Case Number:	CM15-0216109		
Date Assigned:	11/05/2015	**Date of Injury:**	02/28/2003
Decision Date:	12/22/2015	**UR Denial Date:**	10/19/2015
Priority:	Standard	**Application Received:**	11/03/2015

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: 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 62 year old male who sustained an industrial injury on February 28, 2003. Of note, the worker had been previously deemed as permanent and stationary. The worker is being treated for: low back pain, bilateral shoulders and elbow pains. Subjective: March 11, 2015, May 06, 2015 he reported complaint of low back injury and pain. He is still experiencing severe, aching pain in the low back rated at a constant "7" intensity out of 10 that radiates to the right lower extremity. There is also noted complaint of aching pain to the bilateral shoulders, bilateral elbows, and stomach pain. He reported not participating in any therapy at this time and not working. Objective: March 11, 2015, May 06, 2015 noted the lumbar spine, right side "with rather exquisite trigger areas," with note of two on the left with nodules; tenderness in the paraspinous musculature on the left and midline tenderness to palpation. Lumbar ROM found: flexion 20 degrees, extension 15 degrees right rotation 15 degrees and left at 10 degrees. July 16, 2015 PT assessment noted: "patient able to do single leg stance on his left lower extremity with increased stability, compared to the right, and then had greater stability, less back pain with verbal and tactile cueing for abdominal engagement." The POC noted continuing with therapy as "with improvement." Diagnostic: UDS. Medication: May 06, 2015: Tramadol, Prilosec. Treatment: DME cane with ambulation, status post fusion(s) 2004, 2007, 2008 and noted removal of hardware January 2010; July 16, 2015 noted being evaluated with 4 sessions total in physical therapy session treating lumbago. On October 12, 2015 a request was made for 8 session of acupuncture, 8 sessions of chiropractic treatment and compound topical cream

containing: Flurbiprofen, Capsaicin, and Menthol 102GM which were all noncertified by Utilization Review on October 19, 2015.

IMR ISSUES, DECISIONS AND RATIONALES

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

Acupuncture times 8: Upheld

Claims Administrator guideline: Decision based on MTUS Acupuncture Treatment 2007.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low back Problems: Acupuncture.

Decision rationale: Based on ODG guidelines, acupuncture is not recommended for acute low back pain. (Tulder-Cochrane, 2000) (Furlan-Cochrane, 2005) Recommended as an option for chronic low back pain using a short course of treatment in conjunction with other interventions. (See the Pain Chapter.) Acupuncture has been found to be more effective than no treatment for short-term pain relief in chronic low back pain, but the evidence for acute back pain does not support its use. (Furlan-Cochrane, 2005) (Manheimer, 2005) (van Tulder, 2005) (Thomas, 2005) (Ratcliffe, 2006) (Thomas, 2006) (Haake, 2007) (Santaguida, 2009) These authors have reported that acupuncture provides a greater effect than sham treatment, while others have reported non- significant differences between the two modalities. (Brinkhaus, 2006) In this latter case, both modalities were shown to be more effective than no treatment. (Haake, 2007) Acupuncture has not been found to be better than other treatment (either conventional or alternative) in terms of pain or function. Acupuncture has been shown to add to the treatment effect of conventional therapy (improving pain and function) when compared to conventional therapy alone. (van Tulder, 2005) (Manheimer, 2005) (Furlan-Cochrane, 2005) Overall outcomes from trials have been mixed, with some lower-quality trials producing positive results, but trials with higher validity scores tending to be negative or inconclusive. There is a tendency for patient expectations to influence the outcome independently of the treatment itself. (Tulder-Cochrane, 2000) (Cherkin, 2001) (van Tulder-Spine, 1999) (Smith, 2000) (Cherkin-Annals, 2003) (Giles- Spine, 2003) (Muller, 2005) (Airaksinen, 2006) A recent RCT comparing usual care to acupuncture plus usual care found that at 24 months the acupuncture/usual care subjects were significantly more likely to report 12 months pain free and less likely to report they required use of medication for pain (after only 10 treatments that were performed at the beginning of the protocol). (Thomas, 2005) Note: This recent Thomas study prompted the UK Health Tech Assessment to recommend acupuncture for chronic LBP. A recent systematic review of randomized controlled trials concluded that acupuncture versus no treatment, and as an adjunct to conventional care, should be advocated for the treatment of chronic LBP. (Yuan, 2008) This recent quality RCT concluded that actual or sham acupuncture appear to be equally effective for low back pain, raising questions about acupuncture's purported mechanisms of action. (Cherkin, 2009) For an overview of acupuncture and other conditions in which this modality is recommended see the Pain Chapter. Evidence for the benefit of acupuncture is conflicting, with higher-quality trials showing no benefit. (Kinkade, 2007) According to a recent NEJM review, there is continuing debate in the medical community regarding the role of the

