

<b>Case Number:</b>	CM15-0099460		
<b>Date Assigned:</b>	06/01/2015	<b>Date of Injury:</b>	06/16/2003
<b>Decision Date:</b>	07/03/2015	<b>UR Denial Date:</b>	05/13/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/22/2015

### 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 36-year-old male, who sustained an industrial injury on 06/16/2003. He has reported subsequent low back and lower extremity pain with numbness and tingling and was diagnosed with lumbar discopathy with displacement, lumbar radiculopathy and lumbar stenosis. Treatment to date has included oral and topical pain medication. In a progress note dated 03/23/2015, the injured worker complained of low back pain radiating to the left leg associated with numbness, tingling, and weakness in the left leg. Objective findings were notable for tenderness to palpation over the lumbar paraspinal musculature, decreased range of motion secondary to pain and stiffness, positive supine straight leg raise at 20 degrees on the left and diminished sensation to light touch and pinprick in the left L5-S1 dermatomal distribution. A request for authorization of Fexmid, Ultram, Prilosec, topical compound Cyclobenzaprine and Tramadol 10 % 15 grams, topical compound Cyclobenzaprine and Tramadol 10 % 60 grams and one urine drug screen was submitted.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Fexmid 7.5mg #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril) Page(s): 41-42.

**Decision rationale:** Per the MTUS, Cyclobenzaprine is recommended as an option in the treatment of chronic pain using a short course of therapy. It is more effective than placebo in the management of back pain, the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment suggesting that shorter courses may be better. Treatment should be brief. Treatment is not recommended for longer than 2-3 weeks. Unfortunately, a prescription for #120 does not indicate short term treatment and a review of the injured workers medical records do not reveal extenuating circumstances that would warrant deviating from the guidelines and therefore the request for Fexmid 7.5mg #120 is not medically necessary.

**Ultram ER 150mg #90:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Tramadol (Ultram) Page(s): 74-96, 113.

**Decision rationale:** The MTUS states that tramadol is a centrally acting synthetic opioid analgesic and it is not recommended as a first-line oral analgesic. Opioids are recommended for chronic pain, especially neuropathic pain that has not responded to first line recommendations like antidepressants and anticonvulsants. Long term users should be reassessed and monitored per specific guideline recommendations and the dose should not be lowered if it is working. Per the MTUS, Tramadol is indicated for moderate to severe pain. A review of the injured workers medical records reveal inconsistent urine drug screen results with no explanation for this, there is also no documentation of pain or functional improvement with the use of tramadol and therefore the request for Ultram ER 150mg #90 is not medically necessary.

**Prilosec 20mg #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) / Proton Pump Inhibitors (PPIs).

**Decision rationale:** Per the MTUS, Clinicians should weigh the indications for NSAIDs against both GI and cardiovascular risk factors according to specific criteria listed in the MTUS and a selection should be made based on these criteria 1) age > 65 years; (2) history of peptic ulcer, GI

bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Per the ODG, PPI's are "Recommended for patients at risk for gastrointestinal events. Prilosec (omeprazole), Prevacid (lansoprazole) and Nexium (esomeprazole magnesium) are PPIs. Healing doses of PPIs are more effective than all other therapies, although there is an increase in overall adverse effects compared to placebo. Nexium and Prilosec are very similar molecules. (Donnellan, 2010) In this RCT, omeprazole provided a statistically significantly greater acid control than lansoprazole. (Miner, 2010) In general, the use of a PPI should be limited to the recognized indications and used at the lowest dose for the shortest possible amount of time. PPIs are highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. Studies suggest, however, that nearly half of all PPI prescriptions are used for unapproved indications or no indications at all. Many prescribers believe that this class of drugs is innocuous, but much information is available to demonstrate otherwise. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses, including esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Prilosec), pantoprazole (Protonix), dexlansoprazole (Dexilant), and rabeprazole (Aciphex). (Shi, 2008) A trial of omeprazole or lansoprazole had been recommended before prescription Nexium therapy (before it went OTC). The other PPIs, Protonix, Dexilant, and Aciphex, should be second-line. According to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective. (AHRQ, 2011)". However, a review of the injured workers medical records do not reveal past or current gastrointestinal complaints and there is no evidence that the injured worker is at increased risk for a gastrointestinal event and therefore the prophylactic use of prilosec is not medically necessary.

**Topical compound Cyclobenzaprine 10% and Tramadol 10%, 15 grams: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** Per the MTUS, topical analgesics are recommended as an option, they are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Many agents are compounded as monotherapy or in combination for pain control, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. A review of the injured workers medical records that are available to me does not show a trial of recommended first line agents that have failed and per the MTUS, cyclobenzaprine is a muscle relaxant and there is no evidence for use of any muscle relaxant as a topical product therefore the request for Topical compound Cyclobenzaprine 10% and Tramadol 10%, 15 grams is not medically necessary.

**Topical compound Cyclobenzaprine 10% and Tramadol 10%, 60 grams: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** Per the MTUS, topical analgesics are recommended as an option, they are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Many agents are compounded as monotherapy or in combination for pain control, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. A review of the injured workers medical records that are available to me does not show a trial of recommended first line agents that have failed and per the MTUS, cyclobenzaprine is a muscle relaxant and there is no evidence for use of any muscle relaxant as a topical product therefore the request for Topical compound Cyclobenzaprine 10% and Tramadol 10%, 60 grams is not medically necessary.

**One urine drug screen:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for Use of Urine Drug Testing. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain: Criteria for Use of Urine Drug Testing (04/3015).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Drug Testing Page(s): 43. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) / Urine Drug testing.

**Decision rationale:** Per the MTUS, Drug testing is recommended as an option, using a urine drug screen to assess for the use or the presence of illegal drugs before a therapeutic trial of opioids, during ongoing management and to avoid misuse/ addiction. Per the ODG, frequency of urine drug testing should be based on documented evidence of risk stratification including use of a testing instrument. A review of the injured workers medical records did not reveal documentation of risk stratification and without this information medical necessity for Urine Drug Test at this time is not established.