. It is not medically necessary because the provider has not documented symptoms compatible with any 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 could be contributing to the patient's liver dysfunction, which has not been appropriately addressed.

Relafen 750mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 57.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain, NSAIDs (non-steroidal anti-inflammatory drugs), chronic low back p.

Decision rationale: Relafen is brand-name nabumetone, 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. NSAIDs can cause elevated liver function tests, and they should be used with caution in patients with hepatic dysfunction. The clinical findings in this case do support the provision of nabumetone to this patient. This medication has been prescribed or recommended over a period of at least 6 months, which is not short-term use. The patient has neuropathic pain, which has not been shown to respond consistently to NSAID use. There has been no documented increase in function with Relafen. The patient remains totally disabled, which implies a profound level of disability. The secondary provider continued to prescribe Relafen even though the pain specialist had recommended starting naproxen, which raises major concerns about communication among this patient's providers, as does the failure to address the primary provider's concerns about hepatic dysfunction. The patient has hypertension, which puts her at risk for increased blood pressure with NSAID use. Based on the MTUS citations above and on the clinical documentation provided for my review, nabumetone 750 mg #60 is not medically necessary. It is not medically necessary because it is clearly not being prescribed for short-term

symptomatic relief of chronic low back pain, because it is not likely to be useful for the patient's neuropathic pain, because there is no documentation of functional improvement in response to its use, because the patient has hypertension and is at risk for increased blood pressure with NSAID use, and because the patient has hepatic dysfunction which may be caused or exacerbated by NSAID use.

Norco 2.5mg/325 #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 75.

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

Decision rationale: Norco 2.5/325 is a combination of 2.5 mg hydrocodone with 325 mg of 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 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. 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 demonstrate that any of the above criteria have been met. There is no documentation that Norco was introduced individually, with ongoing careful assessment of function. The patient's pain is clearly documented as neuropathic, but there is no mention of whether there is a nociceptive component as well. Neuropathic pain does not necessarily respond well to opioids. A first-line treatment for neuropathic pain, gabapentin, has been prescribed, and it is appropriate to monitor the patient's response to it prior to starting Norco. 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. The patient has been taking an opioid at least intermittently since 2013 without any improvement in her functional level (totally disabled), and opioids should have already been discontinued. Again the provider has not specified dosage, which is of concern in this case because acetaminophen can be hepatotoxic, especially at high doses. Finally, the patient had two negative drug screens during the time she was reported to be taking Norco. This raises concerns about diversion, which have not been addressed. Based on the evidence-based guidelines cited above and the clinical documentation provided for my review, Norco 2.5/325 # 60 is not medically necessary. It is not medically necessary because no appropriate evaluation has been made prior to its use, because no functional goals were set or followed, because it was not discontinued when it

became clear that the patient had had no functional improvement in response to its use, because the patient has hepatic dysfunction which may be exacerbated by the acetaminophen this drug contains, and because the patient's negative drug screens raise concerns about diversion which have not been addressed.