MAXIMUS Federal Services

Case Number:	CM14-0181327		
Date Assigned:	11/06/2014	Date of Injury:	04/18/2006
Decision Date:	12/31/2014	UR Denial Date:	10/15/2014
Priority:	Standard	Application Received:	10/31/2014

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 New York. 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 788 page PDF was carefully reviewed to ensure all relevant information had been examined. The injured worker had a reported day of injury of 18Apr06. He is reported to have slipped on water while taking product out of cooler landing on his R knee. He reported pain in the low back and R knee. After failed conservative management he underwent surgery 23Sep06 for a posterior approach fusion. Pain persisted postop. A pseudo-arthrosis was diagnosed and a second fusion accomplished this time with an anterior approach in Oct07. The member was incarcerated 23Jan09 for DUI Alcohol/Drugs with priors and sentenced to 16 months. Cleared for full work duty 5Mar09, using Motrin for pain management. 6Jul09 work limitations were placed for no heavy lifting over 20lbs and sitting or standing over an hour. He was released on early parole 10Sep09. 2Aug09 a psychological evaluation revealed the following: Alcohol Dependent (with DT's), history dating to pre-teen years. History of adult antisocial behavior related to substance abuse/medical issues. A note 8Sep09 just prior to parole indicated the member s chronic LBP with radiculopathy was controlled with the use of MS Contin, Tylenol #3 and Neurontin. Surgical consultation in Sep felt the hardware may be contributing to his symptoms and they were removed in Sep09. He remained symptomatic after the surgery. 9Apr10 he was complaining of constant LBP, 8/10 with frequent pain and numbness in the R leg controlled with Duragesic patch. A final surgery was accomplished 20Sep12 for interbody and bilateral posterolateral fusion with bilateral laminectomy and foraminotomy at L3-4 and L4-5. The final surgery was accomplished to alleviate foraminal stenosis reported on an MRI not available to me. He continued to complain of pain in the low back radiating into the RLE. On examination there was marked reduction in lumbar ROM. Positive SLR was noted as was decreased sensation in the R L4-5 and S1 dermatomes. The member noted weakness in the R leg and apparently fell getting out his hospital bed at home15May13 resulting in a brief hospitalization for

incapacitating pain for 2 days. CT at that time showed post-surgical changes but no evidence for acute problems and noted that foramina appeared to be widely open. An MRI 16May13 found only post-surgical change with no report of nerve root compression. An EMG 19Aug14 indicated the presence of a bilateral radiculopathy at L5 and S1. PTP consultation 19Aug14 indicated the patient was experiencing increasing weakness in the bilateral lower extremities with a R foot drop. Sensation for light touch and pinprick werer decreased in the back of the R and back and lateral border of the L calf. Both knee and ankle DTR's were absent bilaterally. Markedly decreased lumbar ROM was noted and the inability to heel or toe walk. Using a cane and occasionally to get around, needing assistance below the waste for dressing and hygiene requiring use of home health care. Depression increased to 8/10. On UR urine drug screens on 3Dec13 and 27May14 showed evidence for none of the prescribed medications. At this visit ongoing routine medications were reported to be Oxycontin 40mg Q8h 90, Ambien 10 1hs 30, Xanax 2mg bid 60, Toradol 10mg q12h prn 10, Norco 10/325 1-2 q4-6h 240 and Fluoxetine 1 bid 60. Added were Mirtazepine 15mg 2 qhs 60 for insomnia/chronic pain/depression and Gabapentin 600mg 1 tid 90 for neuropathic pain. Reported drug screens in addition to the two previously discussed include the following dates and missing evidence for use of prescribed medications: 28Mar14 - Ambien, Xanax, Tramadol and Dilaudid, 17Jun14 Ambien, Xanax and Tramadol, 19Aug14 Ambien, Xanax, Oxycontin and Prozac (Venlafexine - Effexor found instead). In dispute is the Non-Certification for the following medications. Oxycontin 40mg 90, Ambien 10mg 30, Xanax 2mg 60, Norco 10/325mg 240, Fluoxetine 20mg 60, Mirtazapine 15mg 60 and Aquatic Therapy 2 X 3.

IMR ISSUES, DECISIONS AND RATIONALES

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

1 Prescription for oxycontin 40mg #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Medical Treatment Guidelines Page(s): 11, 79-81, 86, 87, 93, 95.

