

<b>Case Number:</b>	CM15-0189637		
<b>Date Assigned:</b>	10/06/2015	<b>Date of Injury:</b>	04/09/2002
<b>Decision Date:</b>	12/08/2015	<b>UR Denial Date:</b>	09/11/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/25/2015

### 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: California

Certification(s)/Specialty: Emergency 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 59 year old female, who sustained an industrial injury on 04-09-2002. She has reported subsequent right elbow and bilateral knee pain and was diagnosed with internal derangement of the bilateral knees status post right total knee replacements on the right in 2010 and on the left in 2015 and medial and lateral epicondylar pain on the right elbow. Treatment to date has included pain medication, physical therapy and surgery which were noted to provide some pain relief. The injured worker was noted to have undergone left total knee replacement in 01-2015. A utilization review dated 04-09-2015 shows that requests for Naproxen, Tramadol, Flexeril and Lunesta were approved or modified but it's unclear from the progress notes submitted as to whether these medications were being taken, how long these medications had been prescribed and whether the medications were effective at reducing pain or improving objective function. Documentation shows that Aciphex and Norflex were prescribed since at least 05-07-2015. In a progress note dated 09-01-2015, the injured worker reported increasing right elbow pain from the use of a cane. The severity of pain was not rated. The injured worker also reported numbness on the top of the foot radiating to the toes since the surgery. Objective examination findings showed flexion on the left to 90-100 degrees that was improved "where she has regressed." Knee extension on the right was 180 degrees and flexion was 110 degrees and mild sensory dysfunction on the dorsum of the left foot in the peroneal nerve distribution was noted. The injured worker was noted to have stopped working on 01-28-2015 and the physician noted that the injured worker would return to work on 09-02-2015 "doing her usual job." A request for authorization of retro Flexeril 7.5mg #60, retro Ultracet 37.5mg #60, AcipHex 20mg

for 10-1-15 visit #30, Flexeril 7.5mg for 10-1-15 visit #60, Norflex ER 100mg for 10-1-15 visit #60, Tramadol ER for 10-1-15 visit #30, Lunesta 2mg for 10-1-15 visit #30, four leads TENS unit (unspecified time frame) and conductive garment was submitted. As per the 09-11-2015 utilization review, the aforementioned requests were non-certified.

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

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

#### **Retro Flexeril 7.5mg #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Cyclobenzaprine (Flexeril), Muscle relaxants (for pain).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

**Decision rationale:** The request is for the use of a muscle relaxant to aid in pain relief. The MTUS guidelines state that the use of a medication in this class is indicated as a second-line option for short-term treatment of acute exacerbations of low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, which can increase mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain improvement. Efficacy appears to diminish over time, and prolonged use may lead to dependence. (Homik, 2004) Due to inadequate documentation of a recent acute exacerbation and poor effectiveness for chronic long-term use, the request is not medically necessary.

#### **Retro Ultracet 37.5mg #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

**Decision rationale:** The request is for the use of a medication in the opioid class. The MTUS guidelines state that for ongoing treatment with a pharmaceutical in this class, certain requirements are necessary. This includes not only adequate pain control, but also functional improvement. Four domains have been proposed for management of patients on opioids. This includes pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant drug-related behaviors. As part of the pain treatment agreement, it is advised that "Refills are limited, and will only occur at appointments." In this case, there is inadequate documentation of persistent functional improvement seen. The patient is also taking more potent opioid medication currently. As such, the request is not medically necessary. All opioid medications should be titrated down slowly in order to prevent a significant withdrawal syndrome.

#### **AcipHex 20mg for 10/1/15 visit #30: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** The request is for the use of a medication in the class of a proton pump inhibitor. It is indicated for patients with peptic ulcer disease. It can also be used as a preventative measure in patients taking non-steroidal anti-inflammatories for chronic pain. Unfortunately, they do have certain side effects including gastrointestinal disease. The MTUS guidelines states that patients who are classified as intermediate or high risk, should be treated prophylactically. Criteria for risk are as follows: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Due to the fact the patient does not meet to above stated criteria, the request for use is not medically necessary.

**Flexeril 7.5mg for 10/1/15 visit #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

**Decision rationale:** The request is for the use of a muscle relaxant to aid in pain relief. The MTUS guidelines state that the use of a medication in this class is indicated as a second-line option for short-term treatment of acute exacerbations of low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, which can increase mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain improvement. Efficacy appears to diminish over time, and prolonged use may lead to dependence. (Homik, 2004) Due to inadequate documentation of a recent acute exacerbation and poor effectiveness for chronic long- term use, the request is not medically necessary.

**Norflex ER 100mg for 10/1/15 visit #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

**Decision rationale:** The request is for the use of a muscle relaxant to aid in pain relief. The MTUS guidelines state that the use of a medication in this class is indicated as a second-line option for short-term treatment of acute exacerbations of low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, which can increase mobility. However, in most

LBP cases, they show no benefit beyond NSAIDs in pain improvement. Efficacy appears to diminish over time, and prolonged use may lead to dependence. (Homik, 2004) Due to inadequate documentation of a recent acute exacerbation and poor effectiveness for chronic long-term use, the request is not medically necessary.

**Tramadol ER for 10/1/15 visit #30: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids for chronic pain.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids for chronic pain.

**Decision rationale:** Tramadol is a pain medication in the category of a centrally acting analgesic. They exhibit opioid activity and a mechanism of action that inhibits the reuptake of serotonin and norepinephrine. Centrally acting drugs are reported to be effective in managing neuropathic type pain although it is not recommended as first line therapy. The side effect profile is similar to opioids. For chronic back pain, it appears to be efficacious for short term pain relief, but long term (>16 weeks) results are limited. It also did not appear to improve function. The use of tramadol for osteoarthritis is indicated for short term use only (<3 months) with poor long-term benefit. In this case, the patient does not meet the qualifying criteria. This is secondary to the duration of use, with this medication being indicated on a short-term basis only. As such, the request is not medically necessary.

