

<b>Case Number:</b>	CM15-0110716		
<b>Date Assigned:</b>	06/18/2015	<b>Date of Injury:</b>	05/30/2008
<b>Decision Date:</b>	07/22/2015	<b>UR Denial Date:</b>	05/28/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/09/2015

### 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: Pennsylvania  
 Certification(s)/Specialty: Internal 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 61 year old female who sustained a work related injury May 30, 2008. Diagnoses are discogenic lumbar condition with MRI showing stenosis L3-S1 with facet arthropathy L3-S1 and right foraminal narrowing L3-L4, and chronic pain syndrome. Past history included hypertension and diabetes. Norco, tramadol, flexeril, and neurontin were prescribed since February 2015. Urine drug screening was noted to be requested in February 2015 but no results were submitted or discussed. At a visit on 3/25/15, it was noted that the injured worker is not currently working and that she was on temporary total disability. According to a treating physician's progress report, dated May 13, 2015, the injured worker presented with pain from her buttock down her left leg and an overall weight gain of 30 pounds. Objective findings are documented as tenderness along the facets of the lumbar spine with facet loading being positive in the lumbar spine. Decreased sensation is noted along the right more than the left lower extremity. There was grade 5 strength to resisted function, flexion is 4 degrees, extension 20 degrees, and tilting 20 degrees. She utilizes a back brace, hot and cold wraps, and a two-lead TENS unit. There is limitation with sitting, standing, and walking approximately 10-15 minutes maximum. Work restrictions were noted but return to work was not documented. At issue is the request for authorization for Aciphex, Flexeril, Neurontin, Norco, Norflex, Protonix, Tramadol ER, and Ultracet. On 5/28/15, Utilization Review non-certified requests for the items currently under Independent Medical Review.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Protonix 20 mg #60: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI symptoms and cardiovascular risk Page(s): 68-69.

**Decision rationale:** This injured worker has been prescribed naproxen, a nonsteroidal anti-inflammatory medication (NSAID), and protonix, a proton pump inhibitor (PPI). Per the MTUS, co-therapy with a nonsteroidal anti-inflammatory medication (NSAID) and a proton pump inhibitor (PPI) is not indicated in patients other than those at intermediate or high risk for gastrointestinal events (including age > 65 years, history of peptic ulcer, gastrointestinal (GI) bleeding or perforation, concurrent use of aspirin, corticosteroids and/or an anticoagulant, or high dose/multiple NSAIDS such as NSAID plus low dose aspirin). None of these risk factors were noted to be present for this injured worker. Long term proton pump inhibitor (PPI) use (> 1 year) has been shown to increase the risk of hip fracture. The MTUS, FDA, and recent medical literature have described a significantly increased risk of hip, wrist, and spine fractures, pneumonia, Clostridium-difficile-associated diarrhea, and hypomagnesemia in patients on proton pump inhibitors. Both protonix and aciphex (both PPIs) were requested, which is duplicative and potentially toxic. Due to lack of specific indication, and potential for toxicity, the request for protonix is not medically necessary.

**Tramadol ER 150 mg #30: Upheld**

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

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

**Decision rationale:** This injured worker has chronic back pain. Tramadol has been prescribed for at least three months. Tramadol (ultram) is a centrally acting synthetic opioid analgesic which is not recommended as a first line oral analgesic. Multiple side effects have been reported including increased risk of seizure especially in patients taking selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants (TCAs) and other opioids. This injured worker has also been prescribed norco, another opioid. Tramadol may also produce life-threatening serotonin syndrome. There is insufficient evidence that the treating physician is prescribing opioids according to the MTUS, which recommends prescribing according to function, with specific functional goals, return to work, random drug testing, and opioid contract. No functional goals were discussed, return to work was not documented, no opioid contract was discussed, and although urine drug testing was mentioned to be requested, no results were submitted. Per the MTUS, opioids are minimally indicated, if at all, for chronic non-specific pain, osteoarthritis, "mechanical and compressive etiologies," and chronic back pain. There is no evidence of

significant pain relief or increased function from the opioids used to date. The MTUS states that a therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. There is no evidence that the treating physician has utilized a treatment plan NOT using opioids, and that the patient "has failed a trial of non-opioid analgesics." Ongoing management should reflect four domains of monitoring, including analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors. The documentation does not reflect improvement in pain. Change in activities of daily living, discussion of adverse side effects, and screening for aberrant drug-taking behaviors were not documented. The MTUS recommends urine drug screens for patients with poor pain control and to help manage patients at risk of abuse. There is no record of a urine drug screen program performed according to quality criteria in the MTUS and other guidelines. The current requests include requests for both tramadol and ultracet (tramadol/acetaminophen), which is duplicative and potentially toxic. As currently prescribed, tramadol does not meet the criteria for long term opioids as elaborated in the MTUS and is therefore not medically necessary.

