MAXIMUS Federal Services

Case Number:	CM14-0013798		
Date Assigned:	06/11/2014	Date of Injury:	03/12/2002
Decision Date:	10/01/2014	UR Denial Date:	01/27/2014
Priority:	Standard	Application Received:	02/03/2014

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 Family Medicine and is licensed to practice in California. 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:

This 53-year old heavy equipment operator reported injuries to his R foot, ankle and lower leg after a tractor ran over his R lower extremity on 3/12/2002. He had seven fractures of his R foot. Treatment has included surgeries, a rigid orthotic and physical therapy. He has been treated with Vicodin 5/500, which he has taken up to three times per day for years without escalation. He smokes one pack of cigarettes per day and uses medical marijuana. He remains at regular work. He was referred by his primary treater, who is a pain specialist, to a podiatrist. The podiatrist first saw the patient on 1/6/14. The report from that date states that the patient has chronic foot pain. (The pain level is not noted.) The physical exam was normal except for midfoot tenderness and limited range of motion of the subtalar joint and midfoot. Xrays showed degenerative changes of the hindfoot joints. Diagnoses included chronic pain syndrome, post-traumatic hindfoot arthritis, and R foot pain. A topical compounded cream was prescribed. Future treatment options were discussed, including a softer arch support, cortisone injections and surgery. Follow up was to be on an as-needed basis. A request for authorization of the topical cream was made on 1/24/14. It was non-certified in UR on 1/27/14. A request for IMR of the decision was generated on 1/30/14.

IMR ISSUES, DECISIONS AND RATIONALES

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

PRESCRIPTION OF TOPICAL COMPOUNDED DICLOFENAC 3%, BACLOFEN 2%, BUPIVACAINE 1%, GABAPENTIN 6%, PENTOXIFYLINE 3%, IBUPROFEN 3%, 120GM WITH 1 REFILL: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain; Topical analgesics Page(s): 60, 111-113.

Decision rationale: The first MTUS reference cited above states that medications should be started individually while other treatments are held constant, with careful assessment of function. There should be functional improvement with each medication in order to continue it. The second MTUS guideline states that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical NSAIDS: may be recommended, but only for short-term use (4-12 weeks) for osteoarthritis of the knee, elbow and other joints, excluding osteoarthritis of the spine, hip or shoulder. They are not recommended for neuropathic pain, as there is no evidence to support their use. Topical diclofenac is indicated for 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 arthritis of the spine, hip or shoulder. No more that 8 grams per day should be used in the upper extremity or 16 grams in the lower extremity. Even topically, it is capable of causing GI, cardiac and renal side effects. Gabapentin is not recommended. There is no peer-reviewed literature to support its use. Baclofen is not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product. The third reference states that many of the compounds seen in Workers' Compensation transactions contain four or more drugs and are often dosed well above the FDA-approved topical product. This is commonly seen with compounds using diclofenac as an ingredient. There is no FDA requirement for stability testing of custom compounds. Therefore it is unknown if the creams, gels or ointments are physically stable in the short or long term. Some random sample testing suggests the possibility that sub-or super potent ingredients are present in compounds. There is no requirement for providing patient information on appropriate use or side effects of compounds. There is no FDA requirement for reporting adverse events related to the use of compounds. This paper also states that there are no peer-reviewed publications at all that address topical pentoxyfilline. The UptoDate reference states that bupivacaine, when used as a local anesthetic, has side effects which include bradycardia, heart block, cardiac arrest, apnea, and seizures. Pentoxyfilline is a blood viscosity reducing agent, also can cause cardiac arrhythmias and seizures. A single topical compounded medication containing diclofenac 3%, baclofen 2%, bupivacaine 1%, gabapentin 6%, pentoxyfilline 3%, ibuprofen 3% was dispensed to this patient. Obviously, this means that 6 medications were started at once. No goals were documented in terms of pain levels or functional improvement for the patient. If they had been, it would be impossible to tell which medication or medications had produced the effect. Likewise if side effects occur, it would be impossible to tell which agent(s) caused them. There is no documentation of how often the patient was told to use the medication and how much of it he was to apply at one time. While topical medications in general have less toxicity than their equivalent oral medications, they cannot be presumed to have none. When multiple medications are combined, as they were in this case, there is the possibility of additive toxicities and of forming superpotent ingredients. There are multiple other issues that make this compounded medication problematic in this patient. He is 53 and a smoker, so is likely to be at risk for cardiac disease. Four of the medications have possible cardiac side effects (bupivacaine, pentoxyfilline, diclofenac and ibuprofen.) The diclofenac concentration in the medication is above FDA-approved levels, which increases its potential for toxicity. Two of the medications can cause seizures (bupivacaine and pentoxyfilline). Diclofenac and ibuprofen can both cause GI side effects such as gastritis. Topical Baclofen and Gabapentin are not

indicated per the second MTUS guideline above. Additionally, topical ibuprofen and pentoxyfilline are not FDA-approved, and are therefore experimental and cannot be presumed as safe and efficacious. Non-FDA approved medications are not medically necessary. In summation, four of the agents in this topical compound are not medically indicated and several have potential for serious additive side effects. The medication as a whole is therefore not medically indicated. Based on the evidence-based guidelines and references citied above, and the clinical findings in the case topical diclofenac/baclofen/bupivacaine/gabapentin/ pentoxyfilline/ibuprofen is not medically indicated. It is not medically necessary because it was not started in accordance with MTUS guidelines, appropriate goals for its use were not set, it contains four agents that are not indicated according to MTUS guidelines or are not FDA-approved, and because it contains multiple drugs with potentially serious interactions that could be harmful to the patient.