

Case Number:	CM15-0006740		
Date Assigned:	01/23/2015	Date of Injury:	03/29/1999
Decision Date:	04/03/2015	UR Denial Date:	12/19/2014
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: Pennsylvania

Certification(s)/Specialty: Internal 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:

This 60 year old female sustained an industrial injury on 3/29/99 with subsequent ongoing bilateral knee pain. Current diagnoses included internal derangement of the knee bilaterally status post total joint replacement and chronic pain syndrome. The physician noted that the injured worker also had some element of depression for which she had previously been treated by a psychiatrist. Medical history also includes hypertension. No recent radiologic reports were noted. Prior treatment has included bilateral total knee arthroplasty, knee brace, hot and cold modalities, transcutaneous electrical nerve stimulation (TENS), and medications. On 6/12/14, the physician documented that the injured worker was able to do light cooking and cleaning but that her family members needed to help her with chores. Some sleep issue was noted related to chronic pain. Tylenol No. 3 was noted to be helpful in decreasing pain level, and flexeril was noted to be effective for managing symptoms of spasms. Blood pressure was elevated. On 8/26/14, the physician documented that the injured worker goes to the gym and uses the treadmill, does arm and leg exercises, and does pool activities. Blood pressure was elevated at that visit. It was documented that blood testing for liver and kidney function are being done by her family physician on a once-a-year basis. It was noted that she had difficulty with naproxen and that anti-inflammatory medication might be helpful, and nalfon was prescribed. Trazodone was prescribed and the documentation suggests that this was for psychiatric reasons. In an office visit dated 10/3/14, the injured worker complained of intermittent bilateral knee pain with spasms to the left knee and numbness and tingling to the left leg. The injured worker was not working and receiving retirement and social security disability. Examination showed elevated

blood pressure, right lower extremity extension to 180 degrees and flexion to 90 degrees, and left lower extremity extension to 180 degrees and flexion to 80 degrees. The treatment plan included continuing current medication regimen, doing intermittent sitting, standing and walking as tolerated, continuing home exercises and using ice and heat as needed. It was noted that trazodone was prescribed for depression and insomnia. At a visit on 12/4/14, medications included Tylenol No. 3, flexeril, nalfon, trazodone, and protonix. It was documented that the injured worker has not looked for work, and that work status was suggested to be sedentary type of work. On 12/19/14, Utilization Review issued a modified certification for a request for Flexeril 7.5mg #60 to Flexeril 7.5mg #30 and non-certified requests for Protonix 20 mg for D.O.S 01/09/15, QTY: 60.00, Nalfon 400 mg for D.O.S. 01/09/15, QTY: 60.00, Tylenol #3 for D.O.S. 01/09/15, QTY: 30.00 and Trazodone 50 mg for D.O.S 01/09/15, QTY: 60.00 citing CA MTUS Chronic Pain Medical Treatment Guidelines and the ODG.

IMR ISSUES, DECISIONS AND RATIONALES

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

Protonix 20 mg for D.O.S 01/09/15, QTY: 60.00: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI symptoms, and Cardiovascular Risk Page(s): 68.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI symptoms, and Cardiovascular Risk Page(s): 68.

Decision rationale: The MTUS states that co-therapy with a non-steroidal anti-inflammatory medication (NSAID) and a proton pump inhibitor (PPI) is not indicated in patients other than those at intermediate or high risk for gastrointestinal events (including age > 65 years, history of peptic ulcer, gastrointestinal (GI) bleeding or perforation, concurrent use of aspirin, corticosteroids and/or an anticoagulant, or high dose/multiple NSAIDS such as NSAID plus low dose aspirin). Long term proton pump inhibitor (PPI) use (> 1 year) has been shown to increase the risk of hip fracture. This injured worker has been prescribed an NSAID, but none of the risk factors noted above were documented. No GI signs or symptoms were discussed, and no abdominal examination was documented. Due to lack of indication, the request for protonix is not medically necessary.