**Flexeril 7.5 mg #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines cyclobenzaprine muscle relaxants Page(s): 41-42, 63-66.

**Decision rationale:** This injured worker has chronic back pain. Flexeril has been prescribed for at least three months. The MTUS for chronic pain does not recommend muscle relaxants for chronic pain. Non-sedating muscle relaxants are an option for short-term exacerbations of chronic low back pain. The muscle relaxant prescribed in this case is sedating. The injured worker has chronic pain with no evidence of prescribing for flare-ups. The quantity prescribed implies long term use, not for a short period of use for acute pain. No reports show any specific and significant improvement in pain or function as a result of prescribing muscle relaxants. Per the MTUS chronic pain medical treatment guidelines, cyclobenzaprine (Flexeril, Fexmid, Amrix, Trabadol) is a skeletal muscle relaxant and a central nervous system depressant. It is recommended as an option for a short course of therapy, with greatest effect in the first four days of treatment. Guidelines state that treatment should be brief. Cyclobenzaprine is not recommended to be used for longer than 2-3 weeks. Limited, mixed evidence does not allow for a recommendation for chronic use. The addition of cyclobenzaprine to other agents is not recommended. This injured worker has been prescribed multiple additional agents. In addition, the physician has prescribed both flexeril and norflex, which are both muscle relaxants, which is duplicative and potentially toxic. Due to length of use in excess of the guideline recommendations, and potential for toxicity, the request for flexeril is not medically necessary.

**Norco 10/325 mg #50:** Upheld

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

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

**Decision rationale:** This injured worker has chronic back pain. Norco has been prescribed for at least three months. There is insufficient evidence that the treating physician is prescribing opioids according to the MTUS, which recommends prescribing according to function, with specific functional goals, return to work, random drug testing, and opioid contract. No functional goals were discussed, return to work was not documented, no opioid contract was discussed, and although urine drug testing was mentioned to be requested, no results were submitted. Per the MTUS, opioids are minimally indicated, if at all, for chronic non-specific pain, osteoarthritis, "mechanical and compressive etiologies," and chronic back pain. There is no evidence of significant pain relief or increased function from the opioids used to date. The MTUS states that a therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. There is no evidence that the treating physician has utilized a treatment plan NOT using opioids, and that the patient "has failed a trial of non-opioid analgesics." Ongoing management should reflect four domains of monitoring, including analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors. The documentation does not reflect improvement in pain. Change in activities of daily living, discussion of adverse side effects, and screening for aberrant drug-taking behaviors were not documented. The MTUS recommends urine drug screens for patients with poor pain control and to help manage patients at risk of abuse. There is no record of a urine drug screen program performed according to quality criteria in the MTUS and other guidelines. As currently prescribed, norco does not meet the criteria for long term opioids as elaborated in the MTUS and is therefore not medically necessary.

**Aciphex 20 mg #30:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines  
NSAIDS, GI symptoms and cardiovascular risk Page(s): 68-69.

**Decision rationale:** This injured worker has been prescribed naproxen, a nonsteroidal anti-inflammatory medication (NSAID), and aciphex, a proton pump inhibitor (PPI). Per the MTUS, co-therapy with a nonsteroidal anti-inflammatory medication (NSAID) and a proton pump inhibitor (PPI) is not indicated in patients other than those at intermediate or high risk for gastrointestinal events (including age > 65 years, history of peptic ulcer, gastrointestinal (GI) bleeding or perforation, concurrent use of aspirin, corticosteroids and/or an anticoagulant, or high dose/multiple NSAIDS such as NSAID plus low dose aspirin). None of these risk factors were noted to be present for this injured worker. Long term proton pump inhibitor (PPI) use (> 1 year) has been shown to increase the risk of hip fracture. The MTUS, FDA, and recent medical literature have described a significantly increased risk of hip, wrist, and spine fractures, pneumonia, Clostridium-difficile-associated diarrhea, and hypomagnesemia in patients on proton pump inhibitors. Both protonix and aciphex (both PPIs) were requested, which is duplicative and

potentially toxic. Due to lack of specific indication, and potential for toxicity, the request for aciphex is not medically necessary.

