

Case Number:	CM15-0005495		
Date Assigned:	02/23/2015	Date of Injury:	04/02/2003
Decision Date:	04/10/2015	UR Denial Date:	12/15/2014
Priority:	Standard	Application Received:	01/12/2015

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: Arizona, Michigan

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

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 injured worker is a 53-year-old male, who sustained an industrial injury on 4/2/03. He has reported injury to arms, wrists and ankle after bending over rolling a rock and standing up and twisting his ankle and falling on his arms and wrists. The diagnoses have included right lower extremity complex pain syndrome, right thoracic outlet syndrome, right carpal tunnel syndrome, and chronic pain syndrome. Treatment to date has included medications, spinal cord stimulator, psychiatry, surgery and functional restoration program. Currently, the injured worker complains of bilateral lower extremity continuous severe pain with leg weakness and difficult gait. There was bilateral knee pain continuous with popping, grinding and locking. There was right shoulder and neck pain continuous with restricted range of motion, headaches, right arm fatigue and numbness. The right wrist and forearm he complained of continuous sensitivity to light touch and weakness of right hand. The current medications were listed and the urine drug screen dated 12/3/14 was inconsistent with prescribed medications. He walks with a walker. The physical exam revealed right shoulder positive impingement sign. The thoracic roots test, brachial plexus tinel, Adson's test and costoclavicular abduction test were positive. There was right medial epicondyle tenderness and Cubital tunnel tinel and radial nerve compression tests were positive. The wrist had tenderness and positive tinel and median nerve compression tests. The cervical spine x-ray revealed disc space narrowing and the lumbar spine x-ray revealed disc collapse and degenerative change. The right knee x-ray was negative. On 12/15/14 Utilization Review modified a request for Urine Drug Testing (qty: 4), Elavil 25mg, and Flexeril 10mg. Regarding the Urine Drug Testing (qty: 4), it was modified to certification for a 10 panel random urine drug

screen for qualitative analysis (either through point of care testing or laboratory testing) with confirmatory laboratory testing only performed on inconsistent results times 1 is recommended. Regarding Elavil 25mg it was modified to Elavil 25mg #60, because antidepressants for chronic pain are recommended as first line option for neuropathic pain and the injured worker had complaints of pain and clinical deficits on exam. Regarding the Flexeril 10mg, this was modified to Flexeril 10mg #20 for initiation of downward titration and complete discontinuation of this medication, as longer than 2-3 weeks use is not supported. The (MTUS) Medical Treatment Utilization Schedule and Official Disability Guidelines (ODG) were cited. On 12/15/14 Utilization Review non-certified a request for Carafate 1g, Protonix 40mg, Trazodone 100mg, Lunesta 3mg, Lexapro 20mg, and Klonopin 2mg, noting that regarding the Carafate 1g, the documentation does not provide evidence of gastrointestinal complaints, Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) use, or clinical findings of gastrointestinal upset. Therefore, medical necessity was not established. Regarding the Protonix 40mg, the documentation does not provide evidence of gastrointestinal complaints, Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) use, or clinical findings of gastrointestinal upset. Therefore, medical necessity was not established. Regarding the Trazodone 100mg and Lexapro 20mg, there was no specific documentation of efficacy provided and time allotted for weaning. Regarding the Lunesta 3mg, there was no evidence of objective functional improvement supporting the subjective improvement and no documented sleep issues. Regarding the Klonopin 2mg, there was no documentation of subjective functional improvement with prior use and opportunity for weaning has been provided. The (MTUS) Medical Treatment Utilization Schedule and Official Disability Guidelines (ODG) were cited.

IMR ISSUES, DECISIONS AND RATIONALES

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

Carafate 1g: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MD Consult Drug Monograph, Gastrointestinal Agents.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, NSAIDs, GI symptoms and cardiovascular risk Page(s): 67-68, 68-69. Decision based on Non-MTUS Citation Physicians Drug Reference (PDR).Carafate (Sucralfate).

Decision rationale: Per the MTUS, Clinicians should weigh the indications for NSAIDs against both GI and cardiovascular risk factors according to specific criteria listed in the MTUS and a selection should be made based on these criteria which include (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). Per the PDR, Carafate is a gastrointestinal agent that forms an ulcer-adherent complex that covers the ulcer site and protects it against further attack by acid, pepsin, and bile salts. It is recommended for short-term treatment (up to 8 weeks) of active duodenal ulcer (DU). Maintenance therapy for DU patients at reduced dosage after healing of acute ulcers. A review of the injured workers medical records that are available to me show that he was reported to have gastritis on endoscopy but

there was no report of duodenal ulcers. There is also no documentation of how this medication is being used in this patient and if it now maintenance therapy, it would appear that this medication is not medically necessary in this patient.

Protonix 40mg: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG-TWC Pain Procedure Summary, Proton Pump Inhibitors (PPIs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk Page(s): 68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (chronic).Proton Pump Inhibitors (PPIs).

