

Case Number:	CM14-0028953		
Date Assigned:	06/16/2014	Date of Injury:	04/16/2012
Decision Date:	08/06/2014	UR Denial Date:	03/04/2014
Priority:	Standard	Application Received:	03/06/2014

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 Physical Medicine and Rehabilitation and is licensed to practice in Texas. 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:

The patient is a 52-year-old who was injured on April 15, 2012, Mechanism of injury is unknown. Prior treatment history has included the following medications: tramadol, Motrin, Ambien, ibuprofen, and Norco. The patient has received 6 physical therapy sessions which is helping very little. Diagnostic studies were not submitted for review. Progress note dated December 19, 2013 documented the patient's right shoulder pain is gradually improving. He continues to have weakness and difficulty with motion. Mid and low back pain is mostly across the back. There is tingling and numbness of the right foot. Right elbow pain increases with certain activities. Sometimes there is pain that radiates into the forearm. He has difficulty sleeping due to the pain. Without the Zolpidem he is only able to get 2 hours of sleep and with the Zolpidem is able to get 5-6 hours of sleep. The patient is taking ibuprofen, tramadol, Zolpidem, hydrocodone and omeprazole. Without the ibuprofen and pain medications his pain is usually at an 8/10 and with the medications about a 3-4/10. Objective findings on examination reveal diminished sensation of the 2nd, 3rd, 4th and 5th toes on the right. Right shoulder abduction is 80 degrees. Treatment Plan: Continue ibuprofen, omeprazole and Norco. Prescriptions filled for tramadol 50 mg #200, Zolpidem 10 mg #30. Progress report dated February 21, 2014 documented the patient is taking tramadol, Motrin and Ambien and he is taking these on a limited basis as his medications have been denied. The patient is attending physical therapy and has been to 6 sessions but it is helping very little. He has complaints of right shoulder pain, right elbow pain and numbness in the fingers as well as mid and low back pain. There has been some improvement. He indicates the pain comes and goes across the mid and low back. There is numbness on the right foot toes. Objective findings reveal right shoulder abduction is 100 degrees. Treatment Plan: Prescription for Tramasetron 100/250/2 mg #90, flurbitac 100/100 mg and midazolam. He is to continue Norco, which was previously prescribed

and continue physical therapy. Utilization report dated March 26, 2014 denied the requests for Tramasetron 100/250/2 mg #90, Flurbitac 100/100 mg and Midazolam. Tramadol is a synthetic opiate analgesic. The ODG does not recommend compounded meds as first-line treatment. There is no support to combine with tramadol. The request for Flurbitac 100/100 mg was not certified because nonsteroidal anti-inflammatories should be used at lowest dose for shortest amount of time. There is no support for medication combined with h2 blocker as opposed to these agents separately. Finally, the request for Midazolam/melatonin 10/3 mg #30 was not certified as benzodiazepines are not supported for chronic use and there was no documentation of sleep hygiene.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tramasetron 100/250/2 mg (Tramadol/Acetaminophen/Ondansetron), ninety count:

Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 93-94, 113.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Ondansetron (Zofran®); Opioids; Compound drugs.

Decision rationale: The Official Disability Guidelines do not recommend compound drugs as a first-line therapy for most patients, but recommended as an option after a trial of first-line FDA-approved drugs, if the compound drug uses FDA-approved ingredients that are recommended in ODG. The guidelines state Ondansetron is not recommended for nausea and vomiting secondary to chronic opioid use. Ondansetron is only recommended for specific and acute situations per FDA guidelines, which are not applicable in the case of this patient. In addition, the medical records do not provide a viable rationale for compounding these medications in a product, when all are available standard individually. In addition, according to the February 21, 2014 report, the patient is currently also taking Norco, which is another short-acting opioid, same class as Tramadol.

Flurbitac 100/100 mg (Flurbiprofen/Ranitidine), sixty count: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 69.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Flurbiprofen (Ansaid®) NSAIDs, specific drug list & adverse effects; Compound drugs.

Decision rationale: According to the Official Disability Guidelines, Flurbiprofen (Ansaid, generic available): 50, 100 mg. Dosing: Osteoarthritis and mild to moderate pain: 200-300mg per day at intervals of 2 to 4 divided doses. The maximum daily dose is 300 mg/day and the

maximum divided dose is 100 mg (for instance, 100 mg twice a day). The guidelines indicate PPIs (proton pump inhibitors), (not H₂ receptors), are recommended for patients at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA[acetylsalicylic acid]). The medical records do not reflect that this patient has any these risk factors. Furthermore, the Official Disability Guidelines do not recommend compound drugs as a first-line therapy for most patients, but recommended as an option after a trial of first-line FDA-approved drugs, if the compound drug uses FDA-approved ingredients that are recommended in ODG. However, this product does not meet the ODG criteria for compound medication. Finally, the medical records do not provide a rationale for compounding these medications in a product, when all are available standard individually. The request for Flurbitac 100/100 mg (Flubriprofen/Ranitidine), sixty count, is not medically necessary or appropriate.

Midazolam/Melatonin 10/3 mg, thirty count: 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 Official Disability Guidelines (ODG) Pain, Midazolam; Insomnia treatment; Compound drugs.

Decision rationale: The Official Disability Guidelines recommend pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. Suggestions for improved sleep hygiene: (a) Wake at the same time everyday; (b) Maintain a consistent bedtime; (c) Exercise regularly (not within two to four hours of bedtime); (d) Perform relaxing activities before bedtime; (e) Keep your bedroom quiet and cool; (f) Do not watch the clock; (g) Avoid caffeine and nicotine for at least six hours before bed; (h) Only drink in moderation; & (i) Avoid napping. The Official Disability Guidelines do not recommend compound drugs as a first-line therapy for most patients, but recommended as an option after a trial of first-line FDA-approved drugs, if the compound drug uses FDA-approved ingredients that are recommended in ODG. However, Midazolam is not recommended in ODG. This medication is in the class of medications, Benzodiazepines. Benzodiazepines are not recommended as first-line medication under the ODG. The guidelines states medications of this class are not recommended for long-term use because long-term efficacy is unproven and there is a risk of psychological and physical dependence or frank addiction. The medical records do not provide a rationale that justifies a compound containing a medication that is not recommended under the evidence based guidelines. The medical necessity of this request is not established. The request for Midazolam/Melatonin 10/3 mg, thirty count, is not medically necessary or appropriate.