

<b>Case Number:</b>	CM14-0146147		
<b>Date Assigned:</b>	09/15/2014	<b>Date of Injury:</b>	01/02/2003
<b>Decision Date:</b>	10/15/2014	<b>UR Denial Date:</b>	08/07/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/09/2014

### 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 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 67-year old woman was injured on 1/2/03. Current diagnoses include lumbar degenerative disc disease and lumbar radiculopathy. She also has a diagnosis of non-industrial neck cancer which presumably has been or is being treated, though specifics are not included in the available records. Treatment for the industrial injury has included medications, chiropractic manipulation and multiple epidural steroid injections. The treating physician's note of 7/15/14 states that the patient has no symptoms other than pain, and also that the patient has intermittent tingling and buzzing sensations in her posterior buttocks and legs. Pain is rated as 2/10 with medications, and 6/10 without. The patient is reportedly frustrated due to receiving a denial letter from the insurance company regarding Zanaflex and omeprazole. Current medications at the time of the visit included Zipsor, Omeprazole, Zanaflex, Lidoderm patch, baby aspirin, bisoprolol-hydrochlorothiazide, ciprofloxacin, simvastatin, calcium with vitamin D, and triamterene-hydrochlorothiazide. Positive objective findings included tenderness/spasm of the lumbar paraspinal muscles, decreased back range of motion, and decreased sensation of the medial foot bilaterally. Under a section with the heading "Prescription", the note states that a trial of cyclobenzaprine 5 mg, diclofenac 50 mg, lidocaine 5% ointment, and Nexium 20 mg are all being started at once; with an added note stating that omeprazole was denied by insurance though it was used with "good benefit for GI stress", that Zanaflex was denied by insurance though it was used with "good benefit of muscle reduction", and that Zipsor was denied by insurance though it was used "with good benefit for pain reduction". Later the progress note states that the patient was prescribed cyclobenzaprine, diclofenac, lidocaine 5% ointment, Nexium, Omeprazole, and Zanaflex. The progress note also includes a statement that with medications, the patient can perform household tasks and self-care for 35 minutes or more at a time, whereas without medication could only perform these activities for 10 minutes or less.

There are multiple progress notes from the primary treater in the record with essentially the same wording, which makes it likely that the primary provider is using a template. Of concern is that there are frequent errors regarding medications, such as documenting that a medication was discontinued and prescribed at the same visit, or that the same medication was prescribed using two different names. There is no documentation of any evaluation of GI or cardiovascular risks in the record. Review of Systems intermittently contains GI complaints of decreased appetite and dysphagia, but no abdominal complaints. The patient's work status and functional level is documented identically from 12/31/13 through 9/9/14. The patient is working full time with limitations.

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

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

**Diclofenac 50 mg, sixty count with two refills:** Upheld

**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, page 60; NSAIDs (non-steroidal anti-inflammatory drugs), Chronic I. Decision based on Non-MTUS Citation X Other Medical Treatment Guideline or Medical Evidence: UptoDate, an evidence-based online review service for clinicians, ([www.uptodate.com](http://www.uptodate.com)), Diclofenac (systemic): Drug Information

**Decision rationale:** 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 less 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. 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. NSAIDs are relatively contraindicated in patients with renal insufficiency or cirrhosis. The UptoDate reference states that per BEERS criteria, this drug may be inappropriate for use in geriatric patients (quality of evidence moderate; strength of recommendation strong.) The medical findings in this case do not support the use of diclofenac

50 mg. This medication was started in conjunction with two other medications, making it impossible to isolate the beneficial and bad effects which may occur from diclofenac alone. There is no documentation of any careful assessment of the patient's functional level. The notes repeatedly state that the patient is able to do household chores and self-care for 35 minutes or more, and that she continues to work full time with restrictions. These assessments imply very different functional levels, and make it appear likely that no real assessment of function has been made for some time. This patient has been taking some form of diclofenac for months to years. (Zipsor is diclofenac 25 mg.) There is no documentation of any flare of the patient's chronic low back pain which would require NSAID use. There is no documentation of the patient's cardiovascular or GI risk factors, or of her level of renal function (which may be an issue if she has received

**Nexium 20 mg thirty count with two refills:** 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): pages 68-69. Decision based on Non-MTUS Citation Esomeprazole: drug information

**Decision rationale:** 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 esomeprazole 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 risk for salmonella and campylobacter gastrointestinal infections, clostridium difficile-associated diarrhea, increased incidence of osteoporosis-related fractures of the hip, spine, or wrist; hypomagnesemia and Vitamin B12 deficiency. Nexium is brand-name esomeprazole, which is a proton pump inhibitor. It is impossible to guess from the available clinical records why esomeprazole is being prescribed for this patient. The only possibly pertinent statements from the treating physician are that omeprazole was used "with good benefit for GI stress", and that the patient's GI symptoms include decreased appetite and dysphagia. GI stress, decreased appetite and dysphagia are not indications for Nexium use. There is no documentation of the patient's risk for GI events. There is no documentation of any condition likely to require a PPI (proton pump inhibitor)

prescription, or of any symptoms suggestive of such a condition. It does appear likely that the patient has been taking omeprazole for at least a year, which would put her at risk for the side effects listed above, many of which could be life threatening. (Note that the side effects of esomeprazole are essentially the same as those for omeprazole, which the patient was previously taking and appears to still be taking.) Therefore, the request for Nexium 20 mg thirty count with two refills is not medically necessary or appropriate.