MAXIMUS Federal Services

| Case Number: | CM13-0028221 | | |
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| Date Assigned: | 11/22/2013 | Date of Injury: | 03/31/1995 |
| Decision Date: | 02/24/2014 | UR Denial Date: | 09/05/2013 |
| Priority: | Standard | Application Received: | 09/23/2013 |

## HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Anesthesia, has a subspecialty Certificate in Acupuncture and 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 physician 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:

This injured worker is a 60-year-old female, with a date of injury of 3/31/95, with related back pain and right radicular pain. She has been treated with physical therapy, behavioral therapy, transforaminal epidural steroid injection (TFESI), medial branch blocks, medial branch radiofrequency ablation, and an intrathecal spinal pump, which was later removed. She has an exercise routine that she does on a daily basis at home. She had corrective surgery for scoliosis about 2 years ago which was only modestly helpful. Because of nerve damage in the lower spine, she has spasticity of the back and right leg, which responds to Tizanidine. Her neuropathic radicular pain responds to Gabapentin. The injured worker suffers from delayed gastric emptying secondary to the opiates. This exposes her gastric mucosa to lengthy exposures of gastric acid. Omeprazole is used to treat this secondary effect of the treatment of her industrial injury.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Carisoprodol 350mg, #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

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

**Decision rationale:** Per MTUS, Carisoprodol 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." As this medication is not recommended by the MTUS, it is found not medically necessary.

**Comfort Pac-Tizanidine (topical salicylate) 4mg (2 kits):** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antispasticity/antispasmodic drugs, Section on Salicylate topicals Page(s): 63, 66, 105.

**Decision rationale:** The Comfort Pac-Tizanidine kit contains oral Tizanidine and methyl salicylate topical cream. With regard to salicylate topicals, MTUS indicates they are "recommended. Topical salicylate (e.g., Ben-Gay, methyl salicylate) is significantly better than placebo in chronic pain. (Mason-BMJ, 2004)." I respectfully disagree with the UR physician who claimed, "Topical salicylates and other analgesic preparations have no evidence-based proven efficacy in the treatment of chronic pain syndrome." The UR physician does not specifically mention why they were opposed to the Tizanidine in this compound. Per the 9/23/13 letter from the requesting physician, the injured worker has been provided with these medications for documented, intermittent myofascial pain and spasticity secondary to the industrial injury or sequelae. However, regarding the use of multiple medications, the MTUS 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 as compared with the others." Therefore, it would be optimal to trial each medication individually. Furthermore, the packaging of a topical remedy with a systemic oral agent is not consistent with standard care, and the medical necessity of Tizanadine is addressed elsewhere, so it is the opinion of this Independent Medical Reviewer that this service is, on the whole, not medically necessary.

**Fentanyl 100mcg/hr Patch, #30:** Overturned

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Section on Opioids Page(s): 78, 91, 93.

**Decision rationale:** Per MTUS, Fentanyl transdermal is indicated for management of persistent, chronic pain, which is moderate to severe, requiring continuous, around-the-clock opioid therapy. With regard to long-term users of opioids, MTUS recommends re-assessment: (a) Has the diagnosis changed? (b) What other medications is the patient taking? Are they effective, producing side effects? (c) What treatments have been attempted since the use of opioids? Have they been effective? For how long? (d) Document pain and functional improvement and compare to baseline. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument. (e) Document adverse effects: constipation, nausea, vomiting, headache, dyspepsia, pruritus, dizziness, fatigue, dry mouth, sweating, hyperalgesia, sexual dysfunction, and sedation. (f) Does the patient appear to need a psychological consultation? Issues to examine would include motivation, attitude about pain/work, return-to-work, social life including interpersonal and work-related relationships. (g) Is there indication for a screening instrument for abuse/addiction? See Substance Abuse Screening. With regard to strategies for maintenance, MTUS explicitly recommends: "(a) Do not attempt to lower the dose if it is working." Upon review of the submitted medical records, there is evidence that the injured worker continues to experience severe pain rated 10/10 that is reduced to 5/10 with the use of the current medication regimen including Fentanyl patches. This medication also raises the functional ability of the worker in multiple categories such as family/home responsibilities, social activity, self-care, and sleep. The UR physician cited the MTUS guidelines for opioids dosing, "Recommend that dosing not exceed 120 mg oral morphine equivalents per day..."; however, the guidelines also state "Rarely, and only after pain management consultation, should the total daily dose of opioid be increased above 120 mg oral morphine equivalents. There are other guidelines to consider, and the actual maximum safe dose will be patient-specific and dependent on current and previous opioid exposure, as well as on whether the patient is using such medications chronically." In this circumstance, the primary treating physician (PTP) is a Pain Management specialist by training and practice, and the criteria for exceeding 120 mg morphine equivalent dose factor are satisfied when and if the PTP makes that decision. Additionally, adequate consideration has been given to the frequent re-assessment of the injured worker utilizing the MTUS criteria above. The request is medically necessary.

**Omeprazole 20mg, #30:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68.

**Decision rationale:** The MTUS recommends the use of proton pump inhibitors (PPI) in conjunction with NSAIDs in situations in which the patient is at risk for gastrointestinal (GI) events, including: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of acetylsalicylic acid (ASA), corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). I respectfully disagree with the UR physician's assertion that there is no GI disease and no GI side effects. While the injured worker does not meet the criteria for use of PPI medication in conjunction with NSAIDs, it is noted in the documentation submitted for review that the injured worker is subject to delayed gastric emptying due to the slow-down of GI transit by the opiates used to treat her chronic pain secondary to her industrial injury. This exposes her gastric mucosa to lengthy exposures of acid, causing gastritis. The treating physican cites narcotic bowel syndrome as the reason for treatment with omeprazole; however, the literature he/she cites recommends against omeprazole. It is not clear that the omeprazole is treating any gastritis, dyspepsia, or GERD. Therefore, the request is not medically necessary.

**Tizanidine 2mg, #120:** Overturned

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Section on Antispasticity/antispasmodic drugs Page(s): 63, 66.

**Decision rationale:** Per MTUS, "Tizanidine is a centrally acting alpha2-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for low back pain. (Malanga, 2008) Eight studies have demonstrated efficacy for low back pain. (Chou, 2007) One study (conducted only in females) demonstrated a significant decrease in pain associated with chronic myofascial pain syndrome and the authors recommended its use as a first line option to treat myofascial pain. (Malanga, 2002) May also provide benefit as an adjunct treatment for fibromyalgia." Also, according to MTUS, non-sedating muscle relaxants are recommended with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic lower back pain (LBP). Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. I respectfully disagree with the UR physician's assertion that there is no documentation of spasticity. I find documentation of spasticity associated with spinal cord injury in my review of the records. Per the 10/21/13 note, this request was made in a change of prescription from Carisoprodol, which is not recommended by MTUS. This medication has been used appropriately for ongoing spasticity due to spinal cord and nerve root damage. Note that the prescription of this medication is 2 tablets by mouth twice a day as needed; even when combined with the dosage provided by Comfort Pac-Tizanidine (1-2 tablets by mouth every night as needed), it is 16 mg maximum per day. This is well below the MTUS guideline maximum of 36mg per day. The request is medically necessary.