Decision rationale: Per the MTUS, Clinicians should weigh the indications for NSAIDs against both GI and cardiovascular risk factors according to specific criteria listed in the MTUS and a selection should be made based on these criteria 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). Per the ODG, PPI's are Recommended for patients at risk for gastrointestinal events. Prilosec (omeprazole), Prevacid (lansoprazole) and Nexium (esomeprazole magnesium) are PPIs. Healing doses of PPIs are more effective than all other therapies, although there is an increase in overall adverse effects compared to placebo. Nexium and Prilosec are very similar molecules. (Donnellan, 2010) In this RCT omeprazole provided a statistically significantly greater acid control than lansoprazole. (Miner, 2010) In general, the use of a PPI should be limited to the recognized indications and used at the lowest dose for the shortest possible amount of time. PPIs are highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. Studies suggest, however, that nearly half of all PPI prescriptions are used for unapproved indications or no indications at all. Many prescribers believe that this class of drugs is innocuous, but much information is available to demonstrate otherwise. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses, including esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Prilosec), pantoprazole (Protonix), dexlansoprazole (Dexilant), and rabeprazole (Aciphex). (Shi, 2008) A trial of omeprazole or lansoprazole had been recommended before prescription Nexium therapy (before it went OTC). The other PPIs, Protonix, Dexilant, and Aciphex, should be second-line. According to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective. (AHRQ, 2011). A review of the injured workers medical records that are available to me do not show a trial of other first line PPI's and therefore based on the guidelines the request for Protonix 40mg is not medically necessary.

Elavil 25mg: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for Chronic Pain.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants, Amitriptyline Page(s): 13-16. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG Pain Chronic)Antidepressants for chronic pain.

Decision rationale: Per the MTUS, Antidepressants are recommended as a first line option in the treatment of neuropathic pain. Amitriptyline is a tricyclic antidepressant. Tricyclics are generally considered a first-line agent unless they are ineffective, poorly tolerated or contraindicated. A review of the injured workers medical records show that he is on Elavil 25mg at bedtime Per the ODG, Amitriptyline is also recommended in the treatment of neuropathic pain: The starting dose may be as low as 10-25 mg at night, with increases of 10-25 mg once or twice a week up to 100 mg/day. (ICSI, 2007) The lowest effective dose should be used (Dworkin, 2007). Fibromyalgia: One review recommended the following dosing regimen: Start with low doses, such as 5-10 mg 1-3 hours before bedtime. Dose may be increased by 5 mg at two-week intervals; final dose is dependent upon efficacy and patient tolerability to side effects. Doses that have been studied range from 25 to 50 mg at bedtime. (Goldenberg, 2007). A review of the injured workers medical records show that he does suffer from neuropathic pain and the use of Elavil in this injured worker is medically necessary and appropriate.

Flexeril 10mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain). Decision based on Non-MTUS Citation ODG-TWC Pain Procedure Summary, Non-Sedating Muscle Relaxants.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril) Page(s): 41-42.

Decision rationale: Per the MTUS, Antidepressants are recommended as a first line option in the treatment of neuropathic pain. Amitriptyline is a tricyclic antidepressant. Tricyclics are generally considered a first-line agent unless they are ineffective, poorly tolerated or contraindicated. A review of the injured workers medical records show that he is on Elavil 25mg at bedtime Per the ODG, Amitriptyline is also recommended in the treatment of neuropathic pain: The starting dose may be as low as 10-25 mg at night, with increases of 10-25 mg once or twice a week up to 100 mg/day. (ICSI, 2007) The lowest effective dose should be used (Dworkin, 2007). Fibromyalgia: One review recommended the following dosing regimen: Start with low doses, such as 5-10 mg 1-3 hours before bedtime. Dose may be increased by 5 mg at two-week intervals; final dose is dependent upon efficacy and patient tolerability to side effects. Doses that have been studied range from 25 to 50 mg at bedtime. (Goldenberg, 2007). A review of the injured workers medical records show that he does suffer from neuropathic pain and the use of Elavil in this injured worker is medically necessary and appropriate.

Trazodone 100mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for Chronic Pain.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness & Stress Trazodone (Desyrel).

Decision rationale: The MTUS /ACOEM did not specifically address the use of trazodone therefore other guidelines were consulted. Per the ODG, trazodone is recommended as an option for insomnia, only for patients with potentially coexisting mild psychiatric symptoms such as depression or anxiety. Trazodone was approved in 1982 for the treatment of depression. It is unrelated to tricyclic or tetracyclic antidepressants and has some action as an anxiolytic. Off-label uses include alcoholism, anxiety, insomnia, and panic disorder. Although approved to treat depression, the American Psychiatric Association notes that it is not typically used for major depressive disorder. Over the period 1987 through 1996, prescribing trazodone for depression decreased throughout the decade, while off-label use of the drug for insomnia increased steadily until it was the most frequently prescribed insomnia agent. A review of the injured workers medical records show that he is on multiple antidepressants, he takes trazodone 100mg at bedtime and it is not clear if trazodone is being used to treat his depression or insomnia and there are no subjective or objective documentation of how this medication is to his benefit. Therefore the request for Trazodone 100mg is not medically necessary.

