

<b>Case Number:</b>	CM14-0161526		
<b>Date Assigned:</b>	10/07/2014	<b>Date of Injury:</b>	09/22/2002
<b>Decision Date:</b>	12/26/2014	<b>UR Denial Date:</b>	09/22/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/01/2014

### 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 Occupational 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 claimant injured her low back on 09/22/02. She has postlaminectomy syndrome and chronic low back pain. Lyrica, Flector patches, and Zolpidem ER are under review. On 04/07/14, she reported increased pain. Her sleep was fair and her activity level had decreased. She was on multiple medications including Lyrica, Duragesic patch, Zanaflex, Flector, Ambien CR, Cymbalta, and Norco. She had a slightly antalgic gait. Range of motion was restricted on flexion, extension, lateral bending and lateral rotation. There was hypertonicity and tenderness of the bilateral low back regions. Lumbar facet loading was positive bilaterally and straight leg raising was positive on the right side sitting at 60 and also supine. Reflexes were equal and symmetric. Motor testing was limited by pain. There was no hypotonia or hypertonia. Sensation was decreased to pinprick over the lateral foot and calf on the right side. She was diagnosed with post lumbar laminectomy syndrome with degenerative disc disease and radiculopathy. She was working full-time. She did not want a spinal cord stimulator but used an H wave unit for acute flare ups with good benefit. She was prescribed Duragesic for baseline pain control and Norco for breakthrough pain, Zanaflex for spasms, Cymbalta for nerve pain, Lyrica for nerve pain, and Ambien for insomnia. She was to continue her home exercises. She has an opiate agreement. On 06/05/14, she was seen again and her quality of sleep was poor. Her pain had increased since her last visit. She had been sick and unable to keep her medication down so her pain increased. She was taking Lyrica, Duragesic patches, Flector patches, Norco, Ambien CR, Cymbalta, and Zanaflex. Her physical findings were essentially unchanged. Other than her illness her pain had been stable. She was still using an H wave unit. On 07/24/14, again she reported increased pain. She was working long hours. She was on her same medications. There were no new problems or side effects. She wanted to know if anything else could be done for her pain. Her physical findings were essentially the same. She had a slightly antalgic gait.

Twelve sessions of acupuncture were ordered and she continued her medications and home exercises.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Lyrica 100mg, #90 (30 day supply): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lyrica (pregabalin); Medications for Chronic Pain Page(s): 94, 131.

**Decision rationale:** The history and documentation do not objectively support the request for the use of Lyrica 100mg, #90. The MTUS state "pregabalin (Lyrica) has been documented to be effective in treatment of diabetic neuropathy and postherpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. Pregabalin was also approved to treat fibromyalgia." Also, 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 to 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 medication should show effects within 1 to 3 days ... A record of pain and function with the medication should be recorded. (Mens 2005)" In this case, none of these conditions (diabetic neuropathy, postherpetic neuralgia, or fibromyalgia) appear to be under treatment. The specific benefit to the claimant of this medication has not been described and none can be ascertained from the file. Her pattern of use and functional benefit from this medication are unknown. There is no evidence of trials of other first line drugs such as gabapentin for neuropathic pain and it is not clear why Lyrica is being used. The medical necessity of the ongoing use of Lyrica 100mg, #90 (30 day supply) is not supported.

**Flector DIS 1.3%, #30 (30 day supply): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 143.

**Decision rationale:** The history and documentation do not objectively support the request for Flector DIS 1.3%, #30 (30 day supply). The MTUS state "topical agents may be recommended as an option [but are] largely experimental in use with few randomized controlled trials to determine efficacy or safety. It is primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004)." There is no evidence of failure of all other first line drugs. The claimant received refills of multiple other medications.

She has reported benefit from the use of medications and increased pain without them. However, the specific benefit to her of the use of Flector patches and the anticipated benefit of continued use have not been described. The medical necessity of this request has not been clearly demonstrated. The request is not medically necessary.

**Zolpidem ER 12.5mg, #30 (30 day supply): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation website: [www.nlm.nih.gov](http://www.nlm.nih.gov)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines General Principles, various sections. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG): Formulary - zolpidem

**Decision rationale:** The history and documentation do not objectively support the request for Zolpidem ER 12.5mg, #30 (30 day supply). The MTUS indicate that good sleep patterns are likely to be beneficial in chronic pain situations. However, the use of sleep aids is not specifically addressed. The ODG state "Zolpidem (Ambien) is a prescription short-acting nonbenzodiazepine 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. Various medications may provide short-term benefit. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit-forming, and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term. (Feinberg, 2008) See Insomnia treatment. Ambien CR offers no significant clinical advantage over regular release zolpidem. Ambien CR is approved for chronic use, but chronic use of hypnotics in general is discouraged, as outlined in Insomnia treatment. Ambien CR causes a greater frequency of dizziness, drowsiness, and headache compared to immediate release zolpidem. (Ambien & Ambien CR package insert) Cognitive behavioral therapy (CBT) should be an important part of an insomnia treatment plan. A study of patients with persistent insomnia found that the addition of zolpidem immediate release to CBT was modestly beneficial during acute (first 6 weeks) therapy, but better long-term outcomes were achieved when zolpidem IR was discontinued and maintenance CBT continued. (Morin, 2009) Due to adverse effects, FDA now requires lower doses for zolpidem. The dose of zolpidem for women should be lowered from 10 mg to 5 mg for IR products (Ambien, Edluar, Zolpimist, and generic) and from 12.5 mg to 6.25 mg for ER products (Ambien CR). The ER product is still more risky than IR. In laboratory studies, 15% of women and 3% of men who took a 10-milligram dose of Ambien had potentially dangerous concentrations of the drug in their blood eight hours later. Among those who took Ambien CR, the problem was more common: 33% of women and 25% of men had blood concentrations that would raise the risk of a motor vehicle accident eight hours later. Even at the lower dose of Ambien CR now recommended by the FDA, 15% of women and 5% of men still had high levels of the drug in their system in the morning. (FDA, 2013) According to SAMHSA (Substance Abuse and Mental Health Services Administration) zolpidem is linked to a sharp increase in ED (Emergency Dept) visits, so it should be used safely for only a short period of time."In this case, the claimant has reported problems with sleep but her history of insomnia is unclear and her

pattern of use of this medication, and functional improvement from its use, has not been described. Typically, sleep aids of this type are only recommended for short periods of time. There is no full history of insomnia or description of failed trials of basic sleep hygiene. Chronic use of sleep aids/hypnotics is discouraged. The medical necessity of ongoing use of this medication has not been clearly demonstrated.