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| Case Number: | CM14-0057023 | | |
| Date Assigned: | 07/09/2014 | Date of Injury: | 10/25/2001 |
| Decision Date: | 09/05/2014 | UR Denial Date: | 04/17/2014 |
| Priority: | Standard | Application Received: | 04/28/2014 |

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 Internal Medicine, 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:

Patient is an injured worker with lumbar spine sprain and strain, status post bilateral knee surgeries, and right carpal tunnel syndrome. Date of injury was 10-25-2001. Neurological evaluation note 04/10/14 provided a progress report by [REDACTED]. Regarding the mechanism of injury, patient reported that her right leg gave out as she got out of her car. The date of injury was 10-25-2001. She consulted an orthopedic surgeon who ordered an MRI of both knees and diagnosed her with torn meniscus and performed surgery on the right knee in November 2001 and on the left knee in December 2001. Physical therapy was ordered. She attempted to work after the surgeries but continuing having pain and stopped working for the company in January 2002. She has not been employed since then. In March 2002, the pain in the lower back became more predominant with radiation to both legs. She was referred to a pain management specialist. She recalled multiple nerve blocks, epidural injections and pain medication without lasting improvement. Current complaints included constant moderate right knee pain, lower back pain bilateral radiating to the buttocks down to the knees, right toes and feet numbness, headaches, moderate neck pain, left and right shoulder pain, right elbow pain, right wrist pain, right wrist and hand are weakness, right hand numbness and burning, and tremors. The patient is taking Avinza 75 mg BID, Norco 10/325, Zanaflex. Acupuncture treatments February 2014 was beneficial. The patient is using TENS unit at home which relieves pain. The patient is doing home exercise. Patient has a history of lower back pain with normal MRI 3/4/02. Current medications were Avinza 75 mg twice a day, Norco 10/325 as needed twice a day as needed, Zanaflex 4 mg 2 tablets at night, Lisinopril 10 mg once a day, Prilosec 40 mg once a day, Lipitor 10 mg once a day, NovoLog pump approximately 50 units a day, Mobic 15 mg qD. Patient is using a cream composed of Ketamine 10%, Gabapentin 6%, Cyclobenzapril 6%, Tramadol 8%, Amitriptiline 4%, Clonidine 2%. Physical examination was documented. The patient was awake,

alert and oriented . Speech was normal production and comprehension. Blood pressure 120/84, respiration 16, pulse 70. Cervical spine examination demonstrated normal range of motion. Occipital notch tenderness slight bilaterally. Negative Lhermitte sign was noted. Shoulder examination demonstrated range of motion flexion 176, extension 30, abduction 178, adduction 30, internal rotation 50, external rotation 60 bilaterally. Lumbar spine examination demonstrated paraspinal muscle tenderness bilaterally, right greater than left. Sacroiliac joint tenderness, right. Mild sciatic notch tenderness on the right more than left. Straight leg raising sign negative bilaterally. Range of motion decreased by 10% in all directions. Knee examination demonstrated cracking on range of motion. Tenderness on palpation over the bilateral knees, right greater than left. No swelling, no change in color or temperature. No laxity, no dislocation. Cranial nerves II-XII were normal. Motor Examination demonstrated no focal atrophy, fasciculations, spasticity or rigidity. Individual muscle testing is 5/5 throughout. Positive Tinel's sign right carpal tunnel. Deep tendon reflexes are +2 throughout, +1 ankles. Negative babinski bilaterally. Coordination is intact to finger-nose-finger, rapid alternating movements and heel-to-shin. Gait is normal. Negative Romberg and normal tandem walk. The patient is able to stand on her heels and toes. Diagnostic impressions were lumbar spine sprain and strain; right and left knee pain status-post two surgeries, each knee, status-post baker's cyst resection; right carpal tunnel syndrome. Treatment recommendations were Acupuncture, Cream NCP-10 Lotion, Avinza 75mg BID, Norco 10/325 BID PRN, Zanaflex 4 mg BID PRN, Mobic 15 mg qD as an antiinflammatory, trial of Lyrica 75 mg BID.

IMR ISSUES, DECISIONS AND RATIONALES

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

Avinza 75mg #60 with 3 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment, Chapter 8 Neck and Upper Back Complaints, Chapter 9 Shoulder Complaints, Chapter 10 Elbow Disorders (Revised 2007), Chapter 11 Forearm, Wrist, and Hand Complaints, Chapter 12 Low Back Complaints, Chapter 13 Knee Complaints Page(s): 40-46; 47-78; 181-183; 212-214; 271-273; 308-310; 346-347, Chronic Pain Treatment Guidelines OPIOIDS Page(s): 74-96. Decision based on Non-MTUS Citation http://www.deadiversion.usdoj.gov/faq/mult_rx_faq.htm#7.

