

<b>Case Number:</b>	CM15-0118929		
<b>Date Assigned:</b>	07/23/2015	<b>Date of Injury:</b>	09/20/2004
<b>Decision Date:</b>	09/16/2015	<b>UR Denial Date:</b>	06/01/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/19/2015

### 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: Arizona, Michigan

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 39 year old male who sustained an industrial injury on 09/20/2004 resulting in injury to the low back. Treatment provided to date has included: physical therapy; 8 transforaminal lumbar epidural steroid injections (TLESI); 2 epidural steroid injections; medications; and conservative therapies/care. Diagnostic tests performed include: lumbar discogram (2006) showing bi-valve with posterior fissure at L3-4, posterior central herniation with small epidural leak (indeterminate, probable negative disc with discordant pain and pressures above 50PSI), and clear posterior epidural leak with degeneration and no definitive end-point; MRI of the lumbar spine (2009) showing disc space narrowing with degenerative facet changes and a broad based posterior disc bulge with moderate to severe left foraminal narrowing at L4-5, and a 7mm central disc protrusion at L3-4 resulting in moderate to severe compression of the thecal sac; MRI of the lumbar spine (2012) showing a 5-6mm far left disc extrusion with superimposed severe left hypertrophic facet changes at L5-S1, moderately severe left L5 neural foraminal stenosis with pronounced L5 nerve root impingement, and multilevel mild to moderate hypertrophic disc changes. Comorbidities included hypertension due to non-steroidal anti-inflammatory drugs (NSAIDs). There were no other dates of injury noted. On 05/20/2015, physician progress report noted complaints of ongoing low back pain. The pain was noted to be unchanged and rated 6/10 in severity with medications and 10/10 without medications. The injured worker had undergone the most recent TLESI in 01/2015 with a 70% reduction in pain. However, this was reported to have been temporary as his pain was noted to be returning to baseline. Additional complaints included increased pain in the right leg and poor

sleep. Current medications include Norco, OxyContin, Viagra, Senna, Colace, Provigil, gabapentin and Ambien. The injured worker reported working and volunteering limited hours, takes part in limited social activities, and a decrease in activity level. The physical exam revealed a global antalgic gait, restricted range of motion in the lumbar spine, tender and tight muscle bands upon palpation of the lumbar paravertebral muscles bilaterally, positive lumbar facet loading bilaterally, tenderness over the sacroiliac spine, slightly decreased motor strength in the right lower extremity, decreased sensation over the lateral foot and lateral calf on the right side, decreased reflexes in the right lower extremity, and positive straight leg raise on the right. The provider noted diagnoses of spasm of muscle, lumbar degenerative disc disease, low back pain, lumbar radiculopathy, and lumbar facet syndrome. Plan of care includes continued medications (including: Norco, OxyContin, Viagra, Senna, Colace, Provigil, gabapentin and Ambien), transforaminal lumbar epidural steroid injections at L5-S1 and S1-S2, and follow-up in 4 weeks. The injured worker's work status was permanent and stationary with restrictions. The request for authorization and IMR (independent medical review) includes: Norco 10-325mg #180, OxyContin 20mg #60, Viagra 100mg #10 with 5 refills, Senna 8.6mg #60 with 5 refills, Colace 100mg #60 with 5 refills, and Provigil 200mg #30 with 5 refills.

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

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

#### **1 prescription for Norco 10/325mg #180: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, specific drug list, Hydrocodone/Acetaminophen; Opioids, criteria for use.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96.

**Decision rationale:** Hydrocodone/ Acetaminophen (Norco) is an opioid drug that is used to treat moderate to moderately severe pain. The MTUS discourages long term usage unless there is evidence of "ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. 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. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life." The MTUS also recommends the discontinuation of Norco when there is no overall improvement in function, unless there are extenuating circumstances. Weaning should occur under direct ongoing medical supervision as a slow taper except for the below mentioned possible indications for immediate discontinuation. Upon review of the submitted documentation, the progress reports show that the injured worker had been prescribed Norco and oxymorphone since 2011. The progress reports demonstrate that the injured workers pain is reduced from 10/10 in intensity to 6/10 with the use of opioids, the continued use appears appropriate and is medically necessary.

#### **1 prescription for Oxycontin 20mg #60: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Oxycontin (oxycodone).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96.

