

Case Number:	CM14-0184657		
Date Assigned:	11/12/2014	Date of Injury:	07/23/2011
Decision Date:	01/31/2015	UR Denial Date:	10/07/2014
Priority:	Standard	Application Received:	11/05/2014

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 57-year old firefighter reported multiple injuries due to fall which occurred on 4/2/11 and to cumulative trauma from his usual work. The reported injuries involved the neck, back and all four limbs; in addition the patient claims work-related Gastroesophageal reflux disease, hypertension and heart problems, hearing loss, lung disease and sinus problems. The current primary physician first saw the patient on 4/13/11. Multiple tests were ordered, and records requested. Although the patient's current medications at the time included Relafen, ibuprofen and aspirin, Naproxen was dispensed. Ondansetron, sumatriptan, omeprazole, and Medrox were also dispensed. The records contain multiple progress notes dating forward from 4/13/11 through 5/5/14, from both the primary physician and a pain specialist. Diagnoses include cervical and lumbar discopathy, right shoulder internal derangement, carpal tunnel/double crush syndrome, internal derangement bilateral knees, left ankle internal derangement and bilateral plantar fasciitis. All of the notes document ongoing pain of neck, back, and of various other parts of the body. Medications are dispensed at every visit with the primary treater, which usually include either naproxen or ketoprofen; omeprazole; ondansetron; Tizanidine, Orphenadrine or cyclobenzaprine; tramadol/acetaminophen; and Medrox topical cream. Rationales are given each time medications are dispensed. They are clearly printed from templates and do not appear to be specific for this patient. The primary treater's note occasionally includes the statement that the patient is taking Relafen and ibuprofen provided by his previous provider. Also of concern is that the pain specialist frequently dispenses tramadol 50 mg and either naproxen or ketoprofen. There is no apparent coordination regarding medication dispensing between the primary physician and the pain specialist. There are several notes from an AME who is an internist. These notes document that the patient has a hiatal hernia, and that he has "GI symptoms treated with antacids". He makes a diagnosis of Gastroesophageal reflux disease (GERD), and

recommends that the patient be precluded from taking NSAIDs and be provided with antacids. He did not specifically recommend omeprazole. Again there is no evidence that the primary physician is aware of this advice and is coordinating with him. None of the progress notes specifically describes the patient's functional status in regards to activities he can and cannot perform. From 4/11/13 to 9/12/11 he was at temporary total disability status. He attempted to return to regular work after the 9/12/11 visit, was unable to tolerate it due to back pain, and TTD was resumed. He retired in June 2012 (date approximate, not specified in records) at permanent partial disability status, and has not worked since.

IMR ISSUES, DECISIONS AND RATIONALES

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

Omeprazole Delayed Release Capsules 20mg #120 DOS: 5/25/11, 12/05/11, 02/13/12, 07/16/12, 9/06/12: 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): 68-69. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Other Medical Treatment Guideline or Medical Evidence: UptoDate, an evidence-based online review service for clinicians, (www.uptodate.com) , Omeprazole: drug information; and Clopidogrel: Drug information

Decision rationale: It is impossible to guess from the available clinical records why omeprazole is being prescribed for this patient. The documented reason for dispensing omeprazole is that it should be taken as needed for upset stomach, and that it should be taken in conjunction with pain and anti-inflammatory medications to prophylactically protect his stomach and to prevent any GI complications. GI upset symptoms may include nausea and constipation, for which omeprazole is not indicated. There is no documentation of the patient's risk for GI events. There is no documentation of any condition likely to require a PPI prescription or of any symptoms suggestive of such a condition, except for the diagnosis of GERD made by the AME. (No symptoms are documented even for this diagnosis.) The AME recommended that the patient not take NSAIDs and be provided with antacids, and did not specifically recommend omeprazole. The patient has been taking omeprazole for over a year, which would put him at risk for the side effects listed above, many of which could be life-threatening. Based on the evidence-based references cited above and the available clinical information, because there is no documentation of any benefit to the patient that is likely to outweigh its risks, Prilosec is not medically necessary.

Medrox pain relief ointment 120gm x 2, DOS 12/05/11, 07/16/12, 09/06/12: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain; Topical analgesics Page(s): 111-113.

Decision rationale: Medrox lotion contains a combination of 20% menthol salicylate, 5% menthol and 0.0375% capsaicin. Per one of its major suppliers, Physician Dispensing Solutions, Medrox "is a must-have for any practice looking to generate ancillary income". Per the first citation 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 second citation states that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Capsaicin is recommended as an option in patients who have not responded to or are intolerant to other treatments. There is no evidence supporting formulations which contain over 0.025% capsaicin. It has been shown to have some efficacy in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain. The clinical documentation in this case does not support the use of Medrox ointment. Using it means that three medications are being started at once, and that it would be impossible to determine which of them resulted in any beneficial or harmful effect. The concentration of capsaicin in this ointment exceeds that recommended by MTUS. Lastly, the long-term use of Medrox has not resulted in any significant functional improvement in this patient. Based on the evidence-based guidelines cited above and the clinical documentation provided for my review, because it contains three medications which are being started at once and which cannot be monitored individually, and because it contains one medication with a concentration that exceeds that for which there is supporting evidence, and because its use has not resulted in any significant functional recovery for this patient, the Medrox ointment 120 grams x2 is not medically necessary.

