

<b>Case Number:</b>	CM14-0072623		
<b>Date Assigned:</b>	07/16/2014	<b>Date of Injury:</b>	12/24/2007
<b>Decision Date:</b>	10/07/2014	<b>UR Denial Date:</b>	05/14/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/19/2014

### 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:

The patient is a 50-year-old male who has submitted a claim for failed cervical surgery, cervical spinal stenosis, and dysphagia associated with an industrial injury date of December 24, 2007. Medical records from 2013 to 2014 were reviewed. The patient complained of neck pain, headache, and bilateral shoulder discomfort. He likewise reported mild to moderate discomfort upon swallowing. Physical examination showed tenderness at the paracervical muscles. Cervical range of motion was restricted. Motor strength of both deltoids was graded 4 minus/5. Sensation was diminished at the right lateral shoulder. Gait was normal. Progress reports were handwritten and somewhat illegible. Urine drug screen from March 17, 2014 showed inconsistent results with prescribed medications. Treatment to date has included cervical surgery, testosterone injection on December 5, 2013 and May 10, 2014, and medications such as Nucynta, Opana, and Soma (since 2013). Utilization review from May 14, 2014 denied the requests for Testosterone (200mg/ml, once a week for 10 weeks), Lab - Testosterone level and total Bioavailable, and Testosterone (300mg, injection performed on 5/10/14); modified the request for Nucynta ER (250mg, #150), Opana IR (10mg, #180); denied Lab - CBC with Diff, HgB, and A1C and Soma (350mg, #60).

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Testosterone Injection (200mg/ml, once weekly for 10 weeks): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Testosterone replacement for hypogonadism (related to opioids) Pag.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Testosterone replacement for hypogonadism Page(s): 110-111.

**Decision rationale:** The Chronic Pain Medical Treatment Guidelines state that testosterone replacement for hypogonadism (related to opioids) is recommended in limited circumstances for patients taking high-dose long-term opioids with documented low testosterone levels. In this case, patient has 273.50 total morphine equivalent dose per day. However, progress reports were handwritten and somewhat illegible. It is unclear if patient presented with signs and symptoms of hypogonadism. Patient has been receiving testosterone injections since December 2013; however, submitted records failed to include testosterone level to warrant injection at this time. The medical necessity cannot be established due to insufficient information. Therefore, the request is not medically necessary.

**Nucynta ER (250mg, 150):** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78, 86.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Section, Tapentadol (Nucynta)

**Decision rationale:** As stated on page(s) 78 of the Chronic Pain Medical Treatment Guidelines, there are 4 A's for ongoing monitoring of opioid use: pain relief, side effects, physical and psychosocial functioning and the occurrence of any potentially aberrant drug-related 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. Furthermore, the Official Disability Guidelines Pain Chapter states that tapentadol (Nucynta) is recommended as second line therapy for patients who develop intolerable adverse effects with first line opioids such as, constipation, nausea, or vomiting. In this case, the patient has been on Nucynta since 2013. However, urine drug screen from March 17, 2014 showed inconsistent results with prescribed medications. However, there was no evidence that patient had intolerance to first line opioids. Moreover, the medical records do not clearly reflect continued analgesia and continued functional benefit from medication use. The California MTUS Guidelines require clear and concise documentation for ongoing management. Therefore, the request is not medically necessary.

**Opana IR (10mg, #180):** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78, 86, 93.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Section, Tapentadol (Nucynta)

**Decision rationale:** As stated on page(s) 78 of the Chronic Pain Medical Treatment Guidelines, there are 4 A's for ongoing monitoring of opioid use: pain relief, side effects, physical and psychosocial functioning and the occurrence of any potentially aberrant drug-related 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. Furthermore, the Official Disability Guidelines Pain Chapter states that tapentadol (Nucynta) is recommended as second line therapy for patients who develop intolerable adverse effects with first line opioids such as, constipation, nausea, or vomiting. In this case, the patient has been on Opana IR since 2013. However, urine drug screen from March 17, 2014 showed inconsistent results with prescribed medications. However, there was no evidence that patient had intolerance to first line opioids. Moreover, the medical records do not clearly reflect continued analgesia and continued functional benefit from medication use. The California MTUS Guidelines require clear and concise documentation for ongoing management. Therefore, the request is not medically necessary.

