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| Case Number: | CM15-0064861 | | |
| Date Assigned: | 04/10/2015 | Date of Injury: | 04/23/2009 |
| Decision Date: | 05/15/2015 | UR Denial Date: | 04/01/2015 |
| Priority: | Standard | Application Received: | 04/06/2015 |

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:

The injured worker is a 47 year old female who sustained an industrial injury on 4/23/2009 due to a fall. Diagnoses have included chronic pain syndrome, lumbago, lower extremity pain, torn meniscus, complex regional pain syndrome (CRPS), and depression. Treatment to date has included physical therapy, lumbosacral block at L2, sacroiliac joint injection, heat, ice, activity modification, knee surgery, and medication. Kadian was among prescribed medications in December 2014 -March 2015. At a visit on 12/17/14, the injured worker was noted to be very sedated at the appointment; a pill count was done and showed she was not taking the medication as only 2 Kadian were gone from a 2 week supply. Work status was noted as disabled in February and March of 2015. According to the progress report dated 3/2/2015, the injured worker complained of pain in the lower back and the left knee, occurring for years and on average 7/10 in severity. It was noted that pain was poorly controlled by the treatment and medications utilized thus far. NSAIDs were noted to be tried and failed in the past. Voltaren gel was noted to be minimally beneficial. Multiple daily activities were noted to be impaired by pain including chores, shopping, exercise, walking, and standing. The physician noted that the injured worker was unable to tolerate Norco in the past and that she was requesting rotating to another opioid due to high cost of Kadian. The injured worker reported constipation as a result of medication. The physician noted the presence of an opioid agreement. Examination showed intact sensation and normal strength of the lower extremities. Kadian was discontinued and authorization was requested for new medications including Gabapentin, Flurbiprofen 15%/Baclofen 2%/Cyclobenzaprine 2%/Gabapentin 6%/Lidocaine 2.5%, Celebrex, Miralax

powder, MS Contin and Oxycodone-Acetaminophen. At a visit on 3/17/15, the treating physician noted that another physician had discontinued ambien due to overuse and suicidal ideation. The injured worker was described as tearful and overwhelmed and expressing suicidal ideation, and she was transferred to the emergency room (ER). On 3/31/15, Utilization Review (UR) non-certified requests for Flurbiprofen 15%/Baclofen 2%/Cyclobenzaprine 2%/Gabapentin 6%/Lidocaine 2.5%; Celebrex; and Miralax powder. UR modified requests for MS contin and Oxycodone-acetaminophen. UR certified the request for Gabapentin.

IMR ISSUES, DECISIONS AND RATIONALES

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

Gabapentin 300mg #60: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines anticonvulsants (antiepilepsy drugs (AEDs)) Page(s): 16-22.

Decision rationale: The request for Gabapentin was certified by UR and is medically necessary.

Flurbiprofen 15%, Baclofen 2%, Cyclobenzaprine 2%, Gabapentin 6%, Lidocaine 2.5%: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines medications for chronic pain p. 60, topical analgesics p. 111-113.

Decision rationale: This injured worker has chronic back and knee pain, with diagnosis of complex regional pain syndrome. Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There was no documentation of trial and failure of antidepressants or anticonvulsants. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. Flurbiprofen is a non-steroidal anti-inflammatory drug (NSAID). Topical NSAIDs are indicated for osteoarthritis and tendinitis, in particular that of the knee and elbow or other joints that are amenable to topical treatment. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip, or shoulder. Topical non-steroidals are not recommended for neuropathic pain. Note that topical flurbiprofen is not FDA approved, and is therefore experimental and cannot be presumed as safe and efficacious. Non-FDA approved medications are not medically necessary. Baclofen is not recommended in topical form. The

treating physician has also prescribed an oral NSAID, which is duplicative and potentially toxic. Cyclobenzaprine is a muscle relaxant. The MTUS notes that there is no evidence for use of muscle relaxants as topical products. Gabapentin is an antiepileptic drug and is not recommended in topical form; there is no peer-reviewed literature to support use. Lidocaine is only FDA approved for treating post-herpetic neuralgia, and the dermal patch form (Lidoderm) is the only form indicated for neuropathic pain. No other commercially approved topical formulations of lidocaine (whether creams, lotions, or gels) are indicated for neuropathic pain. As multiple drugs in this compounded topical product are not recommended, the compound is not recommended. As such, the request for Flurbiprofen 15%, Baclofen 2%, Cyclobenzaprine 2%, Gabapentin 6%, Lidocaine 2.5% is not medically necessary.

