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: New York
Certification(s)/Specialty: Anesthesiology

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 49 year old male, who sustained an industrial injury on 8-29-2006. The injured worker is undergoing treatment for: lumbar disc protrusion, lumbar muscle spasm, lumbar radiculopathy, lumbar sprain and strain, lumbar stenosis, insomnia, anxiety and depression. On 8-11-15, he reported low back pain with radiation into the bilateral lower extremities rated 4 out of 10 with medications and 3 out of 10 without medications. On 9-29-15, he reported low back pain rated 4 out of 10 without medications, 3 out of 10 with medications. He indicated pain radiation, tingling, and numbness to the bilateral lower extremities. Objective findings revealed tenderness, and myospasm to the low back. There is no discussion of efficacy of the prescribed medications, adverse side effects, aberrant behaviors or the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. The treatment and diagnostic testing to date has included: medications, magnetic resonance imaging of the lumbar spine (9-2-15) reported to reveal disc protrusion, spinal canal stenosis, facet hypertrophy; multiple sessions of acupuncture. Medications have included: Naprosyn, prilosec, tramadol, cyclobenzaprine. Current work status: off work. The request for authorization is for: 12 physical therapy visits; 2 trigger point injections performed to paralumbar muscles; 60 Prilosec (omeprazole) 20mg; 6 shockwave therapy treatments; 1 ANS test consultation; unknown prescription for Amitriptyline HCL 10 percent-gabapentin 10 percent-bupivacaine HCL 5 percent-hyaluronic acid 0.2 percent in cream base; unknown prescription for Flurbiprofen 20 percent-baclofen 5 percent-camphor 2 percent-menthol 2 percent-dexamethasone micro 0.2 percent-capsaicin 0.025 percent-hyaluronic
Decision rationales: According to the California MTUS Treatment guidelines, physical therapy (PT) is indicated for the treatment of musculoskeletal pain. Active therapy is based on the philosophy that therapeutic exercise and/or activity are beneficial for restoring flexibility, strength, endurance, function, range of motion, and can alleviate discomfort. Patients are instructed and expected to continue active therapies at home as an extension of the treatment process in order to maintain improvement levels. Per ODG, patients should be formally assessed after a "6-visit trial" to see progress made by patient. When the duration and/or number of visits have exceeded the guidelines, exceptional factors should be documented. Additional treatment would be assessed based on functional improvement and appropriate goals for additional treatment. There is no specific indication for the 12 PT sessions requested, which exceed the MTUS and ODG guidelines. Medical necessity for the requested 12 PT visits has not been established. The requested physical therapy sessions are not medically necessary.

2 Trigger point injections performed to paralumbar muscles: Upheld

Decision rationales: According to California MTUS Guidelines, trigger point injections with a local anesthetic may be recommended for the treatment of chronic low back or neck pain with myofascial pain syndrome when all of the following criteria are met: 1) Documentation of
circumscribed trigger points with evidence upon palpation of a twitch response as well as referred pain; 2) Symptoms have persisted for more than three months; 3) Medical management therapies such as ongoing stretching exercises, physical therapy, NSAIDs and muscle relaxants have failed to control pain; 4) Radiculopathy is not present on exam; 5) Not more than 3-4 injections per session; 6) No repeat injections unless greater than 50% pain relief is obtained for six weeks after an injection and there is documented evidence of functional improvement; 7) Frequency should be at an interval less than 2 months; 8) Trigger point injections with any substance other than local anesthetic with or without steroid are not recommended. In this case, there is documentation of radiculopathy on physical exam. According to the above criteria, trigger point injections are recommended for myofascial pain syndrome in the absence of radiculopathy. Medical necessity for the requested injections has not been established. The requested trigger point injections are not medically necessary.

60 Prilosec (Omeprazole) 20mg (dispensed 08/11/2015): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) PPIs.

Decision rationale: According to CA MTUS (2009), proton pump inhibitors (PPIs), such as Omeprazole (Prilosec), are recommended for patients taking NSAIDs with documented GI distress symptoms or specific GI risk factors. There is no documentation indicating the patient has any GI symptoms or GI risk factors. Risk factors include, age >65, history of peptic ulcer disease, GI bleeding, concurrent use of aspirin, corticosteroids, and/or anticoagulants or high-dose/multiple NSAIDs. There was no documentation of any reported GI complaints. Based on the available information provided for review, the medical necessity for Prilosec was not established. The requested medication was not medically necessary.

6 Shockwave therapy treatments: 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), Low Back-Lumbar and Thoracic (Acute and Chronic): Shockwave therapy.

