

<b>Case Number:</b>	CM14-0019970		
<b>Date Assigned:</b>	04/30/2014	<b>Date of Injury:</b>	10/01/2012
<b>Decision Date:</b>	07/08/2014	<b>UR Denial Date:</b>	02/05/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/18/2014

### 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 Orthopedic Surgery and is licensed to practice in 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 35 year old female injured on 10/01/12 due to undisclosed mechanism of injury resulting in head, neck, and low back pain. Current diagnoses included anxiety reaction secondary to chronic pain, sleep disorder, musculoligamentous injury of the knee, lumbosacral spine, and cervical spine, right anterior leg trauma, head trauma, rule out internal derangement of knee and hip bilaterally, rule out bilateral tarsal tunnel syndrome, rule out herniated nucleus pulposus of the cervical spine and lumbar spine, rule out radiculopathy/radiculitis of the lumbar spine, and rule out myositis to the tibialis anterior muscle. Clinical note dated 12/05/13 indicated the injured worker presented complaining of severe low back pain, right thigh pain, left facial and ear pain, left shoulder pain with associated popping in the neck with range of motion. The injured worker continued to report difficulty with activities of daily living including utilization of steps, bending, stooping, household chores, and driving. The injured worker reported neck pain was sharp with radiation into the mid back with bilateral knee pain particularly laterally at the joint lines. Objective findings included severe tenderness and painful range of motion. The injured worker was scheduled for an Agreed Medical Evaluation on 01/13/14 for orthopedic evaluation and Qualified Medical Evaluation for psychology on 02/25/14. Previous request for Terocin patch, compounded medications including Flurbiprofen / lidocaine / Amitryptiline dispensed on 11/05/13, compounded medication containing gabapentin / cyclobenzaprine / Tramadol dispensed on 11/05/13, Somnicin dispensed on 11/05/13, and Genicin dispensed on 11/05/13 was non-certified on 02/05/14.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**MEDICATIONS TEROGIN PATCH DISPENSED ON 11/05/2013: Upheld**

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

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

**Decision rationale:** As noted on page 111 of the Chronic Pain Medical Treatment Guidelines, the safety and efficacy of compounded medications has not been established through rigorous clinical trials. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is no indication in the documentation that these types of medications have been trialed and/or failed. Further, California Medical Treatment Utilization Schedule (CAMTUS), Food and Drug Administration, and Official Disability Guidelines require that all components of a compounded topical medication be approved for transdermal use. Therefore Terogin patch dispensed on 11/05/2013 cannot be recommended as medically necessary as it does not meet established and accepted medical guidelines.

**MEDICATION FLURBIPROFEN /LIDOCAINE /AMITRIPTYLINE DISPENSED ON 11/05/2013: Upheld**

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

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

**Decision rationale:** As noted on page 111 of the Chronic Pain Medical Treatment Guidelines, the safety and efficacy of compounded medications has not been established through rigorous clinical trials. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is no indication in the documentation that these types of medications have been trialed and/or failed. Further, CAMTUS, Food and Drug Administration, and Official Disability Guidelines require that all components of a compounded topical medication be approved for transdermal use. This compound contains: Flurbiprofen and amitriptyline which have not been approved for transdermal use. In addition, there is no evidence within the medical records submitted that substantiates the necessity of a transdermal versus oral route of administration. Therefore Flurbiprofen /Lidocaine /Amitriptyline Dispensed On 11/05/2013 cannot be recommended as medically necessary as it does not meet established and accepted medical guidelines.

**MEDICATION GABAPENTIN /CYCLOBENZAPRINE /TRAMADOL DISPENSED ON 11/05/2013: Upheld**

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

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

**Decision rationale:** As noted on page 111 of the Chronic Pain Medical Treatment Guidelines, the safety and efficacy of compounded medications has not been established through rigorous clinical trials. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is no indication in the documentation that these types of medications have been trialed and/or failed. Further, CAMTUS, Food and Drug Administration, and Official Disability Guidelines require that all components of a compounded topical medication be approved for transdermal use. In addition, there is no evidence within the medical records submitted that substantiates the necessity of a transdermal versus oral route of administration. Therefore gabapentin /cyclobenzaprine /Tramadol dispensed on 11/05/2013 cannot be recommended as medically necessary as it does not meet established and accepted medical guidelines.

**MEDICATION SOMNICIN DISPENSED ON 11/05/2013: 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).

**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), Medical Food.

**Decision rationale:** As noted in the Pain chapter of the Official Disability Guidelines - Online version, the use of herbal medicines or medical foods is not recommended. There is no indication in the documentation that the injured worker has failed previous prescription medications or has obvious contraindications. Additionally, there is no indication that the injured worker cannot utilize the over-the-counter version of this medication. As such, the request for Somnicin dispensed on 11/05/2013 cannot be recommended as medically necessary.

**MEDICATION GENICIN DISPENSED ON 11/05/2013: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 50.

**Decision rationale:** As noted on page 50 of the Chronic Pain Medical Treatment Guidelines, glucosamine is recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. There is no indication in the documentation that the injured worker has been diagnosed with osteoarthritis warranting the use of glucosamine.

Additionally, there is no indication that the injured worker cannot utilize the readily available over-the-counter formulation of this medication. As such, the request for Genicin dispensed on 11/05/13 cannot be recommended as medically necessary.