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| Case Number: | CM14-0154127 | | |
| Date Assigned: | 09/23/2014 | Date of Injury: | 04/07/1995 |
| Decision Date: | 11/05/2014 | UR Denial Date: | 09/11/2014 |
| Priority: | Standard | Application Received: | 09/22/2014 |

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 71-year old woman was involved in a motor vehicle accident on 4/7/95 that resulted in injuries to both wrists. She has had 7 surgeries on the L wrist and 6 surgeries on the R wrist. Current diagnoses include bilateral crush injuries of both wrists, reactive depression due to chronic pain, and L hip pain due to iliac crest bone graft and carpal tunnel syndrome. The available records contain four progress notes from the primary treating physician's office. A 3/19/14 note, signed by a nurse practitioner, documents that the patient's pain levels are 7-8/10 after medication, and 9/10 before medication. The patient is unable to drive or clean her house. Exam findings include only that the patient has a weak grip and decreased thumb range of motion. The plan includes a request for transportation, and an increase of the dose of pain medicine. The patient's opioid medication was changed from Vicodin 5/500 three times per day to Norco 10/325 four times per day. Motrin 800 mg three times per day, Zoloft 100 mg every night, Prilosec 20 mg every day, and lactulose (dose not specified) were continued as before. A 4/21/14 progress note signed by the same NP states that the patient's pain levels have improved to 4/10 after the new medication, and are still 9/10 before medication. The patient has a little constipation, for which she is using prunes. No physical exam is documented except the statement that it has not changed. No discussion of functional level is included. The plan includes dispensing ibuprofen #120 and Prilosec #60. The primary provider cosigned both of these notes. A 7/1/14 progress note, signed by the primary provider himself, notes that the patient continues to be unable to clean her house. It does not mention driving. Occasionally she is able to pull weeds, but "is laid up for about a week after that". Pain levels are noted as 4/10 after medication and 8/10 before. The provider states that the patient is not able to tolerate Motrin due to reflux and some gastritis, and that she needs Prilosec to control her stomach issues. Minimal objective findings are documented. The plan includes continuing her medications,

requesting four sessions of psychotherapy, and requesting 4 hours per week of housekeeping for three months. The final note, dated 8/26/14, is signed by a chiropractor and cosigned by the primary provider. The patient's pain levels and function level are unchanged from the previous two visits. No gastrointestinal symptoms are mentioned. Motrin 800 mg #120, Prilosec 20 mg #60 and Promolaxin 100mg #200 were dispensed.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective Motrin 800mg #120: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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

Decision rationale: Motrin is brand-name ibuprofen, which is an NSAID. The MTUS guidelines cited above states that 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 MTUS references regarding NSAIDs state that NSAIDs are recommended as an option for short-term symptomatic relief. A Cochrane review found that NSAIDs were no more effective than acetaminophen, narcotics or muscle relaxants; and that they were likely to have more side effects than acetaminophen and fewer side effects than narcotics or muscle relaxants. NSAIDs may be used to treat breakthrough and mixed pain conditions such as osteoarthritis with neuropathic pain, but there is only inconsistent evidence to support their use for long-term neuropathic pain. Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. 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. NSAIDs are relatively contraindicated in patients with renal insufficiency or cirrhosis. Patients with cardiovascular risk factors should be treated with naproxen or with non-pharmacological measures. This patient has clearly been taking Motrin for a long time, perhaps for years. Since she is completely disabled and is unable to drive or do housework it does not appear that the use of Motrin has resulted in any functional improvement. The patient's recent increase in her opioid dose produced a dramatic improvement in her pain, making it questionable what Motrin is contributing. There is no documentation of the patient's GI or cardiovascular risk. Motrin is apparently causing GI side effects, which are documented as "reflux and some gastritis". The actual symptoms themselves on and off Motrin are not documented. Since the patient is 71 years old and is taking two antihypertensive medications, she has at least mild cardiovascular risk factors, and may be at considerable risk for cardiovascular disease. Ibuprofen is contraindicated in this case. The evidence-based guidelines cited above and the clinical findings in this case do

not support the continued use of Motrin for this patient. Motrin 800 mg #120 is not medically necessary because its use has not resulted in functional improvement, because it is not clearly helping this patient's pain, because its long-term use is not indicated, because it appears to be causing side effects and because the patient's cardiovascular risk factors make its use inappropriate therefore, this request is not medically necessary.

Retrospective Colace 100mg #200: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47-48. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Up-to-date, an online evidence-based review service for clinicians (www.uptodate.com), Cancer pain management with opioids: Prevention and management of side effects.

Decision rationale: Colace and Promolaxin are both generic names for docusate sodium, which is a stool softener. In this case, it is not clear why the provider is dispensing this drug under one name and requesting authorization for it under another, but it is clearly the same drug. The MTUS guideline cited above states that opioids cause significant side effects up to 35% of the time that include constipation, drowsiness, clouded judgment, memory loss and misuse or dependence. The MTUS guidelines do not address the treatment of opioid-related constipation. The Up-to-date reference cited above states that opioids reduce bowel motility by both direct and anticholinergic mechanisms. Longer gastrointestinal transit time causes excessive water and electrolyte reabsorption from feces, decreased biliary and pancreatic secretion further dehydrate stool. The first line treatment for opioid-associated constipation is a contact cathartic such as Senna, with or without a stool softener, or daily administration of an osmotic laxative such as lactulose. It is not clear that this patient even has opioid-associated constipation, since the clinical notes make only one reference to mild constipation which is controlled by eating prunes. If she does have opioid-associated constipation, docusate sodium is not the treatment of choice, since it does not improve the decreased intestinal motility caused by opioids. The patient is documented as being on an appropriate medication (lactulose). However its dose is not documented and none of the notes mention whether or not the patient is taking and tolerating it. Based on the evidence-based citations and the clinical findings in this case, Colace 100 mg #200 is not medically necessary, because there is insufficient documentation to demonstrate that the patient has constipation that is not well-controlled by other more appropriate medications therefore, this request is not medically necessary.

Retrospective Prilosec 20mg #60: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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), Omeprazole: drug information.

Decision rationale: Prilosec is brand-named 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. 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 findings in this case do not support the use of Prilosec. The patient appears to have been taking Prilosec for months to years, which would put her at risk for the side effects listed above, some of which are life threatening. There is no documentation of the patient's gastrointestinal or cardiovascular risk status. She is 71, which is a risk factor for GI disease. She is also taking two antihypertensive medications, which together with her age would mean that her risk for cardiovascular disease is at least mild. It is clear, as documented above, that continued Motrin is not medically appropriate for this patient. The documentation regarding this patient's GI problems is so scanty that it is difficult to determine what her actual symptoms might be, but since her provider states that they are occurring with Motrin use, they should resolve when Motrin is discontinued. Prilosec 20 mg #60 is not medically necessary in this case because an appropriate evaluation of GI risk factors has not been documented, because the symptoms it was prescribed for are likely to end with cessation of Motrin (which is not medically necessary), and because it has a significant possibility of causing serious side effects therefore, this request is not medically necessary.