

<b>Case Number:</b>	CM15-0003221		
<b>Date Assigned:</b>	01/14/2015	<b>Date of Injury:</b>	01/19/1995
<b>Decision Date:</b>	07/21/2015	<b>UR Denial Date:</b>	12/16/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/07/2015

### 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: Arizona, Michigan

Certification(s)/Specialty: Preventive Medicine, Occupational 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 76-year-old male, who sustained an industrial injury on 1/19/95. He reported knee pain. The injured worker was diagnosed as having chronic pain due to trauma, osteoarthritis involving the ankle and foot, and chronic thoracic or lumbosacral radiculopathy. Infection and inflammatory reaction due to other internal prosthetic device implant, and graft was also noted. Treatment to date has included an open reduction internal fixation of the right periprosthetic fracture and debridement of open fracture in September 2013, removal of infected total knee replacement and removal of infected Synthes plate with 13 screws, complete synovectomy, and placement of temporary antibiotic spacer and implants on 9/9/14. The injured worker also attended physical therapy, received a caudal epidural steroid injection, and was prescribed Voltaren gel, Norco, Lyrica, Cymbalta, and Ambien. Currently, the injured worker complains of bilateral knee pain. The treating physician requested authorization for Norco 10/325mg #180, Lyrica 150mg #89 with 2 refills, Cymbalta 20mg #30 with 1 refill, Ambien CR 12.5mg #45 with 1 refill, and Voltaren 1% #2.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Pharmacy purchase of Norco 10/325mg #180:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for chronic pain.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96.

**Decision rationale:** Per the MTUS, opioids should be discontinued if there is no overall improvement in function, unless there are extenuating circumstances, Opioids should be continued if the patient has returned to work or has improved functioning and pain. Ongoing management actions should include prescriptions from a single practitioner, taken as directed and all prescriptions from a single pharmacy. The lowest possible dose should be prescribed to improve pain and function. Documentation should follow the 4 A's of analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors. Long-term users of opioids should be regularly reassessed. In the maintenance phase, the dose should not be lowered if it is working. Also, patients who receive opioid therapy may sometimes develop unexpected changes in their response to opioids, which includes development of abnormal pain, change in pain pattern, persistence of pain at higher levels than expected when this happens opioids can actually increase rather than decrease sensitivity to noxious stimuli. It is important to note that a decrease in opioid efficacy should not always be treated by increasing the dose or adding other opioids, but may actually require weaning. A review of the injured workers medical records that are available to me did not reveal documentation of pain and functional improvement with the use of Norco, there was no documentation of the 4's of analgesia as required by the guidelines for ongoing management of opioids use and without this information, medical necessity for continued use cannot be determined. This request is not medically necessary.

**Pharmacy purchase of Lyrica 150mg #89 with 2 refills: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AED's) Page(s): 16-22.

**Decision rationale:** Per the MTUS, anti-epilepsy drugs are recommended for neuropathic pain. The choice of specific agents will depend on the balance between effectiveness and adverse reactions. A "good" response to the use of AEDs has been defined as a 50% reduction in pain and a "moderate" response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response of this magnitude may be the "trigger" for the following: (1) a switch to a different first-line agent (TCA, SNRI or AED are considered first-line treatment); or (2) combination therapy if treatment with a single drug agent fails. (Eisenberg, 2007) (Jensen, 2006) After initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. Unfortunately, a review of the injured workers medical records that are available to me did not reveal documentation of pain and functional improvement with the use of Lyrica as required by the guidelines and without this information medical necessity for continued use is not medically necessary.

**Pharmacy purchase of Cymbalta 20mg #30 with 1 refill: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain Page(s): 14-16.

**Decision rationale:** Per the MTUS, antidepressants are recommended as a first line option in the treatment of neuropathic pain and possibly for non- neuropathic pain. Duloxetine (Cymbalta) is FDA approved for anxiety, depression, diabetic neuropathy and fibromyalgia; it is used off label for neuropathic pain and radiculopathy. Unfortunately, a review of the injured workers medical records that are available to me did not reveal documentation of pain or functional improvement with the use of Cymbalta and without this information medical necessity for continued use of Cymbalta is not medically necessary.

**Pharmacy purchase of Ambien CR 12.5mg #45 with 1 refill:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

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

**Decision rationale:** The MTUS did not specifically address the use of Ambien, therefore other guidelines were consulted. Per the ODG, Zolpidem is a prescription short-acting non-benzodiazepine hypnotic, which is recommended for short-term (7-10 days) 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 may. There is also concern that they may increase pain and depression over the long-term, however given the risks there is no clear indication for the continued use of this medication in the injured worker, the risks outweigh the benefits and the continued use of ambien is not medically necessary.

**Pharmacy purchase of Voltaren 1%, QTY: 2:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** Per the MTUS, topical analgesics are recommended as an option, they are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Many agents are compounded as monotherapy or in combination for pain control, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. A review of the injured workers medical records that are available to me does not show documentation of pain or functional improvement with the use of topical Voltaren and without this information medical necessity for continued use is not medically necessary.