

<b>Case Number:</b>	CM15-0024032		
<b>Date Assigned:</b>	02/13/2015	<b>Date of Injury:</b>	01/22/1999
<b>Decision Date:</b>	04/10/2015	<b>UR Denial Date:</b>	01/16/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/09/2015

### 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: District of Columbia, Virginia  
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 45 year old female, who sustained an industrial injury on January 22, 1999. She has reported injury to the cervical and lumbar spine. The diagnoses have included inter-vertebral lumbar disc disorder with myelopathy of the lumbar region, cervical strain, nerve root irritation, failed back surgical syndrome and mechanical complication of dorsal column stimulator. Treatment to date has included medication and DCS unit. Currently, the injured worker complains of worsening low back pain along with weakness and falls, right leg pain with weakness, buckles and falls and mild to moderate neck pain. She also complains of daily headaches coming from neck spasm. Notes stated that she is receiving some benefit from her medication. On January 16, 2015, Utilization Review non-certified 4 Nabumetone 750mg #60, Prevacid 30mg #30 with two refills, Norco 10/325mg #120 and Soma 350mg #60, noting the Official Disability Guidelines and other evidence based guidelines. On February 9, 2015, the injured worker submitted an application for Independent Medical Review for review of 4 Nabumetone 750mg #60, Prevacid 30mg #30 with two refills, Norco 10/325mg #120 and Soma 350mg #60.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**4 Nabumetone 750mg 1-2 times daily #60: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 9792  
Page(s): 72,73.

**Decision rationale:** Per MTUS: Nabumetone (Relafen, generic available): 500, 750 mg. Dosing: Osteoarthritis: The recommended starting dose is 1000 mg PO. The dose can be divided into 500 mg PO twice a day. Additional relief may be obtained with a dose of 1500 mg to 2000 mg per day. The maximum dose is 2000 mg/day. Patients weighing less than 50 kg may be less likely to require doses greater than 1000 mg/day. The lowest effective dose of nabumetone should be sought for each patient. Use for moderate pain is off-label. (Relafen Package Insert) This medication is recommended for short-term usage only and this patient has been on this medication over the recommended period. It would not be medically indicated.

**Prevacid 30mg one daily #30 with 2 refills:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation proton pump inhibitors.

**Decision rationale:** MTUS does not address this medication. Per ODG: proton pump inhibitors (PPI) are recommended for patients at risk for gastrointestinal events. See NSAIDS, GI symptoms and cardiovascular risk. Prilosec (omeprazole), Prevacid (lansoprazole) and nexium (esomeprazole) are PPIs. Omeprazole provides a statistically significantly greater acid control than lansoprazole (Miner 2010). Healing doses of PPIs are more effective than all other therapies although there is an increase in overall adverse effects to placebo. Nexium and Prilosec are very similar molecules. For many people, Prilosec is more affordable than nexium. Nexium is not available in a generic (as in Prilosec). Also, prilosec is more available as an over the counter product while nexium is not. (Donnellan 2010) In general, the use of a PPI should be limited to the recognized indications and used at the lowest dose or the shortest possible amount of time. PPIs are more effective 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. If a PPI is used, omeprazole OTC tablets or lansoprazole 24 HR 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 nexium, prevacid, prilosec, protonix , dexilant and aciphex (Shi 2008). A trial of omeprazole or lansoprazole is recommended before nexium therapy. The other PPIs, protonix, dexilant, 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) (Pain Chapter). The patient had no indications for prevacid. Therefore, this current regimen would not be recommended.

**Norco 10/325mg, one every six hours, quantity: 120:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 9792  
Page(s): 75,91,124.

**Decision rationale:** Per MTUS: Short-acting opioids: also known as "normal-release" or "immediate-release" opioids are seen as an effective method in controlling chronic pain. They are often used for intermittent or breakthrough pain. These agents are often combined with other analgesics such as acetaminophen and aspirin. These adjunct agents may limit the upper range of dosing of short acting agents due to their adverse effects. The duration of action is generally 3-4 hours. Shortacting opioids include Morphine (Roxanol), Oxycodone (OxyIR, Oxyfast Endocodone), Oxycodone with acetaminophen, (Roxilox, Roxicet, Percocet, Tylox, Endocet), Hydrocodone with acetaminophen, (Vicodin, Lorcet, Lortab), Hydrocodone/Acetaminophen (Anexsia, Co-Gesic, Hycet; Lorcet, Lortab; Margesic-H, Maxidone; Norco, Stagesic, Vicodin, Xodol, Zydone; generics available): Indicated for moderate to moderately severe pain. Note: there are no FDA approved hydrocodone products for pain unless formulated as a combination. Side Effects: See opioid adverse effects. Analgesic dose: The usual dose of 5/500mg is 1 or 2 tablets PO every four to six hours as needed for pain (Max 8 tablets/day). For higher doses of hydrocodone (>5mg/tab) and acetaminophen (>500mg/tab) the recommended dose is usually 1 tablet every four to six hours as needed for pain. Hydrocodone has a recommended maximum dose of 60mg/24 hours. The dose is limited by the dosage of acetaminophen, which should not exceed 4g/24 hours. Long-term usage of this medication would not be indicated. Weaning of this medication should be initiated.

**Soma 350mg one to two at bedtime, quantity: 60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 9792  
Page(s): 29.

**Decision rationale:** Per MTUS: Carisoprodol (Soma & #130): Not recommended. This medication is not indicated for long-term use. Carisoprodol is a commonly prescribed, centrally acting skeletal muscle relaxant whose primary active metabolite is meprobamate (a schedule-IV controlled substance). Carisoprodol is now scheduled in several states but not on a federal level. It has been suggested that the main effect is due to generalized sedation and treatment of anxiety. Abuse has been noted for sedative and relaxant effects. In regular abusers the main concern is the accumulation of meprobamate. Carisoprodol abuse has also been noted in order to augment or alter effects of other drugs. This includes the following: (1) increasing sedation of benzodiazepines or alcohol; (2) use to prevent side effects of cocaine; (3) use with tramadol to produce relaxation and euphoria; (4) as a combination with hydrocodone, an effect that some abusers claim is similar to heroin (referred to as a "Las Vegas Cocktail"); & (5) as a combination

with codeine (referred to as “Soma Coma”). (Reeves, 1999) (Reeves, 2001) (Reeves, 2008) (Schears, 2004) There was a 300% increase in numbers of emergency room episodes related to carisoprodol from 1994 to 2005. (DHSS, 2005) Intoxication appears to include subdued consciousness, decreased cognitive function, and abnormalities of the eyes, vestibular function, appearance, gait and motor function. Intoxication includes the effects of both carisoprodol and meprobamate, both of which act on different neurotransmitters. (Bramness, 2007) (Bramness, 2004) A withdrawal syndrome has been documented that consists of insomnia, vomiting, tremors, muscle twitching, anxiety, and ataxia when abrupt discontinuation of large doses occurs. This is similar to withdrawal from meprobamate. (Reeves, 2007) (Reeves, 2004) There is little research in terms of weaning of high dose carisoprodol and there is no standard treatment regimen for patients with known dependence. Most treatment includes treatment for symptomatic complaints of withdrawal. Another option is to switch to phenobarbital to prevent withdrawal with subsequent tapering. A maximum dose of phenobarbital is 500 mg/day and the taper is 30 mg/day with a slower taper in an outpatient setting. Tapering should be individualized for each patient. (Boothby, 2003) For more information and references, see Muscle relaxants. See also Weaning of medications. Per MTUS guidelines, this medication would not be indicated.