

Case Number:	CM14-0052859		
Date Assigned:	07/07/2014	Date of Injury:	01/05/2007
Decision Date:	08/25/2014	UR Denial Date:	04/17/2014
Priority:	Standard	Application Received:	04/21/2014

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 Internal Medicine, and is licensed to practice in Arizona. 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 is a 50-year-old female, who has a date of injury to her lumbar spine, January 5, 2007, when she unloaded something heavy off of a work truck. She is post lumbar fusion, but has persistent lumbar radiculopathy (electromyography (EMG) confirmed, L5 and S1) with pain primarily in her sacrum and buttocks; right more so than left. She describes her pain as constant, burning, pins and needles, which is worsened with weight bearing activity. Her pain is 9/10 without medicine and 5/10 with medicine. She also has another claim injury (date of injury not mentioned) for her right knee, which has been defined as chondromalacia. She has tried heat, massage, transcutaneous electric nerve stimulation (TENS), physical therapy, water therapy all of which have been helpful, but not to an adequate degree. There have been discussions of a Spinal Cord Stimulator. Her medications include Cymbalta, Topamax, Trazodone, Wellbutrin, and Valium. She has been on and off hydrocodone. He was concerned about its usage in conjunction with her Valium and marijuana. Treating physician did have the patient sign a Pain Management Agreement and did check the DEA website for activity. There is no documentation that this patient has subsequently seen a psychiatrist to address her medications, as suggested the pain management. On April 2, 2014 a physician assistant (PA) decided to start a trial of Zohydro (hydrocodone) 20mg, #60. On a follow up visit, April 30, 2014 the complainant was seen by a different PA who told her that she had been unable to fill the Zohydro. This PA chose not to resend the request for the Zohydro because the Pain physician had documented that he was not interested in providing long-term opiates to this patient.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ultracin 0.025 - 28% #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 California Code of Regulations, 9792.20-9792.26, Topical Analgesics Page(s): 111-112. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: UpToDate, Methyl salicylate and menthol: Drug information. U.S. Food and Drug Administration, Topical Pain Relievers May Cause Burns, posted Sept 13, 2012.

Decision rationale: Ultracin is a compounded topical analgesic that contains methyl salicylate 27%, Capsaicin .025%, Menthol 10%. According to the California MTUS, topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. These are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and need to titrate. Many agents are compounded as mono therapy or in combination for pain control (including non-steroidal anti-inflammatory drugs (NSAIDs), opioids, capsaicin local anesthetics, antidepressants, etc. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required (page 111). Capsaicin .025% can be used in persons with osteoarthritis. It is recommended only as an option in patients who have not responded or are intolerant to other treatments. It can be used in chronic non-specific back pain. The Menthol and Methyl salicylate are not mentioned in the MTUS, or ODG. Update describes the combined duo's usage as providing temporary relief of minor aches and pains of muscle and joints associated with arthritis, bruises, simple backache, sprains, and strains. Update lacks data on its efficacy. The FDA website however, indicated that there had been more than 43 reported cases of burns associated with the use of OTC topical muscle and joint pain relievers containing the active ingredients menthol, methyl salicylate and capsaicin. These cases were uncovered by FDA scientists during safety surveillance of FDA's adverse event reporting database and the medical literature. There is no data discussing the efficacy of Ultracin. In light of the potential concerns related to the menthol and Methyl salicylate and the lack of known efficacy data, Ultracin is deemed not medically necessary.

Zohydro ER 20 mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use Page(s): 76.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments, Opioids, On-Going Management Page(s): 78.

Decision rationale: The California MTUS Guidelines related to on-going treatment of opioids, state that there should be documentation and ongoing review of pain relief, functional status, appropriate use, and side effects. Furthermore, there are 4 A's for ongoing monitoring: 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. Clearly the pain specialist who oversees the physician assistants (PA's) who more recently saw this patient had stated that he did not want to continue the patient's Norco (hydrocodone). It is unclear why the first physician assistant decided to give Zohydro (hydrocodone) prescription 20mg twice/daily when she had previously been on only 5mg twice daily. Then two weeks later a different PA decided not to pursue this. He also recommended she see a psychiatrist to assess her medications. The record does not demonstrate medical necessity of the opiates, therefore Zohydro is deemed not medically necessary.