Decision rationale: A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Opioids, for long-term use, cannot be supported as there is a lack of evidence to allow for a treatment recommendation. A meta-analysis found that opioids were more effective than placebo for reducing pain intensity but the benefit for physical function was small and was considered questionable for clinical relevance. Opioids can be recommended on a trial basis for short-term use after there has been evidence of failure of first-line medication options such as acetaminophen or NSAIDs when there is evidence of moderate to severe pain. If chronic use is entertained then before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals. Baseline pain and functional assessments should be made. Function should include social, physical, psychological, daily and work activities. Continuation of the use of opioids would be best assessed on the basis of a return to work with evidence for improved functioning and reduced pain. The primary risk with continued use is that 36 to 56% of users have a lifetime risk for substance use disorders.

Additionally there is the risk of diversion, tolerance and hyperalgesia resulting in gradual increases in medication dosing and evidence for decreasing benefits. The recommended maximal daily dosing for a morphine equivalent dose (MED) is not to exceed 120 mg per day, and for patients taking more than one opioid, the morphine equivalent dose of the different opioids must be added together to determine the cumulative dose. In this case the member is already receiving 180 MED mgs per day with Norco adding 40 mg more. This member was found to have had a stable condition with no documented evidence for a sustained reduction in pain or improvement in practical function related to the use of opioids over an extended period of time despite consuming in excess of the recommended maximum daily morphine equivalent dose. Of note several of the urine drug screens across time have shown an absence of the selected narcotic. The member in the past was found to have a history of alcohol dependence and substance abuse. In the face of evidence for limited utility for improved function, complaints of worsening symptoms and the ongoing risk for rebound pain dependence or diversion, continued use of opioids cannot be supported. Therefore, 1 Prescription for OxyContin 40mg #90 is not medically necessary.

1 Prescription for ambien 10mg #30: Upheld

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

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: FDA directed manufacturers medication insert

Decision rationale: Ambien is not covered explicitly in the MTUS. Per FDA recommendations the medication is not intended for long term use. It has been associated with significant side effects to include depression exacerbation, suicidal ideation, aggressive behavior, complex sleep-related behavior (sleep eating, sleep driving), hallucinations and amnesia. In a patient actively being treated for depression this and this class of medications are not agents that one would want to continue long term. Of additional interest multiple urine drug screens have found the prescribed medication absent from the screen suggesting the possibility of diversion of this product. For these reasons use of this agent and not other more suitable alternatives (Trazadone) cannot be supported. Therefore, 1 Prescription for Ambien 10mg #30 is not medically necessary.

1 Prescription for xanax 2mg #60: Upheld

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

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: FDA directed manufacturers medication insert

Decision rationale: It is unclear from the provided documentation if Xanax was selected to help with the member's anxiety symptoms or muscle spasms. While Diazepam has an FDA approved

indication for use in muscle spasm it is not necessarily a class effect and Alprazolam does not. It is generally not recommended for long term use. Efficacy is unproven and development of dependence is a significant risk. Any potential muscle relaxant effect will generally be lost within a few weeks as tolerance develops risking increasing the dose or frequency and risking unwanted side effects. Because of the relatively short duration of action and the potential for rebound anxiety the class of agents has been superseded by more effective agents such as the SSRI's Paxil and Lexapro. Side effects can include seizures, suicidality, paradoxical CNS stimulation and hypotension. Of note multiple urinary drug screens over an extended period of time showed an absence in testing for this member suggesting the possibility of diversion. Use of Xanax in this situation cannot be supported. 1 Prescription for Xanax 2mg #60 is not medically necessary.

1 Prescription for norco 10/325mg #240: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medical Treatment Guidelines Page(s): 11, 79-81, 86, 87, 93, 95.

Decision rationale: A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Opioids, for long-term use, cannot be supported as there is a lack of evidence to allow for a treatment recommendation. A meta-analysis found that opioids were more effective than placebo for reducing pain intensity but the benefit for physical function was small and was considered questionable for clinical relevance. Opioids can be recommended on a trial basis for short-term use after there has been evidence of failure of first-line medication options such as acetaminophen or NSAIDs when there is evidence of moderate to severe pain. If chronic use is entertained then before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals. Baseline pain and functional assessments should be made. Function should include social, physical, psychological, daily and work activities. Continuation of the use of opioids would be best assessed on the basis of a return to work with evidence for improved functioning and reduced pain. The primary risk with continued use is that 36 to 56% of users have a lifetime risk for substance use disorders. Additionally there is the risk of diversion, tolerance and hyperalgesia resulting in gradual increases in medication dosing and evidence for decreasing benefits. The recommended maximal daily dosing for a morphine equivalent dose (MED) is not to exceed 120 mg per day, and for patients taking more than one opioid, the morphine equivalent dose of the different opioids must be added together to determine the cumulative dose. In this case the member is already receiving 180 MED mgs per day with Norco adding 40 mg more. This member was found to have had a stable condition with no documented evidence for a sustained reduction in pain or improvement in practical function related to the use of opioids over an extended period of time despite consuming in excess of the recommended maximum daily morphine equivalent dose. The member in the past was found to have a history of alcohol dependence and substance abuse. In the face of evidence for limited utility for improved function, complaints of worsening symptoms and the ongoing risk for rebound pain dependence or diversion, continued use of opioids cannot be supported. Therefore, 1 Prescription for Norco 10/325mg #240 is not medically necessary.

