

Case Number:	CM14-0147422		
Date Assigned:	09/15/2014	Date of Injury:	10/23/2012
Decision Date:	01/29/2015	UR Denial Date:	09/05/2014
Priority:	Standard	Application Received:	09/10/2014

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 43-year-old warehouse worker reported injuries to his right elbow and shoulder with a date of 10/23/12. The mechanism of injury is not described in the available records. Treatment to date has included medications, physical therapy and a right elbow arthroscopic surgery with lateral release performed 6/20/14. Current diagnoses include right elbow strain versus lateral epicondylitis, right shoulder sprain, and possible cervical radiculopathy. The available records contain multiple Primary Treating Physician's progress reports that make it apparent that the patient has been taking Anaprox, Fexmid, Ultram ER. and Protonix since at least 3/19/14. All of the notes document that the patient is taking medication, and some of them document that he finds the medications helpful. As far as I am able to ascertain medications are dispensed at every visit, although the plan sometimes notes that they were dispensed, sometimes notes that medications are continued without listing specific medications, and sometimes does not mention medications at all. The patient's functional status is not specifically addressed in any of the notes, and his work status does not change from 3/19/14 through 8/6/14. The work status is always modified with a restriction of limited gripping and grasping on the right, although it is noted that the patient is not working and has been terminated by his employer. Urine drug screens are performed on 4/30/14 and 8/6/14, with point of service testing sent to be confirmed quantitatively in an independent laboratory. There are no results from the independent laboratory in the records, and no comment on results appears in any of the notes. The utilization report of 9/5/14 makes it clear that requests for Anaprox, Fexmid, Ultram and Protonix were partially certified in UR on 5/15/14 and non-certified on 8/15/14 due to lack of documentation regarding functional improvement and of compliance with MTUS guidelines. The primary treater has continued to dispense the medications with retroactive requests for authorization, and has never provided the requested information. On 8/6/14 the primary treater dispensed Anaprox

DS #90. His rationale included that it was for pain and inflammation, and that the patient had failed first-line NSAIDs including ibuprofen, diclofenac and aspirin. He dispensed Protonix 20 mg #60 with the rationale that it was to be used as needed for GI protection and history of gastritis with medications. He dispensed Fexmid .5 mg #60 with the rationale that it was to be used as needed for muscle spasm and pain relief. He dispensed tramadol ER 150 mg #60 with the rationale that it was to be used as a long-acting, less addictive pain reliever in order to decrease the use of opiates. The provider documents an additional rationale that all of the medications allow the patient to perform activities of daily living including walking, using the bathroom and providing self-care. The provider quotes MTUS, ODG and other guidelines liberally. He appears to be under the impression that Fexmid is non-sedating and that tramadol is not an opioid. In addition he performed and retroactively requested a urine drug screen (UDS) on the same date, citing MTUS and ODG guidelines and also stating that the screen was not subject to UR as it is part of routine office practice. All 4 medications and the UDS were non-certified in UR on 9/5/14 based on non-compliance with MTUS Chronic Pain and ODG guidelines.

IMR ISSUES, DECISIONS AND RATIONALES

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

Anaprox-DS Naproxen Sodium 550mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical 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: Anaprox is brand-name naproxen, which is an NSAID. 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. 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 use of Anaprox. This patient has been taking Anaprox for at least 5 months, and probably for much longer. Since the patient is 43 and male, he may well have cardiac risk factors or even cardiac disease, but there is no documentation regarding the presence or absence of these conditions. No blood pressures are recorded in the records, which is concerning. Any patient who is taking an NSAID should be monitored for high blood pressure. There is no documentation of any functional improvement in response to naproxen use. The provider's statements that the patient

is better able to walk and use the bathroom as a result of his medications are ridiculous, since his injuries primarily involve one elbow and shoulder. Based on the MTUS citations above and on the clinical records provided for my review, Anaprox 550 #90 is not medically necessary. It is not medically necessary because there is no documentation of the patient's risk factors for NSAID use or of monitoring for side effects, because it is not recommended for long-term treatment, and because there is no documentation of functional improvement in response to its use.

Fexmid (Cyclobenzaprine) 7.5mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic, Pain, Muscle relaxant. 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: Fexmid is brand name, long-acting cyclobenzaprine, which is a sedating muscle relaxant. 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 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 documentation in this case does not support the use of Fexmid. Although the rationale given for its use is that the patient has muscle spasm, there is no muscle spasm documented on exam. In addition, the patient has been on Fexmid for at least 5 months, which would mean that any current muscle spasm he is experiencing would not be acute. The use for Fexmid clearly extends 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. There is no documentation of any functional improvement due to the use of Fexmid. The provider's statements that the patient is better able to walk and use the bathroom as a result of his medications are ridiculous, since his injuries primarily involve one elbow and shoulder. 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 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, Fexmid 7.5 mg #60 is not medically necessary in this case because there is no evidence to support its short or long-term use, because it increases the risk of seizure when

combined with tramadol, because there is no documentation of functional improvement as a result of taking it, and because its side effects may in fact interfere with this patient's recovery.

