

Case Number:	CM15-0029008		
Date Assigned:	02/23/2015	Date of Injury:	02/13/2002
Decision Date:	04/03/2015	UR Denial Date:	02/04/2015
Priority:	Standard	Application Received:	02/17/2015

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: California

Certification(s)/Specialty: Family Practice

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 male, who sustained an industrial injury on February 13, 2002. Treatment to date has included oral and topical medication. Currently, the injured worker complains of low back pain and bilateral leg pain. In a progress note dated January 28, 2015, the treating providers report was not all there. On February 4, 2015 Utilization Review non-certified a Norco 10/325mg quantity 240, Methadone 10mg quantity 180, Soma 350mg quantity 120, Voltaren gel one percent 500gm, and Zolpidem 10mg quantity 60, noting, Medical Treatment Utilization Schedule Guidelines and Official Disability Guidelines was cited.

IMR ISSUES, DECISIONS AND RATIONALES

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

Methadone 10mg #180: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 61-62. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 76-78, 80.

Decision rationale: The MTUS/Chronic Pain Medical Treatment Guidelines comment on the long-term use of opioids including Methadone. These guidelines have established criteria on the use of opioids for the ongoing management of pain. Actions should include prescriptions from a single practitioner and from a single pharmacy. The lowest possible dose should be prescribed to improve pain and function. There should be an ongoing review and documentation of pain relief, functional status, appropriate medication use and side effects. Pain assessment should include current pain, the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. There should be evidence of documentation of the 4 A's for Ongoing Monitoring. These four domains include pain relief, side effects, physical and psychological functioning, and the occurrence of any potentially aberrant drug-related behaviors. Further, there should be consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain that does not improve on opioids in 3 months. There should be consideration of an addiction medicine consult if there is evidence of substance misuse (Pages 76-78). Finally; the guidelines indicate that for chronic pain, the long-term efficacy of opioids is unclear. Failure to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy (Page 80). Based on the review of the medical records, there is insufficient documentation in support of these stated MTUS/Chronic Pain Medical Treatment Guidelines for the ongoing use of opioids. There is insufficient documentation of the 4 A's for Ongoing Monitoring. The treatment course of opioids in this patient has extended well beyond the timeframe required for a reassessment of therapy. In summary, there is insufficient documentation to support the chronic use of an opioid in this patient. Treatment with Methadone is not considered as medically necessary.

Soma 350mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Carisoprodol (Soma) Page(s): 29.

Decision rationale: The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of Soma (Carisoprodol) as a treatment modality. These guidelines state the following: Soma is not recommended. This medication is not indicated for long-term use. Carisoprodol is a commonly prescribed, centrally acting skeletal muscle relaxant whose primary active metabolite is meprobamate (a schedule-IV controlled substance). Carisoprodol is now scheduled in several states but not on a federal level. It has been suggested that the main effect is due to generalized sedation and treatment of anxiety. Abuse has been noted for sedative and relaxant effects. In regular abusers the main concern is the accumulation of meprobamate. Carisoprodol abuse has also been noted in order to augment or alter effects of other drugs. This includes the following: (1) increasing sedation of benzodiazepines or alcohol; (2) use to prevent side effects of cocaine;

(3) use with tramadol to produce relaxation and euphoria; (4) as a combination with hydrocodone, an effect that some abusers claim is similar to heroin (referred to as a "Las Vegas Cocktail"); & (5) as a combination with codeine (referred to as "Soma Coma"). In this case, per the above cited guidelines, there is no indication for the chronic use of Soma. Soma is not considered as a medically necessary treatment.

Voltaren Gel 1% 500gm: 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), Pain Chapter.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

Decision rationale: The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of topical analgesics, such as Voltaren gel, as a treatment modality. These guidelines state the following: Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required.

Non-steroidal anti-inflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety.

Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use.