Celebrex 200mg #30: Upheld

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

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. This injured worker has chronic pain in the low back and left knee for years, without documentation of acute exacerbation. 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. The MTUS does not recommend chronic NSAIDs for low back pain, NSAIDs should be used for the short term only. Systemic toxicity is possible with NSAIDs. The FDA and MTUS recommend monitoring of blood tests and blood pressure. The treating physician is prescribing oral and transdermal NSAIDs. This is duplicative, potentially toxic, and excessive, as topical NSAIDs are absorbed systemically. The documentation indicates that NSAIDs were tried and failed in the past. Work status was noted as disabled. Due to lack of prior response to NSAIDs and potential for toxicity, the request for celebrex is not medically necessary.

Miralax powder 1 bottle: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Miralax - <http://www.drugs.com/miralax.html>.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Initiating Therapy [with opioids] Page(s): 77. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) chronic pain chapter: opioid induced constipation treatment.

Decision rationale: The MTUS notes that when initiating therapy with opioids, prophylactic treatment of constipation should be initiated. Per the ODG, constipation occurs commonly in patients receiving opioids. If prescribing opioids has been determined to be appropriate, prophylactic treatment of constipation should be initiated. First line treatment includes increasing physical activity, maintaining appropriate hydration, and diet rich in fiber. Some laxatives may help to stimulate gastric motility, and other medications can help loosen otherwise hard stools, add bulk, and increase water content of the stool. The injured worker had reported constipation due to medication, presumably opioids. Although laxatives are indicated when opioids are prescribed, the opioids are not medically necessary in this case. The treating physician has not provided other reasons for laxatives so laxatives would not be medically necessary if opioids are not prescribed. The request IS NOT medically necessary.

MS Contin 15mg #30: Upheld

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

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

Decision rationale: This injured worker has chronic back and knee pain, and has been treated with opioids (kadian) for at least three months, with current requests for MS contin and oxycodone-acetaminophen. There is insufficient 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. There was discussion of an opioid contract, but none of the rest of these aspects of prescribing are in evidence. Work status was noted as disabled, and there was no discussion of return to work. Per the MTUS, opioids are minimally indicated, if at all, for chronic non-specific pain, osteoarthritis, "mechanical and compressive etiologies," and chronic back pain. There is no evidence of significant pain relief or increased function from the opioids used to date. 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." 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. MTUS also details indications for discontinuing opioid medication, such as serious non-adherence or diversion and suicide attempt. A recent pill count was described as inconsistent with the amount of Kadian prescribed. The injured worker was noted to appear sedated at a recent visit, and more recently she was noted to express suicidal ideation. Recent overuse of ambien was documented. An inconsistent pill count, recent overuse of hypnotic medication, sedated appearance at an office visit, and suicidal ideation are consistent with

aberrant behavior and warrant discontinuation of opioid medication. As currently prescribed, MS contin does not meet the criteria for long term opioids as elaborated in the MTUS and is therefore not medically necessary.

Oxycodone-Acetaminophen 7.5mg #30: Upheld

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

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

Decision rationale: This injured worker has chronic back and knee pain, and has been treated with opioids (kadian) for at least three months, with current requests for MS contin and oxycodone-acetaminophen. There is insufficient 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. There was discussion of an opioid contract, but none of the rest of these aspects of prescribing are in evidence. Work status was noted as disabled, and there was no discussion of return to work. Per the MTUS, opioids are minimally indicated, if at all, for chronic non-specific pain, osteoarthritis, "mechanical and compressive etiologies," and chronic back pain. There is no evidence of significant pain relief or increased function from the opioids used to date. 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." 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. MTUS also details indications for discontinuing opioid medication, such as serious non-adherence or diversion and suicide attempt. A recent pill count was described as inconsistent with the amount of Kadian prescribed. The injured worker was noted to appear sedated at a recent visit, and more recently she was noted to express suicidal ideation. Recent overuse of ambien was documented. An inconsistent pill count, recent overuse of hypnotic medication, sedated appearance at an office visit, and suicidal ideation are consistent with aberrant behavior and warrant discontinuation of opioid medication. As currently prescribed, oxycodone-acetaminophen does not meet the criteria for long term opioids as elaborated in the MTUS and is therefore not medically necessary.