

<b>Case Number:</b>	CM15-0129926		
<b>Date Assigned:</b>	07/16/2015	<b>Date of Injury:</b>	07/05/2009
<b>Decision Date:</b>	09/09/2015	<b>UR Denial Date:</b>	06/09/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/06/2015

### 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 56-year-old male, with a reported date of injury of 07/05/2009. The mechanism of injury was not indicated in the medical records provided for review. The injured worker's symptoms at the time of the injury were not indicated. The diagnoses include status post extensive tenolysis and capsulotomy with recurrent extension contracture of the left second, third, fourth, and fifth fingers, right carpal tunnel syndrome, right basal joint degenerative traumatic arthritis, right de Quervain's disease, bilateral carpal tunnel syndrome, left de Quervain's disease, left basal joint degenerative traumatic arthritis, and status post bilateral carpal tunnel release. Treatments and evaluation to date have included therapy, cortisone injection, oral medications, and topical pain medications. The diagnostic studies to date were not indicated. The progress report dated 05/21/2015 indicates that the injured worker complained of increased numbness in the right hand and pain in the fingers and both hands. It was noted that the injured worker was feeling more depressed. The physical examination showed decreased light touch sensation in the bilateral fingers, right greater than left; weakness; and no improvement in range of motion of the left fingers. It was noted that his work status was unchanged, and he was permanent and stationary. The injured worker's work status was indicated as remain off work (temporary total disability) as of the date of the visit for six weeks. The treating physician will consider permanent and stationary in four months. The treating physician requested Flurbiprofen transdermal cream; Cyclobenzaprine, Gabapentin transdermal cream; Eszopiclone (Lunesta); and Pantoprazole (Protonix).

## IMR ISSUES, DECISIONS AND RATIONALES

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

### **Flurbiprofen 20% Transdermal Cream 30 grams: Upheld**

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

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

**Decision rationale:** The CA MTUS Chronic Pain Guidelines indicate that topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. They are "largely experimental in use with few randomized controlled trials to determine effectiveness or safety." There was no evidence of neuropathic pain. The injured worker has been taking oral Gabapentin and Remeron since at least 02/26/2015. Flurbiprofen is a non-steroidal anti-inflammatory agent (NSAID). MTUS indicates that topical NSAIDs may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. The site of application was not specified. Note that topical Flurbiprofen is not FDA approved, and is therefore experimental and cannot be presumed as safe and effective. Non-FDA approved medications are not medically necessary. The only FDA-approved topical NSAIDs are diclofenac formulations. All other topical NSAIDs are not FDA approved. According to the guidelines, "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore, the request for Flurbiprofen transdermal cream is not medically necessary.

### **Cyclobenzaprine 10%, Gabapentin 10%, Transdermal Cream 30 grams: 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:** The CA MTUS Chronic Pain Guidelines indicate that topical analgesics are "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." They are "largely experimental in use with few randomized controlled trials to determine effectiveness or safety." There was no evidence of neuropathic pain. The injured worker has been taking oral Gabapentin and Remeron since at least 02/26/2015. The compounded medication is a combination of Cyclobenzaprine and Gabapentin. Cyclobenzaprine is a muscle relaxant and Gabapentin is an anti-epileptic agent. Topical Gabapentin is not recommended by the guidelines, since there is no peer-reviewed literature to support its use. The guidelines indicate that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore, the request for Cyclobenzaprine and Gabapentin transdermal cream is not medically necessary.

**Eszopiclone (Lunesta) 1mg, #30, with 1 refill: 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 Chapter, Online Version, Eszopiclone (Lunesta).

**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 and Mental chapter, Eszopiclone (Lunesta).

**Decision rationale:** The CA MTUS is silent on Eszopiclone (Lunesta). The non-MTUS Official Disability Guidelines indicate that Eszopiclone (Lunesta) is not recommended for long-term use. It is recommended for short-term use. The injured worker has been taking Eszopiclone since at least 02/26/2015. The guidelines recommend limiting use of hypnotics to a maximum of three weeks in the first two months of injury only, and discourage use in the chronic phase. Lunesta has demonstrated reduced sleep latency and sleep maintenance. This medication is the only benzodiazepine-receptor agonist that the FDA approved for use longer than 35 days for insomnia treatment. According to the guidelines, "The FDA has lowered the recommended starting dose of Eszopiclone (Lunesta) from 2 mg to 1 mg for both men and women." A review of the injured workers medical records that are available to me do not reveal any documentation of improvement in sleep latency, quality or quantity with the use of Lunesta, without this information it is not possible to determine medical necessity for continued use, therefore the request for Eszopiclone (Lunesta) 1mg, #30, with 1 refill is not medically necessary.

**Pantoprazole Sodium (Protonix) 20mg, #30, with 1 refill: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risk. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Proton Pump Inhibitors (PPIs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Proton Pump Inhibitors (PPIs).

**Decision rationale:** This injured worker has been prescribed Flurbiprofen transdermal cream, a non-steroidal anti-inflammatory medication (NSAID), and Pantoprazole, a proton pump inhibitor (PPI). Per the CA MTUS Chronic Pain Guidelines, co-therapy with a non-steroidal anti-inflammatory medication (NSAID) and a proton pump inhibitor (PPI) is not indicated in patients other than those at intermediate or high risk for gastrointestinal events (including age > 65 years, history of peptic ulcer, gastrointestinal (GI) bleeding or perforation, concurrent use of aspirin, corticosteroids and/or an anticoagulant, or high dose/multiple NSAIDs such as NSAID plus low dose aspirin). Long term proton pump inhibitor (PPI) use (> 1 year) has been shown to increase the risk of hip fracture. The injured worker has been taking Pantoprazole since at least 03/26/2015. The Non-MTUS Official Disability Guidelines indicate that proton pump inhibitors (PPIs) are recommended for patients at risk for gastrointestinal events. There was no discussion

of documentation of any GI signs or symptoms in the records. Therefore, the request for Pantoprazole is not medically necessary.