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address opioids. The lowest possible dose should be prescribed to improve pain and function. It is recommend that dosing not exceed 120 mg oral morphine equivalents per day. Frequent evaluation of clinical history and frequent review of medications are recommended. Periodic review of the ongoing chronic pain treatment plan for the injured worker is essential. Patients with pain who are managed with controlled substances should be seen regularly. American College of Occupational and Environmental Medicine (ACOEM) 2nd Edition (2004) Chapter 3 states that opioids appear to be no more effective than safer analgesics for managing most musculoskeletal symptoms. Opioids should be used only if needed for severe

pain and only for a short time. Opioids cause significant side effects. ACOEM guidelines state that the long-term use of opioids is not recommended for neck, back, knee, and upper extremity conditions. Per the U.S. Drug Enforcement Administration (DEA), the issuance of refills for a schedule II controlled substance is prohibited by law. Schedule II drugs have a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous. Avinza is extended release morphine sulfate, a Schedule CII medication. Neurological evaluation report dated 04/10/2014 documented the diagnoses of lumbar spine sprain and strain, status post bilateral knee surgeries, and right carpal tunnel syndrome. The patient was initially injured when her right leg gave out as she got out of her car on 10/25/2001. She had right knee arthroscopic partial medial meniscectomy November 2001 and left knee arthroscopic partial medial meniscectomy December 2001. Lumbar spine MRI 03/04/2002 was reported as normal. She stopped working in January 2002. She has not been employed since then. Physical examination documented minor physical findings. Gait, motor strength, and neurologic examination were normal. Range of motion diminution was minor. No significant objective physical findings were documented. Avinza 75mg BID #60 with 3 refills and Norco 10/325 BID as needed #30 with 3 refills were requested. Medical records document the long-term use of opioids. ACOEM guidelines do not endorse the long-term use of opioids. MTUS guidelines recommend that opioid dosing not exceed 120 mg oral morphine equivalents per day. The patient's opioid regimen is equivalent to 170 morphine equivalents, which exceeds the maximum of 120 morphine equivalents. MTUS guidelines state that the lowest possible dose should be prescribed to improve pain and function. Avinza 75mg BID #60 with 3 refills was requested, which is a total of 240 capsules of a Schedule II drug, a four month supply without regular reevaluation. Per the U.S. Drug Enforcement Administration (DEA), the issuance of refills for a schedule II controlled substance is prohibited by law. Therefore the request for 3 refills of Avinza is prohibited. No significant objective physical findings were documented. Medical records and clinical guidelines do not support the prescription of Avinza 75mg BID #60 with 3 refills. Therefore, the request for Avinza 75mg #60 with 3 refills is Not medically necessary.

Zanaflex 4mg #60 with 1 refill: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)- TWC Pain Procedure Summary.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47-49, Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63-66.

Decision rationale: Medical Treatment Utilization Schedule (MTUS) address muscle relaxants. American College of Occupational and Environmental Medicine (ACOEM) 2nd Edition (2004) states that muscle relaxants seem no more effective than NSAIDs for treating patients with musculoskeletal problems, and using them in combination with NSAIDs has no demonstrated benefit. Muscle relaxants may hinder return to function by reducing the patient's motivation or ability to increase activity. Table 3-1 states that muscle relaxants are not recommended. Chronic Pain Medical Treatment Guidelines (Page 63-66) addresses muscle relaxants. Muscle relaxants should be used with caution as a second-line option for short-term treatment. Zanaflex

(Tizanidine) is associated with hepatotoxicity. Liver function tests (LFT) should be monitored. Medical records document the long-term use of Zanaflex. No significant objective physical findings were documented. Medical records do not document recent liver function tests (LFT), which is required for safe Zanaflex use, per MTUS guidelines. MTUS guidelines do not support the long-term use of muscle relaxants. ACOEM guidelines do not recommend long-term use of muscle relaxants. MTUS and ACOEM guidelines do not support the medical necessity of muscle relaxants. Therefore, the request for Zanaflex 4mg #60 with 1 refill is Not medically necessary.

Norco 10/325 #30 with 3 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment, Chapter 8 Neck and Upper Back Complaints, Chapter 9 Shoulder Complaints, Chapter 10 Elbow Disorders (Revised 2007), Chapter 11 Forearm, Wrist, and Hand Complaints, Chapter 12 Low Back Complaints, Chapter 13 Knee Complaints Page(s): 40-46;47-48;181-183;212-214;271-273; 308-310; 346-347.

