

<b>Case Number:</b>	CM15-0117500		
<b>Date Assigned:</b>	07/08/2015	<b>Date of Injury:</b>	10/18/2012
<b>Decision Date:</b>	09/09/2015	<b>UR Denial Date:</b>	06/10/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/18/2015

### 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: New York

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 55 year old female who sustained an industrial injury on 10/18/2012. Current diagnoses include left knee internal derangement, limited range of motion of the left knee, left knee inflammation, and chronic pain. Previous treatments included medications, physical therapy, functional capacity evaluation, acupuncture, home exercise program, and right intra-articular injection. Previous diagnostic studies include urine toxicology screening. The results of these tests were not discussed. Report dated 06/08/2015 noted that the injured worker was status post right intra-articular injection with 50% improvement, pain in the left knee is still persistent with limited range of motion and radiation to the left lower extremity. Pain level was 9 out of 10 on a visual analog scale (VAS). Physical examination of the left knee was positive for an antalgic gait, tenderness over the medial joint line, under surface of the patella, and pes aserinus region, and decreased range of motion. The treatment plan included request for a left knee intra-articular injection. Disputed treatments include retrospective request for Flur/Dext-180 (Flurbiprofen, Dextromethorphan, Propylene Glycol) 30-day supply (DOS 4/27/15), retrospective request for Gab/Keto/Tram/Cyclo-180 (Gabapentin, Ketoprofen, Tramadol, Cyclobenzaprine, Ethyl Alcohol) 30-day supply (DOS 4/27/15), retrospective request for Zaleplon 10mg #60 (DOS: 4/17/15), retrospective request for Zaleplon 10mg #30 (DOS: 3/23/15), retrospective request for Zaleplon 10mg #30 (DOS: 2/25/15), retrospective request for Zaleplon 10mg #60 (DOS: 1/26/15), retrospective request for omeprazole (APO) 20mg #60 (DOS: 4/17/15), retrospective request for omeprazole (APO) 20mg #60 (DOS: 3/23/15), and retrospective request for omeprazole DR 20mg #60 (DOS: 4/25/15).

## IMR ISSUES, DECISIONS AND RATIONALES

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

### **Retrospective request for Flur/Dext-180 (Flurbiprofen, Dextromethorphan, Propylene Glycol) 30-day supply (DOS 4/27/15): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) <http://www.odg-twc.com/odgtwc/pain.htm#Topicalanaigesics>.

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

**Decision rationale:** The MTUS chronic pain medical treatment guidelines, "topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended." Flurbiprofen, a non-steroidal anti-inflammatory agent (NSAID), is not currently [REDACTED] approved for topical application. The documentation submitted did not support that the injured worker had failed a trial of oral antidepressant or antiepileptic medication. The treating physician's request did not include the concentration, quantity, site of application, or directions for use. As such, the prescription is not sufficient and not medically necessary. Therefore because Flurbiprofen is not approved for topical application and there is no documented failure of a trial of oral antidepressant or antiepileptic medication and the prescription is insufficient the retrospective request for Flur/Dext-180 (Flurbiprofen, Dextromethorphan, Propylene Glycol) 30-day supply (DOS 4/27/15) is not medically necessary.

### **Retrospective request for Gab/Keto/Tram/Cyclo-180 (Gabapentin, Ketoprofen, Tramadol, Cyclobenzaprine, Ethyl Alcohol) 30-day supply (DOS 4/27/15): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) <http://www.odg-twc.com/odgtwc/pain.htm#Topicalanaigesics>.

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

**Decision rationale:** The MTUS chronic pain medical treatment guidelines, "topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended." Ketoprofen, a Non-steroidal anti-inflammatory agent (NSAID), is not currently [REDACTED] approved for topical application. It has a high incidence of photocontact dermatitis. As topical ketoprofen is not [REDACTED] approved, it is therefore experimental and cannot be presumed as safe and efficacious. Non-[REDACTED] approved medications are not medically necessary. Cyclobenzaprine is a muscle relaxant. The MTUS

notes that there is no evidence for use of muscle relaxants as topical products. Gabapentin is not recommended. The treating physician's request did not include the concentration, quantity, site of application, or directions for use. As such, the prescription is not sufficient and not medically necessary. As some of the medications in this compounded topical product are not recommended, the compound is not recommended. Therefore the request for retrospective request for Gab/Keto/Tram/Cyclo-180 (Gabapentin, Ketoprofen, Tramadol, Cyclobenzaprine, Ethyl Alcohol) 30-day supply (DOS 4/27/15) is not medically necessary.

**Retrospective request for Zaleplon 10mg #60 (DOS: 4/17/15): 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) (<http://www.odg-twc.com/odgtwc/pain.htm#insomniatreatment>) and [www.drugs.com](http://www.drugs.com) (<http://www.drugs.com/mtm/zaleplon.html>).

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

**Decision rationale:** The California MTUS, and ACOEM are silent on Zaleplon (Sonata). "The Official Disability Guidelines do not recommend this medication for long term use of treatment of insomnia. Recommendation is for limiting use to three weeks maximum in the first two months of injury only, and discourage use in the chronic phase." Documentation supports the injured working has been taking this medication for a minimum of 6 months. There is no documentation of modifications to assist sleep or sleep studies. Since documentation supports this medication is being used long term, the retrospective request for Zaleplon 10mg #60 (DOS: 4/17/15) is not medically necessary.

