

<b>Case Number:</b>	CM14-0032815		
<b>Date Assigned:</b>	06/20/2014	<b>Date of Injury:</b>	12/27/1999
<b>Decision Date:</b>	08/28/2014	<b>UR Denial Date:</b>	03/04/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/14/2014

### 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 Physical Medicine and Rehabilitation and is licensed to practice in Texas. 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 58 year old female with injury date 12/27/1999. Diagnoses are post lumbar laminectomy syndrome, hip bursitis, spinal/lumbar DDD, low back pain, SI pain, myalgia and myositis NOS right buttock/low back pain consistent with right greater trochanteric bursitis and sacroiliac pain. Several prior UR determinations have been performed regarding medication management. The patient returned for follow-up on 5/22/2014. The employee rates pain 7/10 with medication and 10/10 without meds. Sleep quality is reported to be poor. No others therapies are being tried by the injured worker for pain relief. Activity level has decreased. She takes meds as prescribed, states meds are working well. There is mentions of constipation with medications. The injured worker state that Neurontin and Norco were authorized, and that she paid for Fentanyl patch out of pocket. Family doctor prescribes Wellbutrin and Paxil. She takes OTC meds for constipation. Current medications includes Zanaflex, bisacodyl, senna-s, miralax, tegaderm dressing, Lidoderm patch, duragesic 50mcg, Neurontin, norco, clonazepam, ms contin CR, protonix (other MD), Paxil (other MD), Wellbutrin (other MD). On physical examination, the injured worker appears well groomed, has good hygiene, and appears older than stated age and is underweight. (Vitals: 175 lbs, 5'3", BMI: 31.0.) The injured worker appears to be mild distress, mild-severe pain and tearful. She shows signs of intoxication or withdrawal. Right sided antalgic gait, slowed gait and assisted by cane and wheelchair. On examination of lumbar spine reveals surgical scars, restricted ROM, palpation of paravertebral muscles spasm/tenderness/tight muscle band on both sides, positive FABER on right, TTP on the right, numerous myofascial points of tenderness, motor testing limited by pain, intact sensation, negative SLR, shaking right LE. Prescription: bisacodyl, senna-s, tegaderm patch, Lidoderm 5%, zanaflex, Neurontin, duragesic 50mcg, norco, and miralax. The patient was seen for follow-up on 3/10/2014 for chronic pain complaints of increased back pain that radiates to the right leg, tingling in the leg

and weakness. Pain has increased since last visits and quality of life has worsened, and activity level has decreased. She complains pain is increased due to medication denials. Reports show that the injured worker was treated in the ED 3/5/14 and 3/7/14 for severely increased pain, heart palpitations, and vomiting. She reports increased depression and suicidal ideation since abruptly taken off bupropion and paroxetine, she denies current suicidal ideation and states she will not act on her thoughts. Current medications are Paxil, Wellbutrin, Zanaflex, bisacodyl, senna-s, miralax, tegaderm dressing, Lidoderm 5% patch, Duragesic patch, Neurontin, oxycodone and protonix (by another MD). Oxycodone causes shortness of breath. The 2/2/0/14 Urine toxicology report: results consistent. On examination of the lumbar spine reveals surgical scars, restricted ROM, palpation of paravertebral muscles spasm/tenderness/tight muscle band on both sides, positive FABER on right, TTP on the right, numerous myofascial points of tenderness, motor testing limited by pain, intact sensation, negative SLR, shaking right LE. Prescriptions was given for Norco, miralax, oxycodone, duragesic, zanaflex, Neurontin, Lidoderm, tegaderm dressing, senna-s, bisacodyl, Paxil, and Wellbutrin. Additional information regarding reasons for medications was included in the records. The patient presented for follow-up on 2/20/2014, with continued complaints of increased back pain radiating to the right leg, and lower backache. Pain has increased since last visit. Pain rated 10/10. No new problems or side-effects. Quality of sleep poor, quality of life worsened and activity level decreased. She takes medications as prescribed. The injured worker states medications are less effective and no side effects reported. The injured worker was unable to fill TDF 75mcg/hr. She presents s/p 2/10/2014 appointment where she was prescribed TDF 50mcg/hr and reports severely decreased activity tolerance, to extent only out of bed 4 hours/day. Current medications are Paxil, Wellbutrin, zanaflex, bisacodyl, senna-s, miralax, tegaderm dressing, Lidoderm, duragesic 75 mcg/hr, Percocet, duragesic 50mcg/hr, Neurontin, duragesic 15mcg/hr, oxycodone, and protonix (another MD). On physical examination, she appears well groomed, has good hygiene, and appears older than stated age and is underweight. (Vitals: 178 lbs, 5'3", BMI: 31.53.) Appears in mild distress, mild-severe pain and tearful. She shows signs of intoxication or withdrawal. Right sided antalgic gait, slowed gait and assisted by cane and wheelchair. On examination of lumbar spine reveals surgical scars, restricted ROM, palpation of paravertebral muscles spasm/tenderness/tight muscle band on both sides, positive FABER on right, TTP on the right, numerous myofascial points of tenderness, motor testing limited by pain, intact sensation, negative SLR, shaking right LE. Urine toxicology screen, was positive for Oxycodone. The injured worker was prescribed Oxycodone, Neurontin and duragesic 50mcg/hr. According to to the urine toxicology report dated 2/20/2014, the patient's samples positive for Fentanyl/Norfentanyl, Oxycodone/Noroxycodone/Oxymorphone, and Gabapentin.