Nalfon 400 mg for D.O.S. 01/09/15, QTY: 60.00: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 67-73.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 67-73.

Decision rationale: Per the MTUS, non-steroidal anti-inflammatory drugs (NSAIDs) are recommended as a second line treatment after acetaminophen for treatment of acute exacerbations of chronic back pain. The MTUS does not specifically reference the use of

NSAIDs for long term treatment of chronic pain in other specific body parts. NSAIDs are noted to have adverse effects including gastrointestinal side effects and increased cardiovascular risk; besides these well-documented side effects of NSAIDs, NSAIDs have been shown to possibly delay and hamper healing in all the soft tissues including muscles, ligaments, tendons, and cartilage. NSAIDs can increase blood pressure and may cause fluid retention, edema, and congestive heart failure; all NSAIDs are relatively contraindicated in patients with renal insufficiency, congestive heart failure, or volume excess. They are recommended at the lowest dose for the shortest possible period in patients with moderate to severe pain. Systemic toxicity is possible with NSAIDs. The FDA and MTUS recommend monitoring of blood tests and blood pressure. There is no evidence that the prescribing physician is adequately monitoring for toxicity as recommended by the FDA and MTUS. The injured worker has a history of hypertension and blood pressure as measured at office visits was consistently elevated. The physician documented that the injured worker's family physician ordered yearly blood tests, but the results of testing were not provided or discussed. Due to the potential for toxicity, the request for nalfon is not medically necessary.

Tylenol #3 for D.O.S. 01/09/15, QTY: 30.00: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids - Pain Treatment Agreement Page(s): 89.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines opioids Page(s): p. 74-96.

Decision rationale: There is no evidence that the treating physician is prescribing opioids according to the MTUS, which recommends prescribing according to function, with specific functional goals, return to work, random drug testing, and opioid contract. There should be a prior failure of non-opioid therapy. None of these aspects of prescribing are in evidence. Per the MTUS, opioids are minimally indicated, if at all, for chronic non-specific pain, osteoarthritis, "mechanical and compressive etiologies," and chronic back pain. The injured worker has been prescribed Tylenol No. 3 for at least 6 months. There is no evidence of significant pain relief or increased function from the opioids used to date. The injured worker is not working, and there was documentation of limitations in activities of daily living which were not noted to be improved. No reduction in other medication or decrease in frequency of office visits was documented. The prescribing physician does not specifically address function with respect to prescribing opioids, and does not address the other recommendations in the MTUS. The MTUS states that a therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. There is no evidence that the treating physician has utilized a treatment plan NOT using opioids, and that the patient "has failed a trial of non-opioid analgesics." Ongoing management should reflect four domains of monitoring, including analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors. The documentation does not reflect improvement in pain. Change in activities of daily living, discussion of adverse side effects, and screening for aberrant drug-taking behaviors were not documented. The MTUS recommends urine drug screens for patients with poor pain control and to help manage patients at risk of abuse. There is no record of a urine drug screen program performed according to quality criteria in the MTUS and other guidelines. As currently prescribed, Tylenol No. 3 does

not meet the criteria for long term opioids as elaborated in the MTUS and is therefore not medically necessary.

Trazodone 50 mg for D.O.S 01/09/15, QTY: 60.00: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) - Work Loss Data Institute, ODG Treatment in Workers Compensation, 7th Edition, Treatment Index; Appendix A, ODG Workers Compensation Drug Formulary (updated 4/30/12) Antidepressants.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 15 Stress Related Conditions Page(s): 401-402, Chronic Pain Treatment Guidelines antidepressants Page(s): p. 14-16. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) chronic pain chapter: insomnia treatment.

