

<b>Case Number:</b>	CM14-0015524		
<b>Date Assigned:</b>	02/28/2014	<b>Date of Injury:</b>	09/12/2003
<b>Decision Date:</b>	06/30/2014	<b>UR Denial Date:</b>	01/08/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/06/2014

### 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 Orthopedic Surgery 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:

The injured worker is a 42 year old male who sustained an injury on 09/12/03 when he was sitting on a stool and then fell off. The patient had previous work injury in 1998 due to slip and fall. Prior treatment included extensive amount of chiropractic therapy. The patient was followed for ongoing complaints of chronic low back pain. The patient was referred for recent physical therapy in 2013. The patient was seen on 12/31/13 following an epidural steroid injection which provided 50-60% relief of symptoms. It appeared that the patient recent received H-wave unit. The patient reported less pain with his job duties and more range of motion with the H-wave unit. The patient felt he was able work full duty with the H-wave unit combined with current medications. Medications at this visit included topical medications including capsaicin Ketamine and Diclofenac. The patient was also utilizing Sentra PM for sleep, naproxen, Tramadol, Protonix, and Flexeril. Given the response to the H-wave unit the patient was recommended to purchase the unit for further use. The patient was seen on 01/09/14 with continuing complaints of low back pain radiating to the right lower extremity. The patient felt that this was exacerbated with any heavy lifting. The patient reported that with medications his pain scores decreased to 5/10 on VAS. With without medications the pain was as high as 8/10. On physical examination no specific findings were noted. The patient was recommended to continue with medications. The requested H-wave unit and prescription for topical compounded Ketamine 5% 60g compounded capsaicin .075% Sentra PM quantity 60 compounded Diclofenac 1.5% 60g and Protonix 20mg quantity 60 were denied by utilization review on 01/08/14.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**ONE H WAVE UNIT:** Overturned

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TRANSCUTANEOUS ELECTROTHERAPY Page(s): 116-118.

**Decision rationale:** In regards to the request for a H-wave purchase, the patient was found to have a reduction in pain and improved function with the H-wave unit trial. The patient indicated that in combination with medications his pain scores were improved by approximately 30%. Per guidelines an H-wave unit can be considered an option in the treatment of musculoskeletal pain. Chronic Pain Medical Treatment Guidelines recommend a trial of an H-wave unit prior to purchase and the trial should show functional benefits and pain reduction. Per the reports the patient had noted functional improvement that allowed him to work and pain reduction up to 30% in combination with medications. Therefore, the request is medically necessary.

**ONE PRESCRIPTION OF TOPICAL COMPOUNDED KETAMINE 5% CREAM 60 G QUANTITY 1:** Overturned

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-113.

**Decision rationale:** In regards to the request for topical Ketamine 5%, 60 grams, the records indicate the patient was utilizing Ketamine in combination with other components in the topical cream for the low back. Records indicated the presence of neuropathic pain on physical examination due to disc protrusions in the lumbar spine. The patient had failed previous chiropractic and physical therapy. The patient reported multiple side effects from oral medications including Topamax, Gabapentin, Etodolac, Venlafaxine, and Tramadol. The patient felt that he was obtaining better benefit with the topical compounded medication including Ketamine over standard oral medications. Per Chronic Pain Medical Treatment Guidelines, a topical compounded medication that includes Ketamine, Capsaicin, and Diclofenac would largely be considered experimental/investigational due to the limited evidence in the clinical literature establishing the efficacy of these types of compounded medications over standard oral medications. However, in this case the patient has had side effects from multiple medications and failure of other forms of treatment. The patient is currently working and describes better benefit with the use of a compounded topical medication including Ketamine. Given the noted functional improvement allowing him to work with lower pain scores by 30%, the request is medically necessary on an outlier basis to the guidelines.

**ONE PRESCRIPTION OF TOPICAL COMPOUNDED CAPSAICIN 0.075% CREAM QUANTITY 1:** Overturned

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-113.

**Decision rationale:** In regards to the request for topical capsaicin .0175%, 60 grams, the records indicate the patient was utilizing capsaicin in combination with other components in the topical cream for the low back. Records indicated the presence of neuropathic pain on physical examination due to disc protrusions in the lumbar spine. The patient had failed previous chiropractic and physical therapy. The patient reported multiple side effects from oral medications including Topamax, Gabapentin, Etodolac, Venlafaxine, and Tramadol. The patient felt that he was obtaining better benefit with the topical compounded medication including Ketamine over standard oral medications. Per Chronic Pain Medical Treatment Guidelines, a topical compounded medication that includes Ketamine, Capsaicin, and Diclofenac would largely be considered experimental/investigational due to the limited evidence in the clinical literature establishing the efficacy of these types of compounded medications over standard oral medications. However, in this case the patient has had side effects from multiple medications and failure of other forms of treatment. The patient is currently working and describes better benefit with the use of a compounded topical medication including Ketamine. Given the noted functional improvement allowing him to work with lower pain scores by 30%, the request is medically necessary on an outlier basis to the guidelines.

**ONE PRESCRIPTION OF SENTRA PM MEDICAL FOOD QUANTITY 60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG) PAIN CHAPTER, MEDICAL FOODS

**Decision rationale:** According to Official Disability Guidelines (ODG), this medication is a medical food utilized in the management of sleep. From the clinical records there was no indication of prior use of standard medications for insomnia or sleep issues. There was no identified particular nutritional deficit contributing to sleep loss that would have been addressed with the use of a medical food such as Sentra. No other indications for this medication were noted in the clinical record that would support certification based on Official Disability Guidelines (ODG). The request is not medically necessary.

**ONE PRESCRIPTION OF TOPICAL COMPOUNDED DICLOFENAC SODIUM 1.5% 60 GM QUANTITY 1:** Overturned

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-113.

**Decision rationale:** In regards to the request for topical Diclofenac, 60 grams, the records indicate the patient was utilizing Diclofenac in combination with other components in the topical cream for the low back. Records indicated the presence of neuropathic pain on physical examination due to disc protrusions in the lumbar spine. The patient had failed previous chiropractic and physical therapy. The patient reported multiple side effects from oral medications including Topamax, Gabapentin, Etodolac, Venlafaxine, and Tramadol. The patient felt that he was obtaining better benefit with the topical compounded medication including Ketamine over standard oral medications. Per Chronic Pain Medical Treatment Guidelines, a topical compounded medication that includes Ketamine, Capsaicin, and Diclofenac would largely be considered experimental/investigational due to the limited evidence in the clinical literature establishing the efficacy of these types of compounded medications over standard oral medications. However, in this case the patient has had side effects from multiple medications and failure of other forms of treatment. The patient is currently working and describes better benefit with the use of a compounded topical medication including Ketamine. Given the noted functional improvement allowing him to work with lower pain scores by 30%, the request is medically necessary on an outlier basis to the guidelines.

**ONE PRESCRIPTION OF PANTOPRAZOLE PROTONIX 20 MG QUANTITY 60:**  
Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment 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 CHAPTER, PROTON PUMP INHIBITORS

**Decision rationale:** In regards to the use of Pantoprazole 20mg quantity 60, this reviewer would not have recommended this medication as medically necessary based on the clinical documentation provided for review and current Official Disability Guidelines (ODG) recommendation. The clinical records provided for review did not discuss any side effects from oral medication usage including gastritis or acid reflux. There was no other documentation provided to support a diagnosis of gastroesophageal reflux disease. Given the lack of any clinical indication for the use of a proton pump inhibitor this reviewer would not have recommended the request as medically necessary.