**Decision rationale:** OxyContin is the brand name of a time-release formula of the analgesic chemical oxycodone which is also an opioid. Opioid drugs are available in various dosage forms and strengths. They are considered the most powerful class of analgesics that may be used to manage chronic pain. MTUS discourages long term usage of opioids unless there is evidence of "ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. 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. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life." The MTUS also recommends that prescriptions be prescribed from a single practitioner and taken as directed, and all prescriptions from a single pharmacy. Upon review of the submitted documentation, the progress reports show that the injured worker had been prescribed Norco and oxymorphone since 2011. The progress reports demonstrate that the injured workers pain is reduced from 10/10 in intensity to 6/10 with the use of opioids, the continued use appears appropriate and is medically necessary.

**1 prescription for Viagra 100mg #10 with 5 refills: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Wespes E, Eardley I, Giuliano F, Hatzichristou D, Hatzimouratidis K, Moncade I, Salonia A, Vardi Y. Guidelines on male sexual dysfunction: erectil dysfunction and premature ejaculation. Arnhem (The Netherlands): European Association Urology (EAU).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Physicians Desk Reference (PDR,net) / Viagra (Sildenafil).

**Decision rationale:** The MTUS/ ACOEM and the ODG did not address the use of Viagra, therefore other guidelines were consulted. Per the PDR, Viagra (Sildenafil) is a Phosphodiesterase 5 (PDE5) inhibitor used in the treatment of erectile dysfunction (ED). Unfortunately a review of the injured workers medical records that are available to me did not reveal a clear rationale and benefit from the use of this medication, without this information medical necessity is not established, therefore the request for 1 prescription for Viagra 100mg #10 with 5 refills is not medically necessary.

**1 prescription for Senna 8.6mg #60 with 5 refills: Overturned**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 77. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) / Opioid-induced constipation treatment.

**Decision rationale:** Per the MTUS prophylactic treatment of constipation should be initiated when initiating opioid therapy. Senna is a laxative used for the prophylactic treatment of constipation with opioid use. The ODG states: "if prescribing opioids has been determined to be appropriate, then ODG recommends, under Initiating Therapy, that Prophylactic treatment of constipation should be initiated. Opioid-induced constipation is a common adverse effect of long-term opioid use because the binding of opioids to peripheral opioid receptors in the gastrointestinal (GI) tract." In this case, the injured worker is on Norco and Oxycontin, the prophylactic treatment of constipation is appropriate and medically necessary, therefore the request for 1 prescription for Senna 8.6mg #60 with 5 refills is medically necessary.

**1 prescription for Colace 100mg #60 with 5 refills: Overturned**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 77. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (chronic) Chapter; Opioid-induced constipation treatment.

**Decision rationale:** Per the MTUS prophylactic treatment of constipation should be initiated when initiating opioid therapy. The ODG states: "if prescribing opioids has been determined to be appropriate, then ODG recommends, under Initiating Therapy, that Prophylactic treatment of constipation should be initiated. Opioid-induced constipation is a common adverse effect of long-term opioid use because the binding of opioids to peripheral opioid receptors in the gastrointestinal (GI) tract." In this case, the injured worker is on Norco and Oxycontin, the prophylactic treatment of constipation is appropriate and medically necessary, therefore the request for 1 prescription for Colace 100mg #60 with 5 refills is medically necessary.

**1 prescription for Provigil 200mg #30 with 5 refills: 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 (Modafinil).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (chronic) Chapter; Modafinil (Provigil).

**Decision rationale:** Provigil is an agent that is commonly used to treat uncontrollable sleepiness caused by narcolepsy and sleep apnea. It is also used to treat patients that are sleep deprived due to working odd hours. The MTUS is silent in regards to Provigil; therefore, the ODG was

consulted in the decision of this medication. The ODG states that Provigil is not recommended for use in counteracting sedation effects of narcotic medications until after first considering reducing excessive prescribing of narcotic medications. Indications for use include: excessive sleepiness associated with narcolepsy, obstructive sleep apnea, and shift work sleep disorder. Additionally, before prescribing this medication, "patients should have undergone a complete evaluation and diagnosis in accordance with the International Classification of Sleep Disorders or DSM diagnostic classification". Upon review of the medical records submitted, it appears that the injured worker is being treated for narcotic induced sleepiness, this medication is not recommended for the treatment of narcotic induced sleepiness. As such, the requested Provigil 200mg #30 with 5 refills is not medically necessary.