

<b>Case Number:</b>	CM14-0175478		
<b>Date Assigned:</b>	10/28/2014	<b>Date of Injury:</b>	04/22/2002
<b>Decision Date:</b>	12/16/2014	<b>UR Denial Date:</b>	10/07/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/23/2014

### 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 62-year old woman apparently reported injuries of her neck, right shoulder, left elbow, both wrists, both hands and low back dated 4/22/02. There is no information about the mechanism of injury in the available records. Her medical history is notable for extreme obesity (BMI 70), diabetes, hypertension and coronary artery disease. Her daily medications include Plavix. Treatment for the current injury has included a right carpal tunnel release performed 5/30/14 and a left carpal tunnel and long trigger finger release performed 8/22/14. The recorded diagnoses vary from visit to visit, and include brachial neuritis, cervicgia, shoulder region disease not elsewhere classified, cubital tunnel syndrome, bilateral carpal tunnel syndrome, and bilateral trigger fingers. A 9/4/14 progress note from the primary treater's office documents that the patient's left and right wrist /hand pain is improving, and that her neck and low back pain are unchanged. Exam findings include only that the patient is obese, that she is oriented and that her mood is appropriate, and that she has well-healing surgical incisions of her hands and wrists with some swelling. Plan includes suture removal, refilling current medications, which are not listed, and a request for physical therapy. A 10/14/14 progress note from the primary treater's office states that the patient continues to have constant severe pain in her neck which radiates to both upper extremities, and which is associated with headaches. The pain is worsening. She has constant moderate left wrist pain, which is improving. She has low back pain that is unchanged. She has nausea. The plan includes continuing the current medications, which are not listed, and requesting authorization for physical therapy. The patient is off work. A 5/21/14 request for authorization includes requests for naproxen, ondansetron, omeprazole, tramadol ER, levofloxacin, and orphenadrine. A 6/25/14 request includes Voltaren, orphenadrine, ondansetron, tramadol ER, omeprazole and levofloxacin. A 9/26/14 request includes fenoprofen, cyclobenzaprine, ondansetron, omeprazole, tramadol ER and levofloxacin. . Rationales for the

medications are pre-printed and checked off, so they are obviously not specific for this particular patient. Rationales include the following reasons for dispensing each medication; fenoprofen is for pain and inflammation; cyclobenzaprine is for palpable muscle spasms noted during examination today, as well as for off-label sleep aid; ondansetron is for nausea associated with the headaches that are present with chronic cervical spine pain; omeprazole is for GI symptoms and to prevent complications associated with pain medications and NSAIDs; tramadol is for acute exacerbation of severe pain; and levofloxacin is a routine precaution to avoid postoperative infection. All six of these last medications were non-certified or modified to allow only enough medication for weaning in a UR (utilization review) performed 10/7/14.

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

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

**Omeprazole 20mg #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Official Disability Guidelines, Treatment for Workers Compensation.

**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)) , Omeprazole: drug information; and Clopidogrel: Drug information

**Decision rationale:** Omeprazole 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. 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 omeprazole for this patient. The pre-printed reasons documented for prescribing this medication are insufficient. It is not clear what GI symptoms the patient is having beyond her documented nausea. Omeprazole is not indicated for nausea, or for the constipation that

frequently results from opioid use. The provider has not documented any evaluation of her risk for GI events. She is in fact at very high risk due to concomitant use of Plavix (clopidogrel) and an NSAID, and should not be taking any NSAID, which obviates the need for a PPI. In addition, PPIs reduce the levels of the active form of Plavix and cause increased risk for cardiovascular events. Plavix is contraindicated in this case. It appears that this patient has probably been on omeprazole for at least a year, which puts her at risk for the serious side effects listed above, many of which could be life-threatening. Based on the evidence-based references cited above and the clinical information available for my review, omeprazole 20 mg #120 is not medically necessary because there is no documentation of any benefit to the patient that is likely to outweigh its risks, and it is in fact medically contraindicated due to its interactions with Plavix. This patient is at risk for a cardiovascular event, and her omeprazole should be stopped at once.

