

<b>Case Number:</b>	CM14-0198148		
<b>Date Assigned:</b>	12/08/2014	<b>Date of Injury:</b>	07/27/2013
<b>Decision Date:</b>	01/20/2015	<b>UR Denial Date:</b>	10/28/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/25/2014

### 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 Neurology, has a subspecialty in Neuromuscular Medicine and is licensed to practice in New Jersey. 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 55-year-old woman who sustained a work-related injury on July 2013. Subsequently, the patient developed a chronic low back pain. According to a progress report dated on March 31, 2014, the patient was complaining of ongoing back pain despite the use of pain medications. The patient MRI of the lumbar spine demonstrated facet arthropathy and degenerative disc disease according to another progress report dated on September 29, 2014 the patient was complaining of severe low back pain radiating to both lower extremities with numbness and tingling and weakness. The patient reports also neck pain with numbness and weakness. The patient was reported to have minimal response with Ultracet and fentanyl patch. The patient physical examination demonstrated antalgic gait, and reduced sensation at the L3 L4 L5 and S2 dermatoma. The patient was diagnosed with lumbosacral spondylosis. The provider requested authorization for the following medications.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Pharmacy purchase of Fentanyl Patch 12.5mcg:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Duragesic (fentanyl transdermal system) Page(s): 68.

**Decision rationale:** According to MTUS guidelines, Duragesic (fentanyl transdermal system) is not recommended as a first-line therapy. Duragesic is the trade name of a fentanyl transdermal therapeutic system, which releases fentanyl, a potent opioid, slowly through the skin. It is manufactured by [REDACTED] and marketed by [REDACTED] (both subsidiaries of [REDACTED]). The FDA-approved product labeling states that Duragesic is indicated in the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by other means. In this case, the patient continued to have pain despite the use of high dose of opioids. There is no documentation of continuous monitoring of adverse reactions and of patient's compliance with her medication. In addition, there is no documentation that the patient developed tolerance to opioids or need continuous around the clock opioid administration. Therefore, the prescription of Pharmacy purchase of Fentanyl Patch 12.5mcg is not medically necessary.

**Pharmacy purchase of Tramadol 50mg:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol Page(s): 113.

**Decision rationale:** According to MTUS guidelines, Ultram (Tramadol) is a synthetic opioid indicated for the pain management but not recommended as a first line oral analgesic. In addition and according to MTUS guidelines, ongoing use of opioids should follow specific rules:(a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy.(b) The lowest possible dose should be prescribed to improve pain and function.(c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework. Although, Tramadol may be needed to help with the patient pain, there is no clear evidence of objective and recent functional and pain improvement from its previous use. There is no clear documentation of the efficacy/safety of previous use of Tramadol. Therefore, the prescription of Pharmacy purchase of Tramadol 50mg is not medically necessary.

**Pharmacy purchase of Cymbalta 60mg:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Specific Antidepressants Page(s): 15-16.

**Decision rationale:** Cymbalta is FDA approved for diabetic neuropathy. It is also used off label for neuropathic pain and radiculopathy. There is no high quality evidence to support its use for lumbar radiculopathy. There is no clear evidence that the patient have diabetic neuropathy. A prolonged use of cymbalta in this patient cannot be warranted without continuous monitoring of its efficacy, the drug was used off label. Therefore, the request of Pharmacy purchase of Cymbalta 60mg is not medically necessary.

**Pharmacy purchase of Dendracin Cream 120ml:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate Topicals Section Page(s): 126.

**Decision rationale:** Dendracin is formed by methyl salicylate, menthol and benzocaine. According to MTUS, salicylate topicals is recommended and is better than placebo. Benzocaine (similar to lidocaine) could be recommended in neuropathic pain. There are no strong controlled studies supporting the efficacy of Dendracin or topical analgesics for the treatment of neuropathic pain. There is no documentation of neuropathic pain. There is no documentation of efficacy of previous use of the cream. Therefore, Pharmacy purchase of Dendracin Cream 120ml is not medically necessary.