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

Decision rationale: Extracorporeal shock wave therapy (ESWT) is a noninvasive treatment proposed to treat refractory tendonopathies such as, plantar fasciitis. It has also been introduced as an alternative to surgery for patients that have not responded to other conservative therapies. ESWT is a noninvasive treatment that involves delivery of low or high-energy shock waves via a device to a specific site within the body. These pressure waves travel through fluid and soft tissue; their effects occur at sites where there is a change in impedance, such as the bone/soft
tissue interface. Low-energy shock wave treatments are generally given in one session and usually require some type of anesthesia. The documentation indicates the claimant has chronic low back pain. There is no indication for the use of ESWT for the treatment of chronic low back pain. Medical necessity for the requested procedure has not been established. The requested service is not medically necessary.

**1 ANS test consultation:** 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), Pain (Chronic): Autonomic nervous system function testing.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Autonomic nervous system (ANS) function testing.

**Decision rationale:** According to the ODG, autonomic nervous system (ANS) function testing is not generally recommended as a diagnostic test for chronic regional pain syndrome (CRPS). Based on the information provided, medical necessity for ANS testing has not been established. The requested test consultation is not medically necessary.

**Unknown prescription for Amitriptyline HCL 10%-Gabapentin 10%-Bupivacaine HCL 5%-Hyaluronic Acid 0.2% in cream base:** Upheld

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

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

**Decision rationale:** According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. In this case, the topical analgesic compound contains: Amitriptyline HCL 10%, Gabapentin 10%, Bupivacaine HCL 5%, Hyaluronic Acid 0.2%. Gabapentin is not recommended as a topical agent per CA MTUS Guidelines. There is no peer-reviewed literature to support its use. Medical necessity for the requested topical medication has not been established. The requested topical analgesic compound is not medically necessary.
Unknown prescription for Flurbiprofen 20%-Baclofen 5%-Camphor 2%-Menthol 2%-Dexamethasone micro 0.2%-Capsaicin 0.025%-Hyaluronic Acid 0.2% in cream base:

Upheld

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

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

**Decision rationale:** According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. In this case, the topical analgesic compound contains: Flurbiprofen 20%, Baclofen 5%, Camphor 2%, Menthol 2%, Dexamethasone micro 0.2%, Capsaicin 0.025%, and Hyaluronic Acid 0.2%. There are no clinical studies to support the safety or effectiveness of Flurbiprofen in a topical delivery system (excluding ophthalmic). Baclofen is not recommended. There is no peer-reviewed literature to support the use of topical Baclofen. Capsaicin is recommended only as an option in patients who have not responded to or are intolerant to other treatments. Medical necessity for the requested topical analgesic cream has not been established. The request for the topical analgesic is not medically necessary.

**1 NIOSH:** 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 Medscape Internal Medicine.

**Decision rationale:** The National Institute for Occupational Safety and Health (NIOSH) is the U.S. federal agency responsible for conducting research and making recommendations for the prevention of work-related injury and illness. NIOSH is part of the Centers for Disease Control and Prevention (CDC) within the U.S. Department of Health and Human Services. The CA MTUS and the ODG failed to reveal any guideline recommendations for NIOSH testing as a separate service outside of a normal evaluation and management visit. Based on the information provided, medical necessity for NIOSH testing has not been established. The requested NIOSH testing is not medically necessary.
1 TPII: 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), Low back-Lumbar and Thoracic (Acute and Chronic), Trigger point impedance imaging.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Trigger point impedance imaging (TPII).

Decision rationale: According to the ODG, trigger point impedance imaging (TPII) is not recommended in the treatment of chronic low back pain. Medical necessity for the requested TPII has not been established for this case. The requested TPII is not medically necessary.

1 LINT: 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), Low Back-Lumbar and Thoracic (Acute and Chronic): Hyperstimulation analgesia.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Localized Intense Neuro-stimulation Therapy (LINT).

Decision rationale: According to the ODG, Localized Intense Neuro-stimulation Therapy (LINT) or hyper-stimulation analgesia, is not recommended until there are higher quality studies. Localized manual high-intensity neuro-stimulation devices are applied to small surface areas to stimulate peripheral nerve endings (A fibers), thus causing the release of endogenous endorphins. This procedure, usually described as hyper-stimulation analgesia, has been investigated in several controlled studies. One of the oldest methods of pain relief is generalized hyper- stimulation analgesia produced by stimulating myofascial trigger points by dry needling, acupuncture, intense cold, intense heat, or chemical irritation of the skin. The moderate-to-intense sensory input of hyper-stimulation analgesia is applied to sites over, or sometimes distant from, the pain. Medical necessity for the requested treatment has not been established in this case. The request for this treatment is not medically necessary.