FDA-approved agents: Voltaren Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. In this case the records indicate that the patient has received an adequate trial of an antidepressant or anticonvulsant. Further, the records suggest that the use of Voltaren Gel is as a long-term treatment modality. As stated in the above cited guidelines, Voltaren Gel is only recommended for short-term use. For these reasons, Voltaren Gel is not considered as a medically necessary treatment.

Zolpidem 10mg #60: 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).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Official Disability Guidelines/Pain (Acute & Chronic); Zolpidem.

Decision rationale: Zolpidem is a prescription short-acting non benzodiazepine hypnotic, which is recommended for short-term (7-10 days) treatment of insomnia. Proper sleep hygiene is critical to the individual with chronic pain and often is hard to obtain. Various medications may provide short-term benefit. 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. (Feinberg, 2008) See Insomnia treatment. Ambien CR offers no significant clinical advantage over regular release zolpidem. Ambien CR is approved for chronic use, but chronic use of hypnotics in general is discouraged, as outlined in Insomnia treatment. Ambien CR causes a greater frequency of dizziness, drowsiness, and headache compared to immediate release zolpidem. (Ambien & Ambien CR package insert) Cognitive behavioral therapy (CBT) should be an important part of an insomnia treatment plan. A study of patients with persistent insomnia found that the addition of zolpidem immediate release to CBT was modestly beneficial during acute (first 6 weeks) therapy, but better long-term outcomes were achieved when zolpidem IR was discontinued and maintenance CBT continued. (Morin, 2009) Due to adverse effects, FDA now requires lower doses for zolpidem. The dose of zolpidem for women should be lowered from 10 mg to 5 mg for IR products (Ambien, Edluar, Zolpimist, and generic) and from 12.5 mg to 6.25 mg for ER products (Ambien CR). The ER product is still more risky than IR. In laboratory studies, 15% of women and 3% of men who took a 10-milligram dose of Ambien had potentially dangerous concentrations of the drug in their blood eight hours later. Among those who took Ambien CR, the problem was more common: 33% of women and 25% of men had blood concentrations that would raise the risk of a motor vehicle accident eight hours later. Even at the lower dose of Ambien CR now recommended by the FDA, 15% of women and 5% of men still had high levels of the drug in their system in the morning. (FDA, 2013) According to SAMHSA, zolpidem is linked to a sharp increase in ED visits, so it should be used safely for only a short period of time. In this case, the records indicate that Zolpidem is being used as a long-term treatment for this patient's sleep disorder. Long-term use of Zolpidem is not recommended per the above cited ODG. For this reason, Zolpidem is not considered as medically necessary.

Norco 10/325mg #240: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic pain. Decision based on Non-MTUS Citation ODG, Pain Chapter.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids
Page(s): 76-78, 80.

Decision rationale: The MTUS/Chronic Pain Medical Treatment Guidelines comment on the long-term use of opioids including Norco. These guidelines have established criteria on the use of opioids for the ongoing management of pain. Actions should include prescriptions from a single practitioner and from a single pharmacy. The lowest possible dose should be prescribed to improve pain and function. There should be an ongoing review and documentation of pain relief, functional status, appropriate medication use and side effects. Pain assessment should include current pain, the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. There should be evidence of documentation of the 4 A's for Ongoing Monitoring. These four domains include pain relief, side effects, physical and psychological functioning, and the occurrence of any potentially aberrant drug-related behaviors. Further, there should be consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain that does not improve on opioids in 3 months. There should be consideration of an addiction medicine consult if there is evidence of substance misuse (Pages 76-78). Finally, the guidelines indicate that for chronic back pain, the long-term efficacy of opioids is unclear. Failure to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy (Page 80). Based on the review of the medical records, there is insufficient documentation in support of these stated MTUS/Chronic Pain Medical Treatment Guidelines for the ongoing use of opioids. There is insufficient documentation of the 4 A's for Ongoing Monitoring. The treatment course of opioids in this patient has extended well beyond the timeframe required for a reassessment of therapy. In summary, there is insufficient documentation to support the chronic use of an opioid in this patient. Treatment with Norco is not considered as medically necessary.