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. The expert reviewer is Board Certified in Anesthesiology, Pain Medicine and is licensed to practice in Florida. 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/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:

The injured worker is a 56-year-old male who reported an injury on 10/31/2005 due to an unknown mechanism. Diagnoses were mononeuritis of unspecified site, contracted joint, xerosis, ulcer toes, methicillin resistant staphylococcus aureus, chemical reaction, cellulitis foot, hammer toe, unspecified peripheral vascular disease, AC venous embolism and thrombosis unspecified deep veins lower extremity, tinea pedis, capsulitis, hypertrophy of fat pad knee, pain in soft tissues of limb, and unequal leg length. Past treatments reported were physical therapy, cortisone injections, foot toe strappings and orthotics. Diagnostic studies were an MRI of the right foot on 01/11/2012 which revealed a neuroma capsulitis. Surgical history was on the right foot for tendonotomy and capsulotomy for the toes 3 and 4, and nerve decompression. Physical examination on 07/24/2014 revealed complaints of still having pain in the left forefoot and some edema. Examination of the lower extremities revealed varicosities were not observed. Dorsalis pedis pulses palpable bilaterally. Posterior tibial pulses were palpable bilaterally. Erythema was absent. No edema was present bilaterally. Capillary fill time was 3 bilaterally. Muscle strength was normal. Neurological exam revealed normal sensation to vibratory perception, tactile sensation light touch. Dry integument and tinea lesions present, but greatly improved overall. Neuritis fourth IDS left with some joint contracture fourth in the DF. Pain was now isolated to the plantar branch only, medial fourth, edema and splaying resolving. Medications were Zocor, Prednisone, Celebrex, Omeprazole, Naftin 1% topical gel, Coumadin, Clindamycin 300 mg, and Flector 1.3% transdermal patch. The treatment plan was to continue medications as directed and request alcohol sclerosing injections, manual manipulation, and foot strapping for offloading. The rationale for the Flector patches was that the injured worker continued to receive relief from the use of this topical. The use of a topical could decrease gastrointestinal risk and systemic risk to the injured worker. The injured worker complained of hammer toe and capsulitis, which were
on label uses for the use of complaints. The rationale for the alcohol sclerosing injections was that the injured worker presented with a recurrent neuroma and has partially failed surgery, and high surgery risk, with a history of pulmonary embolism and deep vein thrombosis. Finding an alternative to surgery would make sense, provided the injured worker has higher than average risk. Alcohol injections are part of the standard of care in the community for neuroma/stump neuromas. The rationale for the strappings was this is inflammation that can cause considerable discomfort and, if left untreated, can eventually lead to a weakening of surrounded ligaments that can cause dislocation of the toe. Capsulitis, also referred to as predislocation syndrome, is a common condition that can occur at any age. The request for authorization was submitted for review.

**IMR ISSUES, DECISIONS AND RATIONALES**

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

**Flector Patches, 1box:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS, NON-STEROIDAL ANTIINFLAMMATORY AGENTS Page(s): 111-112.

**Decision rationale:** The request for Flector patches, 1 box is not medically necessary. The California Medical Treatment Utilization Schedule states that nonsteroidal anti-inflammatory agents (NSAIDs) are still undergoing clinical trials. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2 week period. When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. These medications may be useful for chronic musculoskeletal pain, but there are no long term studies of their effectiveness or safety. Indications for the use of topical NSAIDs is for osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment. For neuropathic pain it is not recommended, as there is no evidence to support use. Voltaren gel 1% (diclofenac) is indicated for the relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for the treatment of the spine, hip or shoulder. Maximum dose should not exceed 32 g per day. The request submitted is for Flector patches, 1 box. The medical guidelines support the Voltaren gel 1%. Also, the frequency for the medication was not indicated for the request. Therefore, the request is not medically necessary.

**Alcohol Sclerosing Injections, Left Foot Morton's Neuroma, x6 Injections:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 14 Ankle and Foot Complaints. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Ankle & Foot chapter, Morton's Neuroma treatment.
MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 14 Ankle and Foot Complaints Page(s): 369-371. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Ankle and Foot, Alcohol Injections (for Morton's Neuroma).

