

<b>Case Number:</b>	CM14-0015454		
<b>Date Assigned:</b>	02/28/2014	<b>Date of Injury:</b>	08/10/1999
<b>Decision Date:</b>	06/30/2014	<b>UR Denial Date:</b>	01/23/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/06/2014

### 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 Surgeon and is licensed to practice in Maryland. 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 64-year-old female who is reported to have sustained multiple injuries as a result of a mechanical fall on 08/10/1999. Records indicate that the injured worker had developed cervical and lumbar pain as a result of this fall. The treatment has included oral medications, epidural steroid injections, and physical therapy. The records indicate that the injured worker underwent an epidural steroid injection at C5-6 on 03/11/13 with good results. On physical examination, she is noted to have reduced lumbar range of motion, straight leg raise is reported to be positive bilaterally, left greater than right. There is tenderness to palpation and trigger points noted in the lumbar musculature, sensation is decreased along the posterolateral thigh and calf in an L5-S1 distribution. She is noted to have tenderness of the bilateral knees. Electrodiagnostic testing, such as an electromyography/nerve conduction velocity (EMG/NCV) of the upper extremities performed on 12/07/13 revealed a possible right C6 radiculopathy and bilateral carpal tunnel syndrome. An MRI of the lumbar spine dated 11/02/12 revealed a 4.5mm circumferential disc bulge at L5-S1, with moderate impression on the thecal sac. There is bilateral facet arthrosis at L3-4, L4-5, and L5-S1. There is a 4.5mm disc protrusion at L3-4. The record further indicates that the injured worker has undergone a left total knee replacement in 2002, with revision in 2004 and 2005. A right total knee replacement was done in 2012. The record includes a utilization review determination dated 01/23/14, in which requests for a compounded drug, Somnicin caplets, quantity 30, and Terocin DIS 4-4% were non-certified.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**COMPOUND DRUG #180:** 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:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 112-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Compounded medications

**Decision rationale:** The request for a compounded drug #180 is not supported as medically necessary. This is a vague request and does not specify the components of the medication. The Chronic Pain Guidelines, the Official Disability Guidelines, and the Food and Drug Administration (FDA) 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. Also, the FDA requires that all components of a transdermal compounded medication be approved for transdermal use. The guidelines also indicate that any compounded product that contains at least one (1) drug (or drug class) that is not recommended, is therefore, not medically necessary.

**SOMNICIN CAPSULES #30:** Upheld

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

**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, Medical Foods.

**Decision rationale:** The request for Somnicin Capsules #30 is not supported as medically necessary. Somnicin capsules are considered medical food. The Official Disability Guidelines indicate that the specific requirements for the safety or appropriate use of medical foods have not been established. The guidelines also indicate that there is no scientific evidence that establishes that Somnicin is efficacious in the treatment of chronic pain and sleep disturbance.

**TEROCIN DIS 4-4% #30:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 112-113.

**Decision rationale:** The request for Terocin DIS 4-4% is not supported as medically necessary. The Chronic Pain Guidelines indicate that topical analgesics are noted to be largely experimental in use with few randomized controlled trials to determine efficacy or safety. As such the medical necessity is not established.