Naproxen Sodium tab 550mg #100, DOS: 5/25/11: 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; NSAIDs (non-steroidal anti-inflammatory drugs); NSAIDs; hypertensi.

Decision rationale: Based on the MTUS citations above and on the clinical information provided for my review, naproxen 550 mg # 100 is not medically necessary, because it is likely that the patient is taking other NSAIDs, because an internal medicine AME has recommended that the patient not take NSAIDs due to GERD, because the patient has hypertension and heart disease (which means that NSAIDs are relatively contraindicated and may place him at risk for a cardiac event such as a heart attack), because long-term NSAID use is not recommended by MTUS, because a large component of this patient's pain appears to be neuropathic and not likely to respond to an NSAID, and because naproxen use has not resulted in any significant functional

recovery for this patient. Therefore, Naproxen Sodium tab 550mg #100, DOS: 5/25/11 is not medically necessary.

Cyclobenzaprine Hydrochloride tab 7.5mg #120, DOS: 07/16/12, 09/06/12: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants.

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

Decision rationale: 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. The patient has been on muscle relaxants years, which would mean that any current muscle spasm he is experiencing would not be acute. The prescriptions for Fexmid clearly extend beyond the four days that it is likely to be effective. The use of Fexmid combined with tramadol puts this patient at increased risk for seizure. The patient has not exhibited any significant functional recovery as a result of taking Fexmid. Finally, Fexmid is long-acting and sedating, particularly when combined with an opioid such as tramadol. It actually may make it more difficult for this patient to increase his level of activity and thus interfere with his 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 there is no evidence to support its long-term use, because it increases the risk of seizure when combined with tramadol, because it has produced no substantial functional recovery in this patient, and because its side effects may in fact interfere with this patient's recovery. Therefore, cyclobenzaprine 7.5 mg #120 is not medically necessary.

Tramadol Hydrochloride and Acetaminophen tab (Ultracet) 37.5mg/325mg #120 DOS: 10/24/11, 05/14/12, 7/16/12: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for use for a therapeutic trial of Opioids.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain; Criteria for use of Opioids; Opioids for neuropathic pain; Opioids. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: UptoDate, an online evidence-based review service for clinicians (www.uptodate.com), Tramadol: Drug Information

Decision rationale: 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. A pain agreement is recommended for long-term opioid use, and only one provider should dispense opioids. 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 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 findings in this case do not support the use Ultracet for this patient. There is no documentation of evaluation of whether or not the patient's pain is nociceptive or neuropathic, and most of his diagnoses make it appear that his pain is primarily neuropathic. 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 his potential for abuse. No specific functional goals were set or followed. No pain contract is documented, and it appears that two physicians are dispensing opioids to this patient. (His pain specialist is dispensing tramadol 50 mg). No evaluation for opioid hyperalgesia has been made. Ultracet is being prescribed with cyclobenzaprine, which puts the patient at increased risk for seizure. Most importantly, Ultracet was not discontinued when it became clear that it has not produced any functional improvement. According to the evidence-based citations above and the clinical records provided for my review, tramadol/acetaminophen 37.5/325 mg # 120 is not medically necessary. It is not medically necessary because an appropriate evaluation for opioid use is not documented, because no functional goals were set or followed, because no pain contract is documented, because it appears that two providers are dispensing tramadol without coordinating with each other, because no evaluation for opioid hyperalgesia has been made, because its use with cyclobenzaprine puts the patient at increased risk for seizure, and because the patient has not demonstrated any significant improvement in function as a result of taking it. Therefore,

Tramadol Hydrochloride and Acetaminophen tab (Ultracet) 37.5mg/325mg #120 DOS: 10/24/11, 05/14/12, 7/16/12 is not medically necessary.

Ondansetron ODT tab 8mg #30, DOS 5/25/11: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines TWC Pan Procedure Summary and Mosby's Drug Consult

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: 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. There is a single progress note (the primary treater's initial evaluation on 4/13/11), which states that the patient has neck pain with associated headaches. Medications dispensed at that visit include sumatriptan and Ondansetron, which implies that the patient has migraines and has migraine-associated nausea. However, headaches are not documented again, and sumatriptan is not dispensed again in the multiple progress notes going forward. There is no note documenting that the patient has nausea, including the notes from the internal medicine AME. If the patient has headaches and nausea, simply assuming they are due to his chronic cervical spine pain is inappropriate. No evaluation of headache or nausea is documented. His 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 or nausea, since it is not documented that the patient even has nausea, and since Ondansetron is not indicated for any form of nausea this patient is likely to have. Therefore, Ondansetron ODT tab 8mg #30, DOS 5/25/11 is not medically necessary.