

<b>Case Number:</b>	CM15-0199229		
<b>Date Assigned:</b>	10/14/2015	<b>Date of Injury:</b>	06/14/2013
<b>Decision Date:</b>	11/24/2015	<b>UR Denial Date:</b>	09/11/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/09/2015

### 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: Montana

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 43 year old male IT support worker with a date of injury on 06-14-2013. The injury to the right hand occurred when attempting to install a ceiling mount. The injured worker is undergoing treatment for right radio scaphoid arthritis. In a physician note dated 08-12-2015 there is documentation of right hand pain. It is around the radial aspect of the right hand, at the base of the thumb. It is made worse with gripping, grasping, lifting, pushing, and pulling more than about 3-5 pounds. On examination the right wrist shows fairly well preserved range of motion. There is pain around the volar and dorsal aspect of the radial aspect of the wrist. Tinel is negative. There is documentation he has not found any benefit from any anti-inflammatories. He has Norco prescribed but only takes it intermittently as well as cyclobenzaprine that he uses for headache related condition. These medications cause sedation and he wishes to avoid the use of them secondary to the side effects. Given his intolerance of oral medications Ketamine is prescribed to see if this can improve his functionality in regard to his right hand. Treatment to date has included diagnostic studies, medications, occupational therapy, acupuncture, use of an H-Wave unit, steroid injections, splints, and he is status post two surgical procedures to the right hand. Current medications include Cyclobenzaprine, Relpax, and Hydrocodone. An unofficial Magnetic Resonance Imaging of the right hand done on 09-19-2013 revealed thickening and intermediate signal of the scapholunate ligament, mild synovitis on the carpal tunnel and fusion of the scaphoid, trapezia and trapezoid, mild radio carpal arthrosis with subchondral cystic changes, and degeneration of the ulnar styloid tip attachment to the triangular fibrocartilage. The request for Authorization dated 08-28-2015 is for Ketamine 5% cream 60

grams. On 09-11-2015 Utilization Review non-certifies the request for Ketamine 5% cream 60 grams. The note from the treating physician on 10-26-15 clarified that his chronic symptoms included neuropathic pain and numbness and all previous treatments had been inadequate.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Ketamine 5% cream 60 grams:** Overturned

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Ketamine.

**Decision rationale:** The MTUS states that topical analgesics are recommended as an option as indicated below. They are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) 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. [Note: Topical analgesics work locally underneath the skin where they are applied. These do not include transdermal analgesics that are systemic agents entering the body through a transdermal means. See Duragesic (fentanyl transdermal system).] Topical ketamine is under study and only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatment has been exhausted. Topical ketamine has only been studied for use in non-controlled studies for CRPS I and post-herpetic neuralgia and both have shown encouraging results. The exact mechanism of action remains undetermined. (Gammaitoni, 2000) (Lynch, 2005) See also Glucosamine (and Chondroitin Sulfate). The ODG guidelines note that ketamine is not recommended. There is insufficient evidence to support the use of ketamine for the treatment of CRPS. Current studies are experimental and there is no consistent recommendation for protocols, including for infusion solutions (in terms of mg/kg/hr), duration of infusion time, when to repeat infusions, how many infusions to recommend, or what kind of outcome would indicate the protocol should be discontinued. The safety of long-term use of the drug has also not been established, with evidence of potential of neurotoxicity. Ketamine-induced liver toxicity is a major risk, occurring up to 50% of the time, and regular measures of liver function are

therefore required during such treatments. (Noppers, 2011) Frequent use can cause long-term memory impairment and altered pre-frontal dopaminergic function. (Morgan, 2012) Ketamine is also known as a drug of abuse. Abuse of ketamine can cause cystitis and a contracted bladder, and secondary renal damage can occur in severe cases which might be irreversible, rendering patients dependent on dialysis. (Chu, 2008) (Morgan, 2012) There is no evidence of a cure of CRPS with subanesthetic infusions. The limited results of current research studies on this topic are inconsistent. An early successful retrospective report of 33 patients documented that 54% of patients experienced greater than 3 months of pain relief, with 31% experiencing greater than 6 months of relief. The authors reported the long-term effects of ketamine infusion were unknown and could include neurotoxicity and hepatic dysfunction. (Correll, 2004) Subsequent non-controlled studies have found less impressive findings (using probability statistics due to lack of long-term follow-up of 41% of patients), predicting a 13% to 31% chance of relief lasting more than three weeks. (Patil, 2011) Another study has shown decreased pain scores but no functional improvement. (Sigtermans, 2009) The overall current recommendation is that larger randomized placebo controlled trials occur, looking at dosing and long-term follow-up. (Schwartzman, 2009) In this case the treating physician, in the note of 10-26-15, clarified that the topical ketamine is prescribed for the chronic neuropathic pain associated with this injury, not radiocarpoid arthritis. This would be acceptable since all other treatments have been exhausted without significant benefit. Careful observation for potential side effects, as noted above, should be documented with use of ketamine. The treating physician is a pain specialist and the use of topical ketamine is on a trial basis. The request for Ketamine 5% cream 60 grams is medically necessary.