**Ultracet 37.5 mg #60:** Upheld

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

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

**Decision rationale:** This injured worker has chronic back pain. Tramadol has been prescribed for at least three months. Tramadol (ultram) is a centrally acting synthetic opioid analgesic which is not recommended as a first line oral analgesic. Multiple side effects have been reported including increased risk of seizure especially in patients taking selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants (TCAs) and other opioids. This injured worker has also been prescribed norco, another opioid. Tramadol may also produce life-threatening serotonin syndrome. There is insufficient evidence that the treating physician is prescribing opioids according to the MTUS, which recommends prescribing according to function, with specific functional goals, return to work, random drug testing, and opioid contract. No functional goals were discussed, return to work was not documented, no opioid contract was discussed, and although urine drug testing was mentioned to be requested, no results were submitted. Per the MTUS, opioids are minimally indicated, if at all, for chronic non-specific pain, osteoarthritis, "mechanical and compressive etiologies," and chronic back pain. There is no evidence of significant pain relief or increased function from the opioids used to date. The MTUS states that a therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. There is no evidence that the treating physician has utilized a treatment plan NOT using opioids, and that the patient "has failed a trial of non-opioid analgesics." Ongoing management should reflect four domains of monitoring, including analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors. The documentation does not reflect improvement in pain. Change in activities of daily living, discussion of adverse side effects, and screening for aberrant drug-taking behaviors were not documented. The MTUS recommends urine drug screens for patients with poor pain control and to help manage patients at risk of abuse. There is no record of a urine drug screen program performed according to quality criteria in the MTUS and other guidelines. The current requests include requests for both tramadol and ultracet (tramadol/acetaminophen), which is duplicative and potentially toxic. As currently prescribed, ultracet does not meet the criteria for long term opioids as elaborated in the MTUS and is therefore not medically necessary.

**Neurontin 600 mg #90:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines anticonvulsants Page(s): 16-22.

**Decision rationale:** This injured worker has chronic back pain. Neurontin has been prescribed for at least three months. Per the MTUS, antiepilepsy drugs (AEDs) are recommended for neuropathic pain due to nerve damage. Gabapentin (Neurontin, Gralise) has been shown to be effective for treatment of diabetic neuropathy and postherpetic neuralgia and has been considered a first line treatment for neuropathic pain. The MTUS notes the lack of evidence for treatment of radiculopathy (the apparent reason for the prescription per the treating physician). A "good" response to the use of antiepileptic drugs (AEDs) is defined as a 50% reduction in pain and a "moderate" response as a 30% reduction. Lack of at least a 30% response per the MTUS would warrant a switch to a different first line agent or combination therapy. After initiation of treatment, there should be documentation of pain relief with improvement in function, and documentation of any side effects, with continued use of AEDs dependent on improved outcomes versus tolerability of adverse effects. There was no documentation of at least a moderate response to neurontin, and no documentation of functional improvement as a result of use of neurontin. Return to work was not documented, and there was no discussion of specific improvement in activities of daily living as a result of use of neurontin. Due to lack of presence of neuropathic pain, lack of at least a moderate reduction in pain, and lack of functional improvement, the request for neurontin is not medically necessary.

**Norflex 100 mg #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines muscle relaxants Page(s): 63-66.

**Decision rationale:** This injured worker has chronic back pain. Muscle relaxants have been prescribed for several months. The MTUS for chronic pain does not recommend muscle relaxants for chronic pain. Non-sedating muscle relaxants are an option for short-term exacerbations of chronic low back pain. The muscle relaxant prescribed in this case is sedating. The injured worker has chronic pain with no evidence of prescribing for flare-ups. The quantity prescribed implies long term use, not for a short period of use for acute pain. No reports show any specific and significant improvement in pain or function as a result of prescribing muscle relaxants. Orphenadrine (Norflex) is similar to diphenhydramine, but with greater anticholinergic effects; the mode of action is not clearly understood and effects are thought to be secondary to analgesic and anticholinergic properties. Side effects include drowsiness, urinary retention, and dry mouth; it has been reported in case studies to be abused for euphoria and to have mood elevating effects. The physician has prescribed both flexeril and norflex, which are both muscle relaxants, which is duplicative and potentially toxic. Due to length of use of muscle relaxants in excess of the guideline recommendations, and potential for toxicity, the request for norflex is not medically necessary.