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: Preventive Medicine, Occupational 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 68 year old female, who sustained an industrial injury on February 23, 2015. The injured worker was diagnosed as having cervical musculoligamentous sprain and strain with radiculitis, rule out cervical spine discogenic disease, thoracic musculoligamentous strain and sprain, lumbosacral musculoligamentous strain and sprain with radiculitis, and rule out lumbosacral spine discogenic disease. Treatment and diagnostic studies to date has included physical therapy, medication regimen, x-ray of the lumbar spine, and magnetic resonance imaging of the cervical spine. In a Doctor's First Report dated July 29, 2015 the treating physician reports complaints of pain to the neck and back. Examination performed on July 29, 2015 was revealing for tenderness to the cervical spine; spasms to the bilateral paraspinous muscles, the occipital muscles, the suboccipital muscles, the bilateral trapezius muscles, and the levator scapulae muscles; decreased range of motion; positive compression testing; tenderness to the thoracic spine; spasm and trigger points to the bilateral upper, mid, and lower thoracic regions; lumbar spine tenderness to the bilateral paraspinous muscles, tenderness to the sacroiliac joint, the sciatic notch, the posterior iliac crests, and the gluteal muscles; positive straight leg raise; decreased motor strength to the right upper extremity; and decreased sensation to the right anterolateral thigh, anterior knee, medial leg, and foot. The July 29, 2015 report did not contain the injured worker's current medication regimen and did not indicate the injured worker's pain level as rated on pain scale prior to the use of her medication regimen and after the use of her medication regimen to evaluate the effects of the injured worker's medication regimen. The physical therapy progress note from April 10, 2015 noted the medication of Naproxen (since at
least February 25, 2015). The Doctor’s First Report dated July 29, 2015 noted prior physical therapy "for 5 to 6 weeks". The medical records provided included at least 6 prior sessions of physical therapy performed. The physical therapy progress note from April 10, 2015 noted a pain level of 7 out of 10, with the treating therapist reporting "slower than expected progress" and exercise completion with "minimal" pain. The medical records included x-rays to the lumbar spine performed on July 30, 2015 that was revealing for exaggeration of the lumbar lordosis, osteopenia, discogenic spondylosis at thoracic twelve to lumbar one through lumbar five to sacral one, apophyseal joint arthrosis at lumbar five to sacral one and the x-rays of the cervical spine performed on July 30, 2015 was revealing for osteopenia, discogenic spondylosis to the cervical five to six, uncovertebral joint degenerative changes to cervical three to four through cervical six to seven, apophyseal joint arthrosis at cervical five to six and cervical six to seven, and soft tissue calcification lateral to the cervical four. On July 29, 2015 the treating physician requested transcutaneous electrical nerve stimulation unit, magnetic resonance imaging of the lumbosacral spine, lumbosacral brace, Theramine for a quantity 90 for 1 bottle, Tramadol 50mg with a quantity of 50, Gabacyclotram (gabapentin 10%, Cyclobenzaprine 5%, Tramadol 10%) at 180gms, Flurbi (NAP) cream-LA (Flurbiprofen 20%, Lidocaine 5%, Amitriptyline 5%) 180 grams, and physical therapy for the cervical and lumbar spine two times a week for four weeks, but the documentation provided did not indicate the specific reason or the requested treatments. The treating physician also requested a functional capacity examination to assess that the injured worker can safely meet the physical demands of her job. On August 20, 2015, the Utilization Review determined the request for physical therapy for the cervical and lumbar spine two times a week for four weeks to be modified. On August 20, 2015 the Utilization Review determined the requests for functional capacity evaluation, transcutaneous electrical nerve stimulation unit, magnetic resonance imaging of the lumbosacral spine, lumbosacral brace, Theramine for a quantity 90 for 1 bottle, Tramadol 50mg with a quantity of 50, Gabacyclotram (gabapentin 10%, Cyclobenzaprine 5%, Tramadol 10%) at 180gms, and Flurbi (NAP) cream-LA (Flurbiprofen 20%, Lidocaine 5%, Amitriptyline 5%) 180 grams to be non-certified.

**IMR ISSUES, DECISIONS AND RATIONALES**

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

**Physical Therapy for cervical and lumbar spine 2 times a week for 4 weeks:** 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): Manual therapy & manipulation.

**Decision rationale:** The MTUS Chronic Pain Medical Treatment Guidelines state that 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. Continued physical therapy is predicated upon demonstration of a functional improvement. The original reviewer modified the request to 2 sessions to provide opportunity to demonstrate functional improvement. Physical Therapy for cervical and lumbar spine 2 times a week for 4 weeks is not medically necessary.
FCE: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

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, Functional capacity evaluation (FCE).

