

<b>Case Number:</b>	CM15-0010513		
<b>Date Assigned:</b>	01/28/2015	<b>Date of Injury:</b>	06/13/2011
<b>Decision Date:</b>	03/23/2015	<b>UR Denial Date:</b>	01/07/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/19/2015

### 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: Maryland

Certification(s)/Specialty: Physical Medicine & Rehabilitation, Neuromuscular 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 44 year old male, who sustained an industrial injury on 6/13/2011. The diagnoses have included complex regional pain syndrome (CRPS), reflex sympathetic dystrophy and severe left hand pain. Treatment to date has included physical therapy and pain medications. Surgical history included left index finger amputation and revision and carpal tunnel release. According to the pain management reevaluation dated 12/23/2014, the injured worker had a chief complaint of chronic, severe left hand pain. He reported having some increased pain since returning to work on 12/9/2014. Current medications were noted to be working well. The Celebrex was causing some gastrointestinal issues. He was not sleeping well due to pain. The physician noted that urine drug testing from 10/30/2014 was consistent. On 1/7/2015, Utilization Review (UR) non-certified a request for Zanaflex 4mg QTY 60, noting that there was no explicit documentation of spasm relief from the use of this medication. UR non-certified a request for PC5001 compound cream 150mg, noting there was no documentation of intolerance to oral medications. UR non-certified a request for Nucynta ER 150mg QTY 60 and Nucynta IR 50mg QTY 90, noting that there was no documentation of functional improvement from previous use. UR modified a request for Omeprazole 20mg QTY 60 to Omeprazole 20mg QTY 30 to comply with recommended once daily dosing. The MTUS was cited.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Zanaflex 4MG qty: 60.00: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain) Page(s): 64-66.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) & Tizanidine (Zanaflex, generic available) Page(s): 63 & 66.

**Decision rationale:** Zanaflex 4mg # 60 is not medically necessary per the MTUS Chronic Pain Medical Treatment Guidelines. The guidelines state that muscle relaxants are recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain. Zanaflex has been suggested as a possible adjunct for Fibromyalgia and for myofascial pain. Tizanidine is a centrally acting alpha2-adrenergic agonist that is FDA approved for management of spasticity. The documentation does not indicate spasticity. The documentation is not clear as to why this medication is being used. The request for Zanaflex is not medically necessary.

**PC5001 Compound Cream 150mg: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

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

**Decision rationale:** PC5001 Compound Cream 150mg is not medically necessary per the MTUS Chronic Pain Medical Treatment Guidelines. 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. They 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 no need to titrate. 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). 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. The documentation is not clear on the specific ingredients in this topical cream. Furthermore, the documentation does not indicate intolerance to oral medications therefore the request for PC5001 compound cream is not medically necessary.

**Nucynta ER 150mg QTY: 60.00: 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 Pain (Chronic) Ongoing management

**Decision rationale:** Nucynta ER 150mg QTY: 60.00 is not medically necessary per the ODG and the MTUS Guidelines. The ODG states that Nucynta is recommended only as second line therapy for patients who develop intolerable adverse effects with first line opioids. The MTUS does not support support long term opioid treatment without evidence of functional improvement. Nucynta has the same pain-relieving benefits of OxyIR, as well as the same risks that come with any opioid, but shows a significant improvement in gastrointestinal tolerability compared with oxycodone. In August 2011 FDA approved tapentadol extended release (Nucynta ER) for moderate to severe chronic pain. Nucynta was already approved for acute pain. The documentation indicates that the patient was placed on Nucynta on 10/31/13. The documentation indicates that the patient was taking Percocet prior to this and was to continue his Percocet. The documentation is not clear that the patient developed intolerable side effects from first line opioids. Furthermore, prior use of Nucynta did not reveal evidence of functional improvement. The request for Nucynta ER is not medically necessary.

**Nucynta IR 50mg QTY: 90.00:** 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:** Decision based on MTUS Chronic Pain Treatment Guidelines Ongoing management Page(s): 78-80. Decision based on Non-MTUS Citation Pain (Chronic)

**Decision rationale:** Nucynta IR 150mg QTY: 90.00 is not medically necessary per the ODG and the MTUS Guidelines. The ODG states that Nucynta is recommended only as second line therapy for patients who develop intolerable adverse effects with first line opioids. The MTUS does not support support long term opioid treatment without evidence of functional improvement. Nucynta has the same pain-relieving benefits of OxyIR, as well as the same risks that come with any opioid, but shows a significant improvement in gastrointestinal tolerability compared with oxycodone. The documentation is not clear that the patient developed intolerable side effects from first line opioids. Furthermore, prior use of Nucynta did not reveal evidence of functional improvement. The request for Nucynta IR is not medically necessary.

**Omeprazole 20mg QTY: 60.00:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risk.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 69.

**Decision rationale:** Omeprazole 20mg QTY:60 is medically necessary per MTUS guidelines. The MTUS criteria for a proton pump inhibitor include: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). The MTUS states that the treatment of dyspepsia secondary to NSAID therapy: is to stop the NSAID, switch to a different NSAID, or consider H2-receptor antagonists or a proton pump inhibitor. The documentation indicates that the patient has dyspepsia and is on an NSAID. Furthermore, the follow up appointment with his provider is in 1-2 months therefore a request for Omeprazole 20mg QTY:60 is reasonable and medically necessary.