**Retrospective request for Zaleplon 10mg #30 (DOS: 3/23/15): 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) (<http://www.odg-twc.com/odgtwc/pain.htm#insomniatreatment>) and [www.drugs.com](http://www.drugs.com) (<http://www.drugs.com/mtm/zaleplon.html>).

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

**Decision rationale:** The California MTUS, and ACOEM are silent on Zaleplon (Sonata). "The Official Disability Guidelines do not recommend this medication for long term use of treatment of insomnia. Recommendation is for limiting use to three weeks maximum in the first two months of injury only, and discourage use in the chronic phase." Documentation supports the injured working has been taking this medication for a minimum of 6 months. There is no documentation of modifications to assist sleep or sleep studies. Since documentation supports

this medication is being used long term, the retrospective request for Zaleplon 10mg #60 (DOS: 3/23/15) is not medically necessary.

**Retrospective request for Zaleplon 10mg #30 (DOS: 2/25/15): 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) (<http://www.odg-twc.com/odgtwc/pain.htm#insomniatreatment>) and [www.drugs.com](http://www.drugs.com) (<http://www.drugs.com/mtm/zaleplon.html>).

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

**Decision rationale:** The California MTUS, and ACOEM are silent on Zaleplon (Sonata). "The Official Disability Guidelines do not recommend this medication for long term use of treatment of insomnia. Recommendation is for limiting use to three weeks maximum in the first two months of injury only, and discourage use in the chronic phase." Documentation supports the injured working has been taking this medication for a minimum of 6 months. There is no documentation of modifications to assist sleep or sleep studies. Since documentation supports this medication is being used long term, the retrospective request for Zaleplon 10mg #60 (DOS: 2/22/15) is not medically necessary.

**Retrospective request for Zaleplon 10mg #60 (DOS: 1/26/15): 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) (<http://www.odg-twc.com/odgtwc/pain.htm#insomniatreatment>) and [www.drugs.com](http://www.drugs.com) (<http://www.drugs.com/mtm/zaleplon.html>).

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

**Decision rationale:** The California MTUS, and ACOEM are silent on Zaleplon (Sonata). "The Official Disability Guidelines do not recommend this medication for long term use of treatment of insomnia. Recommendation is for limiting use to three weeks maximum in the first two months of injury only, and discourage use in the chronic phase." Documentation supports the injured working has been taking this medication for a minimum of 6 months. There is no documentation of modifications to assist sleep or sleep studies. Since documentation supports this medication is being used long term, the retrospective request for Zaleplon 10mg #60 (DOS: 1/26/15) is not medically necessary.

**Retrospective request for Omeprazole (APO) 20mg #60 (DOS: 4/17/15): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risk Page(s): 68-69.

**Decision rationale:** According to the California MTUS chronic pain medical treatment guidelines recommend specific guidelines for prescribing proton pump inhibitors (PPI). "PPI's are recommended when patients are identified to have certain risks with the use of NSAID's. Risk factors include age > 65 years, history of peptic ulcer, GI bleeding or perforation, concurrent use of aspirin, corticosteroids, and/or an anticoagulant, and high dose/multiple Non-steroidal anti-inflammatory drug (NSAID). A history of ulcer complications is the most important predictor of future ulcer complications associated with NSAID use." The documentation provided did not indicate that the injured worker had gastrointestinal complaints, nor did it indicate that the injured worker had cardiovascular disease. There were no abdominal examinations included in the records. Therefore the retrospective request for Omeprazole (APO) 20mg #60 (DOS: 4/17/15) is not medically necessary.

**Retrospective request for Omeprazole (APO) 20mg #60 (DOS: 3/23/15): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risk Page(s): 68-69.

**Decision rationale:** According to the California MTUS chronic pain medical treatment guidelines recommend specific guidelines for prescribing proton pump inhibitors (PPI). "PPI's are recommended when patients are identified to have certain risks with the use of NSAID's. Risk factors include age > 65 years, history of peptic ulcer, GI bleeding or perforation, concurrent use of aspirin, corticosteroids, and/or an anticoagulant, and high dose/multiple Non-steroidal anti-inflammatory drug (NSAID). A history of ulcer complications is the most important predictor of future ulcer complications associated with NSAID use." The documentation provided did not indicate that the injured worker had gastrointestinal complaints, nor did it indicate that the injured worker had cardiovascular disease. There were no abdominal examinations included in the records. Therefore the retrospective request for Omeprazole (APO) 20mg #60 (DOS: 3/23/15) is not medically necessary.

**Retrospective request for Omeprazole DR 20mg #60 (DOS: 4/25/15): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risk Page(s): 68-69.

**Decision rationale:** According to the California MTUS chronic pain medical treatment guidelines recommend specific guidelines for prescribing proton pump inhibitors (PPI). "PPI's are recommended when patients are identified to have certain risks with the use of NSAID's. Risk factors include age > 65 years, history of peptic ulcer, GI bleeding or perforation, concurrent use of aspirin, corticosteroids, and/or an anticoagulant, and high dose/multiple Non-steroidal anti-inflammatory drug (NSAID). A history of ulcer complications is the most important predictor of future ulcer complications associated with NSAID use." The documentation provided did not indicate that the injured worker had gastrointestinal complaints, nor did it indicate that the injured worker had cardiovascular disease. There were no abdominal examinations included in the records. Therefore the retrospective request for Omeprazole DR 20mg #60 (DOS: 4/25/15) is not medically necessary.