

<b>Case Number:</b>	CM14-0093236		
<b>Date Assigned:</b>	08/01/2014	<b>Date of Injury:</b>	06/04/2009
<b>Decision Date:</b>	10/06/2014	<b>UR Denial Date:</b>	05/30/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/19/2014

### 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 Occupational 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 claimant was injured on 06/04/09. AndroGel, Nucynta, Norco, and Klonopin are under review. His diagnosis is lumbar degenerative disc disease with chronic lumbar radiculopathy and he was diagnosed with CTS and cervical radiculopathy with double crush. The claimant reportedly complains of neck pain and stiffness and burning pain over the left shoulder blade with numbness in his left hand and weak grip. He has chronic low back pain radiating to the bilateral lower extremities. He had cervical spine tenderness with restricted range of motion. Axial compression caused positive pain in the left scapula. Tinel's and Phalen's are positive at the left wrist. There was sensory hypoesthesia of the first 3 digits of the left hand and over the lateral aspect of the ankles. He has had lumbar ESI, acupuncture, MRI, neurosurgical consult, PT, EMG/NCV, CT myelogram of the lumbar spine, and a wrist splint. He saw [REDACTED] on 01/13/14 for follow-up of his low backache and left upper extremity pain. He complained of increasing neck pain and stiffness with a constant mild to moderate burning sensation that was worse with cold weather. He complained of increased numbness and paresthesias in the first 2 digits of the left hand that was worse with gripping and grasping. He had moderate constant low backache with intermittent spasms and bilateral lower extremity paresthesias were worse on the left side. He was independent in his ADLs. He had tenderness about the neck and shoulder regions. There was mild weakness at the left shoulder with limited range of motion. Hand grip strength was mildly decreased. He was diagnosed with cervical degenerative disc disease with left cervical radiculopathy, lumbar degenerative disc disease with bilateral lumbar radiculopathy, left CTS, left shoulder pain due to adhesive capsulitis status post rotator cuff repair, chronic pain related insomnia, anxiety, and depression. He was given refills of his medications. On 04/17/14, he saw [REDACTED] for his left hand. He had known double crush. He had been wearing a cock-up splint since the last visit. He had pain radiating from his neck down his entire arm and his

hand was puffy. He had positive Phalen's and Tinel's tests at the wrist. Left carpal tunnel release was recommended. On 03/13/14, he saw [REDACTED] and there is no mention of endocrinologic problems. He was on the same medications. He saw [REDACTED] on 02/10/14 for chronic symptoms. There was no significant change and his medications were continued. He was pending approval for neurosurgery. Electrodiagnostic studies showed moderate left carpal tunnel syndrome and EMG showed chronic cervical radiculopathy at 3 levels. On 05/12/14, he saw [REDACTED] again. The carpal tunnel release was pending approval. He had similar symptoms. He stated his sleep is better with Klonopin. His medications were continued. He has been taking the same medications for many months. On 07/14/14, he was seen again. Left carpal tunnel release was pending. There was no significant change in his medications again were continued. There is mention of a low testosterone level done in March 2013 and this was likely due to his narcotic overuse. Repeat testosterone level was ordered that today. His testosterone level was decreased at 85 with a low normal of 241.

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

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

#### **Androgel 50mg Daily: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation <http://www.endo-society.org/guidelines/final/upload/final-angrogens-in-men-standalone.pdf> ; Official Disability Guidelines <http://www.odg-twc.com/odgtwc/pain.htm>

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Chronic opioid use, hypotestosteronism Page(s): 142.

**Decision rationale:** The history and documentation support the request for AndroGel. The MTUS state "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. Hypogonadism has been noted in patients receiving intrathecal opioids and long-term high dose opioids. Routine testing of testosterone levels in men taking opioids is not recommended; however, an endocrine evaluation and/or testosterone levels should be considered in men who are taking long term, high dose oral opioids or intrathecal opioids and who exhibit symptoms or signs of hypogonadism, such as gynecomastia." [REDACTED] stated the claimant had a low testosterone level in 2013 and had been using AndroGel. The testosterone level was repeated off the AndroGel and it was below the normal range on 07/14/14. Continued use of AndroGel 50mg daily appears to be indicated.

#### **Nucynta ER 100mg twice a day Qty 60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 81, 83, 90.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for Chronic Pain and Medications for Chronic Pain Page(s): 110; 94.

