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| Case Number: | CM14-0036221 | | |
| Date Assigned: | 06/25/2014 | Date of Injury: | 07/21/2009 |
| Decision Date: | 07/25/2014 | UR Denial Date: | 03/13/2014 |
| Priority: | Standard | Application Received: | 03/25/2014 |

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 Physical Medicine & Rehabilitation and is licensed to practice in Illinois. 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 injured worker is a 55-year-old male with a reported date of injury on 07/21/2009. The mechanism of injury was noted to be a motor vehicle accident. His previous treatment was noted to include medications. His diagnoses were noted to include brachial neuritis or radiculitis, shoulder impingement, lumbar radiculopathy, stomach function disorders, and antianxiety disorder. The progress note dated 06/16/2014, reported the injured worker noted there had been no significant improvement since the last examination. The physical examination of the cervical spine reported paravertebral muscles were tender and spasms were present. The range of motion was restricted and deep tendon reflexes were normal and symmetrical, and sensation was reduced in the bilateral hands. The physical examination of the shoulders reported that the shoulders were to palpation, range of motion was decreased in flexion and abduction plane, and impingement sign was positive. The physical examination of the lumbar spine noted the paravertebral muscles were tender, spasm was present, range of motion was restricted, straight leg raise test was positive bilaterally, and sensation and motor strength were grossly intact. The medications were noted to include Voltaren 1% gel, compound: ketoprofen 20%/ lidocaine 5%/ gabapentin 6%, carisoprodol 350 mg, tramadol 50 mg, Zantac 75 mg, Norco 5/325 mg, Medrox pain relief ointment, docusate sodium 100 mg, Butrans 5 mcg/HR patch, Protonix DR 40 mg, and Lidoderm 5% patch. The request of authorization form dated 02/19/2014 is for Voltaren gel 1%, ketoprofen 20%, lidocaine 5%, gabapentin 6% (compound), carisoprodol 350 mg, Zantac 75 mg, and Medrox ointment; however, the provider's rationale was not submitted within the medical records.

IMR ISSUES, DECISIONS AND RATIONALES

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

Voltaren Gel 1%, QTY: 1: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

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

Decision rationale: The injured worker has been taking this medication since at least 09/2013. The California Chronic Pain Medical Treatment Guidelines recommend topical analgesics for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The guidelines state topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. Any compounded product that contains at least 1 drug (or drug class) that is not recommended, is not recommended. The efficacy in clinical trials for topical Non-steroidal anti-inflammatory drugs (NSAIDs) modality has been inconsistent, most of these 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 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 the 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. The indications for topical NSAIDs are for osteoarthritis and tendonitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment for short-term use (4 to 12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip, or shoulder. The guidelines state that Voltaren gel 1% is indicated for the 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 the treatment of the spine, hip, or shoulder. The documentation provided does not indicate a problem with the knee, elbow, or other joints that are amenable to topical treatment. The documentation reported complaints of pain to the neck and shoulder and the guidelines do not recommend Voltaren gel for utilization to those body regions. The guidelines state efficacy appears to diminish over time and it is recommended for short-term use such as 4 to 12 weeks and the injured worker has been on this medication for over 6 months. Additionally, the request failed to provide the frequency at which this medication is to be utilized. Therefore, the request for Voltaren Gel 1% is not medically necessary.

Ketoprofen 20% Lidocaine 5% Gabapentin 6% (compound): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Topical Analgesics.