Decision rationale: The Official Disability Guidelines state that a functional capacity evaluation is appropriate if, case management is hampered by complex issues, and the timing is appropriate; such as if the patient is close to being at maximum medical improvement or additional clarification concerning the patient's functional capacity is needed. Functional capacity evaluations are not needed if the sole purpose is to determine a worker's effort or compliance, or the worker has returned to work. There is no documentation in the medical record to support a functional capacity evaluation based on the above criteria. FCE is not medically necessary.

TENS Unit: Overturned

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): Transcutaneous electrotherapy.

Decision rationale: The MTUS does not recommend a TENS unit as a primary treatment modality, but a one-month home-based TENS trial may be considered as a noninvasive conservative option, if used as an adjunct to a program of evidence-based functional restoration. There is documentation that the patient meets the criteria necessary for TENS unit purchase following a successful one-month trial of a rental TENS unit. I am reversing the previous utilization review decision. TENS Unit is medically necessary.

MRI of the lumbosacral spine: Upheld

Claims Administrator guideline: Decision based on MTUS Low Back Complaints 2004.

MAXIMUS guideline: Decision based on MTUS Low Back Complaints 2004, Section(s): Special Studies.

Decision rationale: The MTUS states that unequivocal objective findings that identify specific nerve compromise on the neurologic examination are sufficient evidence to warrant imaging in patients who do not respond to treatment and who would consider surgery an option. When the neurologic examination is less clear, however, further physiologic evidence of nerve dysfunction should be obtained before ordering an imaging study. Indiscriminant imaging will result in false-positive findings, such as disk bulges, that are not the source of painful symptoms and do not
warrant surgery. The medical record fails to document sufficient findings indicative of nerve root compromise, which would warrant an MRI of the lumbar spine. MRI of the lumbosacral spine is not medically necessary.

**Lumbosacral brace:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Low Back Complaints 2004.

**MAXIMUS guideline:** Decision based on MTUS Low Back Complaints 2004, Section(s): Activity.

**Decision rationale:** According to the MTUS, lumbar supports have not been shown to have any lasting benefit beyond the acute phase of symptom relief. Based on the patient's stated date of injury, the acute phase of the injury has passed. At present, based on the records provided, and the evidence-based guideline review, the request is non-certified. Lumbosacral brace is not medically necessary.

**Theramine #90 1 bottle:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

**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), Medical food.

**Decision rationale:** Theramine is a Food and Drug Administration regulated medical food designed to address the increased nutritional requirements associated with chronic pain syndromes and low back pain. Theramine is thought to promote the production of the neurotransmitters that help manage and improve the sensory response to pain and inflammation. Medical food is defined in section 5(b) of the Orphan Drug Act (21 U.S.c.360ee (b) (3)) as a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. Medical foods do not have to be registered with the FDA and as such are not typically subject to the rigorous scrutiny necessary to allow recommendation by evidence-based guidelines. Theramine #90 1 bottle is not medically necessary.

**Tramadol 50mg #50:** 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): Opioids for chronic pain.
**Decision rationale:** The Chronic Pain Medical Treatment Guidelines state that continued or long-term use of opioids should be based on documented pain relief and functional improvement or improved quality of life. Tramadol is a centrally acting synthetic opioid analgesic and it is not recommended as a first-line oral analgesic. Despite the long-term use of Tramadol, the patient has reported very little, if any, functional improvement or pain relief over the course of the last 6 months. Tramadol 50mg #50 is not medically necessary.

**Gabacyclotram (gabapentin 10%, Cyclobenzaprine 5%, Tramadol 10%, 180gms:** 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:** According to the MTUS, there is little to no research to support the use of many of these compounded topical analgesics. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Gabapentin is not recommended. There is no peer-reviewed literature to support use. Gabacyclotram (gabapentin 10%, Cyclobenzaprine 5%, Tramadol 10%, 180gms is not medically necessary.

**Flurbi (NAP) cream-LA (flurbiprofen 20%, Lidocaine 5%, Amitriptyline 5%) 180 grams:** 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): Opioids for chronic pain.

**Decision rationale:** According to the MTUS, there is little to no research to support the use of many of these Compounded Topical Analgesics. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Flurbiprofen topical is not supported by the MTUS. Flurbi (NAP) cream-LA (flurbiprofen 20%, Lidocaine 5%, Amitriptyline 5%) 180 grams is not medically necessary.