**Lab: Testosterone level & total Bioavailable:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Testosterone replacement for hypogonadism (related to opioids) Pag.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Center for Biotechnology Information Database: Laboratory Safety Monitoring of Chronic Medications in Ambulatory Care Settings ([www.ncbi.nlm.nih.gov](http://www.ncbi.nlm.nih.gov))

**Decision rationale:** The California MTUS Guidelines do not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, the Journal of General Internal Medicine was used instead. Literature concludes that a large proportion of patients receiving selected chronic medications do not receive recommended laboratory monitoring in the outpatient setting. In this case, patient has 273.50 total morphine equivalent dose per day. Medical records submitted were handwritten and somewhat illegible; hence, it was unclear if the patient presented with signs and symptoms of hypogonadism. However, the patient has been receiving testosterone injections since December 2013; thus, monitoring of testosterone level may be warranted at this time. Therefore, the request is medically necessary.

**Lab: Complete Blood Count (CBC) with Differential:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Center for Biotechnology Information Database: Laboratory Safety Monitoring of Chronic Medications in Ambulatory Care Settings ([www.ncbi.nlm.nih.gov](http://www.ncbi.nlm.nih.gov))

**Decision rationale:** The California MTUS Guidelines do not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, the Journal of General Internal Medicine was used instead. Literature concludes that a large proportion of patients receiving selected chronic medications do not receive recommended laboratory monitoring in the outpatient setting. In this case, there was no documented indication or rationale presented that may support the request for this patient. The medical necessity cannot be established due to insufficient information. Therefore, the request is not medically necessary.

**Lab: Hemoglobin (Hgb):** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Center for Biotechnology Information Database: Laboratory Safety Monitoring of Chronic Medications in Ambulatory Care Settings ([www.ncbi.nlm.nih.gov](http://www.ncbi.nlm.nih.gov)).

**Decision rationale:** The California MTUS Guidelines do not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, the Journal of General Internal Medicine was used instead. Literature concludes that a large proportion of patients receiving selected chronic medications do not receive recommended laboratory monitoring in the outpatient setting. In this case, there was no documented indication or rationale presented that may support the request for this patient. The medical necessity cannot be established due to insufficient information. Therefore, the request is not medically necessary.

**Lab: A1C:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Center for Biotechnology Information Database: Laboratory Safety Monitoring of Chronic Medications in Ambulatory Care Settings ([www.ncbi.nlm.nih.gov](http://www.ncbi.nlm.nih.gov)).

**Decision rationale:** The California MTUS Guidelines do not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, the Journal of General Internal Medicine was used instead. Literature

concludes that a large proportion of patients receiving selected chronic medications do not receive recommended laboratory monitoring in the outpatient setting. In this case, there was no documented indication or rationale presented that may support the request for this patient. There was no evidence of diabetes mellitus to warrant such. The medical necessity cannot be established due to insufficient information. Therefore, the request is not medically necessary.

**Testosterone Injection (300mg injection performed on 5/10/14): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Testosterone replacement for hypogonadism (related to opioids) Pag.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Testosterone replacement for hypogonadism Page(s): 110-111.

**Decision rationale:** The Chronic Pain Medical Treatment Guidelines state that testosterone replacement for hypogonadism (related to opioids) is recommended in limited circumstances for patients taking high-dose long-term opioids with documented low testosterone levels. In this case, patient has 273.50 total morphine equivalent dose per day. However, progress reports were handwritten and somewhat illegible. It is unclear if patient presented with signs and symptoms of hypogonadism. Patient has been receiving testosterone injections since December 2013; however, submitted records failed to include testosterone level to warrant an injection. The medical necessity cannot be established due to insufficient information. Therefore, the request is not medically necessary.

**Soma (350mg, #60): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Carisoprodol (Soma) and Weaning of Medications, Page(s): 24, 29, 1.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Carisoprodol (Soma), Page(s): 29.

**Decision rationale:** As stated on page 29 of the Chronic Pain Medical Treatment Guidelines, carisoprodol (Soma) is a centrally acting skeletal muscle relaxant that is not indicated for long-term use. Carisoprodol abuse has been noted in order to augment or alter effects of other drugs such as hydrocodone, tramadol, benzodiazepine and codeine. In this case, patient has been on carisoprodol since 2013. However, there is no documentation concerning pain relief and functional improvement derived from its use. Furthermore, this medication is being requested together with opioids, which is not recommended by the guidelines due to high potential of abuse. The most recent physical examination also failed to indicate presence of muscle spasm. Long-term use of muscle relaxant is likewise not recommended. Therefore, the request is not medically necessary.