

<b>Case Number:</b>	CM14-0098895		
<b>Date Assigned:</b>	08/06/2014	<b>Date of Injury:</b>	10/01/2012
<b>Decision Date:</b>	09/24/2014	<b>UR Denial Date:</b>	06/18/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/27/2014

### 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 Anesthesia, has a subspecialty in Acupuncture and Pain 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 36year old female injured worker with date of injury 10/1/12 with related lumbar spine pain. Per progress report dated 5/29/14, she complained of constant stabbing low back pain that was at a level 6/10 with medication. The low back pain radiated into the hip, thigh, and extended to the left knee. The left hip pain was described as stabbing and burning, and rated 5/10. The pain in the left thigh was occasional and 3/10 in intensity. Per physical exam there was tenderness noted over the bilateral, left greater than right, paraspinal muscles at L3-L4, L4-L5, and L5-S1 segments. Straight leg raise test was positive on the left. Sensation was decreased in the left S1 dermatome. Motor weakness was noted in the left L1, L2, S1 and S1 innervated musculature. MRI of the lumbar spine dated 4/2012 revealed broad based disc bulges at L4-L5 and L5-S1. She was refractory to injection. She has been treated with physical therapy and medication management. The date of UR decision was 6/18/14

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Retrospective Request of Cyclo 10%/Tram 10%/Ultraderm 24gm & Fluribiprofen 25%/Ultraderm 24gm (Compound) DOS 5/29/2014: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines: Web Edition.

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

**Decision rationale:** Per MTUS p113 with regard to topical cyclobenzaprine, "There is no evidence for use of any muscle relaxant as a topical product."The MTUS is silent on the use of tramadol topically. However, note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of multiple medications, MTUS p60 states "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually.As topical cyclobenzaprine is not recommended, the compound is not recommended.Per MTUS with regard to Flurbiprofen (p112), "(Biswal, 2006) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety." Flurbiprofen may be indicated. However, as the first compound is not recommended, the request is not medically necessary.

**Retrospective Review of Diclofenac Sod (Voltaren) 100mg, #60 DOS 5/29/14: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines: Web Edition.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 12, 67-68.

**Decision rationale:** With regard to the use of NSAIDs for chronic low back pain, the MTUS CPMTG states "Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another."Both acetaminophen and NSAIDs have been recommended as first line therapy for low back pain. There is insufficient evidence to recommend one medication over the other. Selection should be made on a case-by-case basis based on weighing efficacy vs. side effect profile."The request is indicated for the injured worker's moderate to severe low back pain. I respectfully disagree with the UR physician's assertion that there was no documentation supporting its use. The MTUS does not mandate documentation of functional improvement for the ongoing use of NSAIDs. The request is medically necessary.

**Retrospective Request for Quazepam (Doral) 15mg, #30 DOS 5/29/14: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines: Web Edition.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24.

**Decision rationale:** With regard to benzodiazepines, MTUS CPMTG states "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."The documentation submitted for review indicate that this medication was prescribed for insomnia, however, there was no documentation of information regarding sleep onset, sleep maintenance, sleep quality, and next-day functioning. It was not noted whether simple sleep hygiene methods were tried and failed. The request is not medically necessary.

**Retrospective Request for Pantoprazole (Protonix) 20mg, #60 DOS 5/29/14: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines: Web Edition.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms, & Cardiovascular Risk Page(s): 68.

**Decision rationale:** In the treatment of dyspepsia secondary to NSAID therapy, the MTUS recommends stopping the NSAID, switching to a different NSAID, or considering the use of an H2-receptor antagonist or a PPI. The MTUS Chronic Pain Medical Treatment Guidelines recommend the use of proton pump inhibitors in conjunction with NSAIDs in situations in which the patient is at risk for gastrointestinal events including: (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). CPMTG guidelines further specify: "Recommendations: Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g, ibuprofen, naproxen, etc.) Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is

high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardioprotection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is naproxyn plus low-dose aspirin plus a PPI. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007) (Laine, 2007)"Per ODG TWC, "many prescribers believe that this class of drugs is innocuous, but much information is available to demonstrate otherwise. A trial of omeprazole or lansoprazole is recommended before Nexium therapy. The other PPIs, Protonix, Dexilant, and Aciphex, should also be second-line."Although it is noted that the injured worker is on NSAID therapy, there is no documentation of peptic ulcer, GI bleeding or perforation, or cardiovascular disease in the records available for my review, the injured worker's risk for gastrointestinal events is low, as such, medical necessity cannot be affirmed. Additionally, as noted per the guidelines, Protonix is a second-line medication. The medical records do not establish whether the patient has failed attempts at first line PPIs, such as omeprazole or lansoprazole, which should be considered prior to prescribing a second line PPI such as Protonix. The request is not medically necessary.

**Retrospective Request of Cyclobenzaprine (Flexeril) 7.5mg and Fluribiprofen 25% 7.5gms, #90 (Compound) DOS 5/29/14: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines: Web Edition.

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

**Decision rationale:** Per MTUS p113 with regard to topical Flexeril, "There is no evidence for use of any muscle relaxant as a topical product."Per MTUS with regard to Flurbiprofen (p112), "(Biswal, 2006) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety." Flurbiprofen may be indicated.Regarding the use of multiple medications, MTUS p60 states "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually.Note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. As Flexeril is not recommended, the request is not medically necessary.