Lunesta 3mg: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Med Lett Drugs Ter. 2005 Feb 28; 47(1203):17-9, Eszopiclone (Lunesta).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness & Stress. Eszopiclone (Lunesta).

Decision rationale: The MTUS/ACOEM did not specifically address the use of Lunesta in the injured worker, therefore other guidelines were consulted. Per the ODG, lunesta is not recommended for long-term use, but recommended for short-term use. Recommend limiting use of hypnotics to three weeks maximum in the first two months of injury only, and discourage use in the chronic phase. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit-forming, and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term. In this study, eszopiclone (Lunesta) had a Hazard ratio for death of 30.62 (C.I., 12.90 to 72.72), compared to zolpidem at 4.82 (4.06 to 5.74). In general, receiving hypnotic prescriptions was associated with greater than a threefold increased hazard of death even when prescribed less than 18 pills/year. (Kripke, 2012) The FDA has lowered the recommended starting dose of eszopiclone (Lunesta) from 2 mg to 1 mg for both men and women. Previously recommended doses can cause impairment to driving skills, memory, and coordination as long as 11 hours after the drug is taken. Despite these long-lasting effects, patients were often unaware they were impaired. A review of the injured workers medical records show that he has had long-

term use of Lunesta which is not consistent with the guidelines, therefore the request for lunesta 3 mg is not medically necessary.

Lexapro 20mg: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for Chronic Pain.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants Page(s): 14-16. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (chronic) Antidepressants for Chronic pain and Other Medical Treatment Guidelines Physicians Desk reference (PDR)Lexapro.

Decision rationale: Per the MTUS, Antidepressants are recommended as a first line option in the treatment of neuropathic pain, however the use of lexapro is not specifically addressed. Per the ODG, Escitalopram (Lexapro): Non-FDA approved for the treatment of chronic pain. The PDR describes Lexapro as being used in the acute and maintenance treatment of Major Depressive Disorder (MDD) in adults and adolescents 12-17 yrs of age. Acute treatment of generalized anxiety disorder (GAD) in adults. A review of the injured workers medical records show that he is using lexapro for the treatment of his depression, with subjective and objective evidence of a mood disorder, therefore based on the guidelines and the injured workers clinical presentation the request for Lexapro 20mg is medically necessary.

Klonopin 2mg: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24.

Decision rationale: Per the MTUS, benzodiazepines are not recommended for long-term use because long-term efficacy is unproven and there is risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develop rapidly. Tolerance to anxiolytic effects occurs within months and long term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Therefore based on the guidelines the request for Klonopin 2mg is not medically necessary.

Urine Drug Testing (qty: 4): Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Drug Testing. Decision based on Non-MTUS Citation ODG-TWC Pain Procedure Summary, Urine Drug Testing (UDT).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Drug Testing Page(s): 43. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic).Urine Drug Testing.

Decision rationale: Per the MTUS, Drug testing is recommended as an option, using a urine drug screen to assess for the use or the presence of illegal drugs, however the MTUS did not address frequency of drug testing therefore other guidelines were consulted. Per the ODG Urine drug testing is recommended as a tool to monitor compliance with prescribed substances, identify use of undisclosed substances, and uncover diversion of prescribed substances. The test should be used in conjunction with other clinical information when decisions are to be made to continue, adjust or discontinue treatment. This information includes clinical observation, results of addiction screening, pill counts, and prescription drug monitoring reports. The prescribing clinician should also pay close attention to information provided by family members, other providers and pharmacy personnel. The frequency of urine drug testing may be dictated by state and local laws. Frequency of urine drug testing should be based on documented evidence of risk stratification including use of a testing instrument. See Opioids, tools for risk stratification & monitoring. Patients at "low risk" of addiction/aberrant behavior should be tested within six months of initiation of therapy and on a yearly basis thereafter. There is no reason to perform confirmatory testing unless the test is inappropriate or there are unexpected results. If required, confirmatory testing should be for the questioned drugs only. Patients at "moderate risk" for addiction/aberrant behavior are recommended for point-of-contact screening 2 to 3 times a year with confirmatory testing for inappropriate or unexplained results. This includes patients undergoing prescribed opioid changes without success, patients with a stable addiction disorder, those patients in unstable and/or dysfunction social situations, and for those patients with comorbid psychiatric pathology. Patients at "high risk" of adverse outcomes may require testing as often as once per month. This category generally includes individuals with active substance abuse disorders. A review of the injured workers medical records show that he has been classified as high risk which would require frequent testing and therefore the request for Urine Drug Testing (qty: 4) is medically necessary.