

<b>Case Number:</b>	CM14-0116708		
<b>Date Assigned:</b>	08/04/2014	<b>Date of Injury:</b>	07/29/2005
<b>Decision Date:</b>	09/10/2014	<b>UR Denial Date:</b>	07/03/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/24/2014

### 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 Physical Medicine and Rehabilitation, 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 injured worker is a 50-year-old-female, who sustained injury on 07/29/05. She complains of bilateral low back pain and depression. She describes the pain as burning; cramping; electrical and shooting. Her pain is described as 7/10; severe pain. It is constant pain but variable in intensity; patient notes of increased pain due to the cold weather. Her pain radiates to left L5 distribution; left leg; left toe; pain radiates into the big toe and the second toe on the left foot. Her pain aggravates while bending; walking; and weather change. She states, exercise/physical therapy; heat; medication; position change; and rest alleviate her pain. She continues to do her stretches at home and she does minimal strengthening exercises as part of her HEP. She has sleep difficulty, but is improved with medication. She has a 50% decrease in pain with Flector. Zanaflex results in a 50% decrease in pain. On physical exam, there is tenderness in the spine. There is reduced sensation in the right leg. In palpation of lumbosacral spine, trigger points or muscle spasm was not present. SLR in seated position was positive on both sides. Tenderness was noted over midline of lumbar spine on both sides. Medications prescribed are: Flector, Zanaflex, Zoloft, and Ambien. Assessment: lumbar post-laminectomy syndrome and depressive disorder. Request for Flector 1.3 Transdermal 12 hour patch #60 plus 2 refills; Tizanidine 2 mg. #90 plus 4 refills; Zolpidem 5mg #15 were not medically necessary.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flector 1.3 Transdermal 12 Hour Patch #60 plus 2 refills: Upheld**

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain.

**Decision rationale:** Flector Patch (Diclofenac Epolamine Topical Patch 1.3%): Indicated for acute strains, sprains, and contusions. Not recommended as a first-line treatment. As a Topical Diclofenac, it is recommended for osteoarthritis after failure of an oral NSAID or contraindications to oral NSAIDs, after considering the increased risk profile with Diclofenac, including topical formulations. The efficacy in clinical trials for topical NSAIDs has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. In this case, there is no documentation of an acute strain/sprain/contusion and there is no diagnosis of osteoarthritis. Also, it appears that Flector patch has been used for low back pain in this injured worker, which is not indicated per guidelines. Furthermore, there is no record of monitoring of liver enzymes, as mandated by FDA for chronic use of this topical medication. Therefore, the request is not medically necessary per guidelines.

**Tizanidine 2mg #90 plus 4 refills:** 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 Tizanidine Page(s): 66.

**Decision rationale:** According to the CA MTUS guidelines, Tizanidine (Zanaflex) is a centrally acting alpha2-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for low back pain. In this case, there is no evidence of spasticity (which is different from muscle spasm) due to any neurological disorders such as MS. Furthermore, there is no documentation of substantial spasm that has failed first line therapy. Tizanidine is not indicated for pain according to guidelines. Therefore, the request is considered not medically necessary.

**Zolpidem 5mg #15:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Stress & Mental Illness Chapter: Zolpidem.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Ambien.

**Decision rationale:** CA MTUS guidelines do not address the issue in dispute and hence Official Disability Guidelines (ODG) has been consulted. As per ODG, Zolpidem (Ambien) is a prescription short-acting Non-Benzodiazepine hypnotic, which is approved for the short-term (usually two to six weeks) treatment of insomnia. Proper sleep hygiene is critical to the individual with chronic pain and often is hard to obtain." Additionally, it is unclear from the records for how long he has been prescribed this medication since guidelines only recommend short-term use for 2-6 weeks. Thus, the request is not medically necessary. There is no documentation of any significant improvement in sleep with prior use of this medication. Therefore, the request is considered not medically necessary per guidelines.