

<b>Case Number:</b>	CM14-0009676		
<b>Date Assigned:</b>	02/14/2014	<b>Date of Injury:</b>	03/27/2007
<b>Decision Date:</b>	06/27/2014	<b>UR Denial Date:</b>	12/20/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/24/2014

### 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 Anesthesiology and is licensed to practice in Massachusetts, New Jersey, Connecticut, and Texas. 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 injured worker is a 45 year-old female who is reported to have sustained work related injuries on 03/27/07. The injured worker is reported to have been cleaning a bathroom when she developed low back and left lower extremity pain. She has been treated with oral medications and physical therapy. Physical examination dated 12/31/13 reports tenderness to palpation at the lumbar spine (L5/S1), limited lumbar range of motion, positive straight leg raise, 5/5 strength in the lower extremities, Faber's test is positive on the left. This note reports that the injured worker receives benefit from her medications and continues to work. The injured is reported to have significant side-effects from oral medications which has included gastritis. The record contains a utilization review determination dated 12/20/13 which non-certified requests for Diclofenac Sodium 1.5% 60 grams, Ketamine 5% Cream 60 grams, Synovacin-Glucosamine 500mg, Lunesta one mg, Doxepin 3.3% Gel 60 mg, and Protonix 20 mg.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**RETROSPECTIVE: DICLOFENAC SODIUM 1.5% 60GMS, APPLY TO AFFECTED AREA THREE TIMES A DAY, #1-DISPENSED 5/14/13: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAID's Page(s): 67-73.

**Decision rationale:** The request for Diclofenac Sodium 1.5 % 60 grams is recommended as medically necessary. The submitted clinical records indicate the injured worker has side-effects from her current medication profile which includes gastritis. Per Chronic Pain Medical Treatment Guidelines Topical Diclofenac is recommended for osteoarthritis after failure of an oral non-steroidal anti-inflammatory medications (NSAID). As such, this medication would be appropriate for the treatment of myofascial pain and osteoarthritis. As such the request is recommended as medically necessary.

**RETROSPECTIVE: KETAMINE 5 % CREAM 60GMS, APPLY TO AFFECTED AREA THREE TIMES A DAY, #1-DISPENSED 5/14/13: Upheld**

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

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

**Decision rationale:** The request for Ketamine 5% Cream is not supported as medically necessary. California Medical Treatment Utilization Schedule, the Official Disability Guidelines and US Food and Drug Administration do not recommend the use of compounded medications as these medications are noted to be largely experimental in use with few randomized controlled trials to determine efficacy or safety. Further, the FDA requires that all components of a transdermal compounded medication be approved for transdermal use. This compound contains: Ketamine 5% which have not been approved by the FDA for transdermal use. Any compounded product that contains at least one drug (or drug class) that is not recommended and therefore not medically necessary.

**RETROSPECTIVE: SYNOVACIN-GLUCOSAMINE SULF. 500MG, 1 EVERY DAY TO TWO TIMES A DAY, #90-DISPENSED 5/14/13: Upheld**

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

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

**Decision rationale:** The request for synovacin-glucosamine sulf.500 mg is not supported as medically necessary per Official Disability Guidelines (ODG) Knee Chapter, Glucosamine. The submitted clinical records provide no data to establish the presence of knee osteoarthritis and therefore medical necessity is not established for this supplement.

**RETROSPECTIVE: LUNESTA 1MG, TAKE 1-2 AT BEDTIME AS NEEDED FOR INSOMNIA #60-DISPENSED 5/14/13: 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.

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

**Decision rationale:** The request for Lunesta One mg is not supported as medically necessary. The Official Disability Guidelines do not support the chronic use of sleep aids for the insomnia. It is recommended that sleep aids be used for 1-2 weeks until the normalization of sleep and discontinued. As such the medically necessity for the continued use of this medication is not established.

**RETROSPECTIVE: DOXEPIN 3.3% GEL 60GMS, APPLY TO AFFECTED AREA THREE TIMES A DAY, NERVE PAIN CREAM, #1-DISPENSED 5/14/13: 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): 112-113.

**Decision rationale:** The request for Doxepin 3.3% Gel 60 Grams is not supported as medically necessary. Per California Medical Treatment Utilization Schedule, the Official Disability Guidelines and US Food and Drug Administration do not recommend the use of compounded medications as these medications are noted to be largely experimental in use with few randomized controlled trials to determine efficacy or safety. There are no substantive studies that transdermal Doxepin is effective for the treatment of neuropathic pain. As such the medical necessity is not established.

**RETROSPECTIVE: PROTONIX 20MG, TAKE ONE TABLET TWO TIMES A DAY, #60-DISPENSED 5/14/13: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Proton Pump Inhibitor

**Decision rationale:** Official Disability Guidelines (ODG) Pain, Proton Pump Inhibitor, the request for Protonix 20 mg is recommended as medically necessary. The submitted clinical records indicate the injured worker is generally intolerant of oral medications and has been identified as having medication induced gastritis. As such the medical necessity for this medication as been established.