**Fenoprofen Calcium 400mg #120: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs).

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

**Decision rationale:** Fenoprofen is an NSAID. The MTUS reference above states 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. NSAIDs have no evidence of long-term effectiveness for pain or function. If patients have cardiovascular risk factors, a non-pharmacological choice for pain is the preferred option, followed by acetaminophen or possibly aspirin. 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. The UptoDate reference states that NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. They also may increase the risk for bleeding in patients on anticoagulants (such as Plavix). The clinical findings in this case do not support the use of fenoprofen for this patient. This patient does not just have cardiovascular risk factors; she has known coronary artery disease. Placing her on an NSAID increases her risk for a life-threatening cardiovascular event. This patient has been on multiple NSAIDs, none of which have resulted in any functional improvement. Although fenoprofen was started relatively recently, it can be presumed that it will be no more effective than the NSAIDs used previously, since they all have approximately the same efficacy for pain relief. In addition, adding this medication to a regimen which already includes Plavix unacceptably increases this patient's risk for a GI or other bleed. Based on the evidence-based citations above, and on the clinical information provided for my review, fenoprofen is not medically necessary because it is no more likely to result in functional improvement than the NSAIDs the patient has taken previously and it increases the risk of life-threatening events to the extent that it should be stopped immediately.

### **Ondansetron 8mg #30: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Official Disability Guidelines, Treatment for Workers Compensation.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UptoDate, an online, evidence-based review service for clinicians (www.uptodate.com), Ondansetron: Drug information; Evaluation of headache in adults; Headache syndromes other than migraines; Cervicogenic headache

**Decision rationale:** According to the ondansetron reference cited above, the medical indications for ondansetron (Zofran) include prevention of nausea and vomiting associated with chemotherapy. It may also be used for prevention of postoperative nausea and vomiting and for severe or refractory hyperemesis gravidarum (■■■■ only). Common side effects include headache, malaise/fatigue, and constipation. The headache references list multiple causes for headaches with nausea, which include migraine, cervicogenic headache, and headaches due to medication overuse. Cervicogenic headaches should be unilateral and be precipitated by neck movement or sustained awkward positioning of the neck. It may or may not be accompanied by nausea. The clinical findings in this case do not support the use of ondansetron for this patient. In the first place, simply assuming her headache and nausea are due to her chronic cervical spine pain is inappropriate. It does not appear that any careful evaluation of the headaches has occurred. Her headaches may be due to migraines, or to medication overuse (which may include ondansetron use), or to another cause. In all of these cases, the more appropriate action would be to treat the underlying cause of the headache, rather than just treating the symptom of nausea. In addition, nausea associated with headache is not one of the indications for ondansetron, which is usually reserved for severe forms of nausea associated with chemotherapy and the immediate post-surgical period. According to the evidence-based citations above and to the clinical information provided for my review, ondansetron 8 mg #30 is not medically necessary for this patient, since there has been no appropriate evaluation of the cause of the patient's headaches and since Ondansetron is not indicated for headache-associated nausea.

### **Cyclobenzaprine HCl 7.5mg #120: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants Medications for Chronic Pain Page(s): 60, 63-66. Decision based on Non-MTUS Citation UptoDate, an online evidence-based review service for clinicians (www.uptodate.com), Tramadol: Drug Information

**Decision rationale:** Cyclobenzaprine is a sedating muscle relaxant. Its 7.5 mg form is long-acting, and its common trade name is Fexmid. 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. Per the second reference, non-sedating muscle relaxants are recommended with

caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain. In most low back pain patients, they show no benefit. There is no additional benefit if they are used in combination with NSAIDs. Efficacy appears to diminish over time. Cyclobenzaprine is only recommended for a short course of therapy, as there is no evidence to support its long-term use. Its greatest effect appears to occur within the first four days of treatment. Side effects include drowsiness, urinary retention, dry mouth and headaches. Its use should be avoided in patients with arrhythmias, heart block, heart failure and recent myocardial infarction. Per the Up-to-date reference cited above, tramadol increases the risk of seizures even at recommended doses in patients who have not previously had seizures. This risk is increased in patients on other opioids or cyclobenzaprine. The clinical documentation in this case does not support the use of Fexmid. It is being started at the same time as fenoprofen, which means that it is impossible to determine which medication is causing any beneficial or adverse effect that occurs. Although the pre-printed rationale given for its use is that the patient has acute muscle spasm, there is no muscle spasm documented on exam. In addition, the patient appears to have been on muscle relaxants for months to years, which would mean that any current muscle spasm she is experiencing would not be acute. The prescription for Fexmid clearly extends beyond the four days that it is likely to be effective. The other reason given for the Fexmid prescription is that it is a sleep aid. If the patient has insomnia an evaluation for it should be performed, and a more effective medication prescribed. The use of Fexmid combined with tramadol puts this patient at increased risk for seizure. Finally, Fexmid is long-acting and sedating, particularly when combined with an opioid such as tramadol ER. It actually may make it more difficult for this patient to increase her level of activity and thus interfere with her recovery. Based on the MTUS citations above and on the clinical records provided for my review, cyclobenzaprine 7.5 mg #120 is not medically necessary in this case because it is being started with another drug, because there is no evidence to support its short or long-term use, because it increased the risk of seizure when combined with tramadol, and because its side effects may in fact interfere with this patient's recovery.

**Tramadol ER 150mg #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol (Ultram).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain Opioids for neuropathic pain Opioid Hyperalgesia Opioid dosing P. Decision based on Non-MTUS Citation UptoDate, an online evidence-based review service for clinicians (www.uptodate.com), Tramadol: Drug Information

**Decision rationale:** Tramadol is an opioid medication and therefore falls under guidelines for medications in general and for opioids specifically. According to the first MTUS 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 MTUS 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. 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. Per the UptoDate reference cited above, tramadol increases the risk of seizures even at recommended doses in patients who have not previously had seizures. This risk is increased in patients on other opioids or cyclobenzaprine. The clinical findings in this case do not support the use of tramadol for this patient. Tramadol was introduced in conjunction with cyclobenzaprine, which makes it impossible to determine which medication is causing any beneficial or harmful effect that occurs, and also increases the patient's risk for seizure. There is no documentation of evaluation of whether or not the patient's pain is nociceptive or neuropathic. Her diagnoses include brachial neuritis, cubital tunnel syndrome and carpal tunnel syndrome, all of which cause neuropathic pain by definition. 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, tramadol was not discontinued when it became clear that it has not produced any functional improvement. This patient has been totally disabled for months to years. This is more than adequate evidence that this patient is not responding appropriately to this medication, and that it should be discontinued. Based on the MTUS criteria cited above and on the clinical findings provided for my review, tramadol ER 150 mg #90 is not medically necessary. It is not medically necessary because it was started in conjunction with another medication, because its use with that medication increases the patient's risk of seizure, 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.

**Levofloxacin 750mg #30:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UptoDate, on online, evidence-based review service for clinicians, ([www.uptodate.com](http://www.uptodate.com)), Antimicrobial prophylaxis for prevention of surgical site infection in adults; and Levofloxacin (systemic): Drug information

**Decision rationale:** The UptoDate references above state that antimicrobial prophylaxis is not warranted for clean orthopedic procedures including arthroscopy and other procedures with no implantation of foreign materials. In general, when antimicrobial prophylaxis is warranted, it

involves the use of a narrow-spectrum IV antibiotic which is begun before the surgical incision is made and is continued for less than 24 hours after the surgery is completed. Levofloxacin side effects may include altered cardiac conduction; toxic psychosis; hypersensitivity reactions including anaphylaxis; superinfection which may include C difficile-associated diarrhea; and tendon inflammation or rupture. The clinical findings in this case do not support the provision of thirty tablets of levofloxacin to this patient. Even if it were warranted, the provider has recommended that it be taken daily for 7 days, so it is unclear why the patient would need thirty doses. At the time it was requested, the patient was well over a month post surgery, and her sutures had been removed. Post-surgical prophylaxis for 7 days would be meaningless at this point. In any case, antibiotic prophylaxis was not indicated at all for the surgery performed, which clearly falls into the clean orthopedic procedure category described above. Prescribing this antibiotic exposes this patient to the risk of developing drug-resistant bacteria in addition to the other possible side effects listed above, with absolutely no benefit to be gained by its administration. According to the evidence-based guideline cited above and to the clinical findings provided for my review, levofloxacin 750 mg #30 is not medically necessary, because there is no indication for its use and because it poses risks to the patient that are not balanced by any potential benefit.