

Case Number:	CM14-0206196		
Date Assigned:	12/18/2014	Date of Injury:	08/27/2013
Decision Date:	02/12/2015	UR Denial Date:	11/19/2014
Priority:	Standard	Application Received:	12/09/2014

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 Practice 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 44-year-old berry picker reported injuries to her low back and suprapubic area due to a slip and fall at work on 8/27/13. She was 2-3 months pregnant at the time. She miscarried within several weeks of the accident. The records do not contain any information about her early course of treatment, although she appears to been untreated for at least several months in 2014. She first saw her current primary treater on 9/5/14. The provider documented patient complaints including pain, locking, giving way and limited motion of the lumbar spine. The pain radiated to both buttocks and thighs, with numbness and tingling in the left lower extremity. Exam was notable for tenderness of the paravertebral muscles, limited back range of motion, and patchy decreased sensation of the left lower extremity. Diagnoses included lumbosacral strain and left lumbar radiculopathy. Treatment plan included prescriptions for Norco 2.5, Prilosec and Anaprox, and requests for authorization for 12 PT sessions and for referral to a psychiatrist of psychologist. There are three more visits in the records with the same primary treater, with dates from 9/18/14 to 10/23/14. None of them documents any subjective improvement. The physical exam remains essentially the same. Elavil is added to the patient's medications on 9/18/14 and Tylenol 3 is substituted for Norco 2.5 on 10/23/14, but otherwise no changes are made to the treatment plan. The treater does not document any functional status or functional goals in any of the notes, nor does he document a rationale for the prescription of any medication. The patient was not working at the time of the 9/5/14 visit. At all visits, the provider documents that "the patient would be capable of performing semi-sedentary work, which would allow her to change positions as tolerated. If light duty is not available to the patient, the patient would otherwise be temporarily totally disabled for six weeks time". Since she is a berry picker, it can probably be assumed that she has remained at temporary total disability.

IMR ISSUES, DECISIONS AND RATIONALES

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

Naprosyn 550mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-depressants Page(s): 13.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Functional Improvement; Medications for Chronic Pain; NSAIDs (non-steroidal anti-inflammatory dr.

Decision rationale: Naprosyn is an NSAID. Per the MTUS Chronic Pain citations, all therapies should be focused on the goal of functional improvement rather than just pain elimination, and assessment of treatment efficacy is accomplished by reporting functional improvement. 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 ongoing provision of Naprosyn to this patient. The patient has been taking it for nearly seven weeks with no improvement in symptoms, essentially no change in physical findings, and no documented improvement in functional status. She is well past the point where this prescription could be called short-term. The provider has not checked a single blood pressure after starting this medication, which is at least medically inadvisable. Based on the MTUS citations above and on the medical documentation provided for my review, Naprosyn 550 mg #60 is not medically necessary. It is not medically necessary because its use has extended past what could be called short-term, because it has not resulted in either symptomatic relief or improvement in functional status, and because it may be placing this patient at risk for hypertension and/or a cardiovascular event, which the provider does not seem to be monitoring for.

Prilosec 20mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms, and cardiovascular risk Page(s): 66.

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. 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 has been taking Prilosec at twice the usual dosage for at least two months. The risks of Prilosec are not negligible, and increase with time. 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 places the patient at risk for significant side effects without any documentation of counterbalancing benefits.

Tylenol #3 #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms, and cardiovascular risk Page(s): 68.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain; Criteria for Use of Opioids, Steps to Take Before a Therapeutic Tr.

Decision rationale: Tylenol #3 is brand-name acetaminophen 300 mg with codeine 30 mg. Codeine is an opioid analgesic. Per the MTUS recommendations 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. 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. 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. Red flags indicating that opioid use may not be helpful should be identified, as should risk factors for abuse. Opioids should be discontinued if there is no improvement in function. There is no good evidence that opioids are effective for radicular pain. If long-term use of opioids occurs, there is a need for ongoing pain and function assessments, as well as assessments for side effects, of concurrent other treatments, and of concurrent psychological issues. The clinical findings in this case do not demonstrate that any of the above guidelines have been followed. An opioid (Norco 2.5) was originally prescribed simultaneously with Anaprox. Norco continued to be prescribed with other medications, and then was abruptly changed to Tylenol 3 without explanation. There is no documentation of evaluation of whether or not the patient's pain is nociceptive or neuropathic. Since one of her diagnoses is lumbar radiculopathy, it can be presumed that the provider believes there is at least a neuropathic component to her pain. As discussed above, neuropathic pain does not necessarily respond well to opioids. No assessment is documented 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. Based on the evidence-based guidelines cited above, and the clinical documentation provided for my review, Tylenol 3 #60 is not medically necessary. It is not medically necessary because of the lack of appropriate documentation of the patient's status prior to beginning it and of the reasons for starting it, and because of the failure to set functional goals that will be monitored for its ongoing use.

Elavil 10mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 92.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain; Antidepressants for chronic pain; Tricyclic Antidepressants Page(s).

Decision rationale: Elavil is brand-named amitriptyline, which is a tricyclic antidepressant. Per the MTUS recommendations 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. Antidepressants and particularly tricyclic antidepressants are recommended as a first-line option for chronic pain. Analgesia usually occurs within a week, whereas antidepressant effect takes longer to occur. Assessment of efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesics; sleep quality and duration; and psychological assessment. Side effects, including sedation, should be assessed. These outcome measures should be initiated at one week of treatment, with a recommended trial of at least 4 weeks. Tricyclic antidepressants are

recommended as a first-line option for neuropathic pain, particularly if the patient also has depression, anxiety or insomnia. Tricyclic antidepressants should be used with caution because of their low threshold for toxicity and potential for fatal overdose. A screening ECG is recommended for patients over 40 prior to starting therapy. Starting dose of amitriptyline may be as low as 10-25 mg at night, with increases of 10-25 mg once or twice a week up to 100 mg/day. The lowest effective dose should be used. The clinical findings in this case do not support the continued use of Elavil. This patient has been taking Elavil for over 4 weeks with no documented change in status except that she has been changed to a more potent opioid. The provider did not document a pre-treatment ECG, and does not appear to be monitoring appropriately for side effects. Since the provider does not document pain levels or functional status, it is not clear that he would notice if this medication WAS working. He appears to be unaware of the need to increase the dose gradually if the patient is not responding, and has not done so. (It is also possible that he has not done so because the patient is depressed and he is concerned about suicide/overdose, but this is an issue that should have been explored and documented prior to starting Elavil). Based on the MTUS citations above and on the clinical documentation provided for my review, Elavil 10 mg #30 is not medically necessary. It is not medically necessary because the provider did not perform appropriate evaluation prior to beginning it, has not appropriately monitored for side effects, has not appropriately increased its dosage, has not monitored outcomes appropriately, and because there is no documentation of any positive response to it over a period of more than 4 weeks.