

Case Number:	CM14-0042811		
Date Assigned:	08/06/2014	Date of Injury:	05/14/2010
Decision Date:	09/10/2014	UR Denial Date:	04/01/2014
Priority:	Standard	Application Received:	04/07/2014

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 General Preventive Medicine and is licensed to practice in Indiana. 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:

This injured worker is a 35 year old female with date of injury of 5/14/2010. A review of the medical records indicate that the patient is undergoing treatment for low back pain and right ankle pain. Subjective complaints include continuing low back pain. Objective findings include a positive straight leg raise, tenderness in her low back, and decreased lumbar ROM, MRI findings of degenerative disc disease in the lumbar spine. Treatment has included chiropractic therapy, norco, voltaren, neurontin, terocin, and surgical evaluation. The utilization review dated 4/1/2014 non-certified terocin patches, protonix, tramadol, naproxen, lidopro, and flexeril.

IMR ISSUES, DECISIONS AND RATIONALES

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

Terocin Patches #20: 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, Lidoderm patches Page(s): 111, 56-57.

Decision rationale: Terocin patch is topical pain patch that contains lidocaine and menthol. ODG states regarding lidocaine topical patch, This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia. Medical documents do not document the patient as having

post-herpetic neuralgia. Additionally, Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is no indication in the documentation that these types of medications have been trialed and/or failed. MTUS states regarding topical analgesic creams, There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Lidocaine is not supported by the treatment guidelines. As such, the request for terocin patches #20 is not medically necessary.

Lidopro cream 1 bottle: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin, Salicylate, Topical analgesic Page(s): 28, 105, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Capsaicin topicals, Salicylate topicals, Topical analgesics.

Decision rationale: Lidopro is a topical medication containing Lidocaine, Capsaicin, Menthol, and Methyl Salicylate. CA MTUS recommends capsaicin only as an option in patients who have not responded or are intolerant to other treatments. Additionally, regarding salicylates: Recommended. Topical salicylate(e.g., Ben-Gay, methyl salicylate) is significantly better than placebo in chronic pain. (Mason-BMJ, 2004) See also Topical analgesics; & Topical analgesics, compounded. There is no indication that the patient has failed oral medication or is intolerant to other treatments. Additionally, ODG states Topical OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns, a new alert from the FDA warns. . MTUS states regarding topical analgesic creams, There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Lidocaine is not supported by the treatment guidelines. As such, the request for a Lidopro cream bottle is not medically necessary.

Protonix 10mg # 60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI symptoms & cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), NSAIDS, GI symptoms & cardiovascular risk.

Decision rationale: MTUS states Determine if the patient is at risk for gastrointestinal events: (1) age 65 years or older; (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). And 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). ODG states If a PPI is used, omeprazole OTC tablets or lansoprazole 24HR OTC are recommended for an equivalent clinical efficacy and significant cost savings. 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 is recommended before Protonix therapy. The other PPIs, Nexium, Dexilant, and Aciphex, should also be second-line. According to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective. (AHRQ, 2011) . The medical documents provided do not show a history of GERD or any substantial GI side effects. Additionally, they show no documentation of a failed trial of omeprazole or lansoprazole prior to starting Protonix therapy. As such, the request for Protonix 10MG #60 is not medically necessary.

Tramadol ER 150 mg # 30: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 93-94.

Decision rationale: The MTUS does not recommend Tramadol as it is a synthetic opioid affecting the central nervous system. Tramadol side effects include headaches, which the patient already suffers from and when used with other opiates increases the risk of seizures. The treating physician provided no evidence of failed therapy with first line agents such as NSAIDs, and also failed to show the efficacy of its current use. The request for ongoing Tramadol ER 150mg #30 is not medically necessary.

Naproxen 550mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67-73. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Naproxen, NSAIDs (non-steroidal anti-inflammatory drugs).

Decision rationale: MTUS recommends NSAIDs for osteoarthritis at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain for acute exacerbation's, however, there is no evidence in the medical record that these NSAIDs are for the recent flare-

ups or exacerbation's. The guidelines state that chronic use of prescription NSAIDs is not recommended. Looking at the medical records, it is reasonable to believe the employee could transition to over the counter pain medications such as Tylenol. Therefore, the request for Naproxen 500mg #60 is not medically necessary.

Flexeril 7.5mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine, Medications for chronic pain, Antispasmodics Page(s): 41-42, 60-61, 64-66. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Cyclobenzaprine (Flexeril®) Other Medical Treatment Guideline or Medical Evidence: UpToDate, Flexeril.

Decision rationale: MTUS Chronic Pain medical Treatment states for Cyclobenzaprine, Recommended as an option, using a short course of therapy. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. (Browning, 2001) Treatment should be brief. The medical documents indicate that patient is far in excess of the initial treatment window and period. Additionally, MTUS outlines that Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity. Before prescribing any medication for pain the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. 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) Up to date Flexeril also recommends Do not use longer than 2-3 weeks. Medical documents do not fully detail the components outlined in the guidelines above and do not establish the need for long term/chronic usage of cyclobenzaprine. ODG states regarding cyclobenzaprine, Recommended as an option, using a short course of therapy. The addition of cyclobenzaprine to other agents is not recommended. Several other pain medications are being requested, along with cyclobenzaprine, which ODG recommends against. As such, the request for Flexeril 7.5mg #60 is not medically necessary.