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| Case Number: | CM14-0192259 | | |
| Date Assigned: | 11/25/2014 | Date of Injury: | 06/03/2014 |
| Decision Date: | 01/27/2015 | UR Denial Date: | 11/04/2014 |
| Priority: | Standard | Application Received: | 11/17/2014 |

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 Anesthesiology, has a subspecialty in Acupuncture & Pain 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:

35y/o male injured worker with date of injury 6/3/14 with related low back pain. Per progress report dated 10/22/14, the injured worker complained of frequent 5/10 throbbing low back pain, numbness and tingling, associated with repetitive sitting, repetitive standing, prolonged bending, prolonged kneeling, prolonged twisting, and prolonged squatting. Per physical exam, there was tenderness to palpation of the bilateral SI joints and lumbar paravertebral muscles. There was muscle spasm of the bilateral gluteus and lumbar paravertebral muscles. Straight leg raising test was positive on the left. Treatment to date has included physical therapy, acupuncture, and medication management. The date of UR decision was 11/4/14.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flurbiprofen 20 percent/Baclofen 5 percent/Dexamethasone 2 percent/Menthol 2 percent/Camphor 2 percent/Capsaicin 0.025 percent: 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) Pain (updated 10/30/2014) Compound drugs

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 25, 60, 111-113.

Decision rationale: Per MTUS with regard to Flurbiprofen (p112) "These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) 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." Flurbiprofen may be indicated. Per MTUS p113 with regard to topical baclofen, "Baclofen: Not recommended. There is currently one Phase III study of Baclofen-Amitriptyline-Ketamine gel in cancer patients for treatment of chemotherapy-induced peripheral neuropathy. There is no peer-reviewed literature to support the use of topical baclofen. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." Baclofen is not indicated. Capsaicin may have an indication for chronic lower back pain in this context. Per MTUS p 112 "Indications: There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy." However, the CA MTUS, ODG, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the topical application of menthol, camphor, or dexamethasone. It is the opinion of this IMR reviewer that a lack of endorsement, a lack of mention, inherently implies a lack of recommendation, or a status equivalent to "not recommended". Since these components are not medically indicated, then the overall product is not indicated per MTUS as outlined below. Note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of multiple medications, MTUS p60 states "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually. The request is not medically necessary.

Gabapentin 10 percent/Amitriptyline 10 percent/Bupivacaine 5 percent cream 30gms, 210 g:
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) Pain (updated 10/30/2014) Compound drugs

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 25, 60, 111-113.

Decision rationale: Per MTUS p113 with regard to topical gabapentin: "Not recommended. There is no peer-reviewed literature to support use." Per the article "Topical Analgesics in the

Management of Acute and Chronic Pain" published in Mayo Clinic Proceedings (Vol 88, Issue 2, p 195-205), "Studies in healthy volunteers demonstrated that topical amitriptyline at concentrations of 50 and 100 mmol/L produced a significant analgesic effect ($P < .05$) when compared with placebo and was associated with transient increases in tactile and mechanical nociceptive thresholds." Amitriptyline may be indicated. The guidelines are silent on the use of bupivacaine, however with regard to lidocaine MTUS p 112 states "Further research is needed to recommend this treatment for chronic neuropathic pain disorders and other than post-herpetic neuralgia" and "Non-neuropathic pain: Not recommended. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo (Scudds, 1995)". The injured worker has not been diagnosed with post-herpetic neuralgia. Bupivacaine is not indicated. Regarding the use of multiple medications, MTUS p60 states "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually. Note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. As gabapentin is not recommended, the request is not medically necessary.