

<b>Case Number:</b>	CM14-0146991		
<b>Date Assigned:</b>	09/15/2014	<b>Date of Injury:</b>	05/01/2002
<b>Decision Date:</b>	11/06/2014	<b>UR Denial Date:</b>	08/26/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/10/2014

### 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 Family 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 patient is a 57 year-old woman who was injured at work on 5/1/2002. The injury was primarily to her knees and lower legs. She is requesting review of denial for the following: Zipsor 25mg #90; Soma 350mg #30; and 1 Follow-Up Visit with an Orthopedic Surgeon. Medical records corroborate ongoing care for her injuries. Her chronic diagnoses include: Status Post Bilateral Knee Replacements; Bilateral Tibial Incompetencies in the Lower Extremities; Plantar Fasciitis/Bilateral; and Short Leg Length Discrepancy. She was evaluated by an Orthopedic Surgeon with the most recent note completed on 7/10/2014. At this visit the patient was complaining of some pain over the medial aspect of the patella and in the patellar tendon area of the left knee. Physical examination was notable for crepitus with range of motion. X-rays of the knee and patella were described as "normal." The impression was "status post revision of the left knee with some crepitation most likely secondary to soft tissue." Treatment recommendation was to "recommend progressive ambulation." Follow-up was also recommended if there was a change in status.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Zipsor 25mg #90:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG (Official Disability Guidelines); NSAID's (non-steroidal anti-inflammatory)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67-71.

**Decision rationale:** Zipsor (Diclofenac) is a Non-Selective NSAID. The typical adult dose of Zipsor is 25mg four times a day (Page 71). The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of NSAIDs for the treatment of pain. Specific recommendations are provided for the treatment of osteoarthritis of the knee and hip. NSAIDs such as Zipsor are recommended 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. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with Naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. In this case, the most recent evaluation from the Orthopedic Surgeon indicates that the patient's knee pain is not caused by osteoarthritis. The stated MTUS guidelines indicate that an NSAID such as Zipsor should be used at the lowest dose for the shortest period of time. The records indicate that Zipsor is being used as a chronic treatment for the patient's knee pain. There is no evidence in the record to indicate that there has been an improvement in pain or function. Therefore, Zipsor is not considered as a medically necessary treatment.

**Soma 350mg #30:** Upheld

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

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

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of Carisoprodol (Soma) for the treatment of muscle spasms. Carisoprodol is 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. The medical records do not provide justification for the use of a muscle relaxant. Further, the records indicate that Soma is being prescribed as a chronic treatment for this patient's symptoms. Therefore, based on the above guidelines, there is no justification for the use of Soma. Soma is not a medically necessary treatment.

### **1 Follow up with Orthopaedic Surgeon: Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 13 Knee Complaints Page(s): 334.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 13 Knee Complaints Page(s): 330.

**Decision rationale:** The MTUS/ACOEM Guidelines comment on the indications for follow-up care. These guidelines state that "certain findings on the history and physical examination raise suspicion of serious underlying medical conditions known as red flags (Table 13-1). Their absence rules out the need for special studies, referral, or inpatient care." The medical records do not provide any evidence to suggest the presence of red flag symptoms that warrant further investigation by an Orthopedic Surgeon. The last documented visit by the Orthopedic Surgeon recommended follow-up if "there was a change in status." There is no evidence in the medical records to support a change in the patient's status or the aforementioned red flag signs on history or physical examination. Therefore, there is no medical justification for 1 Follow-Up Visit with an Orthopedic Surgeon rendering this request not medically necessary.