**Decision rationale:** The history and documentation do not objectively support the request for Nucynta 100 mg twice a day #60. The MTUS states "a therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals." In these records, there is no documentation of trials and subsequent failure of or intolerance to first-line drugs such as acetaminophen or nonsteroidal anti-inflammatory drugs or first line opioids. MTUS further explains, "pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts." The ODG state "Nucynta is recommended only as second line therapy for patients who develop intolerable adverse effects with first line opioids. Three large RCTs concluded that tapentadol was efficacious and provided efficacy that was similar to oxycodone for the management of chronic osteoarthritis knee and low back pain, with a superior gastrointestinal tolerability profile and fewer treatment discontinuations. (Afilalo, 2010) (Buynak, 2010) (Lange, 2010) Tapentadol is a centrally acting oral analgesic. It has two mechanisms of action, combining mu-opioid receptor agonism and norepinephrine reuptake inhibition. (Johnson, 2008) Nucynta (tapentadol) was made a Schedule II controlled substance. Nucynta may be abused by crushing, chewing, snorting or injecting the product. These practices pose a significant risk to the abuser that could result in overdose and death. (FDA, 2009) 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; if patients on OxyIR complain of constipation, nausea, and/or vomiting, Nucynta might be considered as a second-line choice." There is no indication that periodic monitoring of the claimant's pattern of use and his specific response to doses of this medication, including assessment of pain relief and functional benefit, has been or will be done. There is no evidence that the claimant has been involved in an ongoing rehab program to help maintain any benefits he receives from treatment measures. Additionally, the 4A's "analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors" should be followed and documented per the guidelines. The claimant's pattern of use of Nucynta is unclear. There is no evidence that a signed pain agreement is on file at the provider's office and no evidence that a pain diary has been recommended and is being kept by the claimant and reviewed by the prescriber. There is no documentation of periodic drug screens to monitor compliance. As such, the medical necessity of the ongoing use of Nucynta 100mg twice a daily has not been clearly demonstrated." This type of medication should be weaned. Therefore this request is not medically necessary.

**Norco 5/325mg 1 three times a day Qty 90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 81, 83, 90.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for Chronic Pain ; Medications for Chronic Pain Page(s): 110; 94.

**Decision rationale:** The history and documentation do not objectively support the request for the opioid, Norco 5/325 mg one TID #90. The MTUS outlines several components of initiating and continuing opioid treatment and states "a therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient

should set goals, and the continued use of opioids should be contingent on meeting these goals." In these records, there is no documentation of trials and subsequent failure of or intolerance to first-line drugs such as acetaminophen or nonsteroidal anti-inflammatory drugs. MTUS further explains, "pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts." There is also no indication that periodic monitoring of the claimant's pattern of use and a response to this medication, including assessment of pain relief and functional benefit, has been or will be done. There is no evidence that he has been involved in an ongoing rehab program to help maintain any benefits he receives from treatment measures. Additionally, the 4A's "analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors" should be followed and documented per the guidelines. The claimant's pattern of use of Norco is unclear other than that he takes it. There is no evidence that a signed pain agreement is on file at the provider's office and no evidence that a pain diary has been recommended and is being kept by the claimant and reviewed by the prescriber. There is no documentation of periodic drug screens to monitor compliance. As such, the medical necessity of the ongoing use of Norco 5/325 mg three times daily has not been clearly demonstrated. This type of medication should be weaned.

**Klonopin 1mg at bed time Qty 30: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy Drugs Page(s): 13-14.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines ; Medications for Chronic Conditions Page(s): 54; 94.

**Decision rationale:** The history and documentation do not objectively support the request for Klonopin 1 mg at bedtime. The MTUS and ODG state "benzodiazepines (Alprazolam) are not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. (Baillargeon, 2003) (Ashton, 2005)"The MTUS state that good sleep hygiene is important in chronic conditions. However, the use of sleep medications is not addressed. The ODG state sleep medications may be recommended for a short period of time while insomnia is being evaluated and basic sleep hygiene techniques are being tried. However, the use of benzodiazepines is not supported. The medical necessity of the ongoing use of Klonopin 1 mg at bedtime has not been clearly demonstrated. This type of medication should be weaned.