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address opioids. The lowest possible dose should be prescribed to improve pain and function. It is recommended that dosing not exceed 120 mg oral morphine equivalents per day. Frequent evaluation of clinical history and frequent review of medications are recommended. Periodic review of the ongoing chronic pain treatment plan for the injured worker is essential. Patients with pain who are managed with controlled substances should be seen regularly. American College of Occupational and Environmental Medicine (ACOEM) 2nd Edition (2004) Chapter 3 states that opioids appear to be no more effective than safer analgesics for managing most musculoskeletal symptoms. Opioids should be used only if needed for severe pain and only for a short time. Opioids cause significant side effects. ACOEM guidelines state that the long-term use of opioids is not recommended for neck, back, knee, and upper extremity conditions. Neurological evaluation report dated 04/10/2014 documented the diagnoses of lumbar spine sprain and strain, status post bilateral knee surgeries, and right carpal tunnel syndrome. The patient was initially injured when her right leg gave out as she got out of her car on 10/25/2001. She had right knee arthroscopic partial medial meniscectomy November 2001 and left knee arthroscopic partial medial meniscectomy December 2001. Lumbar spine MRI 03/04/2002 was reported as normal. She stopped working in January 2002. She has not been employed since then. Physical examination documented minor physical findings. Gait, motor strength, and neurologic examination were normal. Range of motion diminution was minor. No significant objective physical findings were documented. Avinza 75mg BID #60 with 3 refills and Norco 10/325 BID as needed #30 with 3 refills were requested. Medical records document the long-term use of opioids. ACOEM guidelines do not endorse the long-term use of opioids. MTUS guidelines recommend that opioid dosing not exceed 120 mg oral morphine equivalents per day. The patient's opioid regimen is equivalent to 170 morphine equivalents, which exceeds the maximum of 120 morphine equivalents. MTUS guidelines state that the lowest possible dose should be prescribed to improve pain and function. No significant objective physical findings

were documented. Medical records and clinical guidelines do not support the prescription of Norco 10/325 BID as needed #30 with 3 refills. Therefore, the request for Norco 10/325 #30 with 3 refills is Not medically necessary.

Lyrica 75mg #60 with 1 refill: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDS) page 16-20 Pregabalin (Lyrica) page 19-20 Page(s): 16-20; 19-20. Decision based on Non-MTUS Citation FDA Prescribing Information for Lyrica <http://www.drugs.com/pro/lyrica.html>.

Decision rationale: Medical treatment utilization schedule (MTUS) Chronic Pain Medical Treatment Guidelines state that Lyrica (Pregabalin) has been documented to be effective in the treatment of diabetic neuropathy and postherpetic neuralgia, and has FDA approval for both indications. The FDA has given approval of pregabalin as treatment for fibromyalgia. FDA Prescribing Information documents that Lyrica is indicated for neuropathic pain associated with diabetic peripheral neuropathy, postherpetic neuralgia, partial onset seizures, fibromyalgia, neuropathic pain associated with spinal cord injury. Neurological evaluation report dated 04/10/2014 documented the diagnoses of lumbar spine sprain and strain, status post bilateral knee surgeries, and right carpal tunnel syndrome. Physical examination documented minor physical findings. Gait, motor strength, and neurologic examination were normal. Range of motion diminution was minor. No significant objective physical findings were documented. There was no documentation of diabetic peripheral neuropathy, postherpetic neuralgia, partial onset seizures, fibromyalgia, neuropathic pain associated with spinal cord injury - which are the FDA approved indications for Lyrica. The medical records do not support the medical necessity of Lyrica. Therefore, the request for Lyrica 75mg #60 with 1 refill is Not medically necessary.

Cream NCP-10 lotion 150gm #30 with 1 refill: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page 111-113 Page(s): 111-113.

Decision rationale: Medical treatment utilization schedule (MTUS) Chronic Pain Medical Treatment Guidelines addresses topical analgesics. Topical Analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. Topical Baclofen and other muscle relaxants are not recommended. There is no evidence for the use of any muscle relaxant as a topical product. Topical Gabapentin and other antiepilepsy drugs are not recommended. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Neurological evaluation report dated 04/10/2014 documented the diagnoses of

lumbar spine sprain and strain, status post bilateral knee surgeries, and right carpal tunnel syndrome. No significant objective physical findings were documented. Patient was using a cream composed of Ketamine 10%, Gabapentin 6%, Cyclobenzapril 6%, Tramadol 8%, Amitriptyline 4%, Clonidine 2%. Cream NCP-10 Lotion was requested. The components of Cream NCP-10 Lotion are not documented and are unknown. An unknown topical cream lotion cannot be endorsed. MTUS guidelines do not support the use of topical analgesics in general. Therefore, the request for Cream NCP-10 lotion 150gm #30 with 1 refill IS NOT MEDICALLY NECESSARY.