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

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

**Prospective usage of Oxycodone 15mg #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids (therapeutic trial).

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

**Decision rationale:** The medical records indicate the patient should have already been weaned from this medication. Furthermore, the patient reported side effects of shortness of breath with Oxycodone, and is no longer taking this medication. Therefore, the request for Oxycodone 15mg #120 is not medically necessary and appropriate.

**Prospective usage of Duragesic 50 mcg/hr patches #15:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Duragesic (fentanyl transdermal system) page(s) 74-96; 44 Page(s): 74-96, 44.

**Decision rationale:** The MTUS guidelines state Fentanyl is an opioid analgesic with a potency eighty times that of morphine. Fentanyl transdermal (Duragesic; generic available) is indicated for management of persistent chronic pain, which is moderate to severe requiring continuous, around-the-clock opioid therapy. The pain cannot be managed by other means (e.g., NSAIDS). According to the medical records, the patient should have already been weaned from this medication. It does not appear that the treating physician is following recommended treatment protocols. The recent urine toxicology screens indicate significantly positive for fentanyl and Oxycodone metabolites. However, there is no demonstrated objective functional improvement with this medication. Lack of benefit was reported, the patient previously indicated she was essentially non-functional with Duragesic 50 mcg/hr. There has been no change in the patient's physical examination findings nor notable change in the patient's report of function and pain despite use of this opiate. Based on the clinical information provided, the request for Duragesic 50 mcg/hr patches #15 is not medically necessary and appropriate.

**Prospective usage of Paroxetine 20mg:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Anxiety medications in chronic pain.

**Decision rationale:** The Official Disability Guidelines recommends diagnosing and controlling anxiety as an important part of chronic pain treatment, including treatment with anxiety medications based on specific DSM-IV diagnosis as described below. Definition of anxiety disorders: Anxiety disorders for this entry include (1) generalized anxiety disorder (GAD); (2) panic disorder (PD); (3) post-traumatic stress disorder (PTSD); (4) social anxiety disorder (SAD); & (5) obsessive-compulsive disorder (OCD). Many antidepressants, in particular the Selective Serotonin Reuptake Inhibitors (SSRIs) are considered first-line agents in the treatment of most forms of anxiety. Paxil is an SSRI, recommended for treatment of GAD, PD, SAD, OCD, and PTSD as well as major depressive disorder. Ongoing efficacy such as measurable subjective and/or functional benefit with use is not evident. In this case, the patient has been maintained on Paxil, provided with her PCP. However, there is no subjective report of objective findings that

provide evidence of any benefit with this medication. The medical records do not include any recent objective psychological or mental assessment with documentation of the patient's report of how or whether the medication is effective. The patient is also on Wellbutrin. Therefore, the request for Paroxetine 20mg is not medically necessary and appropriate.

**Prospective usage of Senna-S: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Veterans Health Administration, Department of Defense. Clinical practice guideline for management of Opioid Therapy for chronic pain. Washington (DC): Veterans Health Administration, Department of Defense; 2003 Mar. various.page 51.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Long-term Users of Opioids (6-months or more), page(s) 88 Page(s): 88.

**Decision rationale:** Regarding long-term opioid management, the guidelines recommend routine re-assessment should include documentation of any adverse effects with the medications. The medical records do not document any current complaints of constipation. There is no evidence that the patient follows a high fiber diet and increase water intake as means of self-regulating and maintain good bowel function. Furthermore, ongoing chronic use of opioids is not supported. Therefore, the request for Senna-S is not medically necessary and appropriate.

**Prospective usage of Bupropion 300mg: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain: Bupropion (Wellbutrin), page 16 page(s) Page(s): 16.

