

<b>Case Number:</b>	CM15-0034115		
<b>Date Assigned:</b>	03/02/2015	<b>Date of Injury:</b>	05/13/1994
<b>Decision Date:</b>	04/14/2015	<b>UR Denial Date:</b>	01/22/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/24/2015

### 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: Pennsylvania  
 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 73 year old female who has reported low back pain after falling on 5/13/94. The diagnoses have included lumbosacral spondylosis, displacement of lumbar intervertebral disc, post lumbar laminectomy syndrome, opioid dependence and spinal stenosis. Treatment to date has included medications, intrathecal infusion pump, injections and surgery. The most recent surgery was a lumbar fusion in October 2014. Reports from the treating physician during 2014 reflect ongoing low back pain and radiating leg pain. Reports are stereotyped and have much the same information from report to report. Ongoing medications have included Cymbalta, Lyrica, Roxicodone, Pilocarpine tablets, Soma, Lunesta, Aquoral, Numoisyn, Keflex, Salagen, and Celebrex. A pain pump was explanted on 9/30/14. A urine drug screen on 7/30/14 was positive for oxycodone and fentanyl, which had been prescribed. Visits prior to pump explantation included pump refills. None of the reports address the medical necessity for pilocarpine. None of the reports address the specific functional benefit and results of using the current medications. It appears that Sonata was newly prescribed on 1/8/15. Celebrex indications and results of use have not been discussed. Blood pressures were not measured. A urine drug screen on 1/8/15 had a low specific gravity and was positive for oxycodone, acetaminophen, and pregabalin. The abnormal specific gravity was not addressed by the physician. Per the PR2 of 1/8/15 from the treating physician, there was ongoing low back pain that radiated to the lower extremities, hips and buttocks. The pain was better with rest and medication and worsened with movements. She had failed Restoril, Climara, and nonsteroidal anti-inflammatory agents (NSAIDs). Percocet prescribed by another physician and Lunesta were

not effective. Physical exam revealed pain with palpation to the right and left sacroiliac joint and positive Faber's test. The urine drug screen dated 7/30/14 was reportedly consistent with medications prescribed. The current medications were Cymbalta, Lyrica, Roxicodone, Pilocarpine tablets, and Celebrex. Lunesta and Percocet were stopped. Sonata #30, Celebrex, Pilocarpine, oxycodone, and urine drug screen were prescribed. The specific indications for pilocarpine were not addressed. Function was addressed by stating that all activities listed increased the pain. Work status was not addressed. There was no discussion of a sleep disorder. An appeal letter was dated 1/30/15. The same diagnoses were listed. The current medications were listed. The "medications" were working and had no side effects or signs of abuse. Unspecified medications were reported to give pain relief and increased function. Drug testing, CURES reports, and a pain contract were present. Another appeal letter was dated 2/20/15 and had the same text. On 1/22/15 Utilization Review partially certified Lyrica 75mg #60 for Lyrica 75mg #30, Sonata 10mg #30 for Sonata 10mg #7, and Roxicodone 15mg #30 for Roxicodone 15mg #15. On 1/22/15 Utilization Review non-certified Pilocarpine 5mg #180 and Celebrex 200mg #30. The MTUS and the Official Disability Guidelines were cited.

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

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

**Lyrica 75mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 99.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-Epilepsy Drugs (AEDs). Medication trials Page(s): 61-21, 60.

**Decision rationale:** Per the MTUS, pregabalin is recommended for neuropathic pain. There is no good evidence in this case for neuropathic pain. There are no physician reports which adequately address the specific symptomatic and functional benefit from the AEDs used to date. Note the criteria for a "good" response per the MTUS. When provided the chance to appeal the prior Utilization Review decision for Lyrica, the treating physician did not provide any specific information about the ongoing results of using Lyrica. He instead made general references to non-specific benefits of taking all current medications. This does not constitute good evidence of symptomatic and functional benefit, as discussed in the MTUS references above. Pregabalin is not medically necessary based on the lack of any clear indication and the lack of significant symptomatic and functional benefit from its use to date.

