

<b>Case Number:</b>	CM15-0185436		
<b>Date Assigned:</b>	09/25/2015	<b>Date of Injury:</b>	07/20/2015
<b>Decision Date:</b>	11/13/2015	<b>UR Denial Date:</b>	08/21/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/21/2015

### 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: Physical Medicine & Rehabilitation, Pain Management

### 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 32 year old male, who sustained an industrial injury on 7-20-2015. He presented to the Emergency Department after a fall off a ladder and was diagnosed with facial laceration, nasal laceration, contusion, lower lip, lower leg, and laceration of right lower leg. X-rays and CT scans documented no fractures. Diagnoses include headache, cervical muscle spasm, cervical sprain-strain, lumbar muscle spasm, and lumbar sprain-strain. Treatments to date included activity modification. Currently, he complained of neck and low back pain with radiation to the shoulders and bilateral lower extremities. Pain was rated 8 out of 10 VAS. On 8-4-15, the physical examination documented cervical tenderness, muscle spasm and decreased range of motion. The lumbar spine muscles were tender with spasm and decreased range of motion. The plan of care included initiation of physical therapy, a prescription for Norco 5-325mg and topical compound creams. The appeal requested authorization for HMPHCC2 (Flurbiprofen 20%, Baclofen 5%, Camphor 2%, Menthol 2%, Dexamethasone 0.2%, Capsaicin 0.025%, Hyaluronic acid 0.2% in cream base) and HNPC1 (Amitriptyline HCL 10%, Bupivacaine HCL 5%, Hyaluronic acid 0.2% in cream base 240 grams), Norco 5-325mg #60, one functional capacity evaluation, unknown sessions of extracorporeal shockwave therapy, unknown trigger point impedance imaging, and unknown session of localized intense neurostimulation therapy. The Utilization Review dated 8-21-15, denied this request.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Compound medication: HMPHCC2 - Flurbiprofen 20%, Baclofen 5%, Camphor 2%, Menthol 2%, Dexamethasone micro 0.2%, Capsacin 0.025%, Hyaluronic acid 0.2% in cream base: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

**Decision rationale:** Regarding this request, one of the components requested is topical Baclofen. Chronic Pain Medical Treatment Guidelines 8 C.C.R. 9792.20 - 9792.26 MTUS (Effective July 18, 2009) Page 113 of 127 states the following: "Topical 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." Given these guidelines, the topical Baclofen is not medically necessary. Since any formulation must have all components as recommended in order for the formulation to be medically necessary, this request is not medically necessary.

**Compound medication: HNPC1 - Amitriptyline HCL 10%, Gabapentin 10%, Bupivacaine HCL 5%, Hyaluronic acid 0.2%, Hyaluronic acid 0.2% in cream base 240gm: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

**Decision rationale:** Regarding this request, one of the components requested is topical Baclofen. Chronic Pain Medical Treatment Guidelines 8 C.C.R. 9792.20 - 9792.26 MTUS (Effective July 18, 2009) Page 113 of 127 state the following: "Topical 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." Given these guidelines, the topical Baclofen is not medically necessary. Since any formulation must have all components as recommended in order for the formulation to be medically necessary, this request is not medically necessary.

**Norco 5/325mg, #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Neck and Upper Back Complaints 2004, and Low Back Complaints 2004.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use, Opioids for chronic pain.

**Decision rationale:** With regard to this request, the California Chronic Pain Medical Treatment Guidelines state the following about on-going management with opioids: "Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the '4 A's' (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs." Guidelines further recommend discontinuing opioids if there is no documentation of improvement in function and reduction in pain. In the progress reports available for review, the requesting provider did not adequately document monitoring of the four domains. Improvement in function was not clearly outlined. The MTUS defines this as a clinical significant improvement in activities of daily living or a reduction in work restrictions. Furthermore, monitoring for aberrant behaviors such as urine toxicology testing or checking the CURES database is not noted. Given this, the medical necessity of this request cannot be established at this time. Although this opioid is not medically necessary at this time, it should not be abruptly halted, and the requesting provider should start a weaning schedule as he or she sees fit or supply the requisite monitoring documentation to continue this medication.

**Functional capacity evaluation:** 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), Fitness for Duty: Functional Capacity Evaluation.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Fitness for Duty Chapter, Functional Capacity Evaluation and Other Medical Treatment Guidelines ACOEM, Chapter 7, p. 137-138.