**Decision rationale:** According to the MTUS guidelines, Bupropion (Wellbutrin), is a second-generation non-tricyclic antidepressant (a noradrenaline and dopamine reuptake inhibitor) has been shown to be effective in relieving neuropathic pain of different etiologies in a small trial. While bupropion has shown some efficacy in neuropathic pain there is no evidence of efficacy in patients with non-neuropathic chronic low back pain. It is generally a third-line medication for diabetic neuropathy and may be considered when patients have not had a response to a tricyclic or SNRI. The medical records do not document current subjective complaints with corroborating relevant clinical findings and treatment history that meet this guideline. In addition, the patient has been maintained on Wellbutrin as prescribed by her primary care physician. The medical records do not provide evidence of clinically significant improvement or benefit with this medication. There is no subjective report of objective findings that provide evidence of any benefit with this medication. The medical records do not include any objective psychological or mental assessment with documentation of the patient's report of how or whether the medication is effective. Ongoing efficacy with Wellbutrin has not been demonstrated. The patient has also been on Paxil, prescribed by her PCP. Therefore, the request for Bupropion 300mg is not medically necessary and appropriate.

### **Prospective usage of Tizanidine 4mg: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Procedure Summary (last updated 01/07/14), non-sedating muscle relaxants.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain), page(s) 66 Page(s): 66.

**Decision rationale:** The MTUS recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. Recommended for a short course of therapy. Tizanidine is FDA approved for management of spasticity; unlabeled use for low back pain. The medical records does not demonstrate an acute exacerbation present. Objective findings have not changed, and review of the medical records indicate chronic use of muscle relaxants, which is not recommended under the guidelines and is not supported. Therefore, the request for Tizanidine 4mg is not medically necessary and appropriate.

### **Prospective usage of Bisacodyl 5mg: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Veterans Health Administration, Department of Defense. Clinical practice guideline for management of Opioid Therapy for chronic pain. Washington (DC): Veterans Health Administration, Department of Defense; 2003 Mar. page 51.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Long-term Users of Opioids (6-months or more), page(s) 88 Page(s): 88.

**Decision rationale:** According to the MTUS guidelines, long term use of opioids must include re-assessment, which should include documentation of adverse effects, such as constipation. The medical records do document complaints of constipation. Constipation is a common side-effect of chronic opioid use, however the patient is not recommended to continue opioid therapy, as there is no evidence the patient has benefited from opioid use. Furthermore, constipation can be relieved with a fiber-rich diet and increased water intake. The medical necessity for a stool softener is not established. As such, the request for Bisacodyl 5mg is not medically necessary and appropriate.

### **Prospective usage of Miralax Powder: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Veterans Health Administration, Department of Defense. Clinical practice guideline for management of Opioid Therapy for chronic pain. Washington (DC): Veterans Health Administration, Department of Defense; 2003 Mar. page 51.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Long-term Users of Opioids (6-months or more), page(s) 88 Page(s): 88.

**Decision rationale:** According to the MTUS guidelines, long-term use of opioids must include re-assessment, which should include documentation of adverse effects, such as constipation. The medical records do document complaints of constipation. Constipation is a common side-effect of chronic opioid use, however the patient is not recommended to continue opioid therapy, as there is no evidence the patient has benefited from opioid use. Furthermore, constipation can be relieved with a fiber-rich diet and increased water intake. The medical necessity for a laxative is not established. As such, the request for Miralax Powder is not medically necessary and appropriate.

**Prospective usage of Lidocaine 5% Patches:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (lidocaine patch), page(s) 56 Page(s): 56.

**Decision rationale:** The guidelines state topical lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia. The medical records document the patient has used Lidoderm in the past with claim it reduced her right dorsal foot pain from 10/10 to 6/10. However, there had been no documented objective benefit with use. It is noted that there had been no reduction in opioid medications nor improved function. It also appears that she continues prescriptions for oral Neurontin as well. Measurable subjective and/or functional benefit as result of this medication is not demonstrated. It is not clear she has failed trials of standard anti-convulsants. Therefore, the request for Lidocaine 5% Patches is not medically necessary and appropriate.

**Prospective usage of Tegaderm Dressing:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation [https://www.ncmedical.com/item\\_1780.html](https://www.ncmedical.com/item_1780.html).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence:<http://www.3m.com/product/information/Nexcare-Tegaderm-Transparent-Dressing.html>.

**Decision rationale:** According to manufacturer, Nexcare, Tegaderm, Transparent Dressing is the #1 hospital brand in transparent dressings. Tegaderm Dressing can be worn for up to 7 days, it is used to protect wounds and burns, and also for securing IV catheters or other tubing, and for post-surgical dressings. In this case, the dressing is to keep the Fentanyl patch in place. This is not the intended use of this product. Of note, Duragesic patch is a potent morphine derivative on an adhesive patch, which is designed to stay on skin for at least 3 days, and should not require additional adhesive. Therefore, the request for Tegaderm Dressing is not medically necessary and appropriate.