Decision rationale: The request for alcohol sclerosing injections, left foot Morton's neuroma, times 6 injections is not medically necessary. The California ACOEM guidelines state that invasive techniques (e.g., needle acupuncture and injection procedures) have no proven value, with the exception of corticosteroid injection into the affected web space in patients with Morton's neuroma, or into the affected area in patients with plantar fasciitis or heel spurs if 4 to 6 weeks of conservative therapy is ineffective. The Official Disability Guidelines state for alcohol injections (for Morton's neuroma) are recommended as an option, as indicated below. Morton's neuroma is a common cause of metatarsalgia. No single treatment has been identified in the literature. Stepped care is recommended (patient education in footwear or insole changes, followed by alcohol injections and, finally, surgery) ultrasound guided alcohol ablation for the treatment of Morton's neuroma has been a safe procedure that significantly reduces pain, and may offer an alternative therapy to surgery. However, injecting sclerosing alcohol depends on the provider's access to, and comfort with, ultrasound. Alcohol injection of Morton's neuroma has a high success rated, and is well tolerated. Criteria for alcohol injections for Morton's neuroma are 6 months of conservative therapies that have been attempted and have been documented as having failed, a change in shoe types that are reported to result in neuroma like symptoms, change or limitation in activities that are reported to result in neuroma like symptoms. Also, the use of metatarsal pads, (placed proximal through the metatarsal heads) to reduce pressure on the nerve by spreading the metatarsals. Injections are expected to be performed according to the following protocol by using ultrasonic imaging guidance (depends on the provider's access to, and comfort with, ultrasound). If there is clinically significant positive response, symptoms reduced, reported and documented after 2 injections, up to 3 additional (or less if the patient reports elimination of neuroma symptoms) at 14 day intervals. If, however, 2 consecutive injections fail to achieve continued and clinically significant symptoms improve, subsequent injections would not be necessary. This request does not state that ultrasonic imaging guidance is going to be used. Due to the criteria set forth by the medical guidelines, this request is not medically necessary.

Manual Manipulations, Toes 3 and 4 left foot, x6: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Manual therapy & manipulation.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines MANUAL THERAPY AND MANIPULATION Page(s): 58.

Decision rationale: The request for manual manipulations, toes 3 and 4 left foot, times 6 is not medically necessary. The California Medical Treatment Utilization Schedule states manual therapy and manipulation is recommended for chronic pain if caused by musculoskeletal conditions. Manual therapy is widely used in the treatment of musculoskeletal pain. The intended goal of effective manual medicine is the achievement of positive symptomatic or
objective measurable gains in functional improvement that facilitate progression in the patient's therapeutic exercise program and return to productive activities. Recommendations for the ankle and foot are not recommended. Due to the recommendations of the medical guidelines, this request is medically not necessary.

Foot Strapping for Offloading, x6: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 14 Ankle and Foot Complaints. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Return to Work Pathways.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 14 Ankle and Foot Complaints Page(s): 371-371. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Ankle and Foot, Orthotic Devices.

Decision rationale: The request for foot strapping for offloading, times 6 are not medically necessary. The California ACOEM recommends activities and postures that increase stress on structurally damaged ankle or foot tend to aggravate symptoms. Correct undesirable correlated compensatory motions and postures if possible. Weight bearing may be limited during the first few weeks, with gradual return to full weight bearing. Weight bearing with orthotics often returns function to normal very quickly. The Official Disability Guidelines state orthotic devices are recommended for plantar fasciitis, and for foot pain and rheumatoid arthritis. Both prefabricated and custom orthotic devices are recommended for plantar heel pain (plantar fasciitis, plantar fasciosis, and heel spur syndrome). Orthoses should be cautiously prescribed in treating plantar heel pain for those patients who stand for long periods, stretching exercises and heel pads are associated with better outcomes than custom made orthoses in people who stand for more than 8 hours per day. Foot orthosis produce small short-term benefits in function and may also produce small reductions in pain for people with plantar fasciitis, but they do not have long term beneficial effects compared with sham device. The injured worker does not have a diagnosis of plantar fasciitis or rheumatoid arthritis. Therefore, this request is medically not necessary.