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

Decision rationale: The injured worker has been taking this medication since at least 09/2013. The California Chronic Pain Medical Treatment Guidelines primarily recommend topical analgesics for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The guidelines state topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. Any compounded product that contains at least 1 drug (or drug class) that is not recommended, is not recommended. The guidelines recommend lidocaine in the formulation of a dermal patch (Lidoderm) for neuropathic pain and it has been designated for orphan status by the FDA for neuropathic pain. No other commercially approved topical formulations of lidocaine (creams, lotions, or gels) are indicated for neuropathic pain. The guidelines do not recommend lidocaine for non-neuropathic pain as there is only 1 trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. The guidelines state topical NSAIDS in clinical trials, the efficacy has been inconsistent, 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 treatments for osteoarthritis, but either not afterward, or with 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 diminished 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. The guideline indications for topical NSAIDS are for osteoarthritis and tendonitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment, they are recommended for short-term use (4 to 12 weeks). There is little evidence to utilize topical NSAIDS for treatment of osteoarthritis of the spine, hip, or shoulder. The guidelines do not recommend gabapentin for topical modality because there is no peer-reviewed literature to support its use. Therefore, due to the guidelines not recommending lidocaine other than a Lidoderm formulation, and gabapentin not recommended as well as ketoprofen is to be used for osteoarthritis, the request for this medication is not warranted at this time. Additionally, the request failed to provide the frequency at which this medication is to be utilized. Therefore, the request for Ketoprofen 20% Lidocaine 5% Gabapentin 6% (compound) is not medically necessary.

Carisoprodol 350 mg, QTY: 60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (For Pain) Page(s): 29.

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

Decision rationale: The injured worker has been on this medication since at least 09/2013. The California Chronic Pain Medical Treatment Guidelines do not recommend Soma as this medication is not indicated for long-term use. Carisoprodol is a commonly prescribed, centrally

acting, skeletal muscle relaxant whose active metabolite is meprobamate. Carisoprodol abuse has been also noted in order to admit or alter effects of other drugs such as increasing the sedation of benzodiazepines or alcohol, used to prevent the side effects of cocaine, use with tramadol to prevent relaxation euphoria, as a combination with hydrocodone an effect which some abusers claim is similar to heroin, and as a combination with codeine. The injured worker has been taking this medication for over 6 months and the guidelines do not recommend Soma for long-term use. Additionally, the request failed to provide the frequency at which this medication is to be utilized. Therefore, the request for Carisoprodol 350 mg is not medically necessary.

Zantac 75 mg, QTY: 30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS (Non-Steroidal Anti-Inflammatory Drugs).

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

Decision rationale: The injured worker has been taking this medication since at least 09/2013. The California Chronic Pain Medical Treatment Guidelines recommend for the clinician to determine if the patient is at risk for gastrointestinal events such as age greater than 65 years, history of peptic ulcer, gastrointestinal bleeding, or perforation, concurrent use of aspirin, corticosteroids, and/or anticoagulant, or a high dose or multiple NSAIDs. The documentation provided indicated the injured worker does suffer from medication induced stomach upset; however, the injured worker is also taking Protonix for this diagnosis. There is a lack of documentation regarding criteria regarding diagnosis to support the utilization of this medication. Additionally, the request failed to provide the frequency at which this medication is to be utilized. Therefore, the request for Zantac 75 mg is not medically necessary.

Medrox pain relief ointment, QTY: 1: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Topical Analgesics.

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

Decision rationale: The injured worker has been utilizing this medication since at least 09/2013. Medrox pain relief ointment consists of methyl salicylate 20%/menthol 5% and capsaicin 0.0375%. The California Chronic Pain Medical Treatment Guidelines recommend topical analgesics for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The guidelines state topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. Any compounded product that contains at least 1 drug (or drug class) that is not recommended, is not recommended. The guidelines state capsaicin is recommended only as an option in patients who have not responded or are intolerant to other

treatments. Capsaicin is generally available at 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily for postherpetic neuralgia, diabetic neuropathy, and post mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication this increase over a 0.025% formulation would provide any further efficacy. The guidelines do not recommend 0.0375% of capsaicin and the injured worker does not have a diagnosis in regards to osteoarthritis. Additionally, the request failed to provide the frequency at which this medication is to be utilized. Therefore, the request for Medrox pain relief ointment, quantity 1, is not medically necessary.