**Lunesta 2mg for 10/1/15 visit #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, Mental Illness & Stress Chapter, Lunesta.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental illness & Stress/Eszopicolone (Lunesta).

**Decision rationale:** The request is for the use of Lunesta to aid in insomnia. The official disability guidelines state the following regarding this topic: Not recommended for long-term use, but recommended for short-term use. See Insomnia treatment. See also the Pain Chapter. Recommend limiting use of hypnotics to three weeks maximum in the first two months of injury only, and discourage use in the chronic phase. 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. In this study, eszopicolone (Lunesta) had a Hazard ratio for death of 30.62 (C.I., 12.90 to 72.72), compared to zolpidem at 4.82 (4.06 to 5.74). In general, receiving hypnotic prescriptions was associated with greater than a threefold increased hazard of death even when prescribed less than 18 pills/year. (Kripke, 2012) The FDA has lowered the recommended starting dose of eszopiclone (Lunesta) from 2 mg to 1 mg for

both men and women. Previously recommended doses can cause impairment to driving skills, memory, and coordination as long as 11 hours after the drug is taken. Despite these long-lasting effects, patients were often unaware they were impaired. (FDA, 2014) In this case, continued use of this medication is not supported by the guidelines. This is secondary to the duration with long-term use being not advised. As such, the request is not medically necessary.

**Four leads TENS unit (unspecified time frame): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Transcutaneous electrotherapy.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Knee & Leg (acute & chronic)/ TENS.

**Decision rationale:** The request is for the use of a TENS unit for pain relief. The official disability guidelines state the following regarding this topic: Recommended as an option for patients in a therapeutic exercise program for osteoarthritis as a treatment for pain. The addition of TENS plus exercise appears to produce improved function (greater cumulative knee extensor torque, stride length, gait velocity and range of motion) over those treated with exercise only, although the difference has not been found to be significant. (Philadelphia, 2001) (Hulme-Cochrane, 2002) (Ng, 2003) (Cheing, 2004) (BlueCross BlueShield, 2005) (Osiri, 2000) (Mont, 2006) (Garland, 2007) Transcutaneous electrical nerve stimulation offers clinically relevant short-term pain relief for osteoarthritis of the knee, according to a report in the June 22nd issue of BMC Musculoskeletal Disorders. (Bjordal, 2007) Transcutaneous electrical nerve stimulation can help with short-term pain control among patients with hip or knee OA. (Zhang, 2008) A 6-week program of progressive strength training targeting the quadriceps femoris muscle group substantially improves strength and function following total knee arthroplasty for treatment of osteoarthritis, compared to patients who received standard of care therapy; however, addition of neuromuscular electrical stimulation (NMES) to the strength training exercise did not improve outcomes. (Pettersen, 2009) There is no conclusive evidence that TENS reduces knee pain or physical disability from osteoarthritis, even with years of clinical use and a plethora of clinical trials, based on a recent Cochrane Review, because the studies had poor methodological quality, inadequate reporting, and small sample size. Treatment responses -- however minimal -- occurred in 29 of 100 people treated with electrostimulation and in 26 of 100 people who had sham treatments or usual care. (Rutjes, 2009) See also [REDACTED] knee device. In this case, request for a TENS unit is not medically necessary. This is secondary to inadequate evidence of effectiveness for the patient's condition after total knee replacement. Pending this discussion, there is no indication for providing another unit.

**Conductive garment: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Transcutaneous electrotherapy.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Knee & Leg (acute & chronic)/TENS.

**Decision rationale:** The request is for the use of a TENS unit for pain relief. The official disability guidelines state the following regarding this topic: Recommended as an option for patients in a therapeutic exercise program for osteoarthritis as a treatment for pain. The addition of TENS plus exercise appears to produce improved function (greater cumulative knee extensor torque, stride length, gait velocity and range of motion) over those treated with exercise only, although the difference has not been found to be significant. (Philadelphia, 2001) (Hulme-Cochrane, 2002) (Ng, 2003) (Cheing, 2004) (BlueCross BlueShield, 2005) (Osiri, 2000) (Mont, 2006) (Garland, 2007) Transcutaneous electrical nerve stimulation offers clinically relevant short-term pain relief for osteoarthritis of the knee, according to a report in the June 22nd issue of BMC Musculoskeletal Disorders. (Bjordal, 2007) Transcutaneous electrical nerve stimulation can help with short-term pain control among patients with hip or knee OA. (Zhang, 2008) A 6-week program of progressive strength training targeting the quadriceps femoris muscle group substantially improves strength and function following total knee arthroplasty for treatment of osteoarthritis, compared to patients who received standard of care therapy; however, addition of neuromuscular electrical stimulation (NMES) to the strength training exercise did not improve outcomes. (Pettersen, 2009) There is no conclusive evidence that TENS reduces knee pain or physical disability from osteoarthritis, even with years of clinical use and a plethora of clinical trials, based on a recent Cochrane Review, because the studies had poor methodological quality, inadequate reporting, and small sample size. Treatment responses -- however minimal -- occurred in 29 of 100 people treated with electrostimulation and in 26 of 100 people who had sham treatments or usual care. (Rutjes, 2009) See also [REDACTED] knee device. In this case, request for a TENS unit and conductive garment is not medically necessary. This is secondary to inadequate evidence of effectiveness for the patient's condition after total knee replacement. Pending this discussion, there is no indication for providing another unit.