1 Prescription for fluoxetine 20mg #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official DisabilityGuidelines

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: FDA directed manufacturers medication insert

Decision rationale: The MTUS does not directly address Fluozetine (Prozac). It is one of the earlier classes of SSRI's. As such the early medications tend to have a less focused effect on the target receptor and often more potential for side effects. It has been associated with suicidality, mania, serotonin syndrome, SIADH, seizures and hypoglycemia. With a patient with an anxiety disorder it would not be a first option in treating depression. Despite reportedly being on the medication the members reported symptoms of depression had gotten worse and therefore appear to have been ineffective. It was noted as well on multiple urine drug screens that this product was absent from the analysis suggesting the member was either not taking the medication or potentially diverting it. Therefore, 1 Prescription for fluoxetine 20mg #60 is not medically necessary.

1 Prescription for mirtazapine 15mg #60: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medical Treatment Guidelines Part 2 Page(s): 13-16, 16-20, 60. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Comparative Effectiveness of Second-Generation Antidepressants for Accompanying Anxiety, Insomnia and Pain in Depressed Patients: Systematic Review, Thaler KJ et al, Depression and Anxiety 29:495-505 (2012) and Mirtazapine Decreases the Pain Feeling in Healthy Participants, Arnold P, Clin J Pain 24,2:116-119 (2008)

Decision rationale: The RFA characterized the medication for use in the treatment of insomnia, chronic pain and depression .The injured worker suffers from depression in addition to chronic Low Back pain and Myofascial Pain Syndrome. It is however a member of a group of Second Generation Antidepressants (SGA) that includes Bupropion, Mirtazapine, Nefazodone and Trazodone. The Mirtazapine (Remeron) is felt to act on adrenergic inhibitory auto-receptors to increase noradrenergic and serotonergic activity. It is classified as a Tri-Cyclic Antidepressant (TCA). It has been shown to favorably influence descending pain inhibitory systems as well as positively interacting with opiate pathways. It has been shown to be well tolerated with fewer side effects that first generation Tri-Cyclic Antidepressants. Antidepressants are considered first line options for neuropathic pain and possibly for non-neuropathic pain. The TCA's are recommended over selective serotonin reuptake inhibitors (SSRI's). Older generation TCA's were however associated with significant and intolerable side effects not found to the same

degree with Mirtazapine. As a member of a recommended class of agents for management of chronic pain in a specifically studied family of agents (TCA's) and with a better safety profile, being used in conjunction with an opioid analgesic and an Anti-Epileptic Drug (AED) Gabapentin that is also recommended for use in chronic neuropathic pain this agent can be recommended for use in both its contribution to the management of chronic pain but also the reported depression that has not come under control with Fluoxetine. The anti-insomnia benefits of the TCA family stemmed from their high incidence of side effects such as sedation that could be beneficial. In the case with a cleaner profile it is less likely than older generation to be of any benefit. However better management of pain as well as depression would likely improve the members sleep pattern. I do not support the UR decision. Therefore, 1 Prescription for mirtazapine 15mg #60 is medically necessary.

Aquatic physical therapy two times a week for three weeks: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medical Treatment Guidelines Page(s): 22.

Decision rationale: Recommended as an optional form of exercise therapy, where available, as an alternative to land based physical therapy. Aquatic therapy (including swimming) can minimize the effects of gravity, so it is specifically recommended where reduced weight bearing is desirable, for example extreme obesity. Water exercise improved some components of health-related quality of life, balance, and stair climbing in females with fibromyalgia, but regular exercise and higher intensities may be required to preserve most of these gains. However in this situation the specific benefit and utility of aquatic therapy as compared to standard land based PT has not been elucidated. Response to home based independent therapy has not been characterized nor the results of any formal previous PT. Therefore, Aquatic physical therapy two times a week for three weeks is not medically necessary.