Ultram (Tramadol) 150mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines, Opioids.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain, Criteria for use of Opioids, Opioids for neuropathic pain, Opioid. 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: Ultram 150 mg is long-acting tramadol, which 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. 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. There is no documentation of evaluation of whether or not the patient's pain is nociceptive or 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. Tramadol is being prescribed in conjunction with Fexmid, which increases the patient's risk for seizure. Most importantly, tramadol was not discontinued when it became clear that it has not produced any functional improvement. Again, the provider's statements that the patient is better able to walk and use the bathroom as a result of his medications are ridiculous, since his injuries primarily involve one elbow and shoulder. Based on the MTUS criteria cited above and on the clinical findings provided for my review, Ultram 150 mg #60 is not medically necessary. It is not medically necessary because of its use with another medication that 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, and because of the failure to discontinue it when it became clear that it has not produced any functional recovery.

Protonix (Pantoprazole) 20mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical 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 UptoDate, an evidence-based online review service for clinicians, (www.uptodate.com) , Pantoprazole: drug information.

Decision rationale: Protonix is brand-name pantoprazole, which is a 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 pantoprazole 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. Several of these indications are off label in the US. 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 documentation in this case does not support the provision of Protonix to this patient. The provider has documented that it is to be used as needed for GI protection and history of gastritis with medications. There is no documentation of what symptoms the patient that led the provider to conclude that the patient had gastritis, nor of what medications caused the symptoms. There is no documentation of any diagnosis that is an indication for Protonix use. It appears possible or even likely that the patient has been taking Protonix for at least a year, which would put him at risk for the side effects listed above, many of which could be life threatening. According to the evidence-based citations above and to the clinical documentation provided for my review, Protonix 20 mg #60 is not medically necessary for this patient. It is not medically necessary because there is no documentation of any GI risk or other condition that would require its use, and because its use places the patient at unacceptable risk for serious adverse side effects.

Full drug screen: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Urine Drug Testing

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment , Opioids, Criteria for Use, Therapeutic Trial of Opioids; Opioid. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Section, Urine Drug Testing, criteria for use

Decision rationale: Per the MTUS guidelines cited above, an assessment of the likelihood for substance abuse should be made before a therapeutic trial of opioid use is begun. The section on ongoing management of opioid use recommends that regular assessment for aberrant drug taking behavior should be performed. Drug screens should be used in patients with issues of abuse, addiction or poor pain control. The section on steps to avoid misuse/addiction recommends frequent random urine toxicology screens. Per the ODG reference cited, clinicians should be clear on the indication for using a UDS prior to ordering one. Testing frequency should be determined by assessing the patient's risk for misuse, with low-risk patients to receive random testing no more that twice per year. Documentation of the reasoning for testing frequency, need for confirmatory testing, and of risk assessment is particularly important in stable patients with no evidence of risk factors or previous aberrant drug behavior. Standard drug classes should be included in the testing, including cocaine, amphetamines, opiates, oxycodone, methadone, marijuana, and benzodiazepines. Others may be tested as indicated. A complete list of all drugs the patient is taking, including OTC and herbal preparations must be included in the request accompanying the test, as well as documentation of the last time of use of specific drugs evaluated for. Random collection is preferred. Unexpected results (illicit drugs, scheduled drugs that were not prescribed, or negative results for a prescribed drug) should be verified with GCMS. The clinical findings in this case do not support the performance of a UDS. The provider in this case apparently believes that tramadol is not an opioid, so it is unclear why he feels drug testing is necessary. There is no documentation of any risk assessment for aberrant drug behavior, but the patient appears to be at low risk for it. There is no documentation of the reasoning for testing frequency. Drug screens performed at the time of office visits are by definition not random. The provider has not bothered to document the results of a previous drug screen, although he documents that he spent 15 minutes reviewing it on 6/11/14. Based on the guidelines cited above and the clinical information provided, a urine drug screen is not medically necessary. A urine drug screen is not medically necessary based on the lack of documentation of the patient's risk for aberrant drug behavior or of a rationale for the frequency of testing, because the screen performed was not random, and because of the lack of documentation of previous drug screen results.