**Sonata 10mg #30:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain and Insomnia Treatment.

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

**Decision rationale:** The MTUS does not address the use of hypnotics other than benzodiazepines. The Official Disability Guidelines were used instead. The Official Disability Guidelines recommend the short term use of hypnotics like Sonata, discuss the significant side effects (particularly in the elderly), and note the need for a careful evaluation of the sleep difficulties. The recommended dose in the elderly is 5 mg, not 10 mg. The Utilization Review noted the need for short term use at most, and this was the basis for the partial certification. None of the treating physician reports during 2014 and 2015 provide a good analysis of any sleep disorder. The treating physician has not addressed other major issues affecting sleep in this patient, including the use of other psychoactive agents like opioids, which significantly impair sleep architecture. Prescribing in this case meets none of the guideline recommendations. Sonata is not medically necessary based on prescribing for longer-term use contrary to guideline recommendations, excessive dosing, and lack of sufficient evaluation of the sleep disorder.

**Roxicodone 15mg #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 78.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioid management. Opioids, steps to avoid misuse/addiction. Indications, Chronic back pain. Mechanical and compressive etiologies. Medication trials Page(s): 77-81, 94, 80, 81, 60.

**Decision rationale:** There is insufficient evidence that the treating physician is prescribing opioids according to the MTUS, which recommends prescribing according to function, with specific functional goals, return to work, random drug testing, opioid contract, and there should be a prior failure of non-opioid therapy. There is no evidence of random testing, as tests occur at office visits only. The dilute specimen was not addressed by the treating physician. The prescribing physician does not specifically address function with respect to prescribing opioids. There is no evidence of significantly increased function from the opioids used to date. The treating physician has made only the most non-specific and generic references to increased function in his reports, including the Utilization Review appeals. The reports refer to increased pain with all activities, no significant levels of function, and no specific results of using opioids. As currently prescribed, this opioid does not meet the criteria for long term opioids as elaborated in the MTUS and is therefore not medically necessary. This is not meant to imply that some form of analgesia is contraindicated; only that the opioids as prescribed have not been prescribed according to the MTUS and that the results of use do not meet the requirements of the MTUS.

**Pilocarpine 5mg #180:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation [www.drugs.com/pro/pilocarpine.html](http://www.drugs.com/pro/pilocarpine.html).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UpToDate, Pilocarpine (systemic): Drug information. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015.

**Decision rationale:** The request to Independent Medical Review is for a medication which was not adequately defined. The treating physician did not supply sufficient information regarding the nature of the request and its indications. Even in the appeal letters there was no discussion of the specific indications and results of use for pilocarpine. The possible indications are varied and there is no apparent indication for low back pain. The UpToDate reference above describes the usual indications. The request is therefore not medically necessary based on the lack of sufficient indications or results of use provided by the treating physician.

**Celebrex 200mg #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 67-68.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain. NSAIDs for Back Pain - Acute exacerbations of chronic pain. Back Pain - Chronic low back pain. NSAIDs, specific drug list & adverse effects Page(s): 60, 68, 70.

**Decision rationale:** Per the MTUS for chronic pain, page 60, medications should be trialed one at a time, and there should be functional improvement with each medication. No reports show any specific benefit, functional or otherwise. Systemic toxicity is possible with NSAIDs. The FDA and MTUS recommend monitoring of blood tests and blood pressure. There is no evidence that the prescribing physician is adequately monitoring for toxicity as recommended by the FDA and MTUS. This is particularly important with Celebrex, which has an elevated cardiovascular risk profile. The MTUS does not recommend chronic NSAIDs for low back pain. NSAIDs should be used for the short term only. Acetaminophen is the drug of choice for flare-ups, followed by a short course of NSAIDs. The treating physician has been prescribing large quantities of Celebrex chronically, which is counter to the recommendations of the MTUS for treatment of back pain. This NSAID is not medically necessary based on the MTUS recommendations against chronic use, lack of specific functional and symptomatic benefit, and prescription not in accordance with the MTUS and the FDA warnings.