**Decision rationale:** With regard to the request for a functional capacity evaluation, the CA MTUS does not specifically address functional capacity evaluations. Other well-established guidelines include ACOEM and ODG. ACOEM Chapter 7 Functional Capacity Evaluation states on pages 137-138: "The employer or claim administrator may request functional ability evaluations, also known as Functional Capacity Evaluations, to further assess current work capability. These assessments also may be ordered by the treating or evaluating physician, if the physician feels the information from such testing is crucial. Though Functional Capacity Evaluations (FCEs) are widely used and promoted, it is important for physicians and others to understand the limitations and pitfalls of these evaluations." The Official Disability Guidelines specify the following "Guidelines for performing an FCE: If a worker is actively participating in determining the suitability of a particular job, the FCE is more likely to be successful. A FCE is not as effective when the referral is less collaborative and more directive. It is important to provide as much detail as possible about the potential job to the assessor. Job specific FCEs are more helpful than general assessments. The report should be accessible to all the return to work participants. Consider an FCE if1. Complex issues such as hamper case management:

Prior unsuccessful RTW attempts. Conflicting medical reporting on precautions and/or fitness for modified job. Injuries that require detailed exploration of a worker's abilities. 2. Timing is appropriate: Close or at MMI/all key medical reports secured. Additional/secondary conditions clarified. Do not proceed with an FCE if: The sole purpose is to determine a worker's effort or compliance. The worker has returned to work and an ergonomic assessment has not been arranged. (WSIB, 2003)" It is important to note in this case that both the ACOEM and ODG are equivalent in the strength of evidence hierarchy as specify by statute. The ACOEM clearly has less stringent guidelines and allows for a functional capacity evaluation when a requesting provider feels that this testing is crucial despite the potential pitfalls of such an evaluation. In the case of this injured worker, there is no documentation that the worker is felt to be close to the point of maximal medical improvement. There is also no documented failed return to work attempts. The worker has been documented to be on TTD since the injury, but no indication is given of trialing a return to work with or without modifications and failing such an attempt. Given this documentation, this request for FCE is not medically necessary.

**Unknown sessions of extracorporeal shockwave therapy: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Low Back - Lumbar and Thoracic: Shock wave therapy; ODG, Neck and Upper Back : Extracorporeal shock wave therapy (ESWT).

**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 Chapter, Shock wave therapy and Other Medical Treatment Guidelines Anthem Medical Policy # **SURG.00045** Extracorporeal Shock Wave Therapy for Orthopedic Conditions.

**Decision rationale:** Regarding the request for ESWT for the lumbar spine, the California MTUS does not address the issue. The Official Disability Guidelines specifically do not recommend shockwave therapy for the lumbar spine as the available evidence does not support its effectiveness in treating low back pain. The direct excerpt from the Official Disability Guidelines (ODG) Low Back Chapter, Shock wave therapy is as follows: "Not recommended. The available evidence does not support the effectiveness of ultrasound or shock wave for treating LBP. In the absence of such evidence, the clinical use of these forms of treatment is not justified and should be discouraged. (Seco, 2011)" Given this direct non-recommendation by guidelines, the currently requested ESWT for lumbar spine is not medically necessary. Furthermore, although the cervical spine chapter of the ODG does not address shockwave therapy, a national insurance carrier policy is cited with regard to this body region. The policy of Anthem Blue Cross states "Use of Extracorporeal Shock Wave Therapy (ESWT), including but not limited to the use of Extracorporeal Pulse Activation Therapy (EPAT) for the treatment of musculoskeletal conditions is considered investigational and not medically necessary." Given these guidelines, this request is not medically necessary.

**Unknown trigger point impedance imaging: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Low Back - Lumbar and Thoracic: Trigger point impedance imaging (hyper stimulation analgesia).

**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 Chapter, Trigger point impedance imaging and Hyperstimulation analgesia Entries.

**Decision rationale:** Regarding the request for trigger point impedance imaging, California MTUS and ACOEM do not address the issue. The ODG Low Back Chapter states the following regarding trigger point impedance imaging: "Not recommended. See Hyperstimulation analgesia. The Nervomatrix device combines trigger point impedance imaging with hyperstimulation analgesia. (Gorenberg, 2013)" It should be noted that current definition indicate that trigger points are diagnosed clinically based upon palpation per the CPMTG and advanced imaging techniques for trigger point identification is experimental and unsupported by guidelines. Given this, the currently requested trigger point impedance imaging is not medically necessary.

**Unknown sessions of localized intense neurostimulation therapy:** Upheld

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

**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 Chapter, Localized high-intensity neurostimulation.

**Decision rationale:** Regarding the request for Localized Intense Neurostimulation Therapy (LINT), the California MTUS guidelines do not directly address this request. The ODG Low Back Chapter does address LINT, and states it is a form of hyperstimulation analgesia. With regard to the latter, the following citation is noted: "Not recommended until there are higher quality studies. Initial results are promising, but only from two low quality studies sponsored by the manufacturer. Localized manual high-intensity neurostimulation devices are applied to small surface areas to stimulate peripheral nerve endings (A d fibers), thus causing the release of endogenous endorphins. This procedure, usually described as hyperstimulation analgesia, has been investigated in several controlled studies. However, such treatments are time consuming and cumbersome, and require previous knowledge of the localization of peripheral nerve endings responsible for LBP or manual impedance mapping of the back, and these limitations prevent their extensive utilization." Given the paucity of evidence to support this experimental technique, the currently requested LINT is not medically necessary.