Decision rationale: The documentation from the physician notes that trazodone was prescribed for depression and insomnia. Trazodone is a tetracyclic antidepressant used to treat depression and anxiety disorders. Per the MTUS, antidepressants are recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain, unless they are poorly tolerated, contraindicated, or ineffective. Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep quality and duration, and psychological assessment. Sedating antidepressants such as amitriptyline, trazodone, and mirtazapine have been used to treat insomnia; there is less evidence to support their use for insomnia but they may be an option in patients with coexisting depression. The ACOEM states that brief courses of antidepressants may be helpful to alleviate symptoms of depression, but that given the complexity and increasing effectiveness of available agents, referral for medication evaluation may be worthwhile. The documentation indicates that the injured worker had previous treatment by a psychiatrist, but that she is currently not under the care of a psychiatrist. The discussion by the treating physician regarding depression was brief. Trazodone is one of the most commonly prescribed agents for insomnia. Side effects of this drug include nausea, dry mouth, constipation, drowsiness, and headache. Improvements in sleep onset may be offset by negative next-day effects such as ease of awakening. Tolerance may develop and rebound insomnia has been found after discontinuation. No physician reports describe the specific criteria for a sleep disorder. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. There is no evidence of that in this case. For the treatment of insomnia, pharmacologic agents should only be used after careful evaluation of potential causes of sleep disturbance. Specific components of insomnia should be addressed. There was no documentation of evaluation of sleep disturbance in the injured worker, and components of insomnia were not addressed. The treating physician has not addressed major issues affecting sleep in this patient, including the use of other psychoactive agents like opioids, which significantly impair sleep architecture, and depression. Due to insufficient evaluation for depression and lack of evaluation of sleep disturbance, the request for trazodone is not medically necessary.

Flexeril 7.5 mg for D.O.S 01/09/15, QTY: 60.00: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines cyclobenzaprine p. 41-42, muscle relaxants p. 63-66.

Decision rationale: The MTUS for chronic pain does not recommend muscle relaxants for chronic pain. Non-sedating muscle relaxants are an option for short-term exacerbations of chronic low back pain. The muscle relaxant prescribed in this case is sedating. The injured worker has chronic pain with no evidence of prescribing for flare-ups. The quantity prescribed implies long term use, not for a short period of use for acute pain. The injured worker has been prescribed flexeril for at least 6 months. No reports show any specific and significant improvement in pain or function as a result of prescribing muscle relaxants. Per the MTUS chronic pain medical treatment guidelines, cyclobenzaprine (Flexeril, fexmid) is a skeletal muscle relaxant and a central nervous system depressant. It is recommended as an option for a short course of therapy, with greatest effect in the first four days of treatment. Guidelines state that treatment should be brief. The addition of cyclobenzaprine to other agents is not recommended. Limited, mixed evidence does not allow for a recommendation for chronic use. Due to duration of treatment in excess of the guidelines and lack of functional improvement as a result of its use, the request for flexeril is not medically necessary.

Retro Flexeril 7.5 mg dispensed QTY: 60.00: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines cyclobenzaprine p. 41-42, muscle relaxants p. 63-66.

Decision rationale: The MTUS for chronic pain does not recommend muscle relaxants for chronic pain. Non-sedating muscle relaxants are an option for short-term exacerbations of chronic low back pain. The muscle relaxant prescribed in this case is sedating. The injured worker has chronic pain with no evidence of prescribing for flare-ups. The quantity prescribed implies long term use, not for a short period of use for acute pain. The injured worker has been prescribed flexeril for at least 6 months. No reports show any specific and significant improvement in pain or function as a result of prescribing muscle relaxants. Per the MTUS chronic pain medical treatment guidelines, cyclobenzaprine (Flexeril, fexmid) is a skeletal muscle relaxant and a central nervous system depressant. It is recommended as an option for a short course of therapy, with greatest effect in the first four days of treatment. Guidelines state that treatment should be brief. The addition of cyclobenzaprine to other agents is not recommended. Limited, mixed evidence does not allow for a recommendation for chronic use. Due to duration of treatment in excess of the guidelines and lack of functional improvement as a result of its use, the request for flexeril is not medically necessary.