placebo effect in acupuncture, and the most recent well-powered clinical trials of acupuncture for chronic low back pain showed that sham acupuncture was as effective as real acupuncture. The simplest explanation of such findings is that the specific therapeutic effects of acupuncture, if present, are small, whereas its clinically relevant benefits are mostly attributable to contextual and psychosocial factors, such as patients' beliefs and expectations, attention from the acupuncturist, and highly focused, spatially directed attention on the part of the patient. (Berman, 2010) This systematic review found insufficient evidence to support the effectiveness of acupuncture for either acute or subacute low back pain in general, but it may be valuable for some patients. (McIntosh, 2011) Another systematic review found that acupuncture was cost-effective for both subacute or chronic LBP. (Lin, 2011) This passive intervention should be an adjunct to active rehab efforts. Payers may want to consider a trial of acupuncture for acute LBP if it would facilitate participation in active rehab efforts. ODG Acupuncture Guidelines: Initial trial of 3-4 visits over 2 weeks. With evidence of objective functional improvement, total of up to 8-12 visits over 4-6 weeks (Note: The evidence is inconclusive for repeating this procedure beyond an initial short course of therapy.) In this case, there is documentation as to prior acupuncture treatment, but no documentation of functional improvement or decrease in pain medication use. Therefore, based on ODG guidelines and the evidence in this case, the request for acupuncture times 8 is not medically necessary.

Chiro times 8: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Manual therapy & manipulation.

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

Decision rationale: Based on ODG guidelines, manipulation (chiropractic treatment) is recommended for chronic pain if caused by musculoskeletal conditions, only when manipulation is specifically recommended by the provider in the plan of care, if also recommended as an option in the Low Back Chapter and the Neck Chapter. (For more information and references, see those chapters.) Manipulation is manual therapy that moves a joint beyond the physiologic range-of-motion but not beyond the anatomic range-of-motion. Manipulation under anesthesia is not recommended. See also specific body-part chapters below: Low back: Recommended as an option. Therapeutic care - Trial of 6 visits over 2 weeks, with evidence of objective functional improvement, total of up to 18 visits over 6-8 weeks. Elective/maintenance care - Not medically necessary. Recurrences/flare-ups - Need to re-evaluate treatment success, if RTW achieved then 1-2 visits every 4-6 months. Neck and upper back: Recommended as an option. See chapter for specific recommendations according to condition. Head: Recommended for the prophylactic treatment of headaches (not a chronic pain treatment). Hip: Recommended as an option. See chapter for specific recommendations according to condition. Elbow: Recommended only on a short-term limited basis. See chapter for specific recommendations according to condition. Shoulder: Recommended as an option. See chapter for specific recommendations according to condition. Ankle & Foot: Not recommended. Carpal tunnel syndrome: Not recommended.

Forearm, Wrist, & Hand: Not recommended. Knee: Not recommended. Recommended treatment parameters: a. Time to produce effect: 4 to 6 treatments. b. Frequency: 1 to 2 times per week for the first 2 weeks as indicated by the severity of the condition. Treatment may continue at 1 treatment per week for the next 6 weeks. c. Maximum duration: 8 weeks. At week 8, patients should be reevaluated. Care beyond 8 weeks may be indicated for certain chronic pain patients in whom manipulation is helpful in improving function, decreasing pain and improving quality of life. In these cases, treatment may be continued at 1 treatment every other week until the patient has reached MMI and maintenance treatments have been determined. Extended durations of care beyond what is considered "maximum" may be necessary in cases of re-injury, interrupted continuity of care, exacerbation of symptoms, and in those patients with comorbidities. Such care should be re-evaluated and documented on a monthly basis. Treatment beyond 4-6 visits should be documented with objective improvement in function. Palliative care should be reevaluated and documented at each treatment session. (Colorado, 2006) Injured workers with complicating factors may need more treatment, if documented by the treating physician. In this case, the patient has undergone chiropractic treatment, but there is no good documentation of functional improvement or decreased need for pain medication. Therefore, based on ODG guidelines, the request for chiro times 8 is not medically necessary.

Flurbiprofen/ Capsaicin/ Menthol transdermal cream 1-2 grams 1-2 times daily: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic): Capsaicin, topical (chili pepper/cayenne pepper).

Decision rationale: Based on ODG guidelines, topical capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. Formulations: Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for post-herpetic 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 that this increase over a 0.025% formulation would provide any further efficacy. 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. The number needed to treat in musculoskeletal conditions was 8.1. The number needed to treat for neuropathic conditions was 5.7. (Robbins, 2000) (Keitel, 2001) (Mason-BMJ, 2004) The results from this RCT support the beneficial effects of 0.025% capsaicin cream as a first-line therapy for OA pain. (Altman, 1994) Mechanism of action: Capsaicin, which is derived from chili peppers, causes vasodilation, itching, and burning when applied to the skin. These actions are attributed to binding with nociceptors, which causes a period of enhanced sensitivity followed by a refractory period of reduced sensitivity. Topical capsaicin is superior to placebo in relieving chronic neuropathic and musculoskeletal pain. Capsaicin produces highly selective regional

anesthesia by causing degeneration of capsaicin-sensitive nociceptive nerve endings, which can produce significant and long lasting increases in nociceptive thresholds. (Maroon, 2006) Adverse reactions: Local adverse reactions were common (one out of three patients) but seldom serious (burning, stinging, erythema). Coughing has also been reported. Topical OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns, a new alert from the FDA warns. Based on ODG guidelines, capsaicin is used first line for osteo-arthritis, and a higher concentration for post-herpetic neuralgia, diabetic neuropathy or post-matectomy pain. In this case, the patient does not have any of the above indications for treatment with capsaicin. Since one ingredient is not medically necessary in this compound, then the request for flurbiprofen/capsaicin/menthol transdermal cream